K132167

MAY 0 2 2014

Section 5: 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR, Section 807.92 (c).

Submitter Information:

Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: psy@boditech.co.kr
Website: www.boditech.co.kr

Contact Person: **Sang Yeol Park**/ Senior Director/ Ph.D.

Date: **March 03, 2014**

Device Information:

Trade Name: *i*-CHROMA iFOB with *i*-CHROMA Reader
Common Name: *i*-CHROMA iFOB
Classification Name: Automated Occult Blood Analyzer
Class: II
Panel: Hematology
Product Code: OOX
Regulation: 21 CFR § 864.6550

Predicate Device: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer
Predicate K Number: K041408

Device Description:

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

Intended Use(s):

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples. *i*-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Indications for Use(s):

i-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Components of *i*-CHROMA iFOB:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer' and *i*-CHROMA Reader

- The test cartridge contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.

- The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each sample collection tube contains 1 mL detection buffer. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

- Additionally, 'Patient Packs' are provided along with the test cartridge box and also separately on demand.

  Each 'Patient Pack' contains following items:
  - 1 Patient Instructions Leaflet (for sampling instructions)
  - 1 Sample Collection Paper (for fixing onto the toilet bowl)
  - 1 Sample Sac (for enclosing the sample collection tube after sampling)
  - 1 Return Envelop (for submitting the sample collection tube to the laboratory/physician office for testing)

- *i*-CHROMA Reader is a fluorometer instrument which scans the sample-loaded *i*-CHROMA iFOB test cartridge and displays the test result. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other. *i*-CHROMA Reader is marketed/supplied separately on demand.

- The ID chip contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

_i_-CHROMA iFOB Test Cartridge:

_i_-CHROMA iFOB Test Cartridge is composed of a test strip enclosed in a disposable plastic housing.

The components of the test strip are:

- An antibody-immobilized nitrocellulose membrane
- A sample pad
- An absorption pad (also called absorbing pad or absorbent pad)
- A plastic backing

_i_-CHROMA iFOB Sample Collection Tube:

'Sample Collection Tube' is an essential component of _i_-CHROMA iFOB. A box containing 25 pre-filled sample collection tubes, is delivered separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

The sample collection tube is a specially designed plastic container. Each sample collection tube contains 1mL Detection Buffer. Apart from being the container for the detection buffer, the sample collection tube serves the following purposes:

i) Proper sampling of the fecal sample
ii) Thorough mixing of the fecal sample with the detection buffer for ensuring complete extraction of the fecal sample
iii) Application of precise quantity of the sample mixture into the 'Sample well' of the _i_-CHROMA iFOB test cartridge

'_i_-CHROMA iFOB Sample Collection Tube' contains 1 mL 'Detection Buffer'. Approximately 13 mg (±1.82 mg) of human fecal sample is actually delivered into the detection buffer in the '_i_-CHROMA iFOB Sample Collection Tube' following the sampling procedure described in the package insert of _i_-CHROMA iFOB test.

_i_-CHROMA Reader:

_i_-CHROMA Reader is a custom-configured, portable, desktop, fluorescence-scanning instrument for qualitative detection of fecal occult blood (FOB) in human fecal samples; duly mixed with the detection buffer and tested by _i_-CHROMA iFOB.

_i_-CHROMA Reader is intended to be used only in conjunction with _i_-CHROMA iFOB for _in vitro_ diagnostic purpose by laboratories and physician offices. _i_-CHROMA Reader measures 250 mm (L) x 185 mm (W) x 80 mm (H) in size and weighs 1.2 Kg.

The _i_-CHROMA iFOB test cartridge is loaded with the human fecal sample which has been duly mixed with the detection buffer in _i_-CHROMA iFOB Sample Collection Tube as per the standard test procedure recommended by Boditech Med Inc. This sample-

loaded test cartridge is inserted in to the cartridge holder of the *i*-CHROMA Reader for the purpose of being scanned.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes accumulated at the test line as well at the control line.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration. The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

Test Principle:

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human fecal sample is mixed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer binds with hemoglobin in the fecal occult blood (FOB).

When the fecal sample mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, the fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, more the hemoglobin in the human fecal sample, more the complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which is correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner based on an analytical cut-off of 100 ng/mL (hemoglobin in fecal sample mixed with detection buffer) which is equivalent to 8μg i.e. 0.008 mg hemoglobin per gram of stool.

i-CHROMA iFOB and *i*-CHROMA Reader are compatible only with each other.

Substantial Equivalence Information:

Predicate Device: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer

Predicate K Number: K041408

Comparison with the Predicate Device:

Following table summarizes similarities and difference between the test device *i*-CHROMA iFOB and the predicate device OC Auto Micro FOB Test.

SIMILARITIES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Principle	Immunological test system using antigen-antibody reaction for detection of human hemoglobin in human fecal samples.	Immunological test system intended for qualitative detection of fecal occult blood in feces
2	Intended Use	Qualitative detection of fecal occult blood (FOB) in human fecal samples by laboratories and physician offices	Qualitative detection of fecal occult blood in feces by professional laboratories
3	Test Sample	Human fecal sample mixed with detection buffer in the sample collection tube	Feces in an extraction buffer
4	Test Cut-off	100 ng/mL (Human hemoglobin in human fecal sample mixed with detection buffer)	100 ng/mL (Human hemoglobin in feces processed in extraction buffer)
DIFFERENCES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Platform	Fluorescence immunoassay using lateral flow technology	Automated immunoassay using latex fixation
2	Test Time	10 minutes	5~10 minutes

3	Detection Mechanism	Involves scanning/measurement of intensity of fluorescence on the test cartridge membrane	Involves optical measurement of agglutination of latex particles

Standard/Guidance Document Referenced:

USFDA guidance document for industry and FDA staff:
'Review Criteria for Assessment of Qualitative Fecal Occult Blood In Vitro Diagnostic Devices' (Issue date: August 8, 2007)

Summary of Performance Testing (Bench):

- *i*-CHROMA iFOB showed **no prozone/hook effect up to** analyte concentration **2000 ng/mL**.
- *i*-CHROMA iFOB was found to be **equally sensitive to** 'Hemoglobin S' as the **abnormal hemoglobin** associated with sickle cell anemia.
- *i*-CHROMA iFOB showed **no significant cross-reactivity with** any of the eight **animal hemoglobin** (i.e. bovine, chicken, fish, horse/equine, goat, pig/swine, rabbit, and sheep origin) **and no significant interference from** any of the four **endogenous substances** (Ascorbic acid, Bilirubin, Albumin and Myoglobin).
- *i*-CHROMA iFOB **showed high degree of repeatability as well as** between-run, lot-to-lot, instrument-to-instrument and site-site **reproducibility.**
- **Analytical method comparison** study at three US sites performed on spiked human fecal samples **showed high degree of overall percent agreement** as well as **positive** percent agreement **and negative percent agreement between** test results obtained with ***i*-CHROMA iFOB** and the predicate method **OC Auto Micro FOB**.
- **Clinical testing study** at two Korean and one US site involving prospective testing of clinical human fecal samples showed:
  - **More than 96% positive and negative percent agreements** in test results when compared **with** the predicate method **OC Auto Micro FOB.**
  - **95-99.66% accuracy** in test results **with weak positive and weak negative samples.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2014

Boditech Med Inc.
c/o Sang Yoel Park, Ph.D., Senior Director QA & RA
43, Geodudanji 1-gil, Dongnae-myeon
Chuncheon-si, Gang-won-do, 200-883
REPUBLIC OF KOREA

Re: k132167
Trade/Device Name: *i*-CHROMA iFOB with i-CHROMA Reader
i-CHROMA iFOB Controls
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult Blood Test
Regulatory Class: Class II
Product Code: OOX, JJX
Dated: April 23, 2014
Received: April 25, 2014

Dear Dr. Park:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132167

Device Name
i-CHROMA iFOB Controls

Indications for Use *(Describe)*
i-CHROMA iFOB Controls are external quality control reagents intended for monitoring and ensuring acceptable performance of i-CHROMA iFOB test system which is a qualitative in-vitro diagnostic test for detection of fecal occult blood having an analytical cut-off of 100 ng/mL which is equivalent to 8µg i.e. 0.008 mg hemoglobin per gram of stool.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Maria M. Chan -S

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132167

Device Name
i-CHROMA iFOB with i-CHROMA Reader

Indications for Use *(Describe)*

i-CHROMA iFOB in conjunction with i-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

i-CHROMA iFOB is an in vitro diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Maria M. Chan -S

Submitter:
Sang Yeol Park
Senior Director
Boditech Med Inc
Quality Assurance & Regulatory Affairs
43, Geodudanji 1-gil, Dongnae-myeon
Chuncheon-si, Gang-won-do, 200-883, KS
Phone: 82-332-431400
Fax: 82-332-439373

Secondary Contact:
Sang Yeol Park
Senior Director
Boditech Med Inc
Quality Assurance & Regulatory Affairs
43, Geodudanji 1-gil, Dongnae-myeon
Chuncheon-si, Gang-won-do, 200-883, KS

7¿ù 8, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Attn: eSubmitter Team
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Sir or Madam:

This submission dated 7¿ù 8, 2013, is filed pursuant to the In Vitro Diagnostic Device Evaluation and Safety program's Electronic Review (eReview).

The submission is a(n) **510(k) and CLIA Waiver Combination**, **Original Submission**, **Traditional** referring to the product, Reagent, Occult Blood also known as trade name(s): i-CHROMA iFOB with i-CHROMA Reader with model(s): Not Applicable. The classification panel for this submission is HEMATOLOGY. This submission includes a **CLIA Waiver**.

Indications for Use
i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples. *i*-CHROMA iFOB is a rapid, convenient, sensitive and reliable *in vitro* diagnostic test intended for routine physical examination, screening and/or monitoring for gastrointestinal bleeding disorders such as colorectal cancer by laboratories and physician offices.

The prior submissions that are related to this release are as follows: K062981 (i-Chroma CRP Test).
The devices to which substantial equivalence is claimed are as follows: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80.

User Fee Payment ID: (b)(4)Trade [redacted]

Truth and Accuracy Statement
To the best of my knowledge, the data and information submitted in this premarket notification are truthful and accurate, and no material fact has been omitted (as required by 21 CFR 807.87).

Sincerely,

Sang Yeol Park
Senior Director
Boditech Med Inc

Submission Report

Section: Admin

1.0 Type of Submission

Introduction

Department of Health and Human Services
Food and Drug Administration

CDRH PreMarket Review Submission Cover Sheet

Form Approval
OMB No. 0910-0120

Note:	*Please be advised that: 1) under 21 CFR 807.7(1), we may request any additional information that is necessary to reach a determination regarding substantial equivalence and 2) supportive raw data may be provided as attachments to this submission.*
Information:	*Whenever possible, please enter descriptions in executive summary format because this information will be used to generate the FDA Decision summary. If additional information is needed, please attach the appropriate file.*

Section A	**Type of Submission**

Submission Type	*	510(k) and CLIA Waiver Combination
. Submission Sub-Type	*	Original Submission
- Submission Sub-Sub-Type	*	Traditional
Enter the original submission number.		
Is this a bundled submission?	*	No

User Fee Payment ID Number	*	(b)(4)Trade Secret P

MDUFMA Cover Sheet

Please attach the completed MDUFMA Cover Sheet.		*
File Attachment	MDUFMA	

2.0 Contact Information

Section B	**Primary Contact (Submitter, Applicant, or Sponsor)**

Primary Contact Information	*
Contact Information:	
Contact Name	Dr. Sang Yeol Park
Occupation Title	Senior Director
Email Address	psy@boditech.co.kr
Address	
Establishment Name	Boditech Med Inc
Division Name	Quality Assurance & Regulatory Affairs
Address	43, Geodudanji 1-gil, Dongnae-myeon Chuncheon-si, Gang-won-do, 200-883, KS
Telephone Number	82-332-431400
Fax Number	82-332-439373

Section C	**Secondary Contact (Applicant Correspondent, US Agent, or Consultant)**

Secondary Contact Information	
Contact Information:	
Contact Name	Dr. Sang Yeol Park
Occupation Title	Senior Director
Email Address	psy@boditech.co.kr
Address	
Establishment Name	Boditech Med Inc
Division Name	Quality Assurance & Regulatory Affairs
Address	43, Geodudanji 1-gil, Dongnae-myeon Chuncheon-si, Gang-won-do, 200-883, KS
Telephone Number	
Fax Number	

Who should be contacted for issues related to this submission? *	Primary Contact

Section D	**Manufacturing Location (Physical Location of the Manufacturing Plant)**

Manufacturing Location (Optional)	
Establishment Information:	
Establishment Name	Boditech Med Inc.
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
D&B D-U-N-S Number	
Physical Location:	
Address	
Telephone Number	
Fax Number	

3.0 Reason for Submission

Section D3	Reason for Submission - 510(k)

New Device	*	Yes
Additional or Expanded Indications		
Change in technology		
If additional information is required, attach file.		

Section E	Additional Information on 510(k) submissions

Information on Device to which substantial equivalence is claimed. 510(k) Number - Trade or Proprietary or Model Name		*
Item 1	OC Auto Micro FOB Test and Polymedco OC Auto Micro 80	

For this submission, are you including a 510(k) Statement or Summary?	*	510(k) Summary
Enter your 510(k) Summary or Statement.		*
Section 5-510(k) summary has been attached.		
File Attachment	510(k) Summary	

4.0 Product Information

Section F	Product Information

Common or classification name		*
Reagent, Occult Blood		

FDA Document Numbers of all prior related submissions (regardless of outcome)		*
Item 1	K062981 (i-Chroma CRP Test)	

4.1 Trade, Proprietary, or Model Names

Item: 1

Trade, proprietary, or model name for this device	*	i-CHROMA iFOB with i-CHROMA Reader
Model number	*	Not Applicable

5.0 Product Classification

Section G1	Product Classification

Choose the product code for this submission.	
Product Code	REAGENT, OCCULT BLOOD (KHE)
Device Class	CLASS II
Classification Panel	HEMATOLOGY
C.F.R. Section	864.6550 - OCCULT BLOOD TEST.

Add any other product codes that are applicable to this submission.				
Item	Product Code	Device Class	Classification Panel	C.F.R. Section

If the product code(s) is/are unknown, please describe the classification of the product.	
Not Applicable	
If necessary, identify the secondary Classification Panel	
Item	

Section G2	**Intended Use and Indications for Use**

Information:	*Intended use refers to "the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article..." (see 21 CFR 801.4).*

Code of Federal Regulations

Enter the intended use of the product. *

Intended Use(s): *i*-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples. *i*-CHROMA iFOB is a rapid, convenient, sensitive and reliable *in vitro* diagnostic test which aids in the diagnosis of gastrointestinal bleeding disorders such as colorectal cancer.

Indications for Use(s): *i*-CHROMA iFOB is recommended for use in routine physical examination, screening and/or monitoring for gastrointestinal bleeding disorders such as colorectal cancer by laboratories, and physician offices.

.	Intended Use	Prescription

Information:	*For AST devices, the Indication For Use statement should indicate: whether the assay is quantitative (MIC) or qualitative (breakpoint devices); whether results may be read and reported manually; which organism groups the device is indicated for testing; and any instrumentation the device may be used with, if applicable. A typical example of an intended use statement is: "ABC's system is intended for the in vitro qualitative or quantitative determination of antimicrobial susceptibility of rapidly growing aerobic non-fastidious Gram positive and Gram negative organisms on the ABC Instrument."*

Code of Federal Regulations

Information:	*Please attach the Indication(s) for Use Form to the following question.*

Indication(s) for Use Form

Enter the product's indications for use. *

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

i-CHROMA iFOB is a rapid, convenient, sensitive and reliable *in vitro* diagnostic test intended for routine physical examination, screening and/or monitoring for gastrointestinal bleeding disorders such as colorectal cancer by laboratories and physician offices.

Enter any special applications of the device or contraindications not addressed in the Intended Use Statement.
Not Applicable

6.0 Manufacturing/Packaging/Sterilization Sites

Item: 1

Status Change	*	No
Site Operation		
. Manufacturer	*	Yes
. Contract Manufacturer	*	No
. Contract Sterilizer	*	No
. Repackager/Relabeler	*	No

Contact Information	
Contact Information:	
Contact Name	Dr. Sang Yeol Park
Occupation Title	Senior Director
Email Address	psy@boditech.co.kr
Establishment Information:	
Establishment Name	Boditech Med Inc
Division Name	Quality Assurance & Regulatory Affairs
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
D&B D-U-N-S Number	
Physical Location:	
Address	43, Geodudanji 1-gil, Dongnae-myeon Chuncheon-si, Gang-won-do, 200-883, KS
Telephone Number	(82) 33 -243 Ext: 1400
Fax Number	(82) 33 -243 Ext: 9373
Mailing Location:	
Address	43, Geodudanji 1-gil, Dongnae-myeon Chuncheon-si, Gang-won-do, 200-883, KS

7.0 Utilization of Standards

Information:	*Select the CDRH Recognized Standard from the available list.*

Select all standards referenced.			
Item	Standard Title and Reference Number	Category	Organization

Standards Data Report for 510(k)s (FDA Form #3654, Form Approved OMB #0910-0120)

For each standard selected above, please fill out the Standards Data Report for 510(k)s (FDA Form #3654) and attach it here.	
Details	

Did you reference any other standards?	

8.0 Utilization of Guidance Documents

Please enter all referenced Guidance Documents.				
Item	Document Title	Office	Division	Web Page
Item 1	Guidance for Industry and FDA Staff - Review Criteria for Assessment of Qualitative Fecal Occult Blood In Vitro Diagnostic Devices			http://www.fda.gov/cdrh/oivd/guidance/772.html
Item 2	Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff	OIVD		http://www.fda.gov/cdrh/ode/guidance/1567.html
Item 3	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff	ODE		http://www.fda.gov/cdrh/ode/guidance/337.html
Item 4	Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)	OCER		http://www.fda.gov/cdrh/dsma/470.pdf

9.0 Certification of Compliance with Clinical Trials

Information:	*The Food and Drug Administration has issued draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007".*

The draft guidance can be found at: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm

Form FDA-3674, ClinicalTrials.gov Data Bank

Information:	*Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) included a provision that all MA applications are required to be accompanied with certification that all applicable clinical trial information has been submitted to the ClinicalTrials.gov data bank.* *Beginning December 26, 2007, submissions must include form FDA-3674. If your submission includes data from a clinical trial, you must determine if your study is applicable for entry into the clinical trial registry data bank at ClinicalTrials.gov.*

Form FDA-3674, ClinicalTrials.gov Data Bank

For each clinical trial, complete form FDA-3674 and attach it here.	
Details	Not Applicable

Section: CLIA Waiver

Introduction

CLIA Waiver Application	
Note:	*CLIA requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services before accepting materials derived from the human body for laboratory tests. 42U.S.C ¡× 263a(b). Laboratories that perform only tests that are "simple" and that have an "insignificant risk of an erroneous result" may obtain a certificate of waiver. The Secretary has delegated to FDA the authority to determine whether particular tests (waived tests) are "simple" and have "insignificant risk of an erroneous result" under CLIA 69 FR*

	22849.

Note:	*To demonstrate that your device is simple and has an insignificant risk of erroneous result, the following items should be included in your waiver application: a description of your device that demonstrates it is simple to use; a hazard analysis, including flex studies that identify potential sources of error for your device and a description of methods you have implemented to mitigate the risk of these errors; validation studies to demonstrate the ability of the failure alert and fail-safe mechanisms to mitigate the risk of errors (under conditions of stress); a description of the design and results of the clinical studies you conducted to demonstrate that the device has an insignificant risk of erroneous results in the hands of the intended user; and proposed labeling with instructions for use that are consistent with a device that is "simple."*

Refer to the "Draft Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications" for more information.

1.0 Type of Product

Select device type:	*	Qualitative
Select device technology:	*	Rapid Immunochromatographicassay, Lateral Flow

Enter the device technology if you chose "Other."

2.0 Test Principle

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

3.0 Demonstrating Simple

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

4.0 Demonstrating Insignificant Risk of an Erroneous Result

4.1 Tier 1 Risk Analysis and Flex Studies

Note:	*Include a report of the risk analysis results that identifies all potential sources of error, including test system failures and operator errors for your device.*

4.1.1 Design and Results

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

4.1.2 Flex Studies Conclusions

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

4.2 Tier 2 Fail-Safe and Failure Alert Mechanisms

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

External Control Information
Describe the external controls, manufacturer, and if they are included with the device. *

(b)(4)Trade Secret Process

[redacted]

Describe the frequency the controls should be assayed. *

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

4.2.1 Risk Identification and Risk Control Measures

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

4.3 Accuracy

Note:	*The following questions in the Accuracy section demonstrate that your device is "accurate" in the hands of the intended operators. Please attach the data from the studies in an Excel file when applicable.*

4.3.1 Testing Sites and Participants

Note:	*Report the results of the clinical study by each site overall (pooled). The report should include protocol description, number of subjects studied, procedures for subject inclusion and exclusion, description of subject population, description of how specimens were collected and stored, sites that discontinued and the reasons for the discontinuation, and the number of device failures and replacements. Include any invalid results and how these were handled, information about QC procedures that were performed by the users, pertinent tabulations, annotated line listing of results, and clear descriptions and presentations of the statistical analyses.*

Provide the number of sites used and include a description of each site (i.e. physician's office). *

Clinical study to support CLIA waiver of *i*-CHROMA iFOB was conducted at four sites at different demographic locations as per following details

Study site 1:

Site Number: SS-1

(b)(4)Trade Secret Process [redacted]

Study site 2:

Site Number: SS-2

(b)(4)Trade Secret Process [redacted]

Study site 3:

Site Number: SS-3

(b)(4)Trade Secret [redacted]

(b)(4)Trade Secret Process [redacted]

[redacted]

[redacted]

Study site 4:

Site Number: SS-4

(b)(4)Trade Secret Process [redacted]

[redacted]

[redacted]

[redacted]

Provide the number and demographics of the operators at each site and combined ((i.e. education) (including experience and training), and occupation)). *

Study site SS-1: (b)(4)Trade Secret Process [redacted]

Information	Operators enrolled for & participated in the clinical study		
	Operator SS1-O1	Operator SS1-O2	Operator SS1-O3
Education	Bachelor in Clinical Pathology	Bachelor in Clinical Pathology	Bachelor in Biomedical Laboratory Science
Occupation	Medical Laboratory Technician	Medical Laboratory Technician	Medical Laboratory Technician
Experience & Training	4 year experience of diagnostic testing as a certified medical laboratory technician	7 month experience of diagnostic testing as a certified medical laboratory technician	2 year experience of diagnostic testing as a certified medical laboratory technician

Study site SS-2: (b)(4)Trade Secret Process [redacted]

Information	Operators enrolled for & participated in the clinical study	
	Operator SS2-O1	Operator SS2-O2
Education	Bachelor in Clinical Pathology	Bachelor in Clinical Pathology
Occupation	Medical Laboratory Technician	Medical Laboratory Technician
Experience & Training	5 year experience of diagnostic testing as a certified medical laboratory technician	1 year experience of diagnostic testing as a certified medical laboratory technician

Study site SS-3: (b)(4)Trade Secret Process [redacted]

Information	Operators enrolled for & participated in the clinical study		
	Operator SS3-O1	Operator SS3-O2	Operator SS3-O3
Education	Bachelor in Biomedical Laboratory Science	Bachelor in Clinical Pathology	Bachelor in Biomedical Laboratory Science
Occupation	Medical Laboratory	Medical Laboratory	Medical Laboratory

	Technician	Technician	Technician
Experience & Training	6 days experience of diagnostic testing as a certified medical laboratory technician	5 year experience of diagnostic testing as a certified medical laboratory technician	2 year and 8 month experience of diagnostic testing as a certified medical laboratory technician

Study site SS-4: (b)(4)Trade Secret Process [redacted]

Information	**Operators enrolled for & participated in the clinical study**
	Operator SS4-O1
Education	Associate degree with ASCP
Occupation	Physician Office Technician
Experience & Training	5 year experience of diagnostic testing as a certified
Physician Office	
technician	

Study sites and number of operators enrolled for & participated in the clinical study conducted for CLIA waiver of *i*-CHROMA iFOB

No.	**Clinical study site**	**Number of operators enrolled for & participated in the clinical study**
SS-	(b)(4)Trade Secret Process [redacted]	3
SS-		2
SS-		3
SS-		1
		Total 9

Provide the education (including experience and training) and occupation information on operators that were available at the testing site but were not chosen. *

Study site SS-1: (b)(4)Trade Secret Process [redacted]

Information	**Operators available but not chosen to participate in the clinical study**		
	Operator SS1-O4	**Operator SS1-O5**	**Operator SS1-O6**
Education	Bachelor in Biomedical Laboratory Science	Bachelor in Clinical Pathology	Bachelor in Clinical Pathology
Occupation	Senior Medical Laboratory Technician	Medical Laboratory Technician	Medical Laboratory Technician
Experience	10 year experience of diagnostic testing as a	6 year experience of diagnostic testing as a	3 year experience of diagnostic testing as a

& Training	certified medical laboratory technician	certified medical laboratory technician	certified medical laboratory technician

Study site SS-2: (b)(4)Trade Secret Process [redacted]

Information	Operators available but not chosen to participate in the clinical study
	Operator SS2-O3
Education	Bachelor in Biomedical Laboratory Science
Occupation	Senior Medical Laboratory Technician
Experience & Training	3 year experience of diagnostic testing as a certified medical laboratory technician

site SS-3: (b)(4)Trade Secret Process [redacted]

Information	Operators available but not chosen to participate in the clinical study	
	Operator SS3-O4	Operator SS3-O5
Education	Bachelor in Clinical Pathology	Bachelor in Clinical Pathology
Occupation	Medical Laboratory Technician	Medical Laboratory Technician
Experience & Training	1 year experience of diagnostic testing as a certified medical laboratory technician	6 year experience of diagnostic testing as a certified medical laboratory technician

Describe what instructional material was provided to the test operator. *

Test operators who participated in the clinical study for CLIA waiver of *i*-CHROMA iFOB test (conducted at the three Korean sites) were provided with Korean language versions of following instructional material.

1. List of 'Do's and Don'ts for Test Operators'

erim draft of proposed 'Quick Reference Instructions of *i*-CHROMA iFOB'

3. Interim draft of proposed 'Package Insert of *i*-CHROMA iFOB'

4. Interim draft of proposed 'Operation Manual of *i*-CHROMA Reader'

Test operator who participated in the clinical study conducted at the USA site was provided with proper English drafts of the above instructional material.

Provide the results of the operator questionnaire from each site and combined. *

Que. No.	Question with Options	Clinical Study Sites				Combined Responses
		Site SS-1	Site SS-2	Site SS-3	Site SS-4	
		3 Operators	2 Operators	3 Operators	1 Operator	9 Operators
1.	How it was to understand the test instructions.					
a	Very easy	02	01	01	01	05
b	Easy	01	01	02	--	04

c	Somewhat difficult	--	--	--	--	--
d	Difficult	--	--	--	--	--
e	Very difficult	--	--	--	--	--
2. How it was to follow the test instructions.						
a	Very easy	02	01	01	01	05
b	Easy	01	01	02	--	04
c	Somewhat difficult	--	--	--	--	--
d	Difficult	--	--	--	--	--
e	Very difficult	--	--	--	--	--
3. How it was to apply processed fecal sample into 'sample well' of the test cartridge correctly.						
a	Very easy	03	02	02	01	08
b	Easy	--	--	01	--	01
c	Somewhat difficult	--	--	--	--	--
d	Difficult	--	--	--	--	--
e	Very difficult	--	--	--	--	--
4. How it was to process the external controls.						
a	Very easy	01	--	--	01	02
b	Easy	02	02	03	--	07
c	Somewhat difficult	--	--	--	--	--
d	Difficult	--	--	--	--	--
e	Very difficult	--	--	--	--	--
5. How it was to operate the *i*-CHROMA Reader.						
a	Very easy	02	01	01	01	05
b	Easy	01	01	02	--	04
c	Somewhat difficult	--	--	--	--	--
d	Difficult	--	--	--	--	--
e	Very difficult	--	--	--	--	--
6. How it was to read and understand the normal procedural message alerts displayed by *i*-CHROMA Reader.						
a	Very easy	03	02	02	01	08
b	Easy	--	--	01	--	01
c	Somewhat difficult	--	--	--	--	--
d	Difficult	--	--	--	--	--
e	Very difficult	--	--	--	--	--
7. How it was to read and understand the test results displayed by *i*-CHROMA Reader.						
a	Very easy	03	02	02	01	08
b	Easy	--	--	01	--	01
c	Somewhat difficult	--	--	--	--	--
d	Difficult	--	--	--	--	--
e	Very difficult	--	--	--	--	--
8. How it was to read and understand the error message alerts; if any displayed by *i*-CHROMA Reader.						

a	Very easy	01	--	--	--	01
b	Easy	--	--	--	--	--
c	Somewhat difficult	--	--	--	--	--
d	Difficult	--	--	--	--	--
e	Very difficult	--	--	--	--	--
f	I did not encounter any error message alert	02	02	03	01	08
9. How it was to perform the overall testing process.						
a	Very simple	02	01	01	01	05
b	Simple	01	01	02	--	04
c	Somewhat complex	--	--	--	--	--
d	Complex	--	--	--	--	--
e	Highly complex	--	--	--	--	--
10. How the instructional material explains what to do if a test result is invalid?						
a	Very clearly	02	01	01	01	05
b	Clearly	01	01	02	--	04
c	Ambiguously	--	--	--	--	--
d	Vaguely	--	--	--	--	--
11. How the instructional material explains what to do if any error message alert is displayed by the *i*-CHROMA Reader?						
a	Very clearly	02	01	01	01	05
b	Clearly	01	01	02	--	04
c	Ambiguously	--	--	--	--	--
d	Vaguely	--	--	--	--	--
e	Not at all	--	--	--	--	--
12. You could perform the test properly the first time after …..						
a	Merely reading the instructional material	03	02	02	01	08
b	Reading the instructional material as well as contacting the technical assistance services of the manufacturer	--	--	01	--	01
c	Discussing the test with other test operator(s)	--	--	--	--	--
d	Taking help from other test operator(s)	--	--	--	--	--
e	Not at all	--	--	--	--	--

4.3.3 Clinical Studies for Tests with Qualitative Results

Documentation of Comparative Method

Provide the name of the method and type of comparative method (A, B, C, D, or E). Link to Guidance Doc/specific section. *

'OC Auto Micro FOB' test was selected as a comparative method for the purpose of clinical testing conducted to support CLIA-waiver of '*i*-CHROMA iFOB' test.

'OC Auto Micro FOB' has been cleared by the USFDA as a qualitative *in vitro* diagnostic test **(k041408)** but it can present the test results in qualitative as well as quantitative manner.

Hence 'OC Auto Micro FOB' has been considered as the 'Type-A Comparative Method' (quantitative reference method) as per the USDFA guidance document 'Recommendations for CLIA Waiver Applications for Manufacturers of In Vitro Diagnostic Devices'.

Provide a description of the Comparative Method, which includes intended use population/target population, condition of interest/target condition, reference standard for establishing the presence or absence of the condition or characteristic of interest, and diagnostic accuracy of the test. For CMs C and D, provide information supporting traceability. *

OC Auto Micro FOB Test (in conjunction with OC Auto Micro 80 Analyzer) is marketed by Polymedco Inc., USA. It is an immunological test system intended for detection of human hemoglobin in human feces by professional laboratories.

OC Auto Micro FOB test is intended for determination of gastrointestinal bleeding found in a number of gastrointestinal disorders e.g. colitis, polyps, and colorectal cancer.

It is recommended for use in routine physical examinations, monitoring and screening for colorectal cancer or gastrointestinal bleeding.

The test cut-off of OC Auto Micro FOB test is 100 ng/mL (FOB hemoglobin in the fecal sample).

Statistical Analysis

Note: *Provide the following information based on each site as well as a combined analysis over all sites.*

Method Comparison

Provide the calculated percent agreement estimates along with one sided 97.5% lower confidence bounds for the positive and negative result. Note: The positive and negative samples are dete mined by the comparative method. *

Site-wise as well as combined information regarding the calculated percent agreement estimates along with one-sided 97.5% lower confidence bounds for the positive and negative results (obtained with the clinical samples tested by waiver method as well as the comparative method) has been tabulated as follows:

1) Study Site SS-1:

Clinical Study Site Number	Name of the Clinical Study Site	Waiver Method	Comparative Method			Positive Percent Agreement	Negative Percent Agreement
		i-CHROMA iFOB	OC Auto Micro FOB				
			Positive Results	Negative Results	Total Results		
SS-1	(b)(4)Trade Secret Process [redacted]	Positive Results	49	03	52	98.00%	96.15%
		Negative Results	01	75	76		
		Total Results	50	78	128		

Clinical Study Site	Positive Percent Agreement			Negative Percent Agreement		
	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound
	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)
Site SS-1	89.50%	99.65%	**89.50%**	89.29%	98.68%	**89.29%**

2) Study Site SS-2:

Clinical	Name of the	Waiver Method	Comparative Method	Positive	Negative

Study Site Number	Clinical Study Site	*i*-CHROMA iFOB	OC Auto Micro FOB			Percent Agreement	Percent Agreement
			Positive Results	Negative Results	Total Results		
SS-2	(b)(4)Trade Secret Process [redacted]	Positive Results	**50**	02	52	**98.04**	**97.18**
		Negative Results	01	**69**	70		
		Total Results	**51**	**71**	122		

Clinical Study Site	Positive Percent Agreement			Negative Percent Agreement		
	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound
	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)
Site SS-2	89.70%	99.65%	**89.70%**	90.30%	99.22%	**90.30%**

3) Study Site SS-3:

Clinical Study Site Number	Name of the Clinical Study Site	Waiver Method	Comparative Method			Positive Percent Agreement	Negative Percent Agreement
		i-CHROMA iFOB	OC Auto Micro FOB				
			Positive Results	Negative Results	Total Results		
SS-3	(b)(4)Trade Secret Process [redacted]	Positive Results	**51**	03	54	**98.08%**	**97.22%**
		Negative Results	01	**105**	106		
		Total Results	**52**	**108**	160		

Clinical Study Site	Positive Percent Agreement			Negative Percent Agreement		
	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound
	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)
Site SS-3	89.88%	99.66%	**89.88%**	92.15%	99.05%	**92.15%**

4) Study Site SS-4:

Clinical	Name of the	Waiver Method	Comparative Method	Positive	Negative

Study Site Number	Clinical Study Site	*i*-CHROMA iFOB	OC Auto Micro FOB			Percent Agreement	Percent Agreement
			Positive Results	Negative Results	Total Results		
SS-4	(b)(4)Trade Secret Process [redacted]	Positive Results	**32**	03	35	**100%**	**96.05%**
		Negative Results	00	**73**	73		
		Total Results	**32**	**76**	108		

Clinical Study Site	Positive Percent Agreement			Negative Percent Agreement		
	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound
	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)
Site SS-4	89.28%	100%	**89.28%**	89.03%	98.65%	**89.03%**

5) Combined Analysis:

Clinical Study Sites	Waiver Method	Comparative Method			Positive Percent Agreement	Negative Percent Agreement
	i-CHROMA iFOB	OC Auto Micro FOB				
		Positive Results	Negative Results	Total Results		
Study Sites SS-1 to SS-4	Positive Results	**182**	11	193	**98.38%**	**99.70%**
	Negative Results	03	**322**	325		
	Total Results	**185**	**333**	5		

Clinical Study Sites	Positive Percent Agreement			Negative Percent Agreement		
	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound
	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)
Study Sites SS-1 to SS-4	95.34%	99.45%	**95.34%**	94.18%	98.15%	**94.18%**

Test Performance of Qualitative Tests

Provide in tabular format all invalid results obtained. It should capture the number of times a sample and/or specimen needed to be tested in order to obtain a valid result. *

No.	Details of the Invalid Results obtained during Clinical Study					Details of Re-testing At			
	Clinical Study Site, Operator & Date of Testing	Sample Code Number	Test Result by WM *i*-CHROMA iFOB	Test Result By CM OC Auto Micro FOB	Remark regarding Invalid Test Result obtained after Initial Testing	Number of Re-testing Attempts	Whether Valid Result was obtained after Re-testing	Re-testing Attempt	By CH il
1	Study Site: SS-1 Operator: SS1-O1 Date: June 7, 2012	SS1-CS-9	Positive 182.64 ng/mL	Negative 25 ng/mL	Considered invalid due to contrasting test results as well as significant difference in test result values	03	No	1	Po 1 n
								2	Po 2 n
								3	Po 2 n
2	Study Site: SS-1 Operator: SS1-O3 Date: June 27, 2012	SS1-CS-110	Positive 800.29 ng/mL	Positive 1978 ng/mL	Considered invalid due to huge difference in test result values	03	No	1	Po 8 n
								2	Po 7 n
								3	Po 8 n
3	Study Site: SS-1 Operator: SS1-O3 Date: June 27, 2012	SS1-CS-129(?)	iFOB Test Error 28	Positive 323 ng/mL	Possibly due to malfunctioning of internal control of *i*-CHROMA iFOB Test Cartridge	01	Yes	1	Po 2 n

Provide information that shows the percent agreement of the positive and negative results between the waiver method and comparative method is 95% or greater. *

Site-wise as well as combined information regarding the calculated percent agreement estimates of the positive and negative results (obtained with the clinical samples tested by waiver method as well as the comparative method) has been tabulated as follows:

1) Study Site SS-1:

2) Study Site SS-2:

3) Study Site SS-3:

4) Study Site SS-4:

5) Combined Analysis:

Clinical Study Site Number	Waiver Method	Comparative Method			Positive Percent Agreement	Negative Percent Agreement
	i-CHROMA iFOB	OC Auto Micro FOB				
		Positive Results	Negative Results	Total Results		
SS-1	Positive Results	49	03	52	98.00%	96.15%
	Negative Results	01	75	76		
	Total Results	50	78	128		

Clinical Study Site Number	Waiver Method	Comparative Method			Positive Percent Agreement	Negative Percent Agreement
	i-CHROMA iFOB	OC Auto Micro FOB				
		Positive Results	Negative Results	Total Results		
SS-2	Positive Results	50	02	52	98.04	97.18
	Negative Results	01	69	70		
	Total Results	51	71	122		

Clinical Study Site Number	Waiver Method	Comparative Method			Positive Percent Agreement	Negative Percent Agreement
	i-CHROMA iFOB	OC Auto Micro FOB				
		Positive Results	Negative Results	Total Results		
SS-3	Positive Results	51	03	54	98.08%	97.22%
	Negative Results	01	105	106		
	Total Results	52	108	160		

Clinical Study Site Number	Waiver Method	Comparative Method			Positive Percent Agreement	Negative Percent Agreement
	i-CHROMA iFOB	OC Auto Micro FOB				
		Positive Results	Negative Results	Total Results		
SS-4	Positive Results	32	03	35	100%	96.05%
	Negative Results	00	73	73		
	Total Results	32	76	108		

Clinical Study Sites	Waiver Method	Comparative Method			Positive Percent Agreement	Negative Percent Agreement
	i-CHROMA iFOB	OC Auto Micro FOB				
		Positive Results	Negative Results	Total Results		
Study Sites SS-1 to SS-4	Positive Results	182	11	193	98.38%	99.70%
	Negative Results	03	322	325		
	Total Results	185	333	518		

Provide information that shows the percent of positive and negative results should be close to 95%. *

Site-wise as well as combined information regarding the percent of the positive and negative results obtained with 60 aliquots of the weak positive sample and 60 aliquots of the weak negative sample tested by the waiver method has been tabulated as follows:

Testing Site	Operator	Number of Samples Tested		Results Obtained by the Waiver Method			
				Weak Positive Samples		Weak Negative Samples	
		Weak Positive Samples	Weak Negative Samples	True Positive Results	False Negative Results	True Negative Results	False Positive Results
SS-1	Operator SS1-O1	10	10	10	00	10	00
	Operator SS1-O3	10	10	09	01	10	00
	Total	20	20	19 (95%)	01 (5%)	20 (100%)	00 (00%)
SS-2	Operator SS2-O1	10	10	10	00	09	01
	Operator SS2-O2	10	10	10	00	10	00
	Total	20	20	20 (100%)	00 (00%)	19 (95%)	01 (5%)
SS-3	Operator SS3-O1	10	10	10	00	09	01
	Operator SS3-O2	10	10	10	00	10	00
	Total	20	20	20 (100%)	00 00%)	19 (95%)	01 (05%)
Testing Sites SS-1 to SS-3	Grand Total	60	60	59 (98.33%)	01 (1.66%)	58 (96.66%)	02 (3.33%)

Provide information that shows the difference in percents of the positive results and negative results among the three sites (should not be clinically or statistically significant at alpha = 0 05). *

The difference in percent of the true positive results and true negative results among the three testing sites (obtained with 60 aliquots of the weak positive sample and 60 aliquots of the weak negative sample tested by the waiver method) has been tabulated as follows:

Type of Weak Samples Tested by Waiver Method	Site-wise Percent of True Results		
	Site SS-1	Site SS-2	Site SS-3
Weak Positive Samples	95%	100%	100%
Weak Negative	100%	95%	95%

Samples			

The difference in percent of the true positive results and true negative results among the three testing sites was not found to be statistically significant at alpha = 0.05

File Attachment	Clinical Testing for CLIA Waiver

5.0 Labeling

Provide proposed package labeling to demonstrate conformance to 21 CFR 809.10. Include the Quick Reference Instructions, Quality Control Package Insert, and the Instrument Manual.	*
Attached files Appendix 2 i-CHROMA iFOB Package Insert Appendix 3 i-CHROMA iFOB Quick Reference Instruction Appendix 4 i-CHROMA iFOB Control package Insert Appendix 5 i-CHROMA Reader Operation Manual	
File Attachment 1	Control package Insert
File Attachment 2	Reader Operation Manual
File Attachment 3	iFOB Package Insert
File Attachment 4	iFOB Quick Reference Instructions

6.0 Other Supportive Information

Enter any additional supporting information for this submission.	*
There is no additional supporting information	

Section: OIVD Submission

OIVD 510(k)

OIVD 510(k) Submission

In vitro diagnostic (IVD) products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.

IVDs are medical devices as defined in section 210(h) of the Federal Food, Drug, and Cosmetic Act, and may also be biological products subject to section 351 of the Public Health Service Act. Like other medical devices, IVDs are subject to premarket and postmarket controls. IVDs are also subject to the Clinical Laboratory Improvement Amendments (CLIA '88) of 1988.

Is this an Antimicrobial Susceptibility Testing Device?	*	No

Is this a Collection Device?	*	No

Note:	*The 510(k) Short Form is intended for experienced submitters who are familiar with the Turbo 510(k) program and the level of detail that is required when completing the submission.*
Would you like to complete the OIVD 510(k) Short Form? *	No

1.0 Type of Product

Please select one:	*	Both Assay/Reagents Including Controls and Instrument

Select Device Type:	*	Qualitative-Non-numeric

Select device technology:	*	Rapid Immunochromatographicassay, Lateral Flow
Enter the device technology if you chose "Other."		

2.0 System Description

Information:	*Please enter descriptions in executive summary format because this information will be used to generate the FDA Decision summary.*

Device Description

Enter a brief description of the characteristics of the device, i.e., physical design, components, etc. Include information on any specific accessories (e.g., specialized collection devices, materials for pre-analytical steps). *

i-CHROMA iFOB is an mmunoassay system based on antigen-antibody reaction and fluorescence technology wherein the antigen-antibody complexes formed after processing the test sample with the detection buffer are captured while migrating through the test cartridge which is scanned by the i-CHROMA Reader to compute, convert and display the test result in a qualitative (positive or negative) manner.

[Components of i-CHROMA iFOB]:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer'.

- The test cartridge contains a test strip; on the nitrocellulose membrane of which, murine ant bodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.

- The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each sample collection tube contains 1 mL detection buffer. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

Is there an instrument associated with this assay?		*	Yes
.	Has this instrument previously been cleared?	*	Yes
.	Please enter the 510(k) number.		*
	Item 1	K062981	

.	Have there been any modifications to the cleared instrument for this particular assay? *	No
.	Please describe the modification to the cleared instrument.	

Information:	*The following questions relate to the Instrument.*

Modes of Operation
What are the modes of operation (i.e., random access, batch, stat, open tube, closed tube, automatic, manual, etc.)?

Software
What kind of software does the system use (i.e., operating system, user interface, data management, communications, laboratory information system, etc.)? Has the FDA reviewed the applicant's Hazard Analysis and software documentation for this line of product types?

Sample Identification
Describe how samples are identified (i.e., barcode, rack/position, instrument auto numbering, etc.).

Specimen Sampling and Handling
Describe how specimens are mixed (for whole blood), sampled, (i.e., direct open tube or closed tube piercing) and handled (i.e.,manual,etc.).

Assay Types
What kinds of assays are run on the system (i.e., chemistry, immunoassay, cytochemistry, image analysis, Immunohistochemistry, etc.)?

Reaction Types
Describe what types of reactions the system is capable of measuring (i.e., photometric,fluorometric, nephelometric, turbidometric, etc.).

Calibration
Describe the calibration procedures for the system (i.e., use of whole blood and commercial calibration materials).

Quality Control
Describe the quality control procedures and the use of commercial quality control materials for Point-of-Care or home-use devices (i.e., handheld meters, describe any electronic QC procedures or process controls).

Other Supportive Performance Characteristics
Enter other supportive performance characteristics that were not covered in the Performance Characteristics section above. This information could include performance characteristics data unique to an instrument class in your division (i.e., flow cytometer, glucose meter, automated cell locating device, etc.).

Principles of Operation

Provide a description of the technology utilized in the device. Discuss the principles of the device methodology and indicate whether it is well established or new and unproven.

3.0 Substantial Equivalence Information

Item: 1

Note: *The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*

Predicate device *

OC Auto Micro FOB Test and Polymedco OC Auto Micro 80

Describe the item being compared *

Trade Name: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer

510(k) Number: **K041408**

510(k) Holder: **Polymedco Inc.**

510 Furnace Dock Rd,

Cortlandt Manor, NY 10567, USA.

Phone: 1-800-431-2123 or 914-739-5400

Fax: 914-739-5890

Similarities *

SIMILARITIES

No.	Comparison Parameter	Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)	Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)
1	Nature of the Test	Rapid, convenient, sensitive and reliable *in vitro* diagnostic test	Rapid, convenient, sensitive and reliable *in vitro* diagnostic test
2	Intended Use	Qualitative detection of fecal occult blood (FOB) in human fecal samples by laboratories and physician offices	Qualitative detection of fecal occult blood in feces by professional laboratories
3	Indications for Use(s)	Routine physical examination, screening and/or monitoring for gastrointestinal bleeding disorders such as colorectal cancer	(1) Routine physical examinations, (2) Monitoring for bleeding in patients, and (3) Screening for colorectal cancer or gastrointestinal bleeding.

4	User(s)	Laboratories and physician offices	Professional laboratories
5	Test Sample	Human fecal sample mixed/processed with the detection buffer	Feces in an extraction buffer
6	Test Principle	Immunological test system based on fluorescence technology for qualitative detection of human hemoglobin in human fecal samples.	Immunological test system intended for qualitative detection of fecal occult blood in feces
7	Special Instrument Requirement	'*i*-CHROMA Reader' for scanning the *i*-CHROMA iFOB test cartridge which has been loaded with the fecal sample processed with the detection buffer	'Polymedco OC Auto Micro 80 Analyzer' on which the 'OC Auto Sampling Bottle(s)' containing the fecal sample(s) are placed for performing the automated test
8	Work Flow	Fecal sample is collected by the patient in the sample collection tube or an appropriate container which is submitted to the laboratory or physician office for testing.	Fecal sample is collected by the patient/subject in a designated container and tested by the professional laboratory.
9	Sampling and Sample Processing	Sampling is done with the help of the 'Sampling Stick' / 'Sampler' which is a part of the sample collection tube. The fecal sample is thus delivered into the sample collection tube containing the detection buffer which extracts it.	Sampling is done with the help of the 'Sampling Probe' which is a part of the 'OC-Auto Sampling Bottle'. The fecal sample is thus delivered into the sampling bottle containing the buffer which extracts it.
10	Test Cut-off	100 ng/mL (human hemoglobin in the processed human fecal sample)	100 ng/mL (human hemoglobin in processed feces)
11	Presentation of Test Results	Qualitative (Positive if ≥ 100 ng/mL and Negative if < 100 ng/mL)	Qualitative (Positive or Negative)
12	Biohazard and Compatibility with Environment	Ø Used test cartridges and sample collection tubes should be considered as a biohazard. Ø Test components should be handled strictly as per the instructions given in the package insert and the operation manual. Ø Used test cartridges and sample collection tubes should be disposed of in accordance with relevant local, state or federal regulations. Ø If needed, the *i*-CHROMA Reader should be disposed of in accordance	Relevant results have been reported for similar performance characteristics of OC Auto Micro FOB Test

		with applicable regulations.	
13	Compatibility with other Devices	Ø '*i*-CHROMA iFOB' and the '*i*-CHROMA Reader' are compatible only with each other for the purpose of this test system. Ø *i*-CHROMA Reader can also be used for measurement of various analytes/disease markers when used in conjunction with other *in vitro* diagnostic tests manufactured by Boditech Med Inc.	Ø 'OC Auto Micro FOB Test' and 'Polymedco OC Auto Micro 80 Analyzer' are designed to be used together for the purpose of this test system.
14	Chemical Safety	If used in accordance with the warnings, precautions, instructions and procedure prescribed in the package insert, '*i*-CHROMA iFOB' has assured chemical safety profile.	Ø Similar handling precautions and disposal directives are prescribed by the manufacturer.
15	Electrical, Mechanical, Thermal and Radiation Safety	If used in accordance with the warnings, precautions, instructions and procedure prescribed in the operation manual, the in-built safety features of *i*-CHROMA Reader ensures its electrical, mechanical, thermal as well as radiation safety which is already well-established.	'Polymedco OC Auto Micro 80 Analyzer' is reportedly safe on similar counts.

Differences *

DIFFERENCES			
No.	**Comparison Parameter**	**Test Device** **(*i*-CHROMA iFOB with** ***i*-CHROMA Reader)**	**Predicate Device** **(OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Platform/ Format	Lateral flow chromatographic fluorescence immunoassay	Automated immunoassay using latex fixation
2	Test Components	Ø *i*-CHROMA iFOB Test Cartridge Ø *i*-CHROMA iFOB Sample Collection Tube containing the Detection Buffer Ø *i*-CHROMA iFOB ID Chip which contains encoded calibration data	Ø Closed tube-type Sampling Bottle containing the Extraction Buffer Ø Test Reagents (Latex reagent, Buffer, Negative & Positive Controls, Wash Concentrate, and Calibrator)

		& Ø *i*-CHROMA Reader	& Ø OC Auto Micro 80 Analyzer
3	Test Device	Test Cartridge (Test strip enclosed in a plastic housing)	Sampling Bottle containing an extraction buffer
4	Detection Mechanism	Involves scanning/measurement of intensity of fluorescence on the processed sample-loaded test cartridge membrane	Involves optical measurement of agglutination of latex particles

4.0 Test Principle

Enter a brief description of the technology/methodology utilized in the device (i.e., describe how the device works). Describe the principles of the device methodology and whether it is well established or new for the intended use (provide references). Include relevant technical specifications of material and methods not included in the draft package insert (e.g., description of antibodies and epitopes). *

(b)(4)Trade Secret Process

[redacted]

5.0 Performance Characteristics

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

5.1 Analytical Performance

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

5.1.2 Precision (Repeatability/Reproducibility)

Enter a description of studies and results to evaluate estimates of total variability for each specimen type. Include, as appropriate, repeatability (within-run) and reproducibility such as between-day, between-run, within-day, between-sites, between-lots, between instrument, and between operator(s), etc. *

- **Repeatability** was evaluated by examining within-run variability of test results obtained by testing a set of 20 samples at each analyte level in a single run by the same operator using same lot of test components and same instrument.
- **Reproducibility** was evaluated by examining variability of test results under different variable conditions such as between-runs/between-operators, between-days, between-reagent lots, between-instruments and, between-testing sites.
  - **Between-runs/Between-operators variability** was examined by testing a set of 20 samples at each analyte level in each of the two runs conducted by different operators using same lot of test components and same instrument at the same testing site on the same day. Each sample was tested by both the operators.
  - **Between-days variability** was examined by testing 20 aliquots/samples at each analyte level over a period of 20 days (i.e. one sample each day) by the same operator using same lot of test components and same instrument at the same testing site. Two replicates of each aliquot were tested each day.
  - **Between-lots variability** was examined by testing a set of 20 samples at each analyte level using two different lots of test components and same instrument by the same operator at the same testing site on the same day. Each sample was tested using both the lots of test components.
  - **Between-instruments variability** was examined by testing a set of 20 samples at each analyte level using same lot of test components but two instruments having different serial numbers by the same operator at the same testing site on the same day. Each sample was tested using both instruments (having different serial numbers).
  - **Between-testing sites variability** was examined by testing a set of 20 samples at each analyte level using same lot of test components and same instrument by the same operator at two different testing sites on the same day. Each sample was tested at both the testing sites.
  - In each of the above variability studies, precision was evaluated by calculating percent agreement between the test results actually obtained and the test results expected for those samples (considering the analyte level).

Enter a description of specimens (samples) used to study variability including matrix, sample type (e.g., patient samples, spiked samples, control material), and preparation, including analyte levels and how they were established. Describe the relationship between the analyte levels to measuring (reportable) range and medical decision points. *

- (b)(4)Trade Secret Process [redacted]

Enter a description of sources of variability examined (e.g. runs, instruments, operators, days; sites at which variability studies were performed; reagent lots and instruments studies with identifying information). *

Various sources of variability (along with their identifying information) examined for evaluation of repeatability and reproducibility of *i*-CHROMA iFOB are as follows:

(b)(4)Trade Secret Process [redacted]

For Between-testing sites variability study:

Testing Site I: (b)(4)Trade Secret Process, Republic of Korea.

Testing Site II: (b)(4)Trade Secret Process, Republic of Korea.

(b)(4)Trade Secret Process Republic of Korea.

Other identifying information specific to each of variability study has been tabularized as follows:

Sources of variability examined for evaluation of precision of *i*-CHROMA iFOB

No.	Variability Measure	Source of Variability	Samples Tested	Runs/Lots/ Instruments/Sites by Operators	Lot No. of *i*-CHROMA iFOB Used	Serial No. of *i*-CHROMA Reader Used	Variable Conditions	Unchanged Conditions
1	Repeatability	Within-run	3 Levels × 20 Samples on April 13, 2012	Run I by Operator I	FOEGA00	PFR09080571	None	Day, Run, Operator, Lot No., Instrument No. & Testing Site were the same
2	Reproducibility	Between-runs & Between--operators	3 Levels × 20 Samples × 2 Runs on April 13, 2012	Run I by Operator I & Run II by Operator II	FOEGA00	PFR09080571	Runs and Operators were different	Day, Lot No., Instrument No. & Testing Site were the same
		Between-days	3 Levels × (2 Replicate Samples × 20 Days) From March 12 to March 31, 2012	Operator I	FOEGA00	PFR09080571	20 successive days	Operator, Lot No., Instrument No. & Testing Site were the same

		Between-lots	3 Levels × 20 Samples × 2 Lots on April 12, 2012	Lot I & Lot II by Operator I	FOEGA00 & FOEGA01	PFR09080571	Lot No. were different	Day, Operator, Instrument No. & Testing Site were the same
		Between-instruments	3 Levels × 20 Samples × 2 Instruments on April 3, 2012	Instrument I & Instrument II by Operator I	FOEGA00	PFR09080571 & PFR09080574	Instrument Serial No. were different	Day, Operator, Lot No. & Testing Site were the same
		Between-testing sites	3 Levels × 20 Samples × 2 Testing Sites on April 5, 2012	Site I & Sites II by Operator I	FOEGA00	PFR09080571	Testing Sites were different	Day, Operator, Instrument No. & Lot No. were the same

Enter a description of statistical methods used to analyze data; include any model assumptions. *

In each of the above variability studies, precision was evaluated by calculating percent agreement between the test results actually obtained and the test results expected for those samples (considering the analyte level).

For quantitative or qualitative assays with numerical values, report the number of measurements, mean, standard deviation, and %CV for each parameter tested and for each level tested.

For qualitative assays, report the number of replicates, the concentration of the sample, the number of positive and negative results, and the number of invalid or equivocal results, if applicable. For reproducibility studies for qualitative tests, provide an estimate of the precision of the method at analyte concentrations near the cutoff. *

- Each variability study tested 20 aliquots and/or replicates at each of the three analyte (Human Hemoglobin A_0) levels i.e. 50 ng/mL (low level), 125 ng/mL (near cut-off level) and 250 ng/mL (high level).

- In each variability study, the test results at each analyte level show that there is 100% agreement between the test results actually obtained and the test results expected for those samples (considering the analyte level).

- No invalid or equivocal results were obtained during any of the study conducted for evaluating precision of *i*-CHROMA iFOB.

- Quality control test results with *i*-CHROMA iFOB 'Positive' as well as 'Negative' external controls obtained on each day during the precision studies were also within the acceptable ranges.

- In each variability study, the test results at Human Hemoglobin A_0 level of 125 ng/mL (i.e. analyte concentrations near the cutoff) show that there is 100% agreement between the test results actually obtained and the test results expected for those samples (considering the analyte level).

File Attachment	Precision

5.1.3 Linearity/Assay's Measuring (Reportable) Range

State the linear range and the measuring (reportable) range and provide information on how these were established. For quantitative and semi-quantitative assays, provide analytical data to support linearity and to describe recovery of the assay in graphic and tabular form.

Enter the linear range and measuring (reportable) range. Include the measure of deviation from linearity, if applicable.

Enter a description of how reportable range is determined including acceptance criteria or results for accuracy, precision, or other characteristics within this range.

Enter a description of specimen type and preparation including information on matrix, analyte levels, and the methods used to determine the target levels.

Enter the number of samples, the number of replicates, and the statistical methods used.

Enter results such as: estimates of slope, intercept with confidence intervals, and R2 value of regression.

Enter the range of percent recovery at each concentration (observed value/target value).

Describe how results outside the measuring (reportable) range are reported to the user.

Describe validation of instructions for out-of-range specimens, if applicable.

Enter discussion of possible high-dose hook effect, if applicable. *

- Susceptibility of '*i*-CHROMA iFOB Test System' to prozone (hook) effect at excessively high concentration(s) of human hemoglobin in the test sample has been evaluated.

- For investigating prozone effect, 10 replicates of test samples at each of the 6 levels of the analyte viz. 700, 1000, 1300, 1500, 1700, and 2000 ng/mL were tested.

- The test material was human hemoglobin A0 dissolved in a buffered medium containing preservatives.

- Prozone effect was observed at analyte concentration above 1500 ng/mL.

File Attachment	Prozone

5.1.4 Calibrators and Controls

Are calibrators or controls included in the submission?	*	Yes
. If you answered "no" to the above questions explain why.		
. Enter the 510(k) number.		
. Provide information on the commercial source and control preparation methods.		

Enter information if external calibrators or controls are to be cleared with this device. Include analyte levels, matrix, preparation method, value assignment and validation, traceability of the calibrator to a reference material as appropriate, stability study summary, storage conditions, frequency of testing, control reference, acceptance limit, how the recommended calibration and control testing frequency were established, validation of the standard curve by replicate analysis of calibrators, and validation of quality control, as appropriate (e.g., novel, internalized quality control). *

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Enter the description of internal controls, the reaction, functions monitored, and frequency of controls needed, if applicable. *

(b)(4)Trade Secret Process

[redacted]

5.1.5 Traceability, Stability, Expected Values (Controls, Calibrators, Methods)

Where applicable, briefly summarize the following info mation about calibrators and controls: method and acceptance criteria for opened and closed stability studies, traceability to reference material, and description of value assignment, validation, and acceptance criteria. *

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

5.1.6 Analytical Specificity

Enter a description of study design and statistical methods. *

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Enter the specimen description and preparation including matrix, analyte levels present in the sample, and how these levels were established. *

(b)(4)Trade Secret Process

[redacted]

Enter a list of the potentially cross-reactive and interfering substances tested including those where a similar syndrome can be associated with more than one analyte/agent/organism. Also include the concentrations at which these substances were present in the samples (indicate highest concentration tested and/or lowest concentration at which an effect was observed). Finally, include the number of replicates tested for each substance. *

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Enter a description of the positive and negative control samples that served as a reference to identify any interference or cross reactivity. Describe how interference and cross reactivity were defined in relation tothe results obtained for the control samples. *
Above studies were also conducted using i-CHROMA iFOB Positive and Negative Controls as the test material and the test results were compared with the results of studies for evaluation of analytical specificity. Results of both the studies were identical in nature.

Enter a description of the degree of interference or cross-reactivity observed. *

(b)(4)Trade Secret Process

[redacted]

File Attachment 1	Sensitivity to Hb Variants
File Attachment 2	Interference to animal hemoglobin
File Attachment 3	Interference with Endogenous substances

5.1.7 Analytical Characterization of Cut-off

Enter the rationale for the units, cut-off and/or categories of the results. *

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Enter a description of specimen preparation including analyte levels, matrix, and how level was established. *

- Study aimed at analytical characterization of cut-off of *i*-CHROMA iFOB was carried out at the O(b)(4)Trade Secret Process [redacted].
- 200 Test samples were sourced from amongst the human fecal samples received routinely for clinical testing at (b)(4)Trade Secret Process [redacted].
- Each human fecal sample was first tested by the predicate method 'OC Auto Micro FOB Test' and then by *i*-CHROMA iFOB.
- Qualitative as well as quantitative results obtained by both the methods were noted and analyzed by ROC analysis.

Enter a definition of "equivocal zone," if applicable. *

Equivocal zone as applied to *i*-CHROMA iFOB may be defined as the analyte concentration range of 95-105 ng/mL wherein a test sample has an equal probability of being tested positive or negative.

Enter the statistical method used (e.g., Receiver Operator Characteristic Analysis). *

Statistical analysis of the test results obtained during analytical characterization of cut-off of *i*-CHROMA iFOB was done by using ROC Analysis i.e. Receiver Operator Characteristics Analysis.

5.1.8 Instrument Only

Accuracy

Compare each test parameter to either a reference method or a predicate device with the same intended use. Use a testing pool that contains samples representative of the appropriate population. Include an equal number of males and females for which samples span the reportable range. Include specimens that are close to the clinically critical decision point(s). Present the data using linear regression, including 95% confidence intervals for the slope and y-intercept. Provide scatter plots.

Precision/Reproductibility

Provide estimates of intra, inter, lot-to-lot, operator-to-operator, and total imprecision for each measurand parameter of the device using samples that span the testing range.

Linearity

Provide information on how linearity was established and indicate whether this conformed to EP6-PS or any other appropriate methodology.

Carryover

Provide studies to demonstrate lack of overestimation of results due to the carryover effect. The testing pool should consist of samples at clinically meaningful levels. *

Not Applicable

Interfering Substances

Provide studies to show possible interference of substances such as lipids, hemoglobin, bilirubin, etc.

5.2 Comparison Studies Using Clinical Specimens

5.2.1 Method Comparison

Note:	*For method comparison describe bias/agreement between the new device and comparator (i.e., predicate, reference method, disease state or a combination there of as appropriate for the desired claim). This also includes a description of study design and statistical methods. For examples of information to be included in study design description, see the article reporting the STARD initiative (Clin Chem 2003; 49(1): 7-18).*

5.2.1.1 Study Design

Identify the comparator chosen with explanation for why it was selected and information to support its validity. *

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Enter the selection criteria for inclusion and/or exclusion of patients/samples in the study. Examples of selection criteria are: age and sex of patients, medical history (e.g. diagnoses, vaccinations, biopsies, pregnancies, use of select medications), presentation of symptoms, current treatment for disease, high, moderate or low risk for disease(define each -often based on lifestyle or medical history), and specimen collection and storage. *

Collection site:

- Fecal samples from amongst those submitted (b)(4)Trade Secret Process at (b)(4)Trade Secret Process [redacted] (b) [redacted] were used as test samples for the method comparison study.

Selection Criteria:

- Fecal samples of patients meeting following criteria were used for the method comparison study.

  - Patients above the age of 50 years

  - Patients of both sexes

- However following category of fecal samples were excluded from amongst the fecal samples meeting the above-mentioned inclusion criteria:

  - Fecal samples of patients suffering from bleeding hemorrhoids.

  - Fecal samples of patients suffering from constipation bleeding.

  - Fecal samples of patients suffering from urinary bleeding.

  - Fecal samples of female patients collected during menstrual bleeding or collected within three days after cessation of menstrual bleeding.

Sample collection, storage & testing:

- Fecal samples being submitted in specimen cups to the hospital were code-numbered. Demographic details of the patient corresponding to each code-numbered sample were also noted separately in confidential records immediately upon receipt of the sample at the hospital.

  A. After record-entry, the samples were stored at low temperature (2 ~ 8 °C) in the specially designated ice box.

  B. Samples obtained during 9 am–2 pm every day were securely shipped under low temperature conditions (2 ~ 8 °C) during 2 pm–3 pm on the same day to the testing site viz. (b)(4)Trade Secret Process [redacted]

  C. The samples were tested during 3 pm - 5 pm on the same day immediately upon receipt at the testing site.

  D. Each sample was tested first with 'i-CHROMA iFOB' by Operator-I and then with the comparator/predicate method 'OC Auto Micro FOB' by Operator-II.

Enter the sample description (e.g., matrix). *

Normal fecal samples of patients as per the above-mentioned criteria were used for the method comparison study.

Enter setting and locations where data were collected. Include names and addresses of principal investigators. Sites should be representative of the United States population. Include the setting and location of device testing sites if different from collection sites. Also enter the number, training and expertise of the persons executing and reading the tests and how they represent the intended user. *

1) Test samples were sourced from amongst the human fecal samples submitted r(b)(4)Trade Secret Process [redacted] which is a 500-bed multi-specialty hospital.

2) No physician/principal investigator was involved in the method comparison study.

3) Fecal samples were tested at(b)(4)Trade Secret Process [redacted]

4) Each sample was tested first with 'i-CHROMA iFOB' by Operator-I and then with the comparator/predicate method 'OC Auto Micro FOB' by Operator-II.

5) Operator-I was a qualified laboratory technician of the Quality Control Department having six years experience in same capacity.

6) Operator-II was a research associate having master degree in Clinical Pathology, and biological science with seven years experience.

7) Patients whose fecal samples were sourced for the study and the sample collection site as well as the testing site very well represent the United States population intended for use in the context of the proposed test.

Enter when the study was done, including beginning and ending dates of recruitment/testing. *

For the method comparison study, samples were collected and tested during April 16, 2012 ~ April 20, 2012.

Enter population sampling method. Was the study population a consecutive series of recruited participants defined by the selection criteria? Was recruitment based on presenting symptoms or results from previous testing? *

Test samples (subject to the inclusion/exclusion criteria mentioned above) were sourced from amongst the human fecal samples submitted routinely [redacted] b

Enter specimen collection methodology. Include a description of whether specimens were procured from banked collections (retrospective study), or whether they were collected from patients during the study (prospective study). *

(b)(4)Trade Secret Process

[redacted]

Enter information on how the readers of each test were masked to any other clinical information or test results. *

(b)(4)Trade Secret Process

[redacted]

Enter the time interval and allowable storage conditions between specimen collection and testing by each method. Enter validation of these conditions, as appropriate. *

(b)(4)Trade Secret Process

[redacted]

Enter the total number of patients, specimens obtained per patient, and number of measurements taken per specimen. *

(b)(4)Trade Secret Process

[redacted]

Enter the external control results for each day of testing at each site. *

(b)(4)Trade Secret Process

[redacted]

Attach or enter a table to describe clinical and demographic characteristics of the study population to support the intended/indicated use. Provide a table that stratifies and summarizes your data by relevant demographic subpopulations. *

Criteria	Number
Total number of patients from whom fecal samples were obtained for the method comparison study	134
Number of patients above the age of 50 years	134
Number of male patients	77
Number of female patients	57

Enter the number of specimens satisfying the criteria for inclusion that did or did not undergo the new device and/or comparator test; why specimens failed to be tested. *

All the 134 fecal samples satisfying the inclusion criteria were tested by 'i-CHROMA iFOB' as well as the comparator 'OC Auto Micro FOB' test.

For indeterminate results, invalid results, missing responses and outliers: Enter an explanation of how results were placed into each of these categories (should be defined prior to study start). Include total number of specimens, number retested and number discarded in each category (if discarded, explain why). Enter agreement of retested specimens with reference standard. Include information on whether retested specimen results are included in final estimates of sensitivity, specificity or percent agreement. Finally, enter a summary of significant anomalous results (e.g., device failures, excluded outliers). Include data analysis with and without outliers. *

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Enter analyte level distribution among samples to demonstrate that the medical decision points were challenged and the proposed measuring range was covered.

5.2.1.2 Results

Include estimates of agreement with measures of statistical uncertainty (e.g., 95% Confidence Intervals or other appropriate statistical comparison measures). For each testing site, and for all sites combined if justified, for each specimen type described separately, and combined if justified, and for major subgroups of participants, and all participants combined, if justified. *

Following are the estimates of agreement (along with 95% Confidence Intervals as the measure of statistical uncertainty) of the results of method comparison study of 'i-CHROMA iFOB' with the comparator/predicate test 'OC Auto Micro FOB':

Positive Percent Agreement	Negative Percent Agreement	Positive Percent Agreement		Negative Percent Agreement	
		Two-sided 95% Confidence Interval		Two-sided 95% Confidence Interval	
		Lower Bound	Upper Bound	Lower Bound	Upper Bound
91.04%	92.86%	81.81%	95.83%	80.99%	97.54%

File Attachment	Method Comparison

Do you have an equivocal zone with your assay? * Yes

Attach or enter the appropriate table. *

Details of the Study	New Test	Comparator/Predicate Test			Positive Percent Agreement	Negative Percent Agreement
	i-CHROMA iFOB	OC Auto Micro FOB				
		Positive Results	Negative Results	Total Results		
Comparison of 'i-CHROMA iFOB with the predicate method 'OC Auto Micro FOB' using clinical human fecal samples	Positive Results	**61**	03	64	**91.04%**	**92.86%**
	Negative Results	06	**39**	45		
	Total Results	**67**	42	109		

For quantitative tests, enter the description of statistical methods of analysis (e.g., Deming regression, linear regression or other appropriate statistical measures) and results. Results may include regression equation, confidence intervals, correlation coefficient, measure of scatter around the estimated regression line (e.g., standard error of the estimated regression line or other appropriate statistical measures). If the approach is different than the predicate device, explain why.

Include graphs of the new test results against the results of the comparator for each separate specimen type, sample subgroup or testing site (and combined if justified). Other tabular or graphical representations may also be appropriate, e.g., Bland-Altman plots. *

Details of the Study	New Test	Comparator/Predicate Test			Positive Percent Agreement	Negative Percent Agreement
	i-CHROMA iFOB	OC Auto Micro FOB				
		Positive Results	Negative Results	Total Results		
Comparison of '*i*-CHROMA iFOB with the predicate method 'OC Auto Micro FOB' using clinical human fecal samples	**Positive Results**	**61**	03	64	**91.04%**	**92.86%**
	Negative Results	06	**39**	45		
	Total Results	**67**	42	109		

Provide descriptive statistics where applicable: n, mean, standard deviation, minimum, median, maxmum, and stratified results (e.g. by patient enrollment site, lab testing site). *

Results of the method comparison study of '*i*-CHROMA iFOB Test System' were obtained under dual display (Qualitative/Quantitative) mode of '*i*-CHROMA Reader'.

- However, '*i*-CHROMA iFOB' is being proposed as a qualitative in-vitro diagnostic test.

- Commercial '*i*-CHROMA iFOB' test will display the test results in qualitative (Very Low, Negative, Positive or Very High) manner only.

- Hence these statistical parameters were not applied to the test results of method comparison study of '*i*-CHROMA iFOB'.

Describe the adverse events from performing the new or comparator tests. *

No adverse event was reported.

5.2.2 Matrix Description and Comparison

Describe, where appropriate, the additional studies characterizing agreement and precision for each matrix. When appropriate, include an analytical study of specimen transport conditions and analyte stability. *

Relevant studies have already been described under 5.1.1 – 5.1.7 and 5 2.1

5.3 Clinical Studies (where applicable)

Are there clinical studies included in this submission? *	No

Note:	*Also see information in the "comparison studies using clinical specimens" section above as well as the CLSI GP10-A, Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots. Definition and rationale for "Clinical Truth," statistical methods applied.*

Enter the clinical sensitivity and clinical specificity: estimates of diagnostic accuracy with confidence intervals such as sensitivity, specificity, positive and negative predictive values, etc.

Include any other clinical supportive data, statistical analysis, and results if applicable:(e.g., other clinical supporting data such as clinical therapy monitoring

data, etc.).

6.0 Labeling

Provide proposed package labeling to demonstrate conformance to 21 CFR 809.10. Also, include package insert for the predicate device, if available. Labeling at a minimum should include: device components and specifications, reagent composition and important specifications, precautions/warnings, limitations, storage requirements, specimen handling and storage requirements, expiration/stability dating, instructions for reconstitution, mixing, and dilution, assay procedure, calibration, quality controls, results (calculations, formulas), results(interpretation), performance characteristics (summarize reproducibility, etc.), and study design (population studied, N, type of sample, matrix, dilution, target concentrations, etc.).	*
Draft of following instructional materials have already been attached under Section 5.0 of CLIA waiver Appendix 2 i-CHROMA iFOB Package Insert Appendix 3 i-CHROMA iFOB Quick Reference Instruction Appendix 4 i-CHROMA iFOB Control package Insert Appendix 5 i-CHROMA Reader Operation Manual	

Note:	*The minimum requirements above do not include requirements for instruments. Additional labeling recommendations may apply to Class II devices with special controls and Guidance.*

7.0 Other Supportive Information

Enter any additional supporting information for this submission such as: manufacturing information for critical reagents, copies of bibliography references, financial disclosures, and software validation or certification statements, if necessary to support equivalence.	*
Attached Files 1. i-CHROMA Reader Software Validation Report 2. i-CHROMA Reader Electromagnetic Compatibility and Electrical Safety (EMC) Test Report	
File Attachment 1	i-CHROMA READER Software Validation Report
File Attachment 2	i-CHROMA Reader Electromagnetic Compatibility and Electrical Safety (EMC) Test Report

Section 5: 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR, Section 807.92 (c).

Submitter Information: Boditech Med Inc.
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REPIUBLIC OF KOREA.
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Contact Person: **Sang Yeol Park**/ Senior Director/ Ph.D.

Date: **June 28, 2013**

Device Information:

Trade Name: *i*-CHROMA iFOB with *i*-CHROMA Reader
Common Name: *i*-CHROMA iFOB
Classification Name: Reagent, Occult Blood
Class: II
Panel: Hematology
Product Code: KHE
Regulation: 21 CFR § 864.6550

Predicate Device: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer
Predicate K Number: K041408

Device Description:

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

Intended Use(s):

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples. *i*-CHROMA iFOB is a rapid, convenient, sensitive and reliable *in vitro* diagnostic test which aids in the diagnosis of gastrointestinal bleeding disorders such as colorectal cancer.

Indications for Use(s):

i-CHROMA iFOB is recommended for use in routine physical examination, screening and/or monitoring for gastrointestinal bleeding disorders such as colorectal cancer by laboratories, and physician offices.

Components of *i*-CHROMA iFOB:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer'.

- The test cartridge contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.

- The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each sample collection tube contains 1 mL detection buffer. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

***i*-CHROMA iFOB Test Cartridge:**

i-CHROMA iFOB Test Cartridge is composed of a test strip enclosed in a disposable plastic housing.

The components of the test strip are:
- An antibody-immobilized nitrocellulose membrane
- A sample pad
- An absorption pad (also called absorbing pad or absorbent pad)
- A plastic backing

***i*-CHROMA iFOB Sample Collection Tube:**

'Sample Collection Tube' is an essential component of *i*-CHROMA iFOB. A box containing 25 sample collection tubes, is delivered separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

The sample collection tube is a specially designed plastic container. Each sample collection tube contains 1mL Detection Buffer. Apart from being the container for the detection buffer, the sample collection tube acts as the common mechanism for the following:

i) Proper sampling of the fecal sample
ii) Processing or thorough mixing of the fecal sample with the detection buffer for ensuring complete extraction of the fecal sample
iii) Application of precise quantity of the processed fecal sample into the 'Sample well' of the *i*-CHROMA iFOB test cartridge

***i*-CHROMA Reader:**

i-CHROMA Reader is a custom-configured, portable, desktop, fluorescence-scanning instrument for qualitative detection of fecal occult blood (FOB) in human fecal samples; duly

processed and tested by *i*-CHROMA iFOB. *i*-CHROMA Reader can also be used for quantitative determination of various other analytes/disease markers when used in conjunction with other *in vitro* diagnostic immunoassay tests manufactured by Boditech Med Inc.

i-CHROMA Reader is intended to be used only in conjunction with *i*-CHROMA iFOB for *in vitro* diagnostic purpose by laboratories and physician offices. *i*-CHROMA Reader measures 250 mm (L) x 185 mm (W) x 80 mm (H) in size and weighs 1.2 Kg. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other.

The *i*-CHROMA iFOB test cartridge is loaded with the human fecal sample which has been duly pre-processed as per the standard test procedure prescribed by Boditech Med Inc. This sample-loaded test cartridge is inserted in to the cartridge holder of the *i*-CHROMA Reader for the purpose of being scanned.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin (accumulated at the test line). The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which is proportional to intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration. The computed and converted result is displayed by the *i*-CHROMA™ Reader in a qualitative (positive or negative) manner.

Test Principle:

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human fecal sample is processed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer binds with hemoglobin in the fecal occult blood (FOB).

When this processed fecal sample is loaded into the sample well on the test cartridge as per the prescribed test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, the fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, more the hemoglobin in the human fecal sample, more the complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which is proportional to intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

i-CHROMA iFOB and *i*-CHROMA Reader are compatible only with each other.

Substantial Equivalence Information:

Predicate Device: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer

Predicate K Number: K041408

Comparison with the Predicate Device:

Following table summarizes similarities and difference between the test device *i*-CHROMA iFOB and the predicate device OC Auto Micro FOB Test.

SIMILARITIES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Principle	Immunological test system using antigen-antibody reaction for detection of human hemoglobin in human fecal samples.	Immunological test system intended for qualitative detection of fecal occult blood in feces
2	Intended Use	Qualitative detection of fecal occult blood (FOB) in human fecal samples by laboratories and physician offices	Qualitative detection of fecal occult blood in feces by professional laboratories
3	Test Sample	Human fecal sample processed in the detection buffer	Feces in an extraction buffer
4	Test Cut-off	100 ng/mL (Human hemoglobin in human fecal sample processed in detection buffer)	100 ng/mL (Human hemoglobin in feces processed in extraction buffer)
DIFFERENCES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Platform	Fluorescence immunoassay using lateral flow technology	Automated immunoassay using latex fixation
2	Test Time	10 minutes	5~10 minutes
3	Detection Mechanism	Involves scanning/measurement of intensity of fluorescence on the test cartridge membranes	Involves optical measurement of agglutination of latex particles

Standard/Guidance Document Referenced:

USFDA guidance document for industry and FDA staff:
'Review Criteria for Assessment of Qualitative Fecal Occult Blood In Vitro Diagnostic Devices' (Issue date: August 8, 2007**)**

Summary of Performance Testing (Bench):
Summary of Performance Testing (Bench):

- **Measuring**/r**eportable range** of *i*-CHROMA iFOB was found to be **25.00–1000.00 ng/mL** (hemoglobin in the human fecal sample) with the **cut-off** of **100 ng/mL.**
- *i*-CHROMA iFOB showed **no prozone**/**hook effect up to** analyte concentration **1500 ng/mL**.
- *i*-CHROMA iFOB was found to be **equally sensitive to** 'Hemoglobin S' as the **abnormal hemoglobin** associated with sickle cell anemia.
- **No significant interference** was observed **from** of any of the eight **animal hemoglobin** (viz. bovine, chicken, fish, equine, goat, swine, rabbit, and sheep origin) **and** any of the four **endogenous substances** (Ascorbic acid, Bilirubin, Albumin and Myoglobin) tested with *i*-CHROMA iFOB.
- **100%** agreement was observed between the test results actually obtained and the test results expected (considering the analyte level of test samples) in each variability study conducted for evaluating **precision** of *i*-CHROMA iFOB.
- **Method comparison** study involving prospective testing of human fecal samples (subject to the selection criteria) with *i*-CHROMA iFOB and the predicate/ comparator method 'OC Auto Micro FOB' **showed high level of positive and negative percent agreements** between the two methods.
- **Clinical testing study** involving prospective testing of clinical human fecal samples (subject to the selection criteria) over four demographically different clinical testing sites showed:
  - **More than 95% positive and negative percent agreements** in test results when compared **with the predicate method**
  - **95-100% accuracy** in test results **with weak positive and weak negative samples.**

Conclusions:

In view of the matter mentioned above, it can be positively concluded that *i*-CHROMA iFOB is substantially equivalent to the predicate device OC Auto Micro FOB Test.

Classification	Limit of Detection												
Testing Material	For determining the lower limit of detection, 16 levels of Human Hemoglobin A0 viz. 5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, 90, 100, 110, and 120 ng/mL						Operator			Hye Sung Kim, QC Manager			
	For determining the upper limit of detection, 8 levels of Human Hemoglobin A0 viz. 800, 850, 900, 950, 1000, 1100, 1250, and 1500 ng/mL						Device Lot No.			FOEGA00			
							Reader Serial No.			PFR09E080571			
Testing date	2012. 04. 04						Testing Site			R&D Center, Boditech Med Inc.			
Minimum Detection Limit	Conc.(ng/mL)	1	2	3	4	5	6	7	8	9	AV	SD	CV(%)
	5	3.46	4.84	6.28	6.48	5.48	7.56	4.89	6.68	3.18	5.39	1.40	26.02
		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg			
	10	14.39	11.89	14.56	8.44	12.61	11.52	13.25	10.48	7.78	11.49	2.33	20.23
		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg			
	15	13.48	16.78	17.82	11.42	10.98	13.82	13.49	11.33	14.28	13.84	2.28	16.44
		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg			
	20	23.55	19.39	18.49	12.46	18.71	20.46	22.92	19.31	23.74	19.90	3.28	16.48
		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg			
	25	25.19	23.49	25.68	26.62	26.32	24.47	26.69	23.85	24.18	25.15	1.16	4.60
		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg			
	30	29.73	28.36	31.51	32.31	31.79	28.63	28.9	29.3	32.1	30.26	1.52	5.03
		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg			
	35	33.99	35.74	36.2	37.96	33.5	35.62	33.4	35.2	34.8	35.14	1.37	3.89
		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg			
	40	41.65	42.33	43.17	42.55	41.98	38.76	38.5	41.3	43.8	41.40	1.79	4.32
		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg			
	50	49.54	52.33	51.89	49.72	52.69	46.85	49.29	52.55	53.19	50.81	2.03	4.00
		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg			
	Conc.(ng/mL)	1	2	3	4	5	6	7	8	9	AV	SD	CV(%)
	60	61.23	58.09	59.07	63.14	61.84	62.22	58.07	57.76	53.26	59.47	2.90	4.87

Near the Cut-off	60												
		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg			
	70	70.55	68.29	73.51	72.08	69.94	71.03	70.51	73.55	67.44	70.69	1.99	2.81
		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg			
	80	83.66	83.07	81.46	84.52	81.27	78.43	77.14	85.07	79.84	81.45	2.63	3.23
		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg			
	90	93.47	91.08	90.64	93.22	94.61	89.24	88.88	103.07	96.07	93.03	4.26	4.58
		Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos	Neg			
	100	104.22	97.96	102.28	106.38	97.26	105.63	105.58	102.31	98.27	101.99	3.45	3.38
		Pos	Neg	Pos	Pos	Neg	Pos	Pos	Pos	Neg			
	110	113.53	108.27	105.19	109.64	113.36	114.5	116.29	110.85	112.07	111.37	3.27	2.93
		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos			
	120	119.28	122.64	120.84	126.37	124.44	120.74	125.52	126.66	127.37	123.39	3.05	2.47
		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos			
Maximum Detection Limit	Conc.(ng/mL)	1	2	3	4	5	6	7	8	9	AV	SD	CV(%)
	800	789.36	821.62	842.64	803.42	822.67	768.94	785.25	769	842.64	804.55	27.24	3.39
		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos			
	850	846.5	835.67	882.62	823.55	855.46	842.82	853.48	838.64	891.75	852.05	20.83	2.44
		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos			
	900	887.65	882.46	925.55	903.4	925.86	904.38	892.52	932.4	911.63	906.59	17.06	1.88
		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos			
	950	952.32	923.51	967	953.74	966.25	932.14	966.84	945.71	926.87	948.44	16.35	1.72
		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos			
	1000	1006.86	989.45	966.82	1019.5	957.6	982.6	968.24	973.65	986.92	985.16	19.47	1.98
		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos			
	1100	952.36	1035.84	1335.72	983.24	1001.58	978.72	1207.82	1003.49	1000.56	1059.93	122.15	11.52
		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos			
	1250	1056.57	1156.67	1004.57	1005.67	1652.29	1035.26	1104.23	1106.29	1030.51	1140.21	195.37	17.13
		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos			
	1500	1139.12	1898.27	1229.57	1103.53	1201.84	1158.62	1212.75	1189.53	1086.24	1271.95	248.25	19.52
		Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos			

Concentration	Expected Value	Test Value			Total Agreement (%)
		Total	Positive	Negative	
Hb 60 ng/mL	Negative	9	0	9	100
Hb 70 ng/mL	Negative	9	0	9	100
Hb 80 ng/mL	Negative	9	0	9	100
Hb 90 ng/mL	Negative	9	1	8	89
Hb 100 ng/mL	Positive	9	6	3	67
Hb 110 ng/mL	Positive	9	9	0	100
Hb 120 ng/mL	Positive	9	9	0	100

60~120 ng/mL

Test Result				Test Sample Number			PPA	NPA	For PPA			For NPA		
A(+/+)	B(+/-)	C(-/+)	D(-/-)	Total	Positive	Negative			Q1	Q2	Q3	Q1	Q2	Q3
24	3	1	35	63	25	38	96.00	92.11	51.8	5.4	57.7	73.8	7.6	83.7

PPA; Confidence Interval(CI)		NPA; Confidence Interval(CI)	
Lower Bound	Upper Bound	Lower Bound	Upper Bound
80.46	99.29	79.20	97 28

100 ng/mL

Test Result				Test Sample Number			PPA	NPA	For PPA			For NPA		
A(+/+)	B(+/-)	C(-/+)	D(-/-)	Total	Positive	Negative			Q1	Q2	Q3	Q1	Q2	Q3
6	3	0	0	9	6	3	100.00	0.00	15.8	3 8	19.7	3.8	3.8	13.7

PPA; Confidence Interval(CI)		NPA; Confidence Interval(CI)	
Lower Bound	Upper Bound	Lower Bound	Upper Bound
60.97	100.00	0.00	56 15

25 ng/mL

Test Result				Test Sample Number			PPA	NPA	For PPA			For NPA		
A(+/+)	B(+/-)	C(-/+)	D(-/-)	Total	Positive	Negative			Q1	Q2	Q3	Q1	Q2	Q3
0	0	0	9	9	0	9	#DIV/0!	100.00	3.8	#DIV/0!	7.7	21.8	3.8	25.7

PPA; Confidence Interval(CI)		NPA; Confidence Interval(CI)	
Lower Bound	Upper Bound	Lower Bound	Upper Bound
#DIV/0!	#DIV/0!	70.08	100.00

1000 ng/mL

Test Result				Test Sample Number			PPA	NPA	For PPA			For NPA		
A(+/+)	B(+/-)	C(-/+)	D(-/-)	Total	Positive	Negative			Q1	Q2	Q3	Q1	Q2	Q3
9	0	0	0	9	9	0	100.00	#DIV/0!	21.8	3 8	25.7	3.8	#DIV/0!	7.7

PPA; Confidence Interval(CI)		NPA; Confidence Interval(CI)	
Lower Bound	Upper Bound	Lower Bound	Upper Bound
70.08	100.00	#DIV/0!	#DIV/0!

Appendix 6: Clinical Testing for CLIA Waiver

Purpose of study:

- Clinical testing was carried out to demonstrate the accuracy of *i*-CHROMA iFOB at the hands of intended operators through prospective testing using patient samples collected in the intended testing environment.

Clinical testing sites:

- Clinical testing of *i*-CHROMA iFOB was conducted at following four sites at different demographic locations:

(b)(4)Trade Secret Process [redacted]

- These sites were selected to closely replicate the clinical setting actually intended for proposed clinical use of *i*-CHROMA iFOB.
- Details of these clinical testing sites are as follows:

Study site 1:

- Site Number**:** SS-1

(b)(4)Trade Secret Process [redacted]

Study site 2:

- Site Number: SS-2

(b)(4)Trade Secret Process [redacted]

Study site 3:

- Site Number: SS-3

(b)(4)Trade Secret Process [redacted]

(b)(4)Trade Secret Process [redacted]

Study site 4:

- Site Number: SS-4

(b)(4)Trade Secret Process [redacted]

Clinical investigators:

- Clinical investigators were not involved in the clinical testing of *i*-CHROMA iFOB conducted at the four testing sites.

Operators:

- Operators from amongst those available at the testing sites were enrolled to participate in the clinical testing.
- It was aimed to enroll 1-3 operators at each testing sites so as to have the participation of a minimum of 9 operators in total over the 4 clinical testing sites.
- The enrolled operators were chosen on the basis to represent anticipated operators of *i*-CHROMA iFOB in proposed clinical settings in terms of occupation, training and experience.
- Accordingly operators were enrolled to participate in clinical testing of *i*-CHROMA iFOB at the designated testing sites as per following details (**Table 20.1**):

Table A6-1 Site-wise availability, enrolment and participation of operators for the clinical testing study of *i*-CHROMA iFOB

Site No.	Clinical testing site	Number of operators at the testing site	
		Available	Chosen to enroll & participate in the clinical testing
SS-1	(b)(4)Trade Secret Process [redacted]	06	**03** (SS1-O1, SS1-O2 & SS1-O3)
SS-2		03	**02** (SS2-O1 &SS2-O2)
SS-3		05	**03** (SS3-O1, SS3-O2 & SS3-O3)
SS-4		01	**01 (**SS4-O1)
Total		**15**	**09**

(b)(4)Trade Secret Process

[redacted]

[Clinical testing methodology]

Selection of comparative method (CM):

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

General approach for method comparison of '*i*-CHROMA iFOB' with 'OC Auto Micro FOB':

(b)(4)Trade Secret Process

[redacted]

Determination of performance of *i*-CHROMA iFOB at analyte concentrations near the cutoff:

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Instructional materials:

- Test operators who participated in the clinical testing study (conducted at the three Korean sites) were provided with Korean language versions of following instructional materials.

  1. List of 'Do's and Don'ts for Test Operators'
  2. Interim draft of proposed 'Quick Reference Instructions of *i*-CHROMA iFOB'
  3. Interim draft of proposed 'Package Insert of *i*-CHROMA iFOB'
  4. Interim draft of proposed 'Operation Manual of *i*-CHROMA Reader'

- Test operator who participated in the clinical study conducted at the USA site was provided with proper English drafts of the above instructional materials.
- At each testing site, the technician operating the 'OC Auto Micro FOB' referred the relevant instructional material.

Testing and quality control procedure:

(b)(4)Trade Secret Process

[redacted]

Masking:

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Criteria for categorization of test results:

(b)(4)Trade Secret Process

[redacted]

Retesting of invalid and indeterminate results:

(b)(4)Trade Secret Process

[redacted]

Statistical analysis of study results:

(b)(4)Trade Secret Process

[redacted]

Performance criteria:

(b)(4)Trade Secret Process

[redacted]

Results of the study:

- Site-wise details of clinical testing of samples have been shown in **Tables A6-2~7**
- Site-wise as well as combined information regarding the calculated percent agreement estimates along with one-sided 97.5% lower confidence bounds for the positive and negative results obtained with clinical samples tested by '*i*-CHROMA iFOB' as well as the comparative method 'OC Auto Micro FOB') are as follows:

1) Study Site SS-1:

Clinical Study Site Number	Waiver Method	Comparative Method			Positive Percent Agreement	Negative Percent Agreement
	i-CHROMA iFOB	OC Auto Micro FOB				
		Positive Results	Negative Results	Total Results		
SS-1	Positive Results	49	03	52	98.00%	96.15%
	Negative Results	01	75	76		
	Total Results	50	78	128		

Number & Name of Clinical Study Site	Positive Percent Agreement			Negative Percent Agreement		
	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound
	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)
Site SS-1	89.50%	99.65%	89.50%	89.29%	98.68%	89.29%

2) Study Site SS-2:

Clinical Study Site Number	Waiver Method	Comparative Method			Positive Percent Agreement	Negative Percent Agreement
	i-CHROMA iFOB	OC Auto Micro FOB				
		Positive Results	Negative Results	Total Results		
SS-2	Positive Results	50	02	52	98.04	97.18
	Negative Results	01	69	70		
	Total Results	51	71	122		

Number & Name of Clinical Study Site	Positive Percent Agreement			Negative Percent Agreement		
	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound
	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)

Site SS-2	89.70%	99.65%	89.70%	90.30%	99.22%	90.30%

3) Study Site SS-3:

Clinical Study Site Number	Waiver Method *i*-CHROMA iFOB	Comparative Method OC Auto Micro FOB			Positive Percent Agreement	Negative Percent Agreement
		Positive Results	Negative Results	Total Results		
SS-3	Positive Results	51	03	54	98.08%	97.22%
	Negative Results	01	105	106		
	Total Results	52	108	160		

Number & Name of Clinical Study Site	Positive Percent Agreement			Negative Percent Agreement		
	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound
	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)
Site SS-3	89.88%	99.66%	89.88%	92.15%	99.05%	92.15%

Study Site SS-4:

Clinical Study Site Number	Waiver Method *i*-CHROMA iFOB	Comparative Method OC Auto Micro FOB			Positive Percent Agreement	Negative Percent Agreement
		Positive Results	Negative Results	Total Results		
SS-4	Positive Results	32	03	35	100%	96.05%
	Negative Results	00	73	73		
	Total Results	32	76	108		

Number & Name of Clinical Study Site	Positive Percent Agreement			Negative Percent Agreement		
	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound
	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)	Lower Bound	Upper Bound	(same as the Lower Bound of Two-sided 95% Confidence Interval)
Site SS-4	89.28%	100%	89.28%	89.03%	98.65%	89.03%

4) Combined Analysis:

Number and Name of the Clinical Study Sites	Waiver Method *i*-CHROMA iFOB	Comparative Method OC Auto Micro FOB			Positive Percent Agreement	Negative Percent Agreement
		Positive Results	Negative Results	Total Results		
SS-1, 2, 3, 4	Positive Results	182	11	193	98.38%	99.70%
	Negative Results	03	322	325		
	Total Results	185	333	518		

Clinical Study Sites	Positive Percent Agreement			Negative Percent Agreement		
	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound (same as the Lower Bound of Two-sided 95% Confidence Interval)	Two-sided 95% Confidence Interval		Lower One-sided 97.5% Confidence Bound (same as the Lower Bound of Two-sided 95% Confidence Interval)
	Lower Bound	Upper Bound		Lower Bound	Upper Bound	
SS-1 to SS-4	95.34%	99.45%	95.34%	94.18%	98.15%	94.18%

- Site-wise as well as combined information regarding the percent of the positive and negative results obtained with 60 aliquots of the weak positive sample and 60 aliquots of the weak negative sample tested by *i*-CHROMA iFOB has been tabulated as follows:

Name of Testing Site	Operator	Number of Samples Tested		Results Obtained by the Waiver Method			
				Weak Positive Samples		Weak Negative Samples	
		Weak Positive	Weak Negative	True Positive	False Negative	True Negative	False Positive
SS-1	Operator SS1-O1	10	10	10	00	10	00
	Operator SS1-O3	10	10	09	01	10	00
	Total	20	20	19 (95%)	01 (5%)	20 (100%)	00 00%)
SS-2	Operator SS2-O1	10	10	10	00	09	01
	Operator SS2-O2	10	10	10	00	10	00
	Total	20	20	20 (100%)	00 (00%)	19 (95%)	01 (05%)
SS-3	Operator SS3-O1	10	10	10	00	09	01
	Operator SS3-O2	10	10	10	00	10	00
	Total	20	20	20 (100%)	00 00%)	19 (95%)	01 (05%)
SS-1 to SS-3	Grand Total	60	60	59 (98.33%)	01 (1.66%)	58 (96.66%)	02 (3.33%)

- The differences in percent of positive results obtained with aliquots of the weak positive sample among the three sites and also the differences in the percent of negative results obtained with aliquots of the weak negative sample among the three sites are as follows:

Type of Weak Samples Tested by *i*-CHROMA iFOB	Site-wise Percent of True Results		
	Site SS-1	Site SS-2	Site SS-3
Weak Positive Samples	95%	100%	100%
Weak Negative Samples	100%	95%	95%

- The differences in percent of positive results among the three sites and also the differences in percent of negative results among the three testing sites were not found to be statistically significant at alpha = 0.05.

Conclusion:

- Considering the acceptance/performance criteria, results of the clinical testing study establish the accuracy of *i*-CHROMA iFOB as a qualitative in-vitro diagnostic fecal occult blood test for its proposed use in clinical settings.

Annexing

Table A6-2 Summary of Clinical data of *i*-CHROMA iFOB for CLIA Waiver

Table A6-3 Result of Clinical testing at Hospital (SS-1) for CLIA Waiver

Table A6-4 Result of Clinical testing at Out Patient Lab (SS-2) for CLIA Waiver

Table A6-5 Result of Clinical testing at Clinical Pathology (SS-3) for CLIA Waiver

Table A6-6 Result of Clinical testing at Physician's Lab (SS-4) for CLIA Waiver

Table A6-7 Result of Clinical testing of weak Negative & Positive sample for CLIA Waiver

Summary of Cliical Data

Site No.	Classification	Test Result				Test Sample Number			PPA	NPA	For PPA			For NPA		
		A(+/+)	B(+/-)	C(-/+)	D(-/-)	Total	Positive	Negative			Q1	Q2	Q3	Q1	Q2	Q3
1	Hospital	49	3	1	75	128	50	78	98.00	96.15	101.8	5.5	107.7	153.8	7.7	163.7
2	Out Patient Lab	50	2	1	69	122	51	71	98.04	97.18	103.8	5.5	109.7	141.8	6.7	149.7
3	Clinical Pathology	51	3	1	105	160	52	108	98.08	97.22	105.8	5.5	111.7	213.8	7.7	223.7
4	Physician's Lab	32	3	0	73	108	32	76	100.00	96.05	67.8	3.8	71.7	149.8	7.7	159.7

PPA; Confidence Interval(CI)		NPA; Confidence Interval(CI)	
Lower Bound	Upper Bound	Lower Bound	Upper Bound
89.50	99.65	89.29	98.68
89.70	99.65	90.30	99.22
89.88	99.66	92.15	99.05
89.28	100	89.03	98.65

Classification		Clinical Data_Hospital								
Testing Material		Human Fecal samples				Device Lot No.		FOEGA00		
						Reader Serial No.		PFR09E080571		
Testing date		2012. 06. 07~07. 02				Testing Site		Hospital		
#	OPERATOR	DATE	SPECIMEN ID NO.	*i*-CHROMA™ iFOB		OC-SENSOR Micro		AGE	ETHNICITY	GENDER
				+ / -	value(ng/ml)	+ / -	value(ng/ml)			
1	1	6/7	1	Negative	<25.00	Negative	0	54	Asian	M
2	1	6/7	2	Negative	<25.00	Negative	0	63	Asian	F
3	1	6/7	3	Positive	329.65	Positive	265	50	Asian	F
4	1	6/7	4	Negative	<25.00	Negative	0	69	Asian	M
5	1	6/7	5	Negative	<25.00	Negative	10	69	Asian	M
6	1	6/7	6	Positive	276.24	Positive	187	69	Asian	F
7	1	6/7	7	Negative	<25.00	Negative	11	72	Asian	M
8	1	6/7	8	Negative	<25.00	Negative	11	50	Asian	M
9	**1**	**6/7**	**9**	**Positive**	**182.64**	**Negative**	**25**	**50**	**Asian**	**M**
10	1	6/7	10	Negative	<25.00	Negative	3	65	Asian	F
11	1	6/7	11	Negative	<25.00	Negative	12	55	Asian	M
12	1	6/7	12	Negative	<25.00	Negative	13	52	Asian	M
13	1	6/7	13	Negative	<25.00	Positive	108	57	Asian	M
14	1	6/13	14	Positive	543.87	Positive	207	72	Asian	F
15	1	6/13	15	Positive	689.41	Positive	538	56	Asian	M
16	1	6/13	16	Negative	<25.00	Negative	12	83	Asian	F
17	1	6/13	17	Positive	387.36	Positive	183	52	Asian	M
18	1	6/13	18	Negative	<25.00	Negative	11	60	Asian	F
19	1	6/13	19	Negative	<25.00	Negative	5	59	Asian	M
20	1	6/13	20	Positive	367.33	Negative	287	57	Asian	M
21	1	6/13	21	Negative	<25.00	Negative	11	63	Asian	F
22	1	6/13	22	Positive	293.72	Positive	300	90	Asian	M
23	1	6/13	23	Positive	166.39	Positive	175	59	Asian	M
24	1	6/13	24	Positive	124.19	Positive	215	63	Asian	F
25	1	6/13	25	Negative	<25.00	Negative	8	62	Asian	M
26	1	6/13	26	Negative	<25.00	Negative	5	61	Asian	F
27	1	6/13	27	Negative	<25.00	Negative	3	64	Asian	F
28	1	6/13	28	Positive	355.82	Positive	276	74	Asian	M
29	1	6/16	29	Negative	<25.00	Negative	4	64	Asian	F
30	1	6/16	30	Positive	124.19	Positive	215	68	Asian	M
31	1	6/16	31	Positive	422.42	Positive	395	63	Asian	M

32	1	6/16	32	Positive	405.36	Positive	415	72	Asian	F
33	1	6/16	33	Positive	396.18	Positive	307	69	Asian	M
34	1	6/16	34	Negative	<25.00	Negative	13	56	Asian	M
35	1	6/16	35	Negative	<25.00	Negative	13	56	Asian	M
36	1	6/16	36	Negative	<25.00	Negative	4	55	Asian	M
37	1	6/16	37	Negative	<25.00	Negative	4	55	Asian	M
38	1	6/16	38	Positive	592.02	Positive	252	50	Asian	M
39	1	6/16	39	Positive	154.42	Positive	166	54	Asian	F
40	1	6/16	40	Positive	314.25	Positive	366	56	Asian	F
41	1	6/16	41	Negative	<25.00	Negative	2	66	Asian	M
42	1	6/16	42	Negative	35.45	Negative	0	62	Asian	M
43	1	6/16	43	Positive	177.08	Positive	211	69	Asian	F
44	1	6/16	44	Positive	506.16	Positive	473	75	Asian	F
45	1	6/16	45	Negative	54.4	Negative	0	73	Asian	M
46	1	6/16	46	Negative	42.89	Negative	0	76	Asian	M
47	1	6/16	47	Positive	435.37	Positive	287	77	Asian	M
48	1	6/16	48	Negative	<25.00	Negative	0	81	Asian	F
49	2	6/18	49	Negative	<25.00	Negative	8	60	Asian	F
50	2	6/18	50	Negative	58.5	Negative	20	56	Asian	F
51	2	6/18	51	Positive	>1000.0	Positive	815	50	Asian	M
52	2	6/18	52	Negative	<25.00	Negative	20	59	Asian	M
53	2	6/18	53	Negative	<25.00	Negative	6	74	Asian	F
54	2	6/18	54	Positive	460.19	Positive	426	82	Asian	F
55	2	6/18	55	Negative	<25.00	Negative	0	80	Asian	F
56	2	6/18	56	Negative	<25.00	Negative	13	51	Asian	M
57	2	6/18	57	Negative	<25.00	Negative	0	67	Asian	M
58	2	6/18	58	Negative	<25.00	Negative	30	66	Asian	M
59	2	6/18	59	Positive	731.46	Positive	456	71	Asian	F
60	2	6/18	60	Positive	265.09	Positive	198	82	Asian	F
61	2	6/18	61	Positive	164.23	Positive	251	76	Asian	M
62	2	6/18	62	Positive	361.31	Positive	284	79	Asian	F
63	2	6/18	63	Negative	<25.00	Negative	19	72	Asian	M
64	2	6/19	64	Negative	<25.00	Negative	0	79	Asian	M
65	2	6/19	65	Negative	<25.00	Negative	1	54	Asian	M
66	2	6/19	66	Negative	<25.00	Negative	1	58	Asian	M
67	2	6/19	67	Positive	982.62	Positive	400	67	Asian	F
68	2	6/19	68	Positive	543.29	Positive	265	61	Asian	M
69	2	6/19	69	Negative	<25.00	Negative	0	71	Asian	M

70	2	6/19	70	Negative	<25.00	Negative	0	72	Asian	M
71	2	6/19	71	Positive	332.45	Positive	365	74	Asian	F
72	2	6/19	72	Positive	246.21	Positive	187	72	Asian	F
73	2	6/21	73	Negative	<25.00	Negative	16	83	Asian	M
74	2	6/21	74	Negative	<25.00	Negative	0	58	Asian	M
75	2	6/21	75	Positive	321.67	Positive	273	53	Asian	F
76	2	6/21	76	Negative	<25.00	Negative	0	56	Asian	M
77	2	6/21	77	Negative	<25.00	Negative	0	54	Asian	F
78	2	6/21	78	Negative	<25.00	Negative	16	65	Asian	F
79	2	6/21	79	Negative	<25.00	Negative	0	54	Asian	F
80	2	6/21	80	Negative	<25.00	Negative	0	70	Asian	M
81	2	6/21	81	Positive	224.87	Positive	187	84	Asian	F
82	2	6/21	82	Negative	<25.00	Negative	2	72	Asian	M
83	2	6/21	83	Negative	<25.00	Negative	0	63	Asian	M
84	3	6/25	84	Positive	354.38	Positive	277	58	Asian	F
85	3	6/25	85	Negative	<25.00	Negative	0	78	Asian	M
86	3	6/25	86	Positive	177.28	Positive	232	77	Asian	F
87	3	6/25	87	Negative	<25.00	Negative	39	78	Asian	F
88	3	6/25	88	Negative	<25.00	Negative	29	60	Asian	F
89	3	6/25	89	Negative	<25.00	Negative	34	61	Asian	F
90	3	6/25	90	Positive	525.64	Positive	488	68	Asian	F
91	3	6/25	91	Positive	159.68	Positive	148	69	Asian	F
92	3	6/25	92	Positive	175.88	Positive	157	57	Asian	M
93	3	6/25	93	Negative	<25.00	Negative	2	54	Asian	M
94	3	6/25	94	Negative	<25.00	Negative	0	67	Asian	F
95	3	6/25	95	Positive	677.87	Positive	265	72	Asian	F
96	3	6/25	96	Negative	<25.00	Negative	8	71	Asian	F
97	3	6/25	97	Negative	<25.00	Negative	19	68	Asian	F
98	3	6/25	98	Positive	919.28	Positive	765.37	64	Asian	M
99	3	6/25	99	Negative	<25.00	Negative	0	73	Asian	F
100	3	6/25	100	Negative	<25.00	Negative	0	73	Asian	F
101	3	6/25	101	Positive	265.36	Positive	260	70	Asian	F
102	3	6/25	102	Positive	194.42	Positive	188	71	Asian	M
103	3	6/27	103	Negative	<25.00	Negative	16	77	Asian	M
104	3	6/27	104	Negative	<25.00	Negative	0	75	Asian	M
105	3	6/27	105	Positive	685.98	Positive	542	57	Asian	M
106	3	6/27	106	Positive	589.22	Positive	154	75	Asian	F
107	3	6/27	107	Negative	<25.00	Negative	8	51	Asian	M

108	3	6/27	108	Negative	<25.00	Negative	2	61	Asian	M
109	3	6/27	109	Negative	<25.00	Negative	16	55	Asian	M
110	**3**	**6/27**	**110**	**Positive**	**800.29**	**Positive**	**1978**	**85**	**Asian**	**M**
111	3	6/27	111	Negative	<25.00	Negative	0	75	Asian	F
112	3	6/27	112	Negative	<25.00	Negative	10	78	Asian	F
113	3	6/27	113	Positive	330.42	Positive	300	78	Asian	F
114	3	6/27	114	Negative	<25.00	Negative	2	59	Asian	M
115	3	6/27	115	Positive	165.66	Negative	76.87	53	Asian	M
116	3	6/27	116	Negative	<25.00	Negative	4	73	Asian	M
117	3	6/29	117	Negative	<25.00	Negative	64	69	Asian	M
118	3	6/29	118	Positive	262.03	Positive	150	61	Asian	M
119	3	6/29	119	Negative	<25.00	Negative	0	60	Asian	F
120	3	6/29	120	Positive	115.25	Positive	132	81	Asian	M
121	3	6/29	121	Negative	<25.00	Negative	5	65	Asian	F
122	3	6/29	122	Negative	<25.00	Negative	18	76	Asian	F
123	3	7/2	123	Positive	231.6	Positive	151	60	Asian	F
124	3	7/2	124	Positive	242.11	Positive	363	78	Asian	M
125	3	7/2	125	Negative	<25.00	Negative	3	72	Asian	F
126	3	7/2	126	Negative	<25.00	Negative	3	52	Asian	F
127	3	7/2	127	Negative	<25.00	Negative	25	73	Asian	M
128	3	7/2	128	Positive	619.83	Positive	200	67	Asian	F

	Total	+/+	+/-	-/+	-/-
Operator 1	48	19	2	1	26
Operator 2	35	12	0	0	23
Operator 3	45	18	1	0	26
Sum	128	49	3	1	75

Classification		Clinical Data_Out Patient Lab								
Testing Material		Human Fecal samples				Device Lot No.		FOEGA00		
						Reader Serial No.		PFR09E080571		
Testing date		2012. 05. 30~06. 29				Testing Site		Out Patient Lab		
#	OPERATOR	DATE	SPECIMEN ID NO.	i-CHROMA iFOB		OC-SENSOR Micro		AGE	ETHNICITY	GENDER
				+ / -	value(ng/ml)	+ / -	value(ng/ml)			
1	1	5/30	1	Negative	<25.00	Negative	< 10	57	Asian	M
2	1	5/30	2	Positive	332.16	Positive	278.98	84	Asian	F
3	1	5/30	3	Negative	<25.00	Negative	< 10	83	Asian	M
4	1	5/30	4	Negative	<25.00	Negative	< 10	83	Asian	F
5	1	5/30	5	Positive	515.07	Positive	359	71	Asian	M
6	1	5/30	6	Negative	<25.00	Negative	< 10	68	Asian	F
7	1	5/30	7	Positive	126.21	Negative	67	74	Asian	F
8	1	5/30	8	Negative	<25.00	Negative	< 10	55	Asian	M
9	1	5/30	9	Negative	<25.00	Negative	< 10	65	Asian	F
10	1	6/8	10	Negative	<25.00	Negative	< 10	58	Asian	M
11	1	6/8	11	Positive	540.22	Positive	274	56	Asian	M
12	1	6/8	12	Negative	<25.00	Negative	< 10	55	Asian	M
13	1	6/8	13	Negative	<25.00	Negative	< 10	74	Asian	M
14	1	6/8	14	Negative	<25.00	Negative	< 10	74	Asian	M
15	1	6/8	15	Negative	<25.00	Negative	< 10	81	Asian	F
16	1	6/8	16	Positive	702.65	Positive	529	76	Asian	F
17	1	6/8	17	Positive	221.22	Positive	190	62	Asian	M
18	1	6/8	18	Negative	<25.00	Negative	< 10	59	Asian	M
19	1	6/8	19	Negative	<25.00	Negative	< 10	71	Asian	F
20	1	6/8	20	Negative	<25.00	Negative	< 10	71	Asian	F
21	1	6/8	21	Negative	<25.00	Negative	< 10	62	Asian	M
22	1	6/8	22	Positive	346.79	Positive	1535	71	Asian	M
23	1	6/8	23	Negative	<25.00	Negative	< 10	77	Asian	M

24	1	6/8	24	Negative	<25.00	Negative	< 10	75	Asian	F
25	1	6/8	25	Positive	328.15	Positive	597	76	Asian	M
26	1	6/8	26	Positive	225.23	Positive	1986	75	Asian	F
27	1	6/8	27	Negative	<25.00	Negative	< 10	61	Asian	M
28	1	6/14	28	Negative	<25.00	Negative	< 10	71	Asian	F
29	1	6/14	29	Negative	<25.00	Negative	< 10	64	Asian	F
30	1	6/14	30	Positive	672.26	Positive	203	74	Asian	M
31	1	6/14	31	Negative	29.28	Negative	38	78	Asian	M
32	1	6/14	32	Negative	<25.00	Negative	< 10	64	Asian	F
33	1	6/14	33	Positive	398.29	Positive	266	62	Asian	M
34	1	6/14	34	Negative	<25.00	Negative	< 10	69	Asian	M
35	1	6/14	35	Negative	<25.00	Negative	< 10	75	Asian	M
36	1	6/14	36	Negative	<25.00	Negative	< 10	55	Asian	F
37	1	6/14	37	Negative	<25.00	Negative	< 10	87	Asian	M
38	1	6/14	38	Positive	176.29	Positive	267	83	Asian	M
39	1	6/14	39	Negative	<25.00	Negative	< 10	52	Asian	M
40	1	6/14	40	Negative	<25.00	Negative	< 10	51	Asian	M
41	1	6/14	41	Negative	48.3	Negative	< 10	87	Asian	M
42	1	6/14	42	Negative	<25.00	Negative	30	81	Asian	M
43	1	6/14	43	Negative	<25.00	Negative	< 10	76	Asian	F
44	1	6/14	44	Positive	326.62	Positive	206	70	Asian	M
45	1	6/14	45	Negative	<25.00	Negative	< 10	64	Asian	M
46	1	6/14	46	Negative	<25.00	Negative	23	54	Asian	M
47	1	6/14	47	Negative	<25.00	Negative	16	64	Asian	M
48	1	6/14	48	Negative	<25.00	Negative	< 10	78	Asian	M
49	1	6/14	49	Positive	329.27	Positive	209	70	Asian	M
50	1	6/14	50	Negative	<25.00	Negative	16	80	Asian	M
51	1	6/14	51	Positive	668.2	Positive	1674	86	Asian	F
52	1	6/14	52	Negative	<25.00	Negative	< 10	73	Asian	M

53	1	6/18	53	Negative	<25.00	Negative	< 10	67	Asian	F
54	2	6/18	54	Negative	<25.00	Negative	< 10	51	Asian	M
55	2	6/18	55	Positive	809.8	Positive	2021	76	Asian	F
56	2	6/18	56	Negative	<25.00	Negative	< 10	82	Asian	F
57	2	6/18	57	Negative	<25.00	Negative	< 10	69	Asian	F
58	2	6/18	58	Positive	820.65	Positive	650	74	Asian	F
59	2	6/18	59	Negative	<25.00	Negative	< 10	81	Asian	M
60	2	6/18	60	Negative	<25.00	Negative	41	86	Asian	F
61	2	6/18	61	Positive	346.42	Positive	499	55	Asian	M
62	2	6/19	62	Negative	<25.00	Negative	< 10	66	Asian	M
63	2	6/20	63	Positive	763.27	Positive	523	84	Asian	M
64	2	6/20	64	Negative	45.54	Negative	28	79	Asian	F
65	2	6/20	65	Negative	<25.00	Negative	< 10	63	Asian	F
66	2	6/20	66	Negative	<25.00	Negative	< 10	75	Asian	M
67	2	6/21	67	Positive	126.28	Negative	73	59	Asian	F
68	2	6/21	68	Negative	<25.00	Negative	< 10	76	Asian	F
69	2	6/21	69	Positive	241.87	Positive	187	52	Asian	M
70	2	6/21	70	Positive	230.23	Positive	303	60	Asian	M
71	2	6/27	71	Negative	<25.00	Negative	< 10	62	Asian	M
72	2	6/27	72	Negative	<25.00	Negative	< 10	72	Asian	F
73	2	6/27	73	Positive	237.36	Positive	167	63	Asian	F
74	2	6/27	74	Negative	<25.00	Negative	< 10	69	Asian	F
75	2	6/27	75	Negative	<25.00	Negative	< 10	58	Asian	M
76	2	6/27	76	Positive	357.06	Positive	234	78	Asian	F
77	2	6/27	77	Negative	<25.00	Negative	< 10	74	Asian	F
78	2	6/27	78	Negative	<25.00	Negative	58	76	Asian	F
79	2	6/27	79	Negative	<25.00	Negative	21	71	Asian	M
80	2	6/27	80	Positive	145.21	Positive	1929	63	Asian	M
81	2	6/27	81	Negative	<25.00	Negative	< 10	60	Asian	M

82	2	6/27	82	Negative	28.12	Negative	< 10	86	Asian	F
83	2	6/28	83	Negative	30.81	Positive	108	66	Asian	F
84	2	6/28	84	Positive	492.6	Positive	1057	67	Asian	M
85	2	6/29	85	Negative	<25.00	Negative	< 10	77	Asian	M
86	2	6/29	86	Negative	<25.00	Negative	< 10	68	Asian	M
87	2	6/29	87	Positive	366.48	Positive	386	55	Asian	F
88	2	6/29	88	Positive	154.27	Positive	176	62	Asian	F
89	2	6/27	89	Negative	<25.00	Negative	< 10	72	Asian	F
90	2	6/27	90	Negative	<25.00	Negative	< 10	71	Asian	M
91	2	6/29	91	Positive	220.41	Positive	204	59	Asian	M
92	2	6/29	92	Positive	172.08	Positive	184	66	Asian	M
93	2	6/19	93	Negative	32.77	Negative	< 10	83	Asian	M
94	2	6/29	94	Positive	204.65	Positive	225	71	Asian	M
95	2	6/29	95	Positive	384.09	Positive	326	59	Asian	F
96	2	6/29	96	Positive	298.04	Positive	311	54	Asian	M
97	2	6/29	97	Positive	109.42	Positive	111	67	Asian	F
98	2	6/27	98	Negative	<25.00	Negative	< 10	51	Asian	M
99	2	6/29	99	Positive	264.08	Positive	225	63	Asian	F
100	2	6/27	100	Negative	<25.00	Negative	< 10	62	Asian	F
101	2	6/29	101	Positive	471.58	Positive	398	69	Asian	F
102	2	6/29	102	Positive	264.51	Positive	295	73	Asian	F
103	2	6/29	103	Positive	508.43	Positive	553	75	Asian	F
104	2	6/28	104	Negative	<25.00	Negative	< 10	68	Asian	F
105	2	6/28	105	Negative	<25.00	Negative	< 10	57	Asian	F
106	2	6/29	106	Positive	290.65	Positive	312	64	Asian	M
107	2	6/29	107	Positive	310.74	Positive	325	51	Asian	F
108	2	6/29	108	Positive	269.08	Positive	224	71	Asian	F
109	2	6/29	109	Positive	730.77	Positive	466	63	Asian	F
110	2	6/27	110	Negative	<25.00	Negative	< 10	80	Asian	F

111	2	6/29	111	Positive	164.28	Positive	155	66	Asian	M
112	2	6/29	112	Positive	220.95	Positive	210	81	Asian	M
113	2	6/29	113	Positive	281.64	Positive	215	75	Asian	F
114	2	6/27	114	Negative	<25.00	Negative	< 10	80	Asian	M
115	2	6/29	115	Positive	550.97	Positive	487	61	Asian	M
116	2	6/29	116	Positive	269.66	Positive	254	59	Asian	F
117	2	6/29	117	Positive	208.19	Positive	311	60	Asian	F
118	2	6/18	118	Negative	49.24	Negative	65	64	Asian	M
119	2	6/29	119	Positive	107.88	Positive	109	55	Asian	M
120	2	6/29	120	Positive	511.96	Positive	507	63	Asian	M
121	2	6/29	121	Positive	261.95	Positive	245	68	Asian	F
122	2	6/29	122	Positive	416.07	Positive	484	73	Asian	M

	Total	+/+	+/-	-/+	-/-
Operator 1	53	14	1	0	38
Operator 2	69	36	1	1	31
Operator 3	0	-			-
Sum	122	50	2	1	69

Classification		Clinical Data_Clinical Pathology								
Testing Material		Human Fecal samples				Device Lot No.		FOEGA00		
						Reader Serial No.		PFR09E080571		
Testing date		2012. 06. 29~07. 26				Testing Site		Clinical Pathology		
#	Operator	DATE	SPECIMEN ID NO.	i-CHROMA iFOB		OC-SENSOR Micro		AGE	ETHNICITY	GENDER
				+ / -	value(ng/ml)	+ / -	value(ng/ml)			
1	1	6/29	1	Negative	<25.00	Negative	< 10	68	Asian	M
2	1	7/3	2	Negative	<25.00	Negative	< 10	77	Asian	M
3	1	7/3	3	Positive	232.82	Negative	76	75	Asian	M
4	1	7/3	4	Negative	<25.00	Negative	< 10	80	Asian	M
5	1	7/3	5	Negative	<25.00	Negative	< 10	62	Asian	M
6	1	7/3	6	Positive	198.76	Positive	154	80	Asian	M
7	1	7/3	7	Negative	<25.00	Negative	< 10	63	Asian	M
8	1	7/3	8	Positive	143.33	Positive	175	69	Asian	M
9	1	7/3	9	Positive	164.09	Positive	177	81	Asian	F
10	1	7/3	10	Positive	192.64	Positive	106	79	Asian	F
11	1	7/3	11	Negative	<25.00	Negative	< 10	74	Asian	M
12	1	7/3	12	Negative	<25.00	Negative	< 10	73	Asian	M
13	1	7/3	13	Negative	<25.00	Negative	< 10	88	Asian	M
14	1	7/3	14	Negative	41.08	Negative	< 10	83	Asian	M
15	1	7/3	15	Positive	763.71	Positive	323	67	Asian	M
16	1	7/3	16	Negative	<25.00	Negative	< 10	62	Asian	F
17	1	7/4	17	Positive	298.76	Positive	304	54	Asian	M
18	1	7/4	18	Negative	33.18	Negative	< 10	65	Asian	F
19	1	7/4	19	Negative	<25.00	Negative	< 10	76	Asian	M
20	1	7/4	20	Positive	338.21	Positive	325	71	Asian	M
21	1	7/4	21	Positive	369.08	Positive	294	73	Asian	M
22	1	7/4	22	Positive	454.17	Positive	429	82	Asian	M

23	1	7/4	23	Negative	<25.00	Negative	< 10	69	Asian	F
24	1	7/5	24	Negative	<25.00	Negative	< 10	75	Asian	F
25	1	7/5	25	Negative	<25.00	Negative	< 10	80	Asian	M
26	1	7/5	26	Negative	<25.00	Negative	< 10	63	Asian	M
27	1	7/5	27	Positive	543.87	Positive	321	71	Asian	F
28	1	7/5	28	Negative	<25.00	Negative	< 10	51	Asian	F
29	1	7/5	29	Negative	<25.00	Negative	< 10	66	Asian	F
30	1	7/5	30	Negative	<25.00	Negative	< 10	54	Asian	M
31	1	7/5	31	Positive	820.45	Positive	1837	72	Asian	M
32	1	7/5	32	Positive	>1000.0	Positive	2100	76	Asian	F
33	1	7/5	33	Negative	<25.00	Negative	< 10	79	Asian	F
34	1	7/9	34	Positive	420.43	Positive	176	67	Asian	M
35	1	7/9	35	Negative	<25.00	Negative	< 10	69	Asian	M
36	1	7/9	36	Negative	<25.00	Negative	< 10	60	Asian	M
37	1	7/9	37	Negative	<25.00	Negative	< 10	76	Asian	F
38	1	7/9	38	Negative	<25.00	Negative	< 10	50	Asian	M
39	1	7/9	39	Negative	<25.00	Negative	< 10	78	Asian	F
40	1	7/9	40	Positive	203.46	Negative	75	78	Asian	F
41	1	7/10	41	Negative	<25.00	Negative	< 10	60	Asian	M
42	1	7/10	42	Negative	<25.00	Negative	< 10	61	Asian	F
43	1	7/10	43	Negative	<25.00	Negative	< 10	58	Asian	M
44	1	7/11	44	Positive	>1000.0	Positive	1118	71	Asian	M
45	1	7/11	45	Positive	705.19	Positive	168	55	Asian	M
46	1	7/11	46	Negative	<25.00	Negative	< 10	73	Asian	M
47	1	7/11	47	Negative	69.99	Negative	73	82	Asian	M
48	1	7/11	48	Negative	<25.00	Negative	< 10	65	Asian	M
49	1	7/11	49	Negative	<25.00	Negative	< 10	82	Asian	M

50	1	7/16	50	Negative	<25.00	Negative	< 10	70	Asian	M
51	2	7/16	51	Negative	<25.00	Negative	< 10	71	Asian	F
52	2	7/16	52	Negative	<25.00	Negative	< 10	62	Asian	M
53	2	7/16	53	Positive	620.44	Positive	435	60	Asian	M
54	2	7/16	54	Negative	<25.00	Negative	< 10	87	Asian	F
55	2	7/16	55	Positive	218.07	Positive	713	81	Asian	F
56	2	7/16	56	Negative	<25.00	Negative	< 10	51	Asian	M
57	2	7/16	57	Negative	<25.00	Negative	15	52	Asian	F
58	2	7/16	58	Positive	197.29	Positive	132	65	Asian	M
59	2	7/16	59	Negative	<25.00	Negative	11	53	Asian	F
60	2	7/16	60	Negative	<25.00	Negative	< 10	73	Asian	F
61	2	7/16	61	Negative	27.17	Negative	< 10	80	Asian	F
62	2	7/16	62	Negative	<25.00	Negative	< 10	85	Asian	F
63	2	7/16	63	Negative	<25.00	Negative	< 10	83	Asian	M
64	2	7/16	64	Negative	<25.00	Negative	< 10	51	Asian	F
65	2	7/16	65	Positive	499.5	Positive	335	61	Asian	F
66	2	7/16	66	Negative	<25.00	Negative	< 10	78	Asian	M
67	2	7/16	67	Positive	946.69	Positive	>1000	67	Asian	F
68	2	7/16	68	Negative	<25.00	Negative	< 10	77	Asian	M
69	2	7/16	69	Positive	>1000.0	Positive	>1000	71	Asian	M
70	2	7/16	70	Negative	<25.00	Negative	< 10	66	Asian	F
71	2	7/16	71	Positive	142.93	Positive	134	65	Asian	M
72	2	7/16	72	Negative	66.16	Negative	84	91	Asian	F
73	2	7/16	73	Positive	254.37	Positive	177	58	Asian	M
74	2	7/17	74	Negative	<25.00	Negative	< 10	72	Asian	M
75	2	7/17	75	Negative	<25.00	Negative	< 10	76	Asian	M
76	2	7/17	76	Positive	216.34	Positive	266	64	Asian	M

77	2	7/17	77	Positive	651.33	Positive	539	61	Asian	M
78	2	7/17	78	Positive	297.07	Positive	362	63	Asian	F
79	2	7/17	79	Negative	75.76	Positive	187	59	Asian	F
80	2	7/17	80	Negative	<25.00	Negative	< 10	71	Asian	M
81	2	7/17	81	Negative	<25.00	Negative	< 10	68	Asian	F
82	2	7/19	82	Positive	245.06	Positive	140	61	Asian	M
83	2	7/19	83	Negative	<25.00	Negative	< 10	80	Asian	F
84	2	7/19	84	Positive	487.27	Positive	850	76	Asian	M
85	2	7/19	85	Positive	526.89	Positive	>1000	58	Asian	F
86	2	7/19	86	Negative	38.36	Negative	76	74	Asian	F
87	2	7/19	87	Negative	<25.00	Negative	< 10	62	Asian	M
88	2	7/19	88	Positive	643.21	Positive	584	59	Asian	F
89	2	7/19	89	Positive	298.66	Positive	312	54	Asian	F
90	2	7/19	90	Positive	228.08	Positive	251	67	Asian	M
91	2	7/19	91	Negative	34.72	Negative	18	66	Asian	M
92	2	7/19	92	Negative	<25.00	Negative	< 10	86	Asian	F
93	2	7/19	93	Negative	<25.00	Negative	< 10	51	Asian	F
94	2	7/19	94	Negative	<25.00	Negative	< 10	71	Asian	M
95	2	7/19	95	Positive	380.76	Positive	189.27	50	Asian	M
96	2	7/19	96	Negative	<25.00	Negative	< 10	73	Asian	F
97	2	7/19	97	Positive	431.22	Positive	415	74	Asian	F
98	2	7/19	98	Positive	333.15	Positive	352	71	Asian	F
99	2	7/19	99	Positive	140.28	Positive	162	69	Asian	F
100	2	7/19	100	Positive	124.61	Positive	125	75	Asian	M
101	2	7/19	101	Negative	<25.00	Negative	< 10	80	Asian	F
102	2	7/19	102	Negative	<25.00	Negative	< 10	66	Asian	F
	2	7/19	103	Positive	269.47	Positive	219	69	Asian	F

103	2	7/19	104	Negative	<25.00	Negative	< 10	80	Asian	M
104	2	7/19	105	Positive	517.28	Positive	514	78	Asian	M
105	2	7/19	106	Positive	447.98	Positive	428	71	Asian	M
106	2	7/19	107	Negative	<25.00	Negative	< 10	57	Asian	F
107	2	7/23	108	Positive	129.69	Positive	185	101	Asian	M
108	3	7/23	109	Negative	<25.00	Negative	< 10	72	Asian	M
109	3	7/23	110	Negative	<25.00	Negative	< 10	65	Asian	M
110	3	7/23	111	Negative	<25.00	Negative	< 10	56	Asian	F
111	3	7/23	112	Positive	>1000.0	Positive	>1000	57	Asian	F
112	3	7/23	113	Negative	<25.00	Negative	25	79	Asian	M
113	3	7/23	114	Negative	<25.00	Negative	26	65	Asian	M
114	3	7/23	115	Positive	243.06	Positive	571	66	Asian	M
115	3	7/23	116	Positive	106.07	Positive	104	72	Asian	F
116	3	7/23	117	Negative	<25.00	Negative	< 10	69	Asian	F
117	3	7/23	118	Negative	<25.00	Negative	< 10	71	Asian	F
118	3	7/23	119	Negative	<25.00	Negative	30	63	Asian	M
119	3	7/23	120	Negative	<25.00	Negative	< 10	62	Asian	M
120	3	7/23	121	Positive	603.4	Positive	225	77	Asian	M
121	3	7/23	122	Negative	<25.00	Negative	23	77	Asian	M
122	3	7/23	123	Negative	<25.00	Negative	< 10	59	Asian	M
123	3	7/23	124	Negative	<25.00	Negative	< 10	60	Asian	F
124	3	7/23	125	Negative	<25.00	Negative	< 10	92	Asian	M
125	3	7/23	126	Positive	232.25	Positive	>1000	71	Asian	M
126	3	7/23	127	Negative	<25.00	Negative	< 10	53	Asian	F
127	3	7/23	128	Negative	38.39	Negative	< 10	77	Asian	M
128	3	7/23	129	Negative	<25.00	Negative	< 10	66	Asian	F
129	3	7/23	130	Negative	<25.00	Negative	30	58	Asian	M

130	3	7/24	131	Negative	<25.00	Negative	< 10	62	Asian	F
131	3	7/24	132	Negative	<25.00	Negative	< 10	69	Asian	M
132	3	7/24	133	Negative	<25.00	Negative	< 10	61	Asian	M
133	3	7/24	134	Positive	972.3	Positive	>1000	80	Asian	M
134	3	7/24	135	Negative	<25.00	Negative	< 10	63	Asian	M
135	3	7/24	136	Negative	<25.00	Negative	< 10	69	Asian	F
136	3	7/24	137	Positive	626.14	Positive	757	81	Asian	F
137	3	7/24	138	Negative	30.21	Negative	< 10	71	Asian	F
138	3	7/25	139	Negative	<25.00	Negative	< 10	57	Asian	F
139	3	7/25	140	Negative	<25.00	Negative	< 10	52	Asian	F
140	3	7/25	141	Negative	<25.00	Negative	< 10	50	Asian	M
141	3	7/25	142	Negative	<25.00	Negative	< 10	66	Asian	M
142	3	7/25	143	Positive	352.35	Positive	386	72	Asian	M
143	3	7/25	144	Negative	<25.00	Negative	< 10	71	Asian	M
144	3	7/25	145	Negative	<25.00	Negative	< 10	66	Asian	M
145	3	7/25	146	Negative	<25.00	Negative	< 10	81	Asian	F
146	3	7/25	147	Negative	<25.00	Negative	< 10	75	Asian	F
147	3	7/25	148	Negative	<25.00	Negative	< 10	69	Asian	M
148	3	7/26	149	Negative	<25.00	Negative	< 10	83	Asian	F
149	3	7/26	150	Negative	<25.00	Negative	< 10	68	Asian	M
150	3	7/26	151	Negative	28.64	Negative	< 10	67	Asian	F
151	3	7/26	152	Negative	<25.00	Negative	< 10	79	Asian	M
152	3	7/26	153	Positive	146.65	Negative	87	87	Asian	M
153	3	7/26	154	Negative	57.03	Negative	< 10	52	Asian	M
154	3	7/26	155	Negative	<25.00	Negative	< 10	66	Asian	M
155	3	7/26	156	Negative	<25.00	Negative	< 10	60	Asian	F
156	3	7/26	157	Positive	138.28	Positive	178	77	Asian	M

157	3	7/26	158	Negative	<25.00	Negative	< 10	80	Asian	M
158	3	7/26	159	Positive	758.63	Positive	>1000	87	Asian	M
159	3	7/26	160	Negative	<25.00	Negative	< 10	71	Asian	M

	Total	+/+	+/-	-/+	-/-
Operator 1	50	15	2	0	33
Operator 2	58	26	0	1	31
Operator 3	52	10	1	0	41
Sum	160	51	3	1	105

Classification	Clinical Data_Physician's Lab									
Testing Material	Human Fecal samples					Device Lot No.		FOEGA00		
						Reader Serial No.		PFR09E080577		
Testing date	2012. 04. 17~05. 04					Testing Site		Physician's Lab		
#	OPERATOR	DATE	SPECIMEN ID NO.	*i*-CHROMA™ iFOB		OC-SENSOR Micro		AGE	ETHNICITY	GENDER
				+ / -	value(ng/ml)	+ / -	value(ng/ml)			
1	1	17 April 2012	1	Negative	<25.00	Negative	0	70	Caucasian	F
2	1	17 April 2012	2	Negative	<25.00	Negative	31	84	Caucasian	F
3	1	17 April 2012	3	Negative	<25.00	Negative	11	84	Caucasian	M
4	1	17 April 2012	4	Negative	<25.00	Negative	4	61	Black	M
5	1	17 April 2012	5	Negative	<25.00	Negative	9	66	Black	F
6	1	17 April 2012	6	Negative	<25.00	Negative	6	70	Caucasian	F
7	1	17 April 2012	7	Negative	<25.00	Negative	6	63	Caucasian	M
8	1	17 April 2012	8	Negative	<25.00	Negative	0	72	Hispanic	M
9	1	18 April 2012	9	Negative	<25.00	Negative	16	73	Caucasian	M
10	1	18 April 2012	10	Negative	79.5	Negative	75	76	Caucasian	F
11	1	18 April 2012	11	Negative	<25.00	Negative	8	68	Hispanic	M
12	1	18 April 2012	12	Negative	<25.00	Negative	0	71	Caucasian	M
13	1	18 April 2012	13	Negative	46.9	Negative	22	78	Caucasian	F
14	1	19 April 2012	14	Positive	449.7	Positive	1622	55	Caucasian	F
15	1	19 April 2012	15	Negative	<25.00	Negative	18	76	Hispanic	F
16	1	19 April 2012	16	Negative	<25.00	Negative	2	73	Caucasian	M
17	1	19 April 2012	17	Negative	65	Negative	41	67	Caucasian	M
18	1	19 April 2012	18	Positive	800.9	Positive	844	66	Black	M
19	1	19 April 2012	19	Negative	<25.00	Negative	11	62	Hispanic	M
20	1	19 April 2012	20	Negative	<25.00	Negative	2	62	Caucasian	F
21	1	20 April 2012	21	Negative	<25.00	Negative	20	62	Caucasian	F
22	1	20 April 2012	22	Positive	743.5	Positive	773	62	Caucasian	F
23	1	20 April 2012	23	Negative	<25.00	Negative	1	80	Hispanic	M
24	1	20 April 2012	24	Negative	<25.00	Negative	6	60	Hispanic	M
25	1	20 April 2012	25	Negative	<25.00	Negative	5	76	Caucasian	M

26	1	20 April 2012	26	Negative	<25.00	Negative	0	70	American Indian	F
27	1	20 April 2012	27	Negative	<25.00	Negative	6	51	Hispanic	F
28	1	20 April 2012	28	Positive	>1000	Positive	1269	84	Hispanic	F
29	1	20 April 2012	29	Positive	186.1	Positive	124	64	Asian	M
30	1	20 April 2012	30	Negative	85.7	Negative	2	68	Black	M
31	1	20 April 2012	31	Negative	<25.00	Negative	1	56	Black	F
32	1	20 April 2012	32	Negative	<25.00	Negative	0	78	Caucasian	F
33	1	20 April 2012	33	Positive	723.7	Positive	683	69	Asian	F
34	1	20 April 2012	34	Negative	<25.00	Negative	18	81	Caucasian	M
35	1	20 April 2012	35	Negative	<25.00	Negative	16	85	Caucasian	M
36	1	20 April 2012	36	Positive	367.4	Positive	613	81	Caucasian	M
37	1	20 April 2012	37	Negative	<25.00	Negative	6	83	Hispanic	F
38	1	20 April 2012	38	Negative	<25.00	Negative	2	55	Hispanic	F
39	1	20 April 2012	39	Positive	500	Positive	1010	64	Hispanic	F
40	1	20 April 2012	40	Negative	<25.00	Negative	8	71	Caucasian	M
41	1	23 April 2012	41	Negative	<25.00	Negative	0	73	Caucasian	M
42	1	23 April 2012	42	Positive	>1000	Positive	589	74	Caucasian	M
43	1	23 April 2012	43	Negative	<25.00	Negative	0	72	Caucasian	M
44	1	23 April 2012	44	Positive	>1000	Positive	326	69	Black	F
45	1	23 April 2012	45	Negative	<25.00	Negative	0	85	Caucasian	M
46	1	23 April 2012	46	Negative	<25.00	Negative	0	62	Hispanic	M
47	1	23 April 2012	47	Negative	<25.00	Negative	0	91	Caucasian	M
48	1	23 April 2012	48	Positive	887.3	Positive	655	66	Hispanic	M
49	1	24 April 2012	49	Negative	<25.00	Negative	29	78	Hispanic	M
50	1	24 April 2012	50	Negative	<25.00	Negative	16	65	Hispanic	M
51	1	24 April 2012	51	Negative	30.3	Negative	13	63	Hispanic	M
52	1	24 April 2012	52	Negative	<25.00	Negative	9	77	Caucasian	M
53	1	24 April 2012	53	Negative	<25.00	Negative	13	63	Black	M
54	1	24 April 2012	54	Negative	<25.00	Negative	1	62	Hispanic	M
55	1	24 April 2012	55	Negative	31.9	Negative	18	85	Caucasian	M
56	1	24 April 2012	56	Negative	<25.00	Negative	12	71	Caucasian	M

57	1	24 April 2012	57	Positive	801.9	Positive	920	67	Black	M
58	1	24 April 2012	58	Positive	>1000	Positive	1101	78	Black	M
59	1	25 April 2012	59	Negative	31.6	Negative	31	50	Caucasian	F
60	1	25 April 2012	60	Negative	28.4	Negative	11	53	American Indian	F
61	1	25 April 2012	61	Negative	43	Negative	9	68	Caucasian	F
62	1	25 April 2012	62	Negative	31.1	Negative	0	57	Hispanic	F
63	1	25 April 2012	63	Negative	43.8	Negative	0	74	Caucasian	M
64	1	25 April 2012	64	Negative	50.8	Negative	12	51	Hispanic	F
65	1	25 April 2012	65	Negative	31	Negative	8	64	Caucasian	M
66	1	26 April 2012	66	Negative	40.8	Negative	8	51	Hispanic	M
67	1	26 April 2012	67	Positive	124	Positive	191	75	Hispanic	F
68	1	26 April 2012	68	Positive	440.7	Positive	218	81	Black	F
69	1	26 April 2012	69	Positive	288.9	Positive	506	71	Caucasian	F
70	1	26 April 2012	70	Positive	172	Negative	34	71	Black	F
71	1	26 April 2012	71	Negative	34.5	Negative	52	71	Caucasian	M
72	1	26 April 2012	72	Positive	719.3	Positive	118	73	Black	F
73	1	26 April 2012	73	Negative	69.7	Negative	8	66	Caucasian	M
74	1	26 April 2012	74	Negative	32.4	Negative	16	59	Hispanic	M
75	1	26 April 2012	75	Positive	350.6	Negative	18.3	55	Caucasian	F
76	1	26 April 2012	76	Negative	32	Negative	9	68	Caucasian	M
77	1	26 April 2012	77	Positive	104.8	Positive	237	53	Caucasian	F
78	1	26 April 2012	78	Positive	>1000	Positive	167	73	Asian	M
79	1	27 April 2012	79	Negative	<25.00	Negative	4	52	Hispanic	F
80	1	27 April 2012	80	Negative	<25.00	Negative	6	87	Hispanic	F
81	1	27 April 2012	81	Negative	<25.00	Negative	0	60	Caucasian	F
82	1	27 April 2012	82	Negative	<25.00	Negative	0	66	Hispanic	M
83	1	27 April 2012	83	Negative	<25.00	Negative	0	87	Hispanic	F
84	1	27 April 2012	84	Positive	105.5	Negative	13	54	Hispanic	M
85	1	27 April 2012	85	Negative	60.5	Negative	15	59	Caucasian	M
86	1	27 April 2012	86	Negative	75.9	Negative	11	69	Hispanic	M
87	1	27 April 2012	87	Positive	110.9	Positive	133	70	Black	M

88	1	27 April 2012	88	Positive	103.9	Positive	145	56	Black	M
89	1	30 April 2012	89	Negative	<25.00	Negative	8.4	63	Caucasian	F
90	1	30 April 2012	90	Negative	<25.00	Negative	0.9	68	Hispanic	M
91	1	30 April 2012	91	Negative	<25.00	Negative	0.5	80	Caucasian	M
92	1	30 April 2012	92	Negative	<25.00	Negative	0.2	59	Hispanic	F
93	1	30 April 2012	93	Positive	538.7	Positive	489	68	Asian	F
94	1	30 April 2012	94	Negative	<25.00	Negative	0.5	74	Caucasian	F
95	1	30 April 2012	95	Positive	>1000	Positive	510	77	Hispanic	F
96	1	30 April 2012	96	Positive	566.3	Positive	408	73	Caucasian	M
97	1	30 April 2012	97	Positive	317.2	Positive	437	59	Caucasian	F
98	1	30 April 2012	98	Negative	36.6	Negative	43	59	Caucasian	M
99	1	01 May 2012	99	Positive	296.5	Positive	142.5	68	Black	M
100	1	01 May 2012	100	Negative	54.3	Negative	88	58	Caucasian	M
101	1	01 May 2012	101	Positive	149.9	Positive	213	56	Caucasian	M
102	1	01 May 2012	102	Positive	383.7	Positive	216	58	Caucasian	M
103	1	01 May 2012	103	Negative	76.7	Negative	62	71	Hispanic	F
104	1	01 May 2012	104	Positive	254.1	Positive	163	65	Hispanic	M
105	1	01 May 2012	105	Negative	46.9	Negative	53	78	Black	F
106	1	02 May 2012	106	Positive	143.2	Positive	138	67	Asian	F
107	1	03 May 2012	107	Positive	176.4	Positive	166	72	Caucasian	M
108	1	04 May 2012	108	Positive	254.9	Positive	232	65	Caucasian	M

	Total	+/+	+/-	-/+	-/-
Operator 1	108	32	3	0	73
Operator 2	-	-			-
Operator 3	-	-			-
Sum	108	32	3	0	73

Classification		Weak Neg & Pos			
Testing Material		Human Fecal samples Weak Neg(90~99ng/mL) Weak Pos(100~110)		Device Lot No.	FOEGA00
				Reader Serial No.	PFR09E080571
Testing date		2012. 07. 29~08. 11		Testing Site	Hospital, Out Patient, Clinical pathology
Site	#	OPERATOR	DATE	Weak Negative	Weak Positive
Site 1	1	1	7/29	Negative	Positive
Site 1	2	1	7/29	Positive	Positive
Site 1	3	1	7/29	Negative	Positive
Site 1	4	1	7/29	Negative	Positive
Site 1	5	1	7/29	Negative	Positive
Site 1	6	1	7/29	Negative	Positive
Site 1	7	1	7/29	Negative	Positive
Site 1	8	1	7/29	Negative	Positive
Site 1	9	1	7/29	Negative	Positive
Site 1	10	1	7/29	Negative	Positive
Site 1	11	2	7/29	Negative	Positive
Site 1	12	2	7/29	Negative	Positive
Site 1	13	2	7/29	Negative	Positive
Site 1	14	2	7/29	Negative	Positive
Site 1	15	2	7/29	Negative	Positive
Site 1	16	2	7/29	Negative	Positive
Site 1	17	2	7/29	Negative	Positive
Site 1	18	2	7/29	Negative	Positive
Site 1	19	2	7/29	Negative	Positive
Site 1	20	2	7/29	Negative	Positive
Site 2	1	1	8/3	Negative	Positive
Site 2	2	1	8/3	Negative	Positive
Site 2	3	1	8/3	Negative	Positive
Site 2	4	1	8/3	Negative	Positive
Site 2	5	1	8/3	Negative	Positive
Site 2	6	1	8/3	Negative	Positive
Site 2	7	1	8/3	Negative	Positive
Site 2	8	1	8/3	Negative	Positive
Site 2	9	1	8/3	Negative	Positive
Site 2	10	1	8/3	Negative	Positive
Site 2	11	2	8/3	Negative	Positive
Site 2	12	2	8/3	Negative	Positive
Site 2	13	2	8/3	Negative	Positive
Site 2	14	2	8/3	Negative	Positive
Site 2	15	2	8/3	Negative	Positive
Site 2	16	2	8/3	Negative	Positive

Site 2	17	2	8/3	Negative	Negative
Site 2	18	2	8/3	Negative	Positive
Site 2	19	2	8/3	Negative	Positive
Site 2	20	2	8/3	Negative	Positive
Site 3	1	1	8/11	Negative	Positive
Site 3	2	1	8/11	Negative	Positive
Site 3	3	1	8/11	Negative	Positive
Site 3	4	1	8/11	Negative	Positive
Site 3	5	1	8/11	Negative	Positive
Site 3	6	1	8/11	Negative	Positive
Site 3	7	1	8/11	Negative	Positive
Site 3	8	1	8/11	Negative	Positive
Site 3	9	1	8/11	Positive	Positive
Site 3	10	1	8/11	Negative	Positive
Site 3	11	2	8/11	Negative	Positive
Site 3	12	2	8/11	Negative	Positive
Site 3	13	2	8/11	Negative	Positive
Site 3	14	2	8/11	Negative	Positive
Site 3	15	2	8/11	Negative	Positive
Site 3	16	2	8/11	Negative	Positive
Site 3	17	2	8/11	Negative	Positive
Site 3	18	2	8/11	Negative	Positive
Site 3	19	2	8/11	Negative	Positive
Site 3	20	2	8/11	Negative	Positive

Testing Site	Operator	No. of Testing Sample	Test Result			
			Weak Negative		Weak Positive	
			True Negative	False Positive	True Positive	False Negative
Site 1 Hospital	1	10	9	1	10	0
	2	10	10	0	10	0
	%		95	5	100	0
Site 2 Out Patient Lab	1	10	10	0	10	0
	2	10	10	0	9	1
	%		100	0	95	0
Site 3 Clinical Pathology	1	10	9	1	10	0
	2	10	10	0	10	0
	%		95	5	100	0
Sum		60	58	2	59	1
Percent of Results(%)_overall			**96.7**	**3.3**	**98.3**	**1.7**

Package Insert

i-CHROMA iFOB CONTROLS

INTENDED USE

i-CHROMA iFOB Controls are the quality control reagents intended for monitoring and ensuring acceptable performance of *i*-CHROMA iFOB test system which is a qualitative *in-vitro* diagnostic test for detection of fecal occult blood having a lower analytical detection limit of 25 ng/mL and the cut-off of 100 ng/mL (hemoglobin in human fecal samples).

These controls must be tested regularly if '*i*-CHROMA iFOB Test' is being used under CLIA-waived status. *i*-CHROMA iFOB test results of human fecal samples should not be considered valid and accurate unless supported or corroborated with acceptable tests results of *i*-CHROMA iFOB Controls tested by the same *i*-CHROMA iFOB test system.

i-CHROMA iFOB Controls represent assayed test materials containing 'Human Hemoglobin A_0' as the analyte.

REAGENTS, ASSIGNED TARGET VALUES AND RANGES

'*i*-CHROMA iFOB Negative Control' and '*i*-CHROMA iFOB Positive Control' are the two control reagents containing different levels of the analyte 'Human Hemoglobin A_0' as follows:

No.	Control Reagent		Assigned Target Value	Acceptable Range
1	Low	*i*-CHROMA iFOB Negative Control	50 ng/mL	45-55 ng/mL
2	High	*i*-CHROMA iFOB Positive Control	150 ng/mL	135-165 ng/mL

Human Hemoglobin A_0 is dissolved in a buffered liquid medium containing preservative.

i-CHROMA iFOB Controls have been tested and found safe and non-reactive for Hepatitis B Surface antigen (HBsAg), Hepatitis C (HCV), HIV-1 and HIV-2.

MATERIALS SUPPLIED

'*i*-CHROMA iFOB Control Set' is to be procured separately from other components of the '*i*-CHROMA iFOB Test'

The control set contains:

i-CHROMA iFOB Negative Control	1 mL/Vial
i-CHROMA iFOB Positive Control	1 mL/Vial

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Grabber	
Capillary Tubes (10 µL)	200 pieces/Bottle

STORAGE AND STABILITY

Vials of *i*-CHROMA iFOB Controls must be stored at 2~8 ℃/35.6~46.4° F in a refrigerator and should not be used beyond the expiration date or beyond one month after opening the vials for the first time; whichever is earlier.

Appropriate storage conditions for the controls may allow a maximum variation of ±10% of the labeled analyte concentration when tested with *i*-CHROMA iFOB.

WARNINGS AND PRECAUTIONS

- Strictly follow the instructions and test procedure as described in this package insert; otherwise quality control test results may be misleading or erroneous.
- Refer to the 'Package Insert of *i*-CHROMA iFOB' and 'Operation Manual of *i*-CHROMA Reader' for detail information and operating instructions.
- A control test should be performed using test Cartridge, sample collection tube and ID chip; all having exactly matching lot number. Never interchange test products from different lots.
- Do not use the test cartridge or sample collection tube if it has been already used, damaged or stored under improper conditions.
- Misleading or erroneous test result(s) may be obtained with test components which are past the expiration date or stored improperly or not matching with each other.
- Use *i*-CHROMA iFOB test cartridge and *i*-CHROMA Reader only with each other.
- Controls, test cartridge and sample collection tube must be allowed to attain ambient temperature (15~37℃/59~98.6℉) before testing.
- Controls, used test cartridge and used sample collection tube should be considered as potentially infectious and hence must be disposed of in accordance with appropriate local, state or federal requirements.

FREQUENCY OF TESTING

i-CHROMA iFOB Controls should be tested with *i*-CHROMA iFOB under following circumstances:

- At least once weekly before testing fecal samples.

- In case of any concern regarding functional integrity of the 'Test Cartridge(s)' and/or 'Detection Buffer in Sample Collection Tube(s)'.
- In case of any question concerning validity or accuracy of test results.
- Before using any new lot of test components.
- Before using any new shipment of test components even if it belonged to a previously received lot.
- Once every month for routinely checking stability of stored test components.
- If the test is being performed by a new operator.
- If the operator has not performed the test within last 7 days.

TESTING PROCEDURE

Arranging test setup:

1) Arrange following test components:

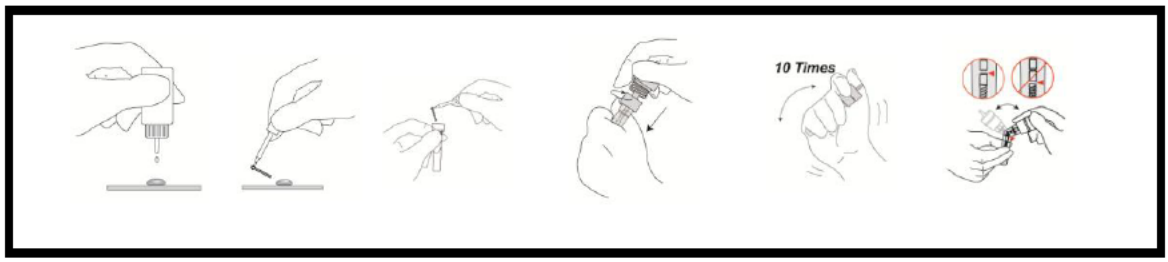
   - *i*-CHROMA iFOB Control Set
   - *i*-CHROMA iFOB Test Cartridge & ID Chip
   - *i*-CHROMA iFOB Sample Collection Tube
   - *i*-CHROMA Reader

2) All these test components must have been stored properly under recommended storage conditions.
3) Check whether lot number of the ID chip is exactly same as lot numbers of the test cartridge and the sample collection tube.
4) Ensure that test cartridge and sample collection tubes or the controls have not passed respective expiration dates.
5) Allow the test components to attain ambient temperature (15~37° C/59~98.6° F) for about 30 min.

Testing *i*-CHROMA iFOB Controls

1) Results of control testing may be observed under the normal qualitative (negative/ positive) display mode of *i*-CHROMA Reader. However the user can observe the results in dual display (qualitative/quantitative) mode also. Refer the i-CHROMA Reader Operation Manual for setting the *i*-CHROMA Reader in dual display mode.
2) Unscrew cap of the Sample Collection Tube and remove sampler.
3) Squeeze out 2 drops of 'Negative' control from the vial onto a parafilm or other similar clean surface.
4) Hold a capillary tube with the grabber and withdraw the control into it by touching one of the ends to the drop of control squeezed on to the parafilm.
5) Carefully drop the filled capillary tube into the sample collection tube such that it falls into the detection buffer reservoir.
6) Re-apply the sampler back into sample collection tube and tighten its cap.
7) Shake the sample collection tube 10 times

8) Hold it in vertical position and cut the sampling stick by bending the cap 2-3 times as shown.
9) Allow the sample collection tube to stand for 10 minutes in vertical position.
10) If the *i*-CHROMA Reader has already been switched 'On', it automatically displays the default 'MENU'.
11) Select 'Test Mode' and insert '*i*-CHROMA iFOB ID Chip' in the 'ID chip port'. *i*-CHROMA Reader ejects the cartridge holder.
12) Remove the '*i*-CHROMA iFOB Test Cartridge' from its original pouch and place it on a flat surface.
13) Invert the sample collection tube and squeeze out 3 drops of the processed control sample into the sample well of the test cartridge.
14) Immediately insert the sample-loaded test cartridge in the cartridge holder and press 'Select'.
15) *i*-CHROMA Reader will automatically scan the inserted test cartridge after 10 minutes to compute and display the control testing result.
16) Perform the test with 'Positive' control also using new sample collection tube and test cartridge.



INTERPRETATION OF TEST RESULTS

- '*i*-CHROMA iFOB Negative Control' test results must be obtained as 'iFOB Test Negative' while '*i*-CHROMA iFOB Positive Control' test results must be obtained as 'iFOB Test Positive'.
- If the control test results are observed in dual (i.e. qualitative/quantitative) display mode of *i*-CHROMA Reader, numerical values of the test results must be in the range of 45.0-55.0 ng/mL with the negative control and 135.0-165.0 ng/mL with the positive control.
- If expected results are obtained with the controls, then:

  - It assures acceptable performance of *i*-CHROMA iFOB Test system.
  - Test results with fecal samples are most likely to be accurate and valid.

- If results obtained with any or both the controls are not-as-expected or out-of-acceptable range, then:

  - It may be due to one of the following reasons:

    - Proper technique or correct procedure was not followed while testing the controls.
    - Quality/Functional integrity of the controls and/or other components of the test system might have been adversely affected due to improper storage and/or handling.
    - The test system being used may not be performing effectively and hence tests performed on clinical human fecal samples using this test system may yield results of questionable validity and/or accuracy.
  - Test the controls again after correcting any error that might have occurred.
  - If test results with the controls continue to be unacceptable; then:
    - Do not perform further tests on the fecal samples or do not report any result.
    - Contact the manufacturer for technical assistance.

LIMITATIONS

- The acceptable ranges recommended for the *i*-CHROMA iFOB controls are intended only as guidelines. Laboratories should determine the ranges based on their own test system and tolerance limits.
- *i*-CHROMA iFOB control testing may have its own limitations. It is remotely possible that test results with fecal samples may be misleading or erroneous even when control test results are as-expected or within-acceptable range.
- *i*-CHROMA iFOB Controls have been tested by recognized methods and found to be safe and negative for communicable disease agents. However, no test method can offer complete assurance that products derived from human source are free from infectious agents.

Note: Please refer to the table below to identify various symbols on the product labels

	Read instructions for use
	Use by
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
IVD	*In vitro* diagnostic medical device
	Temperature limitation

	Do not Reuse

For technical assistance please contact:
Boditech Med Inc.'s Technical Services
Phone: + 82 33 243 1400
E-mail: support@boditech.co.kr

Boditech Med Incorporated
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.

Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr

Website: www.boditech.co.kr

Classification	Interference with Animal Hemoglobin		
Testing Material	Low; Hemoglobin in Liquid Buffer, 50ng/mL	Operator	Hye Sung Kim, QC Manager
	High; Hemoglobin in Liquid Buffer, 200ng/mL	Device Lot No.	FOEGA00
Interference	Animal Hemoglobin, each 200ng/mL	Reader Serial No.	PFR09E080571
Testing date	2012. 04. 27	Testing Site	R&D Center, Boditech Med Inc.

Low; Hemoglobin in Liquid Buffer, 50ng/mL										
Animal Hb	1	2	3	4	5	6	7	8	9	10
Beef	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
	48.26	51.35	52.02	48.35	52.09	51.23	52.06	53.44	51.08	50.21
Chicken	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
	53.19	52.08	50.24	48.62	52.98	53.67	51.07	54.26	53.07	51.34
Fish	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
	50.16	53.28	54.19	50.84	51.26	51.37	50.24	48.19	48.61	48.52
Horse	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
	48.65	43.26	45.82	47.19	48.69	51.25	53.61	45.62	51.09	53.27
Goat	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
	53.62	51.55	52.08	53.24	51.09	53.22	54.61	53.77	49.83	46.77
Pig	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
	52.64	52.33	51.04	49.88	45.68	51.22	53.62	54.09	51.34	50.11
Rabbit	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
	49.89	46.35	46.77	49.28	53.47	48.55	49.39	51.06	49.35	48.44
Sheep	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
	53.66	52.06	51.21	50.43	51.92	47.32	53.62	51.06	50.33	48.09

High; Hemoglobin in Liquid Buffer, 200ng/mL										
Animal Hb	1	2	3	4	5	6	7	8	9	10
Beef	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	200.25	208.69	201.38	207.46	201.22	198.65	199 98	205.07	200.25	201.36
Chicken	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	201.38	195.24	197.68	205.49	211.35	206.88	201 38	194.56	206.37	201.38
Fish	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	198.56	200.99	196.54	212.23	200.35	198.00	212 14	193.72	189.45	212.65
Horse	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	201.36	204.16	205.69	207.14	209.87	211.00	205.49	206.09	199.36	207.98
Goat	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	201.89	205.64	209.65	202.95	203.56	195.13	191 25	215.36	205.47	201.00
Pig	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	210.36	198.44	208.23	211.75	208.14	203.58	212.00	197.00	202.35	199.44
Rabbit	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	198.52	205.65	211.24	192.53	213.65	208.45	203 88	189.35	199.66	215.98
Sheep	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	194.23	189.25	216.86	198.54	192.71	202.65	211.69	191.54	209.71	183.71

Interference with Animal Hemoglobin																		
Test Result				Test Sample Number			PPA	NPA	For PPA			For NPA			PPA; Confidence Interval(CI)		NPA; Confidence Interval(CI)	
A(+/+)	B(+/-)	C(-/+)	D(-/-)	Total	Positive	Negative			Q1	Q2	Q3	Q1	Q2	Q3	Lower Bound	Upper Bound	Lower Bound	Upper Bound
80	0	0	80	160	80	80	100.00	100.00	163.8	3.8	167.7	163.8	3.8	167.7	95.42	100.00	95.42	100.00

Classification	Interference with Endogenous Substances		
Testing Material	Low; Hemoglobin in Liquid Buffer, 50ng/mL	Operator	Hye Sung Kim, QC Manager
	High; Hemoglobin in Liquid Buffer, 250ng/mL	Device Lot No.	FOEGA00
Interference	Endogeneous Substances, each 500ng/mL	Reader Serial No.	PFR09E080571
Testing date	2012. 04. 29	Testing Site	R&D Center, Boditech Med Inc.

Interferences	Hb Conc.	1	2	3	4	5	6	7	8	9	10
Ascorbic Acid (500ng/ml)	50ng/mL	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		50.21	50.92	51.35	53.2	49.68	52.62	54.15	53.78	52.71	51.44
	250ng/mL	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		256.35	256.67	255.1	253.23	253.78	254.12	263.84	249.28	255.86	271.24
Bilirubin (500ng/ml)	50ng/mL	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		50.6	48.78	47.9	52	50.74	49.22	48.54	52.61	51.47	50.75
	250ng/mL	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		257.01	254.55	248.55	256.55	258.92	259.21	246.35	257.17	265.94	251.93
Albumin (500ng/ml)	50ng/mL	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		50.4	49.85	49.62	52.59	50.46	48.33	47.26	51.38	53.49	50.22
	250ng/mL	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		256.68	255.6	251.82	254.88	255.1	249.88	250.74	255.92	250.71	246.96
Myoglobin (500ng/ml)	50ng/mL	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		50.17	50.69	51.51	53.7	49.58	51.61	54.78	52.19	51.27	51.43
	250ng/mL	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		254.34	256.15	255.72	252.79	253.13	254.15	262.13	258.13	255.13	261.22

Interference with Endogenous Substances																		
Test Result				Test Sample Number			PPA	NPA	For PPA			For NPA			PPA; Confidence Interval(CI)		NPA; Confidence Interval(CI)	
A(+/+)	B(+/-)	C(-/+)	D(-/-)	Total	Positive	Negative			Q1	Q2	Q3	Q1	Q2	Q3	Lower Bound	Upper Bound	Lower Bound	Upper Bound
40	0	0	40	80	40	40	100.00	100.00	83.8	3.8	87.7	83.8	3.8	87.7	91.24	100.00	91.24	100.00

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Secret
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

BODITECH MED INC
43, Geodudanji 1-gil, Dongnae-myeon

Chuncheon-si
Korea, Republic of
Gang-won-do
200883
KR

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Sang Yeol Park

2.1 E-MAIL ADDRESS
psy@boditech.co.kr

2.2 TELEPHONE NUMBER (include Area code)
+82-332431400

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[ ] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)Trade Secret Process

08-Feb-2013

Form FDA 3601 (01/2007)

Classification	Method Comparison		
Testing Material	- Human Fecal samples above Age 50 - Fob Value > 25ng/mL by i-CHROMA iFOB	Operator	Hye Sung Kim, QC Manager
		Device Lot No.	FOEGA00
		Reader Serial No.	PFR09E080571
Testing date	2012. 04. 16~20	Testing Site	R&D Center, Boditech Med Inc.

ID No.	I-CHROMA	Predicate	ID No.	I-CHROMA	Predicate	ID No.	I-CHROMA	Predicate	ID No.	I-CHROMA	Predicate	ID No.	I-CHROMA	Predicate
1	Pos	Pos	31	Neg	Neg	61	Pos	Pos	91	Pos	Pos	121	Pos	Pos
	893.84	1140		51.34	28		455.95	422		157.67	213		286.44	342
2	Neg	Neg	32	Very Low	Neg	62	Neg	Pos	92	Neg	Neg	122	Neg	Neg
	25.54	41		*	12		84.99	102		95.65	76		80.73	71
3	Pos	Pos	33	Pos	Pos	63	Pos	Pos	93	Pos	Pos	123	Neg	Neg
	986.68	1059		254.97	206		337.28	418		233.48	210		29.41	5
4	Very Low	Neg	34	Neg	Neg	64	Neg	Pos	94	Neg	Pos	124	Neg	Neg
	*	23		55.23	48		82.47	103		85.67	121		31.57	57
5	Neg	Neg	35	Very High	Pos	65	Pos	Pos	95	Very Low	Neg	125	Very High	Pos
	54.08	48		*	1021		339.47	417		*	22		*	1123
6	Neg	Neg	36	Pos	Pos	66	Pos	Pos	96	Neg	Neg	126	Pos	Pos
	44.7	48		123.78	197		784.15	876		64.37	51		214.95	189
7	Pos	Pos	37	Very Low	Neg	67	Very Low	Neg	97	Very High	Pos	127	Pos	Pos
	751.22	815		*	21		*	24		*	870		483.25	511
8	Pos	Pos	38	Pos	Pos	68	Pos	Pos	98	Pos	Pos	128	Pos	Pos
	687.28	785		356.71	401		453.84	391		243.57	197		120.84	153
9	Neg	Neg	39	Neg	Neg	69	Neg	Neg	99	Neg	Pos	129	Neg	Neg
	37.46	22		46.77	52		35.12	37		52.79	108		27.53	12
10	Pos	Pos	40	Pos	Pos	70	Pos	Neg	100	Very Low	Neg	130	Neg	Neg
	553.94	770		246.58	196		102.66	92		*	18		49.74	54
11	Pos	Pos	41	Neg	Neg	71	Neg	Neg	101	Neg	Neg	131	Pos	Pos
	410.15	383		77.28	65		52.41	18		67.52	82		179.65	245
12	Very Low	Neg	42	Very Low	Neg	72	Pos	Pos	102	Pos	Pos	132	Very Low	Neg
	*	19		*	19		342.87	354		153.2	189		*	13
13	Neg	Neg	43	Pos	Pos	73	Neg	Neg	103	Pos	Pos	133	Pos	Neg
	32.15	25		242.14	298		43.74	33		209.69	121		111.15	97
14	Pos	Pos	44	Very High	Pos	74	Neg	Neg	104	Very High	Pos	134	Neg	Neg
	551.77	641		*	1087		93.98	89		*	962		66.27	63
15	Neg	Neg	45	Neg	Neg	75	Very Low	Neg	105	Pos	Pos			
	64.63	84		27.23	19		*	24		831.35	760			
16	Pos	Pos	46	Pos	Pos	76	Pos	Pos	106	Very Low	Neg			
	712.42	627		712.84	627		294.77	334		*	12			
17	Pos	Neg	47	Pos	Pos	77	Very Low	Neg	107	Pos	Pos			

17	111.82	93	47	132.85	187	77	*	12	107	275.19	187		
18	Pos	Pos	48	Neg	Neg	78	Pos	Pos	108	Neg	Neg		
	217.56	187		26.36	21		254.11	324		78.12	54		
19	Pos	Pos	49	Very Low	Neg	79	Neg	Pos	109	Neg	Neg		
	125.45	187		*	21		98.25	121		84.29	78		
20	Very Low	Neg	50	Pos	Pos	80	Pos	Pos	110	Pos	Pos		
	*	16		234.97	243		292.01	307		251.23	145		
21	Pos	Pos	51	Pos	Pos	81	Pos	Pos	111	Pos	Pos		
	458.07	587		465.27	544		574.51	594		132.88	107		
22	Neg	Pos	52	Pos	Pos	82	Neg	Neg	112	Pos	Pos		
	98.69	175		129.8	153		46.12	15		116.84	165		
23	Very Low	Neg	53	Pos	Pos	83	Very Low	Neg	113	Pos	Pos		
	*	27		346.95	441		*	11		213.48	185		
24	Pos	Pos	54	Pos	Pos	84	Neg	Neg	114	Pos	Pos		
	253.19	301		483.95	534		76.88	84		108.46	154		
25	Pos	Pos	55	Pos	Pos	85	Pos	Pos	115	Very Low	Neg		
	498.44	566		384.33	248		322.74	281		*	10		
26	Neg	Neg	56	Pos	Pos	86	Pos	Pos	116	Pos	Pos		
	86.81	66		496.99	586		246.67	264		148.37	173		
27	Neg	Neg	57	Very High	Pos	87	Pos	Pos	117	Neg	Neg		
	31.84	11		*	1120		647.22	551		41.22	77		
28	Very Low	Neg	58	Pos	Pos	88	Pos	Pos	118	Neg	Neg		
	*	7		413.66	474		198.22	263		34.87	43		
29	Neg	Neg	59	Neg	Neg	89	Very High	Pos	119	Neg	Neg		
	75.06	60		27.36	10		*	1201		73.98	73		
30	Neg	Neg	60	Neg	Neg	90	Pos	Pos	120	Neg	Neg		
	82.69	12		54.26	52		331.25	249		87.29	65		

Test Result				Test Sample Number			PPA	NPA	For PPA			For NPA		
A(+/+)	B(+/-)	C(-/+)	D(-/-)	Total	Positive	Negative			Q1	Q2	Q3	Q1	Q2	Q3
61	3	6	39	109	67	42	91.04	92.86	125.8	9 9	141.7	81.8	7.6	91.7

PPA; Confidence Interval(CI)		NPA; Confidence Interval(CI)	
Lower Bound	Upper Bound	Lower Bound	Upper Bound
81.81	95.83	80 99	97.54

Excluded data		
	Very Low	18
	Very High	7

Classification	Repeatability_Within Run		
Testing Material	Low; Hemoglobin in Liquid Buffer, 50ng/mL	Operator	Hye Sung Kim, QC Manager
	Medium; Hemoglobin in Liquid Buffer, 125ng/mL	Device Lot No.	FOEGA00
	High; Hemoglobin in Liquid Buffer, 250ng/mL	Reader Serial No.	PFR09E080571
Testing date	2012. 04. 13	Testing Site	R&D Center, Boditech Med Inc.

No.	Hemoglobin 50 ng/mL	Hemoglobin 125 ng/mL	Hemoglobin 250 ng/mL
1	Neg	Pos	Pos
	49.10	117.47	223.54
2	Neg	Pos	Pos
	46.62	121.65	246.29
3	Neg	Pos	Pos
	54.38	127.82	236.29
4	Neg	Pos	Pos
	52.32	118.20	246.19
5	Neg	Pos	Pos
	47.93	119.58	264.29
6	Neg	Pos	Pos
	48.67	121.41	246.29
7	Neg	Pos	Pos
	53.25	123.46	248.17
8	Neg	Pos	Pos
	53.47	120.26	236.99
9	Neg	Pos	Pos
	46.22	126.25	254.1
10	Neg	Pos	Pos
	45.18	121.24	243.25
11	Neg	Pos	Pos
	48.07	115.64	237.75
12	Neg	Pos	Pos
	53.26	121.94	256.21
13	Neg	Pos	Pos
	51.08	116.35	246.39
14	Neg	Pos	Pos
	48.26	123.51	246.59
15	Neg	Pos	Pos
	46.31	124.62	249.26
16	Neg	Pos	Pos
	53.27	118.27	264.37
17	Neg	Pos	Pos
	48.36	122.31	254.19
18	Neg	Pos	Pos
	53.18	126.28	246.35
19	Neg	Pos	Pos
	46.38	125.28	246.39
20	Neg	Pos	Pos
	52.34	119.64	255.36

Repeatability_Within Run					
Concentration	Expected Value	Test Value			Total Agreement (%)
		Total	Positive	Negative	
Low, Control (50 ng/mL)	Negative	20	0	20	100
Medium, Control (125 ng/mL)	Positive	20	20	0	100
High, Control (250 ng/mL)	Positive	20	20	0	100

Reproducibility_Between-Run			
Testing Material	Low; Hemoglobin in Liquid Buffer, 50ng/mL	Operator	Run 1; Hye Sung Kim, QC Manager Run 2; Taek kyu Oh, Researcher
	Medium; Hemoglobin in Liquid Buffer, 125ng/mL	Device Lot No.	FOEGA00
	High; Hemoglobin in Liquid Buffer, 250ng/mL	Reader Serial No.	PFR09E080571
Testing date	2012. 04. 13	Testing Site	R&D Center, Boditech Med Inc.

No.	Run 1			No.	Run 1		
	50ng/mL	125ng/mL	250ng/mL		50ng/mL	125ng/mL	250ng/mL
1	Neg	Pos	Pos	1	Neg	Pos	Pos
	48.67	121.06	239.52		50.94	117.26	255.14
2	Neg	Pos	Pos	2	Neg	Pos	Pos
	51.38	120.64	249.79		51.23	119.54	245.68
3	Neg	Pos	Pos	3	Neg	Pos	Pos
	50.52	124.05	265.99		52.48	122.44	239.58
4	Neg	Pos	Pos	4	Neg	Pos	Pos
	50.43	124.91	233.83		50.42	120.87	256.48
5	Neg	Pos	Pos	5	Neg	Pos	Pos
	50.57	125.21	239.79		52.63	121.64	245.99
6	Neg	Pos	Pos	6	Neg	Pos	Pos
	48.67	123.28/	255.21		51.38	129.52	243.12
7	Neg	Pos	Pos	7	Neg	Pos	Pos
	50.94	126.65	265.99		50.52	118.91	251.13
8	Neg	Pos	Pos	8	Neg	Pos	Pos
	52.48	125.39	271.16		50.43	122.18	246.65
9	Neg	Pos	Pos	9	Neg	Pos	Pos
	50.6	124.19	243.49		48.78	124.31	234.61
10	Neg	Pos	Pos	10	Neg	Neg	Pos
	49.26	123.07	246.93		52.01	125.62	248.23
11	Neg	Pos	Pos	11	Neg	Pos	Pos
	50.48	122.07	246.34		50.01	125.07	235.35
12	Neg	Pos	Pos	12	Neg	Pos	Pos
	51.23	119.64	252.7		51.23	123.66	250.57
13	Neg	Pos	Pos	13	Neg	Pos	Pos
	47.25	116.52	246.32		52.01	125.37	248.72
14	Neg	Pos	Pos	14	Neg	Pos	Pos
	52.55	125.27	241.58		50.28	125.84	242.52
15	Neg	Pos	Pos	15	Neg	Pos	Pos
	50.41	122.11	255.12		52.03	126.43	255.21
16	Neg	Pos	Pos	16	Neg	Pos	Pos
	53.22	125.36	243.65		51.46	126.34	251.97
17	Neg	Pos	Pos	17	Neg	Pos	Pos
	51.45	119.52	255.91		53.25	123.34	260.26
18	Neg	Pos	Pos	18	Neg	Pos	Pos
	52.67	125.34	246.96		51.02	119.67	246.65
19	Neg	Pos	Pos	19	Neg	Pos	Pos
	48.52	119.27	246.78		51.16	126.25	251.13

20	Neg	Pos	Pos	20	Neg	Pos	Pos
	48.17	123.00	241.55		49.25	127.64	241.35

Between-Run		Run 1				Run 2				Total			
Concentration	Expected Value	Test Value			Total Agreement (%)	Test Value			Total Agreement (%)	Test Value			Total Agreement (%)
		Total	Positive	Negative		Total	Positive	Negative		Total	Positive	Negative	
Low, Control (50 ng/mL)	Negative	20	0	20	100	20	0	20	100	40	0	40	100
Medium, Control (125 ng/mL)	Positive	20	20	0	100	20	20	0	100	40	40	0	100
High, Control (250 ng/mL)	Positive	20	20	0	100	20	20	0	100	40	40	0	100

Reproducibility_Between-Day						
Testing Material		Low; Hemoglobin in Liquid Buffer, 50ng/mL		Operator	Hye Sung Kim, QC Manager	
		Medium; Hemoglobin in Liquid Buffer, 125ng/mL		Device Lot No.	FOEGA00	
		High; Hemoglobin in Liquid Buffer, 250ng/mL		Reader Serial No.	PFR09E080571	
Testing date		2012. 03. 12 ~ 03. 31		Testing Site	R&D Center, Boditech Med Inc.	
Day	50ng/mL		125ng/mL		250ng/mL	
1	Neg	Neg	Pos	Pos	Pos	Pos
	46.98	50.42	115.26	123.25	246.85	250.47
2	Neg	Neg	Pos	Pos	Pos	Pos
	53.45	50.45	121.33	124.57	261.23	258.96
3	Neg	Neg	Pos	Pos	Pos	Pos
	50.37	51.95	118.49	124.53	251.97	255.12
4	Neg	Neg	Pos	Neg	Pos	Pos
	48.38	52.14	118.31	126.36	269.48	256.88
5	Neg	Neg	Pos	Pos	Pos	Pos
	51.65	49.82	119.29	128.59	250.90	264.06
6	Neg	Neg	Pos	Pos	Pos	Pos
	46.98	53.45	124.05	125.64	271.29	266.89
7	Neg	Neg	Pos	Pos	Pos	Pos
	50.42	50.37	126.39	124.29	251.97	256.25
8	Neg	Neg	Pos	Pos	Pos	Pos
	51.95	48.38	122.25	125.09	263.28	253.91
9	Neg	Neg	Pos	Pos	Pos	Pos
	50.74	47.9	128.64	127.53	256.26	241.25
10	Neg	Neg	Pos	Pos	Pos	Pos
	49.98	50.46	124.35	122.54	230.07	248.49
11	Neg	Neg	Pos	Pos	Pos	Pos
	51.02	48.67	125.63	118.29	265.96	259.82
12	Neg	Neg	Pos	Pos	Pos	Pos
	50.92	50.98	124.09	119.97	254.36	251.1
13	Neg	Neg	Pos	Pos	Pos	Pos
	46.98	50.85	125.19	125.64	258.91	244.3
14	Neg	Neg	Pos	Pos	Pos	Pos
	53.16	50.94	118.94	125.09	256.77	257.51
15	Neg	Neg	Pos	Pos	Pos	Pos
	49.39	51.97	124.26	124.36	249.82	245.08
16	Neg	Neg	Pos	Pos	Pos	Pos
	50.73	50.23	119.59	125.04	239.79	257.71
17	Neg	Neg	Pos	Pos	Pos	Pos
	50.00	52.16	126.39	126.97	250.79	255.94
18	Neg	Neg	Pos	Pos	Pos	Pos
	50.54	51.38	124.18	122.41	256.75	253.91
19	Neg	Neg	Pos	Pos	Pos	Pos
	49.35	50.24	129.06	123.06	233.82	256.25
20	Neg	Neg	Pos	Pos	Pos	Pos
	51.86	50.24	127.29	129.53	268.78	265.52

Between-Day					
Concentration	Expected Value	Test Value			Total Agreement (%)
		Total	Positive	Negative	
Low, Control (50 ng/ml)	Negative	40	0	40	100
Medium, Control (125 ng/ml)	Positive	40	40	0	100
High, Control (250 ng/ml)	Positive	40	40	0	100

Reproducibility_Between-Lot			
Testing Material	Low; Hemoglobin in Liquid Buffer, 50ng/mL	Operator	Hye Sung Kim, QC Manager
	Medium; Hemoglobin in Liquid Buffer, 125ng/mL	Device Lot No.	Lot 1; FOEGA00 Lot 2; FOEGA01
	High; Hemoglobin in Liquid Buffer, 250ng/mL	Reader Serial No.	PFR09E080571
Testing date	2012. 04. 12	Testing Site	R&D Center, Boditech Med Inc.

No.	Lot 1			No.	Lot 2		
	50ng/mL	125ng/mL	250ng/mL		50ng/mL	125ng/mL	250ng/mL
1	Neg	Pos	Pos	1	Neg	Pos	Pos
	50.43	121.62	244.15		45.84	117.29	252.34
2	Neg	Pos	Pos	2	Neg	Pos	Pos
	47.25	125.34	246.93		48.1	123.64	253.93
3	Neg	Pos	Pos	3	Neg	Pos	Pos
	48.28	120.49	266.78		49.74	118.28	258.5
4	Neg	Pos	Pos	4	Neg	Pos	Pos
	50.99	122.65	253.07		51.43	121.64	245.64
5	Neg	Pos	Pos	5	Neg	Pos	Pos
	49.55	123.25	227.42		47.21	120.75	260.08
6	Neg	Pos	Pos	6	Neg	Pos	Pos
	46.38	120.84	265.99		54.35	117.28	246.65
7	Neg	Pos	Pos	7	Neg	Pos	Pos
	51.00	119.46	256.86		48.63	128.19	271.16
8	Neg	Pos	Pos	8	Neg	Pos	Pos
	51.21	118.37	248.32		47.26	126.3	249.14
9	Neg	Pos	Pos	9	Neg	Pos	Pos
	50.37	125.47	244.35		50.45	125.49	248.7
10	Neg	Pos	Pos	10	Neg	Pos	Pos
	50.62	124.16	246.65		45.23	122.58	265.99
11	Neg	Pos	Pos	11	Neg	Pos	Pos
	50.29	120.57	253.25		51.33	124.73	251.13
12	Neg	Pos	Pos	12	Neg	Pos	Pos
	52.35	120.91	253.98		52.46	128.08	245.72
13	Neg	Pos	Pos	13	Neg	Pos	Pos
	52.62	120.46	226.15		50.29	125.43	271.16
14	Neg	Pos	Pos	14	Neg	Pos	Pos
	48.46	119.68	255.14		54.11	122.07	274.14
15	Neg	Pos	Pos	15	Neg	Pos	Pos
	48.49	121.53	249.79		48.29	119.69	255.91
16	Neg	Pos	Pos	16	Neg	Pos	Pos
	48.52	118.09	239.52		50.67	120.83	251.97
17	Neg	Pos	Pos	17	Neg	Pos	Pos
	49.31	128.64	243.65		51.99	122.57	271.16
18	Neg	Pos	Pos	18	Neg	Pos	Pos
	51.28	125.08	226.68		54.33	123.46	260.26
19	Neg	Pos	Pos	19	Neg	Pos	Pos
	53.42	118.49	265.99		49.11	127.48	255.21

20	Neg	Pos	Pos	20	Neg	Pos	Pos
	53.07	119.57	242.52		52.87	124.61	238.86

Between-Lot		Lot 1				Lot 2				Total			
Concentration	Expected Value	Test Value			Total Agreement (%)	Test Value			Total Agreement (%)	Test Value			Total Agreement (%)
		Total	Positive	Negative		Total	Positive	Negative		Total	Positive	Negative	
Low, Control (50 ng/mL)	Negative	20	0	20	100	20	0	20	100	40	0	40	100
Medium, Control (125 ng/mL)	Positive	20	20	0	100	20	20	0	100	40	40	0	100
High, Control (250 ng/mL)	Positive	20	20	0	100	20	20	0	100	40	40	0	100

Reproducibility_Between-Instrument

Testing Material	Low; Hemoglobin in Liquid Buffer, 50ng/mL	Operator	Hye Sung Kim, QC Manager
	Medium; Hemoglobin in Liquid Buffer, 125ng/mL	Device Lot No.	FOEGA00
	High; Hemoglobin in Liquid Buffer, 250ng/mL	Reader Serial No.	Reader 1; PFR09E080571 Reader 2; PFR09E080574
Testing date	2012. 04. 03	Testing Site	R&D Center, Boditech Med Inc.

No.	Reader 1			No.	Reader 2		
	50ng/mL	125ng/mL	250ng/mL		50ng/mL	125ng/mL	250ng/mL
1	Neg	Pos	Pos	1	Neg	Pos	Pos
	50.42	121.35	240.18		50.71	121.66	256.25
2	Neg	Pos	Pos	2	Neg	Pos	Pos
	47.27	120.86	256.44		48.1	127.33	263.57
3	Neg	Pos	Pos	3	Neg	Pos	Pos
	49.85	124.16	242.08		53.24	124.29	263.28
4	Neg	Pos	Pos	4	Neg	Pos	Pos
	51.61	127.89	250.47		49.00	126.25	236.13
5	Neg	Pos	Pos	5	Neg	Pos	Pos
	47.12	117.75	261.23		49.74	122.32	250.79
6	Neg	Pos	Pos	6	Neg	Pos	Pos
	53.28	122.58	246.85		51.31	119.28	257.71
7	Neg	Pos	Pos	7	Neg	Pos	Pos
	47.7	123.64	239.79		50.29	121.49	263.28
8	Neg	Pos	Pos	8	Neg	Pos	Pos
	50.68	125.92	241.05		51.43	121.31	255.94
9	Neg	Pos	Pos	9	Neg	Pos	Pos
	52.78	125.49	251.97		50.18	117.19	254.58
10	Neg	Pos	Pos	10	Neg	Pos	Pos
	50.99	124.39	257.51		53.29	118.94	256.75
11	Neg	Pos	Pos	11	Neg	Pos	Pos
	48.38	119.46	255.37		54.16	118.59	249.74
12	Neg	Pos	Pos	12	Neg	Pos	Pos
	47.11	118.55	253.45		46.23	124.56	242.76
13	Neg	Pos	Pos	13	Neg	Pos	Pos
	48.92	121.31	269.16		45.97	128.53	241.95
14	Neg	Pos	Pos	14	Neg	Pos	Pos
	49.35	125.46	229.27		50.67	121.44	259.82
15	Neg	Pos	Pos	15	Neg	Pos	Pos
	51.03	122.46	227.09		47.38	118.29	256.25
16	Neg	Pos	Pos	16	Neg	Pos	Pos
	47.95	119.29	251.97		45.68	119.53	253.91
17	Neg	Pos	Pos	17	Neg	Pos	Pos
	53.49	125.88	259.30		51.72	119.68	263.28
18	Neg	Pos	Pos	18	Neg	Pos	Pos
	47.17	119.29	277.51		53.87	122.42	251.13
19	Neg	Pos	Pos	19	Neg	Pos	Pos
	48.23	122.52	253.73		49.22	126.59	249.51

20	Neg	Pos	Pos	20	Neg	Pos	Pos
	48.71	124.29	253.91		46.64	119.87	251.97

Between-Instrument		Reader 1				Reader 2				Total			
Concentration	Expected Value	Test Value			Total Agreement (%)	Test Value			Total Agreement (%)	Test Value			Total Agreement (%)
		Total	Positive	Negative		Total	Positive	Negative		Total	Positive	Negative	
Low, Control (50 ng/mL)	Negative	20	0	20	100	20	0	20	100	40	0	40	100
Medium, Control (125 ng/mL)	Positive	20	20	0	100	20	20	0	100	40	40	0	100
High, Control (250 ng/mL)	Positive	20	20	0	100	20	20	0	100	40	40	0	100

Reproducibility_Between-Site

Testing Material	Low; Hemoglobin in Liquid Buffer, 50ng/mL	**Operator**	Hye Sung Kim, QC Manager
	Medium; Hemoglobin in Liquid Buffer, 125ng/mL	**Device Lot No.**	FOEGA00
	High; Hemoglobin in Liquid Buffer, 250ng/mL	**Reader Serial No.**	PFR09E080571
Testing date	2012. 04. 05	**Testing Site**	Site 1; (b)(4)Trade Secret [redacted] (b) [redacted] Site 2; (b)(4)Trade [redacted] Secret Process

No.	Site 1			No.	Site 2		
	50ng/mL	125ng/mL	250ng/mL		50ng/mL	125ng/mL	250ng/mL
1	Neg	Pos	Pos	1	Neg	Pos	Pos
	50.29	121.31	229.27		51.43	121.57	271.16
2	Neg	Pos	Pos	2	Neg	Pos	Pos
	46.23	125.41	253.25		48.49	121.28	245.69
3	Neg	Pos	Pos	3	Neg	Pos	Pos
	50.45	119.54	252.62		47.38	122.59	229.5
4	Neg	Pos	Pos	4	Neg	Pos	Pos
	51.23	124.73	241.04		49.52	123.67	254.11
5	Neg	Pos	Pos	5	Neg	Pos	Pos
	47.26	127.12	255.14		49.11	118.69	255.91
6	Neg	Pos	Pos	6	Neg	Pos	Pos
	50.71	122.39	248.7		51.99	122.13	258.5
7	Neg	Pos	Pos	7	Neg	Pos	Pos
	45.68	118.52	227.09		50.26	122.70	241.69
8	Neg	Pos	Pos	8	Neg	Pos	Pos
	49.22	122.67	227.09		49.35	127.25	251.97
9	Neg	Pos	Pos	9	Neg	Pos	Pos
	48.1	122.48	229.27		51.24	120.55	255.21
10	Neg	Pos	Pos	10	Neg	Pos	Pos
	50.29	125.68	245.72		46.81	123.68	246.98
11	Neg	Pos	Pos	11	Neg	Pos	Pos
	50.42	123.98	226.15		50.67	125.89	263.28
12	Neg	Pos	Pos	12	Neg	Pos	Pos
	48.1	125.68	240.18		47.12	125.47	248.14
13	Neg	Pos	Pos	13	Neg	Pos	Pos
	49.22	120.91	277.51		50.99	119.52	235.65
14	Neg	Pos	Pos	14	Neg	Pos	Pos
	50.98	125.55	235.61		51.21	124.65	244.13
15	Neg	Pos	Pos	15	Neg	Pos	Pos
	53.87	123.67	250.47		50.18	123.25	250.79
16	Neg	Pos	Pos	16	Neg	Pos	Pos
	48.16	125.84	239.44		50.29	120.41	241.95
17	Neg	Pos	Pos	17	Neg	Pos	Pos
	49.73	118.64	261.94		51.47	126.59	250.29
18	Neg	Pos	Pos	18	Neg	Pos	Pos

18	45.99	125.44	239.44	18	50.96	125.38	246.35
19	Neg	Pos	Pos	19	Neg	Pos	Pos
	46.23	128.58	250.28		49.52	120.22	254.58
20	Neg	Pos	Pos	20	Neg	Pos	Pos
	50.42	119.97	263.78		48.12	125.45	264.55

Between-Site		Site 1				Site 2				Total			
Concentration	Expected Value	Test Value			Total Agreement (%)	Test Value			Total Agreement (%)	Test Value			Total Agreement (%)
		Total	Positive	Negative		Total	Positive	Negative		Total	Positive	Negative	
Low, Control (50 ng/mL)	Negative	20	0	20	100	20	0	20	100	40	0	40	100
Medium, Control (125 ng/mL)	Positive	20	20	0	100	20	20	0	100	40	40	0	100
High, Control (250 ng/mL)	Positive	20	20	0	100	20	20	0	100	40	40	0	100

Classification	Prozone (Hook) Effect		
Testing Material	Hemoglobin in Liquid Buffer, 700, 1000, 1300, 1500, 1700, 2000 ng/mL	Operator	Hye Sung Kim, QC Manager
		Device Lot No.	FOEGA00
		Reader Serial No.	PFR09E080571
Testing date	2012. 04. 11	Testing Site	R&D Center, Boditech Med Inc.

Conc. [ng/ml]	1	2	3	4	5	6	7	8	9	10	AVG
700	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	712.31	735.69	689.12	675.23	753.21	711.02	700.89	690.13	725.33	718.13	711.11
1000	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	967.14	932.15	1088.95	1075.22	928.44	1007.31	913.2	917.55	1033.94	999.96	986.39
1300	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	1232.55	1154.25	1105.61	1244.05	1157.58	1132.64	1254.61	1266.33	1244.54	1258.94	1205.11
1500	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	1368.29	1421.54	1405.84	1368.28	1422.61	1470.52	1399.61	1406.52	1432.84	1480.64	1417.67
1700	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	1400.11	1319.28	1320.15	1659.84	1532.11	1353.11	1321.19	1300.45	1297.15	1265.81	1376.92
2000	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	1314.26	1328.04	1416.46	1373.53	1473.2	1230.42	1328.97	1411.69	1236.72	1111.3	1322.46

IMMUNOFLUOROMETER EQUIPMENT

i-CHROMA Reader

Operation Manual

IMMUNOFLUOROMETER EQUIPMENT

Please read this manual thoroughly before you start testing with

i-CHROMA Reader

This manual provides all the information required for operating the i-CHROMA Reader.
Carefully follow the instructions given in this manual.

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1. Important Information

Intended Use:

i-CHROMA Reader is a portable fluorescence-scanning instrument for measuring the concentration of designated analyte(s) in human blood, urine and other test samples; duly processed and tested in accordance with various i-CHROMA Immunoassay Tests manufactured by Boditech Med Incorporated.

i-CHROMA Reader is to be used only in conjunction with various **i**-CHROMA Immunoassay Tests and meant only for in vitro diagnostic purpose only.

i-CHROMA Reader can be used for screening, monitoring and/or routine physical examination in centralized laboratories of hospitals and physicians clinics.

Please note:

- The user of i-CHROMA Reader in conjunction with the i-CHROMA Immunoassay Test should not arrive at any conclusion and/or should not take any decision of medical/therapeutic importance after knowing the test result without first consulting his/her physician.

- Unless otherwise explicitly stated in the package insert; use only fresh blood, urine or other test sample for testing with the *i*-CHROMA Immunoassay Test in conjunction with the *i*-CHROMA Reader.

- i-CHROMA Reader is compatible only with various i-CHROMA Immunoassay Tests manufactured by Boditech Med Incorporated. Use of i-CHROMA Reader in conjunction with immunoassay test devices of other marketed brands may yield misleading results.

- In order to obtain accurate results, the i-CHROMA Immunoassay Tests should be performed and scanned/read on the i-CHROMA Reader in an environment having temperature 15~37℃ (59~98.6 ℉) and maximum relative humidity 75%.

- The test set up should be exposed to the ambient temperature for at least 30 minutes until just prior to performing the test actually.

- Avoid exposure of *i*-CHROMA Reader to dust, water or any other liquid and direct sunlight. Similarly refrain from throwing, shaking, dropping or mishandling the i-CHROMA Reader, which may damage its internal parts.

- Do not operate the i-CHROMA Reader in close proximity of cellular or cordless telephones and electrical or electronic equipment like microwave oven that are sources of electromagnetic radiation, as these may interfere with normal functioning of the i-CHROMA Reader.

- Do not disassemble the i-CHROMA Reader in any case.

Following list explains various symbols, which the user will find in this i-CHROMA Reader operation manual, i-CHROMA product labels & packaging and the i-CHROMA Test package inserts.

IVD	For in vitro diagnostic use
CE	This product fulfills the requirements of Directive 98/79/EC on In Vitro Diagnostic Medical Devices
	Caution! Risk of electric shock
	Attention! Read instructions before use
	LASER Hazard
	Manufacturer
	Direct Current
	Separate collection for electrical and electronic equipment
	Bio Hazard

2. Safety Information

⚠	The user must ensure that i-CHROMA Reader functions safely and it is in proper working condition before being used. Be sure to read thoroughly and follow all instructions, warning and cautions before using i-CHROMA Reader.
	i-CHROMA Reader is based on a high voltage circuit. Never attempt to remove or open any part of the i-CHROMA Reader casing.
	Use of damaged or improperly adjusted i-CHROMA Reader or improper use of **i-CHROMA** Reader could result in personal injury.
	Ensure that the voltage setting of i-CHROMA Reader matches the power supply voltage.
	Use i-CHROMA Reader only for its intended use described in this manual.
	Do not use i-CHROMA Reader with such accessories which are not recommended and/or supplied by Boditech Med Incorporated.
	Do not place anything on top of i-CHROMA Reader even when it is lying idle.
	Unless otherwise instructed specifically, do not insert anything into any opening, socket or holder provided in the i-CHROMA Reader. Similarly do put not anything in any hose or attach anything to any coupling of the i-CHROMA Reader.
	Do not use i-CHROMA Reader in outdoor settings.
	Being electrical equipment, misuse or unwarranted use of i-CHROMA Reader may cause electrocution, burns, fire and other hazards. Use only the power adapter provided with i-CHROMA Reader.
	Never attempt to look into the laser aperture. Never attempt to use mirror or other devices to observe the laser beam or the lens.
	Do not allow i-CHROMA Reader to come in contact with liquid in any manner. If i-CHROMA Reader becomes wet, unplug it before touching it.

3. Principle of Operation

i-CHROMA Reader is a fluorescence scanning instrument to be used in conjunction with various i-CHROMA Immunoassay Tests which are based on antigen-antibody reaction and fluorescence technology.

i-CHROMA Reader uses a semiconductor diode laser as the excitation light source for illuminating the i-CHROMA test cartridge (loaded with the test sample which has been duly processed as per the standard test procedure prescribed by Boditech Med. Inc.) thereby triggering fluorescence from the fluorochrome-labeled complexes of analyte accumulated on the test line of the test cartridge membrane.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluoresced light. Intensity of the fluorescence is scanned and converted into an electric signal which is proportional to the intensity of fluorescence produced on the test cartridge membrane.

The on-board microprocessor computes concentration of the analyte in the test sample based on a pre-programmed calibration. The computed and converted result is displayed on the display screen of the i-CHROMA Reader.

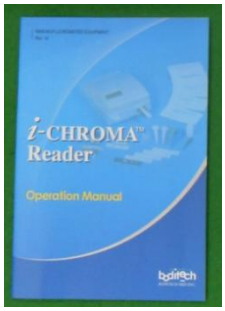
4. Commercial Package Contents

i-CHROMA Reader consists of several items included in the system. For proper operation of the system, the user must know the technical name and use of each item.

The user must ensure that following items are part of the commercial package. If any item is missing, please contact our sales distributor or Boditech Med Inc.'s Technical Services at +82 33 243 1400 in Republic of Korea

1. i-CHROMA Reader
2. Plastic Cover for i-CHROMA Reader
3. Power Cable and Connection Cable
4. Box for Power Cable and Connection Cable
5. i-CHROMA Reader Operation Manual
6. Envelope containing i-CHROMA System Check Cartridge and System Check ID Chip

1	2	3	4

5 	6		

5. Technical Specifications

Physical Description

- Dimensions 250 mm (L) x 185 mm (W) x 80 mm (H)
- Weight 1.2 Kg
- Power supply 100-240 V AC, 50/60 Hz, 3-5 A
- Data output On-board Display Screen and Printers

Permissible Environmental Conditions

- Temperature 15 ℃ ~37 ℃
- Humidity Maximum Relative Humidity 75 %
- Setting Dry, clean, flat and horizontal surface in an indoor setting away from direct sunlight, mechanical vibration and magnetic field

Optical Description

- Light source Laser Diode, 2.5 mW, 637 nm
- Detector Silicon Photo Diode

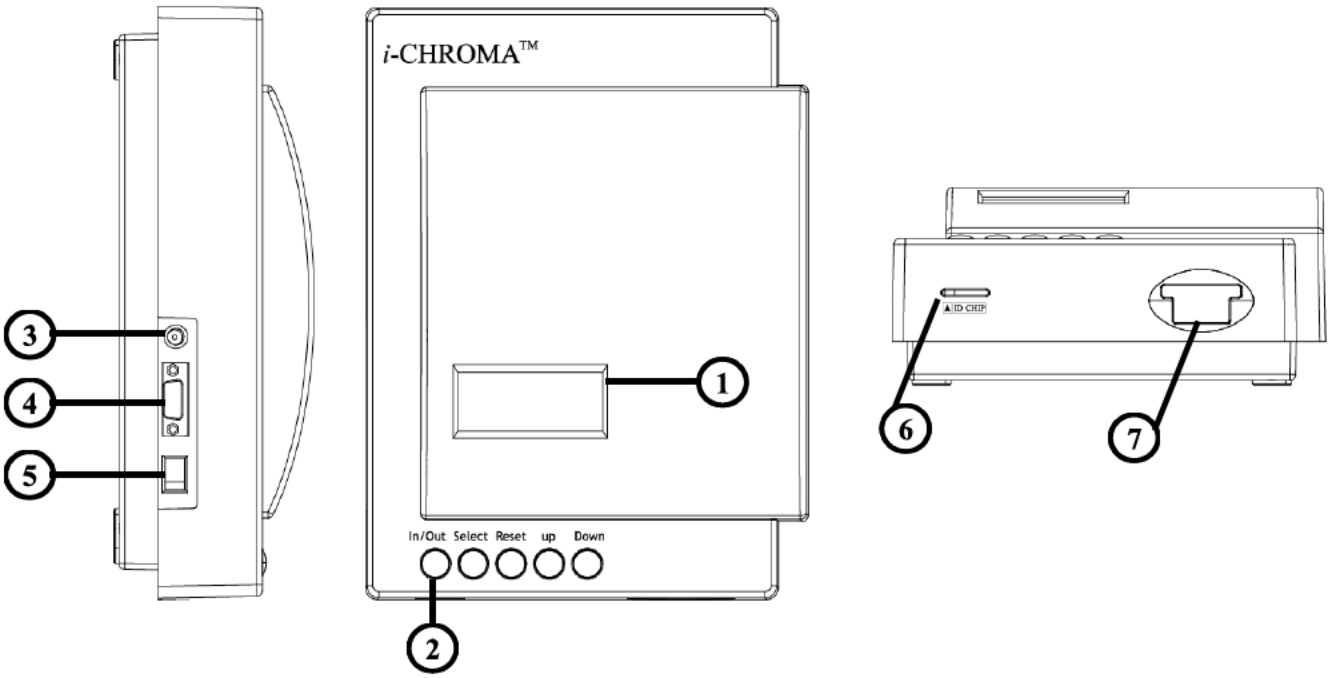
Other

- Driver Motor 12 V
- Interface RS-232 Serial Port (For Printer)
- Printer Thermal (Optional)
- Display LCD (16 x 4 Characters)
- Key Pad 5 Function Keys

i-CHROMA Reader meets the EMC guideline as per EN61326-2-6:2006.

6. Functional and Operational Elements

①	LCD Window	Displays test result, date, procedural and error message alerts etc.
②	Function Keys	Used to select Menu, Reset , Up and Down functions and In/Out movement of the test cartridge holder
③	Power Jack	Connects the power cord to the i-CHROMA Reader
④	Serial Port	Connects the printer or RS232 Cable to the i-CHROMA Reader
⑤	Power Switch	Turns the power On/Off
⑥	ID Chip Port	For inserting the ID Chip
⑦	Test Cartridge Port	Accommodates the cartridge holder meant for inserting the sample-loaded i-CHROMA Test Cartridge



7. Initial Installation Procedure

⚠	Before using the **i-CHROMA Reader**, make sure you have read the warning and cautions described previously in the 'Safety Information' section of this manual.
	Ensure that the voltage setting matches the power supply voltage.

Power requirements

i-CHROMA Reader will work on household power line i.e. 110-120 V or 220-240 V AC with 50 ~ 60 Hz. If you are uncertain of your power line, consult your utility manager.

Set up

i-CHROMA Reader should be placed on a dry, clean, flat, and horizontal surface in an indoor setting away from direct sunlight, mechanical vibration and any source of electromagnetic radiation (power transformers for example).

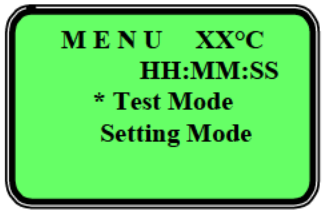
To set-up i-CHROMA Reader for the first time, remove the contents from the package. Inspect the contents for any physical damage and/or missing component(s).

Installation

1. Connect the power cord to the *i*-CHROMA Reader. (**Figure 1**)
2. Plug-in the power cord into an external power outlet.
3. Turn 'ON' the power switch provided on the left side of *i*-CHROMA Reader. (**Figure 2**)
4. *i*-CHROMA Reader will execute a series of self-checking routine; upon successful completion of which the screen will initially display the following:
   (Actual display may differ in textual content and manner depending on the version of the software programed which is subject to up-gradation).

Figure 1: Connect the Power Cord

Figure 2: Turn Power Switch 'On'



(XX°C stands for the ambient temperature and HH:MM:SS stands for time being displayed in Hour : Minute : Second)

5. i-CHROMA Reader is now ready for use.

8. Operation

Operation of i-CHROMA Reader is based on five primary functions; each of which is controlled by one or more keys in the key pad provided on the front panel of the i-CHROMA Reader.

The software programmed in the i-CHROMA Reader has been designed in a concise and user-friendly manner for convenience of the user.

Each of these five primary functions of i-CHROMA Reader is described in the following section.

Function Keys

The term 'cursor' used in the successive description stands for the '*' mark displayed on the screen of i-CHROMA Reader.

Key	Description of the function
In/Out	This key/function moves the 'Cartridge Holder' in and out of the main body of i-CHROMA Reader. This key is also used to end the test run. At the end of the test run, the cartridge holder stays protruded outside the main body of the i-CHROMA Reader. Pressing this key retracts the cartridge holder back into the main body of the i-CHROMA Reader.
Select	This key/function selects and executes the command denoted by the position of the cursor.
Reset	This key/function reverts the system to the immediate previous mode or the 'MENU' mode
Up	This function moves the cursor upwards the line of commands being displayed on the screen at the given time.
Down	This function moves the cursor downwards the line of commands being displayed on the screen at the given time.

9. Procedure for System Check

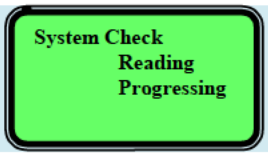
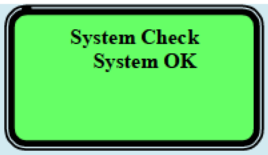
⚠	The 'System Check' is performed to ascertain whether the i-CHROMA Reader is functioning properly.

Following steps describe the recommended system check procedure for i-CHROMA Reader using the 'System Check Device' which consists of a 'System Check Cartridge' and a 'System Check ID Chip'.

i-CHROMA Reader 'System Check Cartridge' and 'System Check ID Chip'

Applicable Steps and On-Screen Displays

1	When you turn the power switch 'ON', the i-CHROMA Reader will automatically perform a self-check routine (displayed as 'Self-Test Mode') up on completion of which; the system displays the default 'MENU'. (**Ver : VX:XX** stands for the version number of the software programmed in the i-CHROMA Reader at the given time).	**Please Wait** **Self Test Mode** **Ver : VX.XX**
2	In the default 'MENU', the cursor (*) normally denotes 'Test Mode'. Press 'Select' key to proceed. The cursor (*) can be moved with 'Up' or 'Down' key so that it denotes the 'Test Mode' before pressing the 'Select' key to proceed.	**M E N U XX°C** **HH:MM:SS** *** Test Mode** **Setting Mode**
3	The message 'Insert ID Chip' is displayed on the screen.	**Insert** **ID Chip**
4	Insert the 'System Check ID Chip' in the 'ID Chip Port'.	
5	*i*-CHROMA Reader will automatically eject the cartridge holder. The message 'Insert Control Cartridge' will be displayed on the screen.	**Insert** **Control Cartridge** **Select to Start**

6	Insert the 'System Check Cartridge' into the 'Cartridge Holder' Press the 'Select' key.	
7	The cartridge holder along with the 'System Check Cartridge' will move into the *i*-CHROMA Reader i-CHROMA Reader will scan the 'System Check Cartridge'.	
8	The 'System Check' test result will be displayed on the screen. You can print it also. The cartridge holder along with the 'System Check Cartridge' will be automatically ejected. Press the 'Reset' key twice. Screen will return to the 'MENU' mode. Remove the 'System Check ID Chip' from the 'ID Chip Port'. Now you can proceed to perform the tests on controls or samples.	

⚠	If you receive 'System Check Error S1' or 'System Check Error S2', contact Boditech Med Inc.'s Technical Services.

10. Test Cartridge Handling

The processed test sample should be loaded into the ‘Sample Well’ of the ‘i-CHROMA Test Cartridge’.

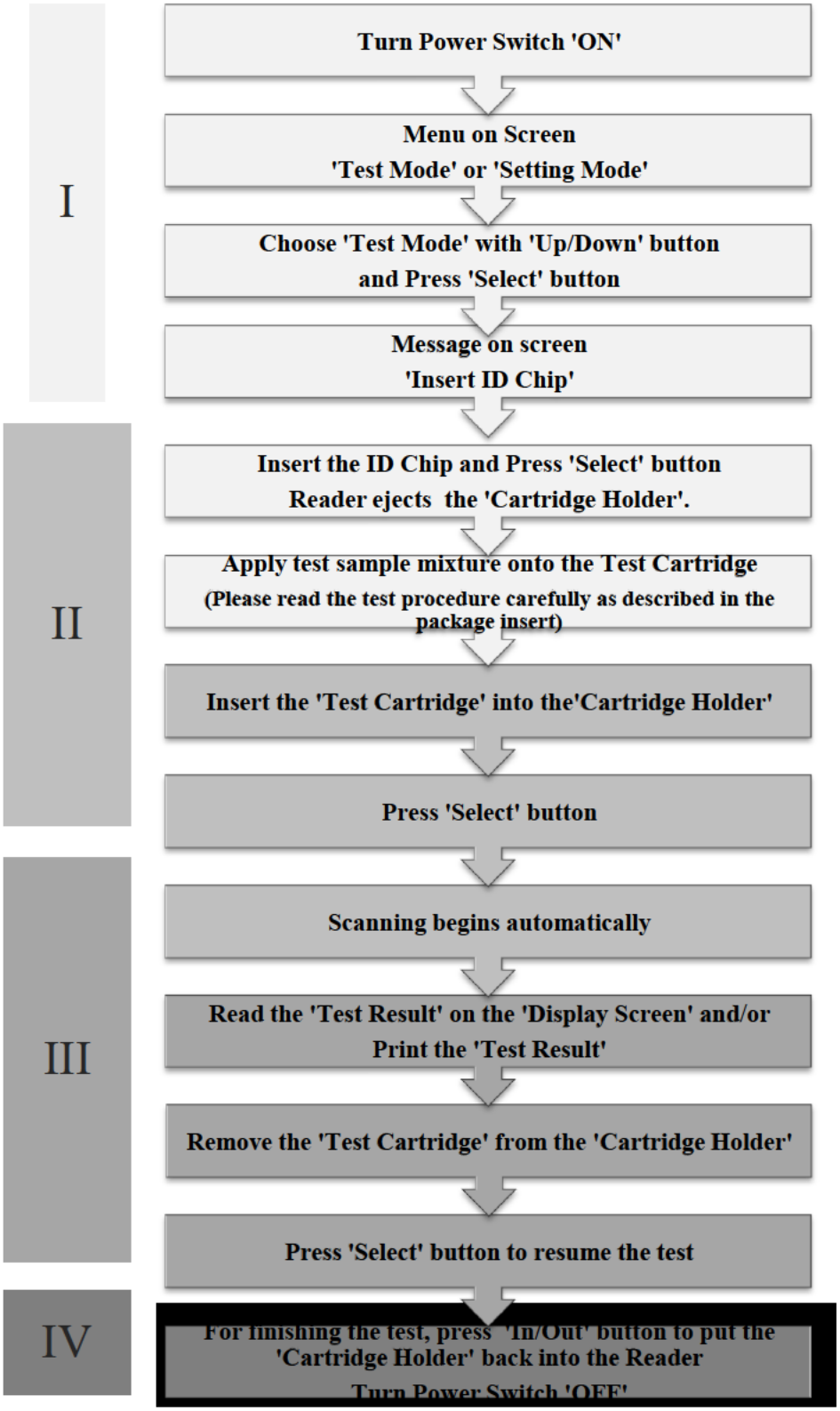
The sample-loaded test cartridge should be inserted into the cartridge holder in the direction pointed by the ‘Arrow’ specially marked on the test cartridge so that the sample well is oriented towards the i-CHROMA Reader.

For inserting the sample-loaded test cartridge, push it gently using your thumb or the index finger, all the way into the cartridge holder until it comes to a stop. Use of excessive force for this purpose may result in mechanical failure of the system.

The used test cartridge should be treated as being potentially infectious and be disposed of in accordance with local, state or federal regulations regarding the disposal of bio-hazardous materials.

	For reducing the chances of bio-hazards, high temperature autoclaving of the used i-CHROMA test cartridges followed by their incineration is recommended.

11. Flow Chart for Test Mode



12. Procedure for Test Mode

⚠	Actual display may differ in textual content and manner depending on the version of the software programed which is subject to up gradation. If the scanning process is interrupted abruptly or an error message is displayed on the screen, you will hear an alarm sound. (Refer to chapter 14 'Troubleshooting'.)

Following steps describe the operational part of i-CHROMA Reader for performing a test using the specific 'i-CHROMA Test Cartridge'.
Before performing any i-CHROMA Test, please read the respective package insert carefully for other details of the test procedure.

Applicable Steps and On-Screen Displays

1	When you turn the power switch 'ON', the i-CHROMA Reader will automatically perform a self-check routine (displayed as 'Self-Test Mode') up on completion of which; the system displays the default 'MENU'.	**Please Wait** **Self Test Mode** **Ver : X.XX**
2	In the default 'MENU', the cursor (*) normally denotes 'Test Mode'. Press 'Select' key to proceed. The cursor (*) can be moved with 'Up' or 'Down' key so that it denotes the 'Test Mode' before pressing the 'Select' key to proceed.	**M E N U XX°C** **HH:MM:SS** *** Test Mode** **Setting Mode**
3	The message 'Insert ID Chip' is displayed on the screen.	**Insert** **ID Chip**
4	Insert the appropriate and matching 'ID Chip' in the 'ID Chip Port'.	
5	*i*-CHROMA Reader will automatically eject the cartridge holder. The message 'Insert XXXXXX Cartridge' will be displayed on the screen. Prepare the 'Test Cartridge' as per the details described in the procedure of the test being performed. (XXXXXX represents name of the 'i-CHROMA Test' being performed. Please refer the package insert of the respective 'i-CHROMA Test'.)	**Insert XXXXX** **Cartridge** **Select to Start**

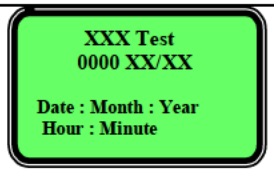
6	Insert the test cartridge (loaded with processed test sample or control) into the cartridge holder. Press 'Select' key.	
7	The cartridge holder along with the test cartridge will move into the i-CHROMA Reader. i-CHROMA Reader will scan the inserted test cartridge.	**XXXXX Test** **Reading** **Progressing**
8	The test result will be displayed on the screen. You can also print the test result (optional). The cartridge holder along with the test cartridge will be automatically ejected. Remove the test cartridge from the cartridge holder.	**XXXXX Test** **Test Result**
9	If you wish to perform the same type of test again, repeat the procedure mentioned in step no. 5 and 6 for testing another sample using a new test cartridge. If you do not wish to perform another test immediately, Press 'Reset' key twice. System will return to the 'MENU' mode. Remove the 'ID Chip. You can perform another test after some time by repeating the procedure mentioned in step no. 2 - 8. If you do not wish to perform any more test further, press the 'In/Out' key. The cartridge holder will move back inside the i-CHROMA Reader. Remove the 'ID Chip. Turn the power switch 'OFF' Disconnect the power cable. Keep the i-CHROMA Reader covered till further use.	**M E N U XX°C** **HH:MM:SS** *** Test Mode** **Setting Mode**

13. Procedure for Setting the Mode

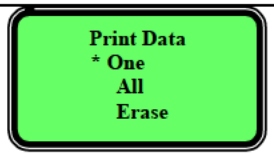
1	When you turn the power switch 'ON', i-CHROMA Reader will automatically perform the pre-programmed system self-check routine (displayed as 'Self-Test Mode') up on completion of which; the system displays the default 'MENU'.	Please Wait Self Test Mode Ver : X.XX
2	In the default 'MENU', the cursor (*) normally denotes '**Test Mode**'.	M E N U XX°C HH:MM:SS * Test Mode Setting Mode
3	Move the cursor with 'Up' or 'Down' key so that it denotes the 'Setting Mode'. Press 'Select' key to proceed.	M E N U XX°C HH:MM:SS Test Mode * Setting Mode
4	Move the cursor again with 'Up' or 'Down' key so that it denotes 'Time Set'. Press 'Select' key to proceed.	* Time Set Recall Result Display Mode
5	'Time Set' mode is for setting the date/time when you install the i-CHROMA Reader for the first time or reuse the i-CHROMA Reader after not using it for more than a month. Press 'Select' key for starting with setting date and/or time.	MENU RESET SET SELECT Date. Month. Year Hour : Minute Insert ID Chip
6	Keep on pressing the 'Select' key to move forward from Date → Month → Year → Hour → Minute while setting date and/or time. Press 'Reset' key to move backward. Enter the desired value for date, month, year, hour and minute by repeatedly pressing 'UP' or 'Down' Keys. When you finish setting the date and time, you can go back to 'Menu' mode step by step by pressing the 'Reset' key.	PRE RESET NEXT SELECT Date. Month. Year Hour : Minute Insert ID Chip

Procedure for Recalling Previous Results

Enter the system into the 'Setting Mode' and then select the 'Recall Result' function in the similar manner as done for arriving at the 'Time Set' function.
Recall Result' mode is used to recall or retrieve stored/previous test results.
You can recall and print up to 1000 stored test results.
You can search the test result(s) date-wise/time-wise by pressing 'Up' or 'Down' keys.

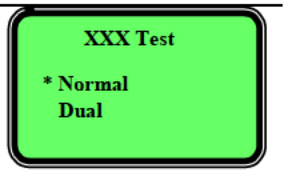


For printing the test result(s), press 'Select' key.
Select 'One' mode (for printing a single test result) or 'All' mode (for printing the entire stored data) with 'Up' or 'Down' key and then press 'Select' key to proceed.
When you finish noting/printing the test result(s), you can go back to 'Menu' mode step by step by pressing the 'Reset' key.



Procedure for setting 'Display' Mode

Enter the system into the 'Setting Mode' and then select the 'Display' function in the similar manner as done for arriving at the 'Time Set' function.
'Display' mode is used to set the manner in which i-CHROMA Reader would display the test results.

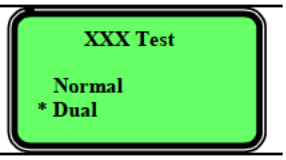


Example:
The default display mode is 'Normal' in which i-CHROMA Reader displays the 'i-CHROMA iFOB' test results in a qualitative manner such as 'iFOB Test Very Low', 'iFOB Test Negative', 'iFOB Test Positive' or 'iFOB Test Very High'.
However, the user may set the i-CHROMA Reader in 'Dual' display mode only for observing the quality control test results with 'i-CHROMA iFOB Controls'.

In dual display mode, i-CHROMA Reader would display 'i-CHROMA iFOB' test results in qualitative/quantitative manner such as:

- iFOB Test Very Low; < 25.0 ng/mL
- iFOB Test Negative; XX.X ng/mL (Range 25.0 – 99.99)
- iFOB Test Positive; XX.X ng/mL (Range 100.0 – 1000.0)
- iFOB Test Very High; > 1000.0 ng/mL

If you wish to observe the 'i-CHROMA iFOB Control' test results in qualitative/quantitative manner as above, select 'Dual' by moving the cursor with 'Up'/'Down' keys.
You can revert to 'Menu' mode by pressing the 'Reset' key.



'Dual' display mode should be used only for observing the test results of 'i-CHROMA iFOB Controls'.

Before testing human fecal samples, i-CHROMA Reader must be set back into the 'Normal' mode.

14. Troubleshooting

Though the i-CHROMA Reader in conjunction with the i-CHROMA Tests has been designed to be a perfectly working system, it may encounter some operational problems occasionally. The symptoms, probable causes and recommended remedial/corrective measures for these problems have been listed in the table below.

Operational stage	Symptom / Error message	Probable cause(s) of Symptom or Error message alert displayed	Corrective action(s)
Power switch turned 'ON'	No sign of functioning.	Power failure	Check whether the external power outlet is alive.
		Main power switch is 'Off'.	Turn the main power switch 'On'.
		Poor connection between the power cable and the power adapter	Remove the power cable from the power adaptor and reconnect firmly.
		Faulty power adapter	Contact Technical Services.
	'Screen Display' does not function properly.	Electrostatic discharge circuit of LCD device is faulty.	Contact Technical Services.
		Malfunctioning of the LCD device	
	'Self-test Mode' followed by 'OK' followed by 'MENU'	➢ *i*-CHROMA Reader has automatically performed the preprogrammed 'System Self-Check' ➢ Key electronic components representing major functions of *i*-CHROMA Reader are working in order.	Select 'Test Mode' and perform the 'System Check' using '*i*-CHROMA System Check ID Chip & Cartridge'.
	'Self-test Mode' followed by 'Error 21 Turn Off the Power'	Malfunctioning of photo interrupter and/or motor	Contact Technical Services.
	'Self-test Mode' followed by 'Error 22 Turn Off the Power'	Malfunctioning of barcode signal sensor	Contact Technical Services.
	'Self-test Mode' followed by 'Error 23 Turn Off the Power'	Malfunctioning of LEDs and/or the detector (for hemoglobin measurement)	Contact Technical Services.
	'Self-test Mode' followed by 'Error 24 Turn Off the Power'	Malfunctioning of illuminating light source (laser)	Contact Technical Services.

Test Mode	Insert ID Chip	Proper 'ID Chip' should be inserted for performing specific test	Refer 'Quick Reference Instructions'& 'Package Insert' of the test as well as 'Operation Manual' of *i*-CHROMA Reader.
		Inserted ID Chip could not be sensed by the *i*-CHROMA Reader due to: ➢ Malfunctioning of the 'ID Chip Socket' ➢ Malfunctioning of the inserted ID Chip due to physical damage or faulty circuit	Contact Technical Services.
	Invalid Item	Inserted ID Chip was sensed but the calibration data encoded in the inserted ID Chip was found unacceptable	Contact Technical Services.
	Cartridge holder not ejected at all or not ejected as and when prompted	Malfunctioning of software	Turn the power 'Off' and turn it 'On' again.
		Mechanical failure	Contact Technical Services.
	Cartridge holder not ejected smoothly or buzzing noise heard during ejection	Temporary mechanical misalignment of test cartridge holder	Press 'Reset' button.
	Caution! Barcode Error	Barcode printed on face of the inserted test cartridge has been partially obscured due to presences of blemishes or misprinting.	Repeat the test by re-inserting the test cartridge properly in the cartridge holder.
	'Caution! ID Chip Lot Number Mismatch'	Lot number of the ID Chip is not exactly same as the lot number of inserted test cartridge.	Repeat the test using ID Chip and test cartridge having exactly same lot number.
	'Caution! ID Chip Cartridge Mismatch'	ID Chip does not match with the inserted test cartridge.	Repeat the test using exactly matching ID Chip and Test Cartridge.
	Caution! Error	Test cartridge has been inserted but: ➢ Without loading the test sample **or** ➢ After loading too little quantity (just 1 drop) of the processed sample.	Repeat the test after correcting the error
	Error 26~29	Malfunctioning of the inserted test cartridge such that the signal generated at its test line or control line could not be detected/processed by the Reader.	Repeat the test with a new test cartridge.
'System Check'	System Check Error S1	Malfunctioning of main photo sensor and/or the illuminating light source (laser)	Contact Technical Services.

System Check Error S2	Malfunctioning of LEDs and/or the LED photo sensor	Contact Technical Services.

15. Care, Handling and Storage

Do not disassemble the i-CHROMA Reader. If you have any questions, please contact our local distributor or authorized representative.

Please use the i-CHROMA Reader gently. Avoid throwing, shaking or dropping it, which may damage its internal components.

Keep the i-CHROMA Reader free of dust. Occasionally clean or wipe the exterior of the i-CHROMA Reader with a soft cloth slightly dampened with water.

Do not use industrial solvents for cleaning the i-CHROMA Reader.

Do not wash the i-CHROMA Reader or pour any liquid over it.

Handle the i-CHROMA Reader with care and avoid exposing it to direct sunlight and/or extreme temperatures.

Do not expose the i-CHROMA Reader to an environment having high humidity such as bathroom, kitchen etc.

Store and transport the i-CHROMA Reader in dry conditions having temperatures 15~35℃ (59~95°F).

It is recommended to use the carrying case whenever required.

Expose the test system to ambient temperature for at least 30 minutes until just prior to performing the test actually.

16. Maintenance, Servicing and Disposal

No maintenance other than proper replacement and periodic cleaning is required for the i-CHROMA Reader normally. Occasional cleansing of the exterior with a soft and dry cloth is sufficient. However, if any service or maintenance were to be required, i-CHROMA Reader should be sent to Boditech Med Inc.

Power Supply

⚠	Ensure that the voltage setting of i-CHROMA Reader matches the power supply voltage.

Use only the AC/DC power adapter provided with the i-CHROMA Reader. In case the power adapter needs replacement, you should contact Boditech Med Inc. or its authorized representative. Boditech Med Inc. provides CE certified Class 2 power adapters, rated at +12V 3-5A.

Return Procedure

Should your i-CHROMA Reader malfunction, first call Boditech Med Inc.'s Technical services on +82 33 243 1400 for consultation. If it is decided that the unit be returned to Boditech Med Inc., a return authorization number will be issued. Boditech Med Inc. will then send a replacement for the i-CHROMA Reader. The user is expected to utilize the packaging supplies accompanying the replacement to ship the malfunctioning unit. Verify the return authorization number on the package and send the malfunctioning unit to Boditech Med Inc. upon receiving the replacement for i-CHROMA Reader.

Transportation and Storage

The original shipping container/box should be used to ship or transport i-CHROMA Reader. The same container/box is also recommended for storing i-CHROMA Reader over an extended period of non-use.

⚠	When transporting or storing i-CHROMA Reader, keep it dry in an upright position and protect it from mechanical shocks.

Disposal

If the i-CHROMA Reader is to be disposed of for any reason, the user is advised to observe standing applicable ordinances regarding disposal of electrical equipment.

	Important! At the end of its useful life, the i-CHROMA Reader could be sent back to Boditech Med Inc. for recycling or proper disposal. Alternatively it should be disposed of in accordance with local regulations.

17. Statement of Conformity

Boditech Med Inc. declares that i-CHROMA Reader meets the CE Mark Requirements according to Annex III, IV, VII of the in-vitro diagnostic medical devices Directive 98/79/EC following standards:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
ISO 9002:1994 Quality systems – Model for quality assurance in production, installation and servicing
EN 980:2008 Symbols for use in the labeling of medical devices
ISO 18113-1:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements
ISO 18113-5:2009 In vitro diagnostic medical devices- Part 5 – In vitro diagnostic instruments for self-testing
EN 13532:2002 General requirements for in vitro diagnostic medical devices for self-testing
EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2009 Medical devices - Application of risk management to medical devices
IEC 61010-1:2001 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC 61010-2-101:2001 Safety requirements for electrical equipment for measurement, control and laboratory use: Particular requirements for in vitro diagnostic (IVD) medical equipment.
EN 61326-2-6:2006 Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
IEC 62304:2006 Medical device software- Software life cycle processes

18. Warranty

i-CHROMA Reader has passed strict quality assurance and testing procedures. Boditech Med Inc.'s expressed and implied warranties are conditional upon full observance of Boditech Med Inc.'s published directions with respect to the use of Boditech Med Inc.'s products. Under no circumstances whatsoever shall Boditech Med Inc. be held liable for any indirect or consequential damages.

To avail the warranty service, the consumer must return the defective i-CHROMA Reader or its component along with proof of purchase to the nearest Boditech Med Inc's Technical Services.

Warranty Information

1 During the warranty period (12 months from the date of purchase), defective or spontaneously malfunctioning i-CHROMA Reader or its components will be repaired free of cost or may be compensated for in accordance with consumer protection rules and regulations.

2 The consumer may be charged for repair of i-CHROMA Reader even during the warranty period in following cases:

- 2.1 Improper use or misuse
- 2.2 Consumer's intentional mishandling, abuse or neglect of the product(s)
- 2.3 Unauthorized repair or replacement of any component
- 2.4 Lots product warranty or changes in contents
- 2.5 Damages or defects due to fire, pollution, earthquake or other natural disasters.

For after-sales inquiry, please contact:

Boditech Med Incorporated
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPIUBLIC OF KOREA.

Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr
Website: www.boditech.co.kr

Warranty Card

Thank you for purchasing i-CHROMA Reader.
Please fill the required information and send one copy of this warranty card within 30 days of purchasing the i-CHROMA Reader.

Product Name	
Serial No.	
Date of Manufacture	
Warranty Period	12 months from the date of purchase
Date of Purchase	Year _____ Month ____ Day
Manufacturer	Boditech Med Inc.

19. Contact Information

For technical assistance, please contact:
Boditech Med Inc.'s Technical Services
Tel: + 82 33 243 1400
E-mail: support@boditech.co.kr

Boditech Med Incorporated
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.

Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr

Website: www.boditech.co.kr

Classification	Sensitivity to Hemoglobin Variants		
Testing Material	Low; Hemoglobin S in Liquid Buffer, 50ng/mL	Operator	Hye Sung Kim, QC Manager
	Medium; Hemoglobin S in Liquid Buffer, 125ng/mL	Device Lot No.	FOEGA00
	High; Hemoglobin S in Liquid Buffer, 250ng/mL	Reader Serial No.	PFR09E080571
Testing date	2012. 05. 08	Testing Site	R&D Center, Boditech Med Inc.

Hemoglobin S 50 ng/mL	1	2	3	4	5	6	7	8	9	10
	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
	49.25	49 28	53.24	53.05	48.27	51.62	53.69	52.82	51.88	50.19
	11	12	13	14	15	16	17	18	19	20
	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
	49.28	48.66	51.07	52.34	50.16	52.61	53.84	53.62	50.19	46.57
Hemoglobin S 125 ng/mL	1	2	3	4	5	6	7	8	9	10
	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	125.63	124.07	122.66	123.32	125.28	124.61	120.95	124.21	128.66	124.75
	11	12	13	14	15	16	17	18	19	20
	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	124.61	126.39	120.54	121.11	123.66	124.44	120.51	120.84	120.64	120 19
Hemoglobin S 250 ng/mL	1	2	3	4	5	6	7	8	9	10
	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
	253.69	250.48	248.19	247.55	246.33	245.18	243.51	244.77	253.08	256.65
	11	12	13	14	15	16	17	18	19	20
	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
	249.19	246.65	258.34	261.08	254.88	260.19	247.77	250.31	250.64	249.53

Test Result				Test Sample Number			PPA	NPA	For PPA			For NPA		
A(+/+)	B(+/-)	C(-/+)	D(-/-)	Total	Positive	Negative			Q1	Q2	Q3	Q1	Q2	Q3
40	0	0	20	60	40	20	100.00	100.00	83.8	3.8	87.7	43.8	3 8	47.7

PPA; Confidence Interval(CI)		NPA; Confidence Interval(CI)	
Lower Bound	Upper Bound	Lower Bound	Upper Bound
91.24	100.00	83.89	100.00

Classification	Stability testing of non-processed human fecal samples in specimen cups					
Testing Material	Fecal Samples		Operator		Hye Sung Kim, QC Manager	
			Device Lot No.		FOYBA08	
			Reader Serial No.		PFR09E080575	
Testing date	2013. 02. 17~2013. 02. 21		Testing Site		R&D Center, Boditech Med	
Human Fecal Sample	Initial Test Result (0hr) (ng/mL)	Storage Temperature	Test Results(ng/mL)			
			After 24hrs	After 48hrs	After 72hrs	After 96hrs
Sample 1	65.35 ng/mL Negative	4 ℃	66.21	60.17	57.27	53.06
			Negative	Negative	Negative	Negative
		25 ℃	67.27	65.81	59.22	55.26
			Negative	Negative	Negative	Negative
		37 ℃	65.23	63.12	57.28	41.52
			Negative	Negative	Negative	Negative
		45 ℃	66.74	58.21	51.58	42.18
			Negative	Negative	Negative	Negative
Sample 2	135.83 ng/mL Positive	4 ℃	133.28	126.42	111.53	104.87
			Positive	Positive	Positive	Positive
		25 ℃	136.27	134.25	116.22	104.87
			Positive	Positive	Positive	Positive
		37 ℃	135.23	134.71	96.43	85,27
			Positive	Positive	Negative	Negative
		45 ℃	104.26	85.41	74.27	32.61
			Positive	Negative	Negative	Negative
Sample 3	270.10 ng/mL Positive	4 ℃	268.91	263.22	255.17	236.01
			Positive	Positive	Positive	Positive
		25 ℃	272.34	275.14	236.87	223.42
			Positive	Positive	Positive	Positive
		37 ℃	240.41	227.24	199.41	156.28
			Positive	Positive	Positive	Positive
		45 ℃	207.32	177.73	103.27	89.52
			Positive	Positive	Positive	Negative

Classification	Stability testing of processed human fecal samples in sample collection tube					
Testing Material	Fecal Samples		Operator		Hye Sung Kim, QC Manager	
			Device Lot No.		FOYBA08	
			Reader Serial No.		PFR09E080575	
Testing date	2013. 02. 17~2013. 02. 21		Testing Site		R&D Center, Boditech Med	
Human Fecal sample	Initial Test Result (0hr) (ng/mL)	Storage Temperature	Test Results(ng/mL)			
			After 24hrs	After 48hrs	After 72hrs	After 96hrs
Sample 1	75.26 Negative	4 ℃	75.92	76.27	74.32	75.01
			Negative	Negative	Negative	Negative
		25 ℃	78.23	83.07	66.33	65.32
			Negative	Negative	Negative	Negative
		37 ℃	78.17	71.22	64.87	60.48
			Negative	Negative	Negative	Negative
		45 ℃	76.22	62.7	49.11	29.53
			Negative	Negative	Negative	Negative
Sample 2	185.23 Positive	4 ℃	181.85	179.28	192.31	187.15
			Positive	Positive	Positive	Positive
		25 ℃	183.25	188.15	153.27	132.11
			Positive	Positive	Positive	Positive
		37 ℃	181.43	139.14	120.52	103.69
			Positive	Positive	Positive	Positive
		45 ℃	176.43	105.23	86.22	76.24
			Positive	Positive	Negative	Negative
Sample 3	43.23 Negative	4 ℃	45.21	43.79	46.11	42.94
			Negative	Negative	Negative	Negative
		25 ℃	40.12	41.25	38.15	31.07
			Negative	Negative	Negative	Negative
		37 ℃	46.15	42.16	34.87	30.14
			Negative	Negative	Negative	Negative
		45 ℃	42.77	40.62	36.21	24.18
			Negative	Negative	Negative	Negative
Sample 4	241.31 Positive	4 ℃	238.47	228.56	251.29	249.51
			Positive	Positive	Positive	Positive
		25 ℃	228.14	234.58	200.07	185.62
			Positive	Positive	Positive	Positive
		37 ℃	238.54	201.51	186.75	165.14
			Positive	Positive	Positive	Positive
		45 ℃	238.65	184.28	122.26	83.25
			Positive	Positive	Positive	Negative
Sample 5	178.47 Positive	4 ℃	170.25	173.69	182.35	182.34
			Positive	Positive	Positive	Positive
		25 ℃	172.15	174.25	181.57	150.21
			Positive	Positive	Positive	Positive
		37 ℃	170.59	135.28	127.15	104.17
			Positive	Positive	Positive	Positive
		45 ℃	170.26	146.21	86.14	74.27
			Positive	Positive	Negative	Negative

Classification			Stability of Sample Collection Tube_2℃											
Testing Material			Low; Hemoglobin in Liquid Buffer, 50ng/mL					Operator		Hye Sung Kim, QC Manager				
			Medium; Hemoglobin in Liquid Buffer, 250ng/mL					Device Lot No.		FOGJA00, FOGJA01, FOGJA02				
			High; Hemoglobin in Liquid Buffer, 750ng/mL					Reader Serial No.		PFR09E080571				
Testing date			2010. 11. 22~2012. 10. 25					Testing Site		R&D Center, Boditech Med Inc.				
Lot	Conc. [ng/ml]	0M	2M	4M	6M	8M	10M	12M	14M	16M	18M	20M	22M	24M
Lot 1	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		48.5	50.65	54.08	47.93	48.72	46.56	46.17	49.31	53.04	50.1	52.02	53.1	44.2
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		226.33	267.17	253.14	244.61	246.08	247.21	230.27	274.96	246.5	241.18	253.82	254.37	212.3
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		819.1	818.58	686.32	812.25	696.63	691.66	741.31	806.98	784.64	691.31	758.25	795.83	621.85
Lot 2	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		48.46	51.61	52.74	49.31	47.7	53.82	48.49	47.12	48.54	54.11	49	51.14	43.81
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		264.85	259.48	235.78	254.61	245.63	274.32	269.32	247.85	257.25	264.96	257.31	249.68	203.8
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		817.38	715.66	699.15	804.14	721.52	713.57	686.63	682.06	707.03	679.83	724.73	709.09	617.89
Lot 3	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		49.55	51.03	45.63	47.21	47.38	45.79	46.38	47.95	46.25	54.35	45.68	49.73	42.22
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		245.99	264.06	246.64	233.83	269.48	269.4	246.51	225.73	234.01	227.01	259.45	273.85	220.28
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		763.4	793.44	702.1	803.35	722.94	719.56	767.87	824.61	745.49	715.45	752.47	714.16	635.88
Average	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		48.84	51.1	50.82	48.15	47.93	48.72	47.01	48.13	49.28	52.85	48.9	51.32	43.41
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		245.72	263.57	245.19	244.35	253.73	263.64	248.7	249.51	245.92	244.38	256.86	259.3	212.13
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		799.96	775.89	695.86	806.58	713.7	708.26	731.94	771.22	745.72	695.53	745.15	739.69	625.21

Classification			Stability of Sample Collection Tube_8℃											
Testing Material			Low; Hemoglobin in Liquid Buffer, 50ng/mL					Operator		Hye Sung Kim, QC Manager				
			Medium; Hemoglobin in Liquid Buffer, 250ng/mL					Device Lot No.		FOGJA00, FOGJA01, FOGJA02				
			High; Hemoglobin in Liquid Buffer, 750ng/mL					Reader Serial No.		PFR09E080571				
Testing date			2010. 11. 22~2012. 10. 25					Testing Site		R&D Center, Boditech Med Inc.				
Lot	Conc. [ng/ml]	0M	2M	4M	6M	8M	10M	12M	14M	16M	18M	20M	22M	24M
Lot 1	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		49.93	51.41	45.59	52.83	45.91	45.42	48.71	47.03	51.57	51.7	46.77	51.79	45.75
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		238.16	249.63	240.55	228.57	250.92	240.36	225.35	234.4	231.19	265.41	234.75	251.76	228.67
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		694.08	806.2	810.13	712.33	794.32	818.02	783.43	815.48	680.64	798.3	820.65	707.07	747.35
Lot 2	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		50.62	52.79	51.99	46.27	54.45	46.51	51.09	52.07	48.12	49.36	52.57	50.25	48.37
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		237.28	250.5	241.52	239.13	235.32	271.08	255.73	241.04	258.04	250.36	252.5	229.14	239.49
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		823.95	821.43	797.42	714.66	762.84	763.72	774.3	813.34	697.2	698.11	774.09	757.52	772.84
Lot 3	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		48.54	50.34	52.8	53.29	49.68	51.84	50.16	51.29	52.62	48.14	48.34	54.96	50.65
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		273.25	245.77	271.93	245.85	248.02	227.72	233.57	272.58	255.83	259.18	271.52	236.63	241.5
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		793.72	810.95	728.36	715.33	811.3	786.39	740.24	769.11	757.4	765.29	806.64	716.24	725.36
Average	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		49.7	51.51	50.13	50.8	50.01	47.92	49.99	50.13	50.77	49.73	49.23	52.33	48.26
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		249.56	248.63	251.33	237.85	244.75	246.39	238.22	249.34	248.35	258.32	252.92	239.18	236.55
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		770.58	812.86	778.64	714.11	789.49	789.38	765.99	799.31	711.75	753.9	800.46	726.94	748.52

Classification		Stability of Sample Collection Tube_25℃								
Testing Material		Low; Hemoglobin in Liquid Buffer, 50ng/mL				Operator		Hye Sung Kim, QC Manager		
		Medium; Hemoglobin in Liquid Buffer, 250ng/mL				Device Lot No.		FOGJA00, FOGJA01, FOGJA02		
		High; Hemoglobin in Liquid Buffer, 750ng/mL				Reader Serial No.		PFR09E080571		
Testing date		2010. 11. 22~2011. 12. 29				Testing Site		R&D Center, Boditech Med Inc.		
Lot	Conc. [ng/ml]	0M	1M	2M	4M	6M	8M	14M	12M	14M
Lot 1	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		54.37	52.63	51.6	52.89	53.14	52.75	49.3	47.92	43.12
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		246.84	263.57	273.69	244.93	243.82	251.6	263.75	241.57	189.41
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		743.56	732.67	782.42	766.68	701.15	798.26	793.43	754.97	559.64
Lot 2	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		51	53.49	49.27	48.63	51.72	51.21	53.87	47.39	41.05
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		259.9	268.33	243.76	229.62	268.43	254.16	253.64	250.46	158.54
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		762.51	712.83	743.65	723.91	796.73	759.8	743.23	719.32	531.17
Lot 3	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		51.53	53.63	49.86	47.53	49.32	52	51.86	50.38	41.05
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		243.65	256.15	258.95	271.37	255.79	246.42	241.91	233.54	189.54
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		723.44	743.14	769.87	778.96	715.61	749.83	779.54	798.58	553.17
Average	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		52.3	53.25	50.24	49.68	51.39	51.99	51.68	48.56	41.74
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		250.13	262.68	258.8	248.64	256.01	250.73	253.1	241.86	179.16
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		743.17	729.55	765.31	756.52	737.83	769.3	772.07	757.62	547.99

Classification			Stability of Cartridge_4℃											
Testing Material			Low; Hemoglobin in Liquid Buffer, 50ng/mL					Operator		Hye Sung Kim, QC Manager				
			Medium; Hemoglobin in Liquid Buffer, 250ng/mL					Device Lot No.		FOGJA00, FOGJA01, FOGJA02				
			High; Hemoglobin in Liquid Buffer, 750ng/mL					Reader Serial No.		PFR09E080571				
Testing date			2010. 11. 22~2012. 10. 25					Testing Site		R&D Center, Boditech Med Inc.				
Lot	Conc. [ng/ml]	0 mo.	2mo.	4mo.	6mo.	8mo.	10mo.	12mo.	14mo.	16mo.	18mo.	20mo.	22mo.	24mo.
Lot 1	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		46.86	48.98	52.7	48.65	54.93	46.39	47.55	52.35	48.41	50.93	52.72	50.26	53.52
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		266.79	264.72	255.65	272.82	274.65	274.28	233.48	242.6	274.85	227.95	239.5	249.95	232.58
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		796.98	701.42	733.28	737.43	752.02	697.75	735.12	786.44	681.37	696.79	784.24	676.13	720.97
Lot 2	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		47.73	51.68	51.98	52.88	49.27	46.25	52.47	45.65	53.6	49.57	45.48	47.65	48.76
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		236.2	244.29	244.76	226.79	233.67	245.02	237.18	270.12	239.09	245.82	230.54	231.91	261.56
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		772.17	713.21	771.1	780.22	760.55	798.09	733.42	751.2	724.91	728.51	764.34	799.77	819.14
Lot 3	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		48.02	45.65	48.71	49.2	52.39	54.28	47.72	46.32	51.8	51.52	50.59	45.94	52.79
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		248.72	244.3	245.58	245.08	237.14	235.35	259.82	256.06	246.93	230.07	253.72	226.68	241.05
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		717.29	716.12	723.33	749.37	811.8	816.52	764.56	680.89	717.43	713.54	699.31	703.5	689.66
Average	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		47.54	48.77	51.13	50.24	52.2	48.97	49.25	48.11	51.27	50.67	49.6	47.95	51.69
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		250.57	251.1	248.66	248.23	248.49	251.55	243.49	256.26	253.62	234.61	241.25	236.18	245.06
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		762.15	710.25	742.57	755.67	774.79	770.79	744.37	739.51	707.9	712.95	749.3	726.47	743.26

Classification			Stability of Cartridge_30℃											
Testing Material			Low; Hemoglobin in Liquid Buffer, 50ng/mL					Operator		Hye Sung Kim, QC Manager				
			Medium; Hemoglobin in Liquid Buffer, 250ng/mL					Device Lot No.		FOGJA00, FOGJA01, FOGJA02				
			High; Hemoglobin in Liquid Buffer, 750ng/mL					Reader Serial No.		PFR09E080571				
Testing date			2010. 11. 22~2012. 10. 25					Testing Site		R&D Center, Boditech Med Inc.				
Lot	Conc. [ng/ml]	0 mo.	2mo.	4mo.	6mo.	8mo.	10mo.	12mo.	14mo.	16mo.	18mo.	20mo.	22mo.	24mo.
Lot 1	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		53.07	50.99	49.35	52.46	48.1	46.23	48.29	49.74	45.97	54.33	51.43	50.67	51.31
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		239.51	254.86	247.49	249.98	263.5	235.88	262.89	228.28	250.92	273.94	262.63	233.74	241.85
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		763.28	821.69	690.08	716	801.84	755.11	713.54	801.01	766.06	794.61	824.68	732.84	756.49
Lot 2	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		51.21	47.17	47.85	50.3	48.23	51.48	50.45	49.22	45.99	47.26	45.23	46.64	53.37
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		226.15	242.08	266.69	253.98	256.44	256.29	253.25	240.18	274.38	274.14	236.13	258.66	238.86
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		753.7	720.18	732.65	685.03	692.06	779.69	683.83	691.73	824.87	762.02	698.21	677.12	817.46
Lot 3	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		49.7	53.98	47.27	49.11	49.79	52.36	52.13	52.31	47.9	48.42	45.16	49.19	53.18
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		266.78	269.16	247.37	253.07	229.27	226.15	245.64	259.82	239.72	227.42	227.09	261.94	260.08
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		798.07	800.37	807.17	684.44	768.74	765.51	815.92	760.05	729.7	717.93	698.2	790.04	692.52
Average	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		51.33	50.71	48.16	50.62	48.71	50.02	50.29	50.42	46.62	50	47.27	48.83	52.62
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		244.15	255.37	253.85	252.34	249.74	239.44	253.93	242.76	255.01	258.5	241.95	251.45	246.93
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		771.68	780.75	743.3	695.16	754.21	766.77	737.76	750.93	773.54	758.19	740.36	733.33	755.49

Classification		Stability of Cartridge_37℃							
Testing Material		Low; Hemoglobin in Liquid Buffer, 50ng/mL			Operator		Hye Sung Kim, QC Manager		
		Medium; Hemoglobin in Liquid Buffer, 250ng/mL			Device Lot No.		FOGJA00, FOGJA01, FOGJA02		
		High; Hemoglobin in Liquid Buffer, 750ng/mL			Reader Serial No.		PFR09E080571		
Testing date		2010. 11. 22~2011. 12. 29			Testing Site		R&D Center, Boditech Med Inc.		
Lot	Conc. [ng/ml]	0 mo.	2mo.	4mo.	6mo.	8mo.	10mo.	12mo.	14mo.
Lot 1	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		47.25	47.11	54.4	48.28	48.92	50.16	45.84	54.16
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		242.47	266.34	226.27	274.27	257.45	258.71	243.81	240.41
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		686.61	709.27	788.88	763.6	739.72	816.64	820.89	779.87
Lot 2	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		45.14	49.08	52.69	45.9	48.49	48.68	53.61	45.14
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		229.09	232	274.76	258.96	252.19	255.97	267.86	266.4
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		760.22	760.01	709.62	744.88	734.91	823.78	705.64	719.67
Lot 3	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		54.56	49.1	51.84	51.73	50.69	50.87	48.98	46.66
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		235.46	255.06	232.93	233.31	247.67	260.66	243.4	273.02
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		698.22	792.17	760.63	687.22	724.99	719.17	816.89	682.46
Average	50	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg
		48.98	48.43	52.98	48.64	49.37	49.9	49.48	48.65
	250	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		235.67	251.13	244.65	255.51	252.44	258.45	251.69	259.94
	750	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos
		715.02	753.82	753.04	731.9	733.21	786.53	781.14	727.33

Classification	Stability testing of the External Control_Unopened						
Testing Material	Control Lot 1: FOCXE04		Operator	Hye Sung Kim, QC Manager			
	Control Lot 2: FOCXE05		Device Lot No.	FOYBA08			
	Control Lot 3: FOCXE06		Reader Serial No.	PFR09E080575			
Testing date	2012. 12. 27~2013. 04. 20		Testing Site	R&D Center, Boditech Med Inc.			
Lot No.	Storage Temperature	Concentration	Test Results				
			0 month	After 1	After 2	After 3	After 4
Lot. 1	2 ℃	Negative (50 ng/mL)	50.11	52.23	52.76	51.32	47.38
			Negative	Negative	Negative	Negative	Negative
		Positive (150 ng/mL)	151.79	153.22	149.87	145.92	142.06
			Positive	Positive	Positive	Positive	Positive
	8 ℃	Negative (50 ng/mL)	51.24	50.31	51.27	52.41	49.54
			Negative	Negative	Negative	Negative	Negative
		Positive (150 ng/mL)	153.62	150.63	148.17	147.09	148.66
			Positive	Positive	Positive	Positive	Positive
	25 ℃	Negative (50 ng/mL)	50.79	52.48	49.31	48.22	45.02
			Negative	Negative	Negative	Negative	Negative
		Positive (150 ng/mL)	148.29	152.34	143.22	133.08	128.21
			Positive	Positive	Positive	Positive	Positive
Lot. 2	2 ℃	Negative (50 ng/mL)	52.25	50.76	53.82	48.96	47.34
			Negative	Negative	Negative	Negative	Negative
		Positive (150 ng/mL)	149.31	147.45	145.76	143.39	140.76
			Positive	Positive	Positive	Positive	Positive
	8 ℃	Negative (50 ng/mL)	53.08	50.88	51.24	53.07	51.41
			Negative	Negative	Negative	Negative	Negative
		Positive (150 ng/mL)	148.08	146.07	153.24	151.07	143.07
			Positive	Positive	Positive	Positive	Positive
	25 ℃	Negative (50 ng/mL)	51.76	49.44	50.07	44.52	42.35
			Negative	Negative	Negative	Negative	Negative
		Positive (150 ng/mL)	148.28	154.76	147.29	141.29	130.63
			Positive	Positive	Positive	Positive	Positive
Lot. 3	2 ℃	Negative (50 ng/mL)	51.53	48.28	47.27	46.63	41.77
			Negative	Negative	Negative	Negative	Negative
		Positive (150 ng/mL)	153.06	146.29	144.52	138.91	136.02
			Positive	Positive	Positive	Positive	Positive
	8 ℃	Negative (50 ng/mL)	50.67	51.22	50.49	53.08	48.19
			Negative	Negative	Negative	Negative	Negative
		Positive (150 ng/mL)	153.24	151.43	147.66	142.08	143.81
			Positive	Positive	Positive	Positive	Positive
	25 ℃	Negative (50 ng/mL)	49.65	50.62	47.29	46.28	42.05
			Negative	Negative	Negative	Negative	Negative
		Positive (150 ng/mL)	154.87	150.52	141.27	132.65	128.25
			Positive	Positive	Positive	Positive	Positive

Classification	Stability testing of the External Control_Opened			
Testing Material	Control Lot 1: FOCXE04		Operator	Hye Sung Kim, QC Manager
	Control Lot 2: FOCXE05		Device Lot No.	FOYBA08
	Control Lot 3: FOCXE06		Reader Serial No.	PFR09E080575
Testing date	2012. 12. 27~2013. 02. 23		Testing Site	R&D Center, Boditech Med Inc.

Lot No.	Storage Temperature	Concentration	Test Results		
			After 0 month	After 1 month	After 2 months
Lot. 1	2 ℃	Negative (50 ng/mL)	52.31	47.27	44.28
			Negative	Negative	Negative
		Positive (150 ng/mL)	149.27	144.24	148.42
			Positive	Positive	Positive
	8 ℃	Negative (50 ng/mL)	51.37	50.19	44.61
			Negative	Negative	Negative
		Positive (150 ng/mL)	151.09	148.33	145.04
			Positive	Positive	Positive
	25 ℃	Negative (50 ng/mL)	48.77	46.41	41.08
			Negative	Negative	Negative
		Positive (150 ng/mL)	154.88	133.81	132.76
			Positive	Positive	Positive
Lot. 2	2 ℃	Negative (50 ng/mL)	50.59	46.28	46.81
			Negative	Negative	Negative
		Positive (150 ng/mL)	149.31	147.45	145.76
			Positive	Positive	Positive
	8 ℃	Negative (50 ng/mL)	50.22	48.26	45.17
			Negative	Negative	Negative
		Positive (150 ng/mL)	150.44	147.21	139.52
			Positive	Positive	Positive
	25 ℃	Negative (50 ng/mL)	52.23	47.19	42.15
			Negative	Negative	Negative
		Positive (150 ng/mL)	148.28	154.76	147.29
			Positive	Positive	Positive
Lot. 3	2 ℃	Negative (50 ng/mL)	51.53	48.28	47.27
			Negative	Negative	Negative
		Positive (150 ng/mL)	153.06	146.29	144.52
			Positive	Positive	Positive
	8 ℃	Negative (50 ng/mL)	50.64	51.22	47.28
			Negative	Negative	Negative
		Positive (150 ng/mL)	150.84	142.18	139.08
			Positive	Positive	Positive
	25 ℃	Negative (50 ng/mL)	49.65	50.62	44.29
			Negative	Negative	Negative
		Positive (150 ng/mL)	154.87	134.51	124.07
			Positive	Positive	Positive

Software Validation Report

Report No. : SF.VL.01 (Rev.2)

Prepared by: 2011.3.23

Approved by: 2011.5.1

Boditech Med Inc.

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Appendix I: *i*-CHROMA iFOB System Information

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1. Background

1.1 Lateral Flow Assay

Immunoassays have been widely used in many important areas of medical practice and pharmaceutical industry such as diagnosis of diseases, therapeutic drug monitoring, clinical pharmacokinetic and bioequivalence studies in drug discovery since the mid-1960s. Clinical immunoassays in connection with medical diagnosis are usually performed either in central laboratorie(s) of hospitals or clinics using a variety of instrument-based technologies or on-site/near-patient (also known as point-of-care/POC) using rapid test techniques.

Rapid immunoassays are commonly designed in two configurations. First type is the 'Flow-through System', which involves multiple steps. The test device based on flow-through mechanism generally uses a reagent-containing matrix layered on a porous material. Test sample is applied to and flows through the porous material, and analyte in the sample reacts with the reagent(s) to produce a detectable signal on the porous material. These devices are generally encased in a plastic housing or casing with calibrations to aid in the detection of the particular analyte. The test procedure may take as long as 20 minutes. One sample is tested per test device.

The second type of rapid immunoassays is the 'Lateral Flow System' which is a single step technique. The test device based on lateral flow mechanism also uses a porous membrane for performing analyte detection. However, instead of drawing the sample through the membrane perpendicularly, the sample is permitted to flow laterally from an application zone to a reaction zone on the membrane surface. The capture reagent is present in the reaction zone, and the captured analyte can be detected by a variety of protocols, including direct visualization of visible moieties associated with the captured analyte. Tests results are obtained in 10-30 minutes after loading the test device with the sample. Lateral flow test devices can be designed so as to test for a single or multiple analyte(s).

As the flow-through type immunoassay involves multiple steps and requires greater operational skill, this format is less commonly used as compared to the lateral flow type.
Lateral flow tests; also known as immunochromatographic strip tests have been a popular tool for performing rapid immunoassays since their introduction in the mid-1980s. Lateral flow tests have been developed using combinations of various features. Hence it is customary to accept a broad definition of lateral flow tests to include any immunochromatographic strip test/device based on fluid migration or flow technology using a paper, nitrocellulose or similar support material with or without being enclosed in a housing/casing. Further, it may be used for testing a single or multiple analyte(s) and the test device may be read either manually or by using an instrument or reader. The lateral flow format is thus so versatile that rapid immunoassay test manufacturers have developed these tests for variety of situations requiring rapid testing.

At present, lateral flow tests are widely used for diagnostic purposes in hospitals, clinics,

physician offices, and clinical laboratories. They are meant for the qualitative and quantitative detection of a wide variety of antigens and antibodies in various biological samples including whole blood, plasma, serum, urine, saliva, sweat, tears, biopsied tissue and fluids. They are also used in veterinary medicine. Apart from diagnostic purposes, lateral flow tests offer an important tool in manufacturing, quality control and product safety assurance in pharmaceutical, biologics and food production. These tests also find important applications in water safety evaluation and environmental testing. More recently lateral flow tests are being developed to measure the products of nucleic acid amplification.

Lateral flow immunochromatographic tests have proved to be an ideal tool for variety of applications by virtue of their following features:

- Simple and user-friendly design/format which enables use by non-technical or non-laboratory personnel and thus supporting point-of-care/home testing
- Minimal operator-dependent steps and easy interpretation of test results
- Short processing time (5-30 minutes to get the results) offers rapid testing
- High sensitivity, specificity and accuracy
- Good stability with shelf-lives of 12-24 months mostly without necessitating refrigeration
- Requires very small volumes of test samples
- Amenable to various types of test samples
- Versatility of applications

Favorable technological and commercial aspects of the lateral flow tests include:

- Established technology which can be integrated with on-board electronics, reading instrument system and information systems
- Relative ease of manufacture because of already developed equipment and processes
- Prospects of easy scale-up to high-volume production
- Relatively low cost and short timeline of product development and regulatory approval
- Huge market potential

Combined with the principles of thin layer and paper chromatography, the development of lateral flow immunoassays is the result of convergence of several technological landmarks tracing back to the 1950s with the invention of first antigen-antibody radioimmunoassay (RIA) reaction by Burson and Yallow. The enzyme immunoassays (EIA) introduced in the 1960s offered significant advantages over the radioimmunoassay in respect of replacement of radioisotopes with enzymes, higher specificities, faster reaction times and longer shelf-lives. The lateral flow technology continued to be refined over the years and established firmly in the late 1980s with the filing of several patents on the lateral flow technology platform. Significant amongst them were those filed by Becton Dickinson & Co, Uniliver and Carter Wallace. Since then over 500 patents have been filed on various aspects of this technology.

The trend towards more decentralized healthcare delivery obviously resulted in the decentralization of laboratory diagnostic services as well. Immunoassays account for approximately 30% of all marketed diagnostic tests. Technological innovations in lateral flow tests have facilitated the move to bring diagnostic testing closer to the patient—be it at home, at work place, in the hospital bedside or the pharmacy. The pharmacies and retail shopping malls are rapidly becoming the focal point for Over-the-Counter (OTC) testing and screening related to heart diseases and diabetes. In current scenario, most of the marketed Point-Of-Care Testing (POCT) systems cover infectious diseases, life style-related conditions like cardiac diseases and diabetes, fertility issues like pregnancy detection and drug abuse detection/monitoring.

Furthermore, the noteworthy aspect of almost all of these lateral flow immunoassays tests is the use of single-use test devices. It is not realistic to expect that any medical practice or clinic would have the storage space, inventory control system and inclination to keep some 20 to 30 different test devices on hand. Therefore considerable research has been ongoing for the past 15 years for a multipurpose POCT platform for lateral flow immunoassays.

Remote monitoring and testing of patients-at-risk; both at home and in hospitals or clinics; is fast-emerging as a primary proactive strategy to keep individuals out of hospital emergency and acute care wards. Point-of-Care testing as the new frontier of health care delivery promises to achieve this objective. Patients with diabetes and many other chronic diseases or conditions as well as the elderly and those suffering from HIV/AIDS are being increasingly targeted for such near-patient testing.

Advances in functional genomics, bioinformatics, microelectronics and miniaturization have dramatically changed the diagnostic test technology in recent years. Improvements in the biomedical engineering-based clinical devices with inputs derived from the information and computer technologies have been opening up new markets for rapid diagnostic test products. Global economic instability and rising healthcare costs coupled with increasing demand for rapid test results to reduce the need and duration of hospitalization has further influenced the development of rapid diagnostic test products. Near-patient testing is one of the most rapidly growing segments as the tests that were once carried out in central laboratories; are now available as near-patient tests. All these factors would have a further positive impact on research, development and commerce of POCT segment.

Though the market is witnessing commercial unveiling of newer and newer near-patient, rapid diagnostic test products based on advanced lateral flow technologies, POC testing has still a long way to go so far its worldwide coverage is concerned. Globally about 10% of the immunoassay-based diagnostic tests are performed in settings other than a hospital or commercial laboratory. In the U.S. alone, there are approximately 41,000 small to medium-sized physician office practices and freestanding alternate-site laboratories, which are licensed under Clinical Laboratory Improvement Amendments (CLIA) for high or moderate complexity testing. Most of these sites do not currently have

immunodiagnostic testing capability. The potential for POC testing and lateral flow immunoassays is enormous and new hope has been placed in microchip and miniaturized systems in this context.

All these terms such as decentralized, rapid, near-patient, point-of-care testing etc. refer to an approach to diagnostic testing that uses light weight, readily portable and easy-to-use devices; designed to perform complex biological tests at the site where they are needed most. Traditionally these tests are usually performed in laboratories equipped with large instruments. The main market-driving force behind the POCT diagnostic products is the enhanced portability and networking capabilities that allow rapid immediate patient care. So far, the commercialization such portable diagnostic devices for POC testing has been restrained by the lack of suitable miniaturized, low power consuming, optical detection systems.

Membrane lateral flow is the technology most commonly adopted in rapid disposable POCT systems. This technology lacks desired sensitivity and in most cases provides only qualitative or Yes/No type test results. Testing of new analytes will not be shifted to POC settings until the results are comparable with those obtained with the tests performed in the central laboratory systems. This would obviously require quantitative measurement of analyte(s) in the test samples. Membrane lateral flow is generally appropriate for qualitative assays, but for technical reasons it does not lend itself to quantitative assays.

The success of lateral flow technology-based POCT techniques depends on the evolution of the technology but is also influenced by how POCT market unfolds. Miniaturization of traditional diagnostic techniques has led to the introduction of a number of innovative point-of-care tests and devices. *In vitro* diagnostics manufacturers have developed and are designing technological innovations that provide more patient-friendly, cost-effective, multiplexed POC testing platforms coupled with high-end software capabilities. Decentralized testing directives aimed at nearer-the-patient testing coupled with newer healthcare trends and novel therapeutics are set to redefine and refocus the role of laboratory diagnostic services in healthcare.

Though development of new age microchip-based diagnostic POCT systems has been a considerably challenging issue, miniaturization of conventional laboratory tests is not new as best exemplified by the Glucose Meter for self-testing of blood glucose by patients and individuals. Such miniaturized versions of conventional laboratory tests are already available for about 70 analytes and there are at least 50 companies selling these miniaturized test products around the world. Development of molecular biology-based tests, decentralization of out-patient testing, increased self-testing and trend towards home-patient testing are fuelling the demand for miniaturization of POCT products and thereby for the next generation of more sophisticated diagnostic devices commonly referred to as chips.

Modern medicine is entering an era characterized by emergence of biomedical therapeutics and devices utilizing the principles of genomics, bioinformatics and miniaturization/ portability of medical devices. These frontiers of medical science are set to revolutionize the diagnosis, treatment and monitoring of diseases such as Alzheimer's

disease, rheumatoid arthritis, cancer, heart diseases, HIV/AIDS, hepatitis C, other contagious and hereditary diseases. Clinical/laboratory testing play a critical role in post-genomic medicine. Molecular immunoassays and cell-based tests are beginning to prove their role in the earlier diagnosis of diseases, improvement in drug efficacy and physicians' ability to monitor the success of the chosen intervention.

Newer diagnostic test methodologies mainly include the DNA probe tests for viruses, bacteria, genetic markers etc. as well as blood and cell-based tests for disease-specific markers such as those for diabetes, cancer, osteoporosis, arthritic conditions and cardiac disease. These new tests would allow physicians to tailor therapeutics derived from combinatorial chemistry, antisense therapy and gene therapies for specific patient and disease. Increased knowledge of disease physiology derived from molecular biology and human genome studies will enhance the position of analytes used in chronic conditions such as cardiovascular disease, autoimmune disorders and diabetes. The function of genes is measured by presence of tangible products - proteins of every size and molecular structure. Thus immunoassays combined with DNA probe studies will have an important place in the new era of disease-based medicine.

For POC tests to become more meaningful and more acceptable to healthcare professionals, they must combine the benefits of new miniaturized technologies with digital capture of test results which are then correlated to algorithms embedded in the device chips which further transform a unique set of test data into an actionable piece of information. A step further would be to make home-testing for chronic diseases interactive so that the patient can be advised to take action when necessary. Similarly, POC information systems can aid the physicians in determining the significance of a laboratory test result. However, all new immunoassays and especially those designed for rapid testing will have to prove themselves on the parameters of medical research, health economics and improved patient outcomes.

1.2 Fecal Occult Blood test

Colorectal cancer (CRC) is the third most common malignant cancer worldwide and the second leading cause of cancer deaths in the United States. 143,460 newly-diagnosed cases of CRC and 51,690 deaths due to the same had been projected in the United States for the year 2012. Though, CRC incidence declined by 2.9% per year in white men and 2.2% per year in white women between 2004 to 2008, it has been increasing by 1.7% per year in adults younger than 50 years since 1992. From 2004 to 2008, mortality from CRC declined by 2.7% per year in men and 2.5% per year in women. The incidence of CRC is higher in men than in women.

Fecal Occult Blood (FOB) is a widely accepted early marker for screening of colorectal cancer. Screening methods for colorectal cancer include the guaiac-based FOB tests, immunochromatographic fecal occult blood (iFOB) test, barium enema, sigmoidoscopy and colonoscopy. Large randomized controlled trials have shown that iFOB screening can result in decreased colorectal cancer mortality.

Conventional Fecal Occult Blood Tests (FOBTs) use the chemical 'Guaiac', which is sensitive to hemoglobin peroxidase activity. Since the late 1970s, these conventional guaiac-based FOBTs have been the primary screening method for colorectal cancer. These tests have a number of limitations such as diet restrictions because of sensitivity to dietary peroxidase, low sensitivity to clinically significant colorectal neoplasis, low specificity due to non-specificity for human hemoglobin, sample handling and others.

An alternative to guaiac-based FOBTs is immunochemical testing, which detects only the heme portion of human hemoglobin rather than detecting peroxidase activity, which is prone to dietary interference. Immunochemical FOBTs use specific monoclonal antibodies for capture and detection of FOB hemoglobin in the human stools. Immunochemical FOBTs overcome the major limitations associated with the conventional guaiac-based FOBTs. Over the years, iFOBTs have been slowly replacing the guaiac-based tests.

In July 2002, the 'Eliminate Colorectal Cancer Act' was passed by the U.S. Senate Health, Education, Labor and Pensions Committee. The act mandated all private health insurance plans to pay for screening tests for colorectal cancer for people over age 50 and people younger than 50 who are at high risk of the disease. Supporting provisions in favor of iFOBTs were announced by the Medicare accordingly. A Current Procedural Terminology (CPT) code was assigned with a reimbursement of $18.56. This act thus opened the market to immunological FOBTs in the United States.

As a result, many leading medical diagnostic companies established their iFOBT products in the US market. Prominent amongst them were the market leader Beckman Coulter alongwith its subsidiary SmithKline Diagnostics (FlexSure OBT and Hemoccult ICT), Wampole Laboratory LLC (Clearview ULTRA FOB Test), Immunostics Inc. (Immunostics' Hema-Screen), Cenogenics Corporation's Subsidiary Lab Diagnostic Company, Inverness Medical Innovations (now Alere) and Polymedco (OC-Light).

Several immunochemical tests later came to the market which included mainly the Instant-View FOBT (Alfa Scientific Design), *i*Screen FOB (BioScan Screening Systems Inc.), InSure FIT (Enterix Inc.) and QuickVue iFOB (Quidel Corporation). Flushable home FOB tests such as EZ Detect Colon Disease Test (Biomerica) and ColoCARE (Helena Laboratories) also became available. With the demand for iFOB tests expected to expand, several companies have launched automated systems like the clinical laboratory improvement amendments (CLIA)-waived Polymedco's OC-Auto Micro 80 FOBT Analyzer.

The global market for professional FOBT sector (which includes tests prescribed by a physician and performed in the laboratory) was estimated at $274 million in 2005 and projected to reach $340 million in 2012 with a compound annual growth rate (CAGR) of 3%. In this segment, the conventional guaiac-based FOBTs are being increasingly challenged by a number of immunochemical tests that have been automated. These iFOBTs now completely dominate the market segment in Japan and contribute to about 40% of the market segment in the U.S. and Europe.

The market for OTC FOBT sector (which includes tests prescribed by a physician and performed by the individual in a non-professional setting; usually at home) was estimated at $66 million in 2005. Consumer ads in health magazines continue to push the market for these home-based FOBT products. Consumer awareness of the value of colon cancer screening has fuelled about 8% annual growth in this segment. Conventional guaiac-based FOBTs and iFOBTs make up 90-95% of the market segment while the Flushable FOBTs accounting for the remaining 5-10%. The flushable test segment is expected to grow at 7-10% per year.

Despite of certain technological limitations, FOBTs continue to remain the only reliable screening method for colon cancer. Therefore national healthcare systems of various nations have initiated screening programs based on the FOB tests and also made financial provisions for the same. Similar developments were observed on the non-government front also. In June 2003, the CEOs of several dozen major U.S. corporations, including SAS, Wal-Mart, General Motors, and Bristol-Myers Squibb agreed to include comprehensive cancer screening with tests such as colonoscopies, mammograms and prostate specific antigen (PSA) into their health benefits plans beginning in 2004. These tests are usually covered only when there is a suspicion of cancer, not as a routine preventive screen.

Fecal Occult Blood (FOB) screening for Colorectal Cancer (CRC) has; beyond doubt established itself as a simple and effective public health intervention to prevent and minimize the impact of this disease on the community. Immunological Fecal Occult Blood Tests (iFOBTs) by virtue of their sensitivity, specificity, reliability and rapidity, will continue to dominate this front. Increased policy support from government as well as non-governmental sector coupled with ever-increasing public awareness and technological advancement in this field will continue to attach considerable medical and commercial importance to the iFOBTs.

2. *i*-CHROMA iFOB

2-1 Introduction

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

i-CHROMA iFOB is a rapid, convenient, sensitive and reliable *in vitro* diagnostic test intended for routine physical examination, screening and/or monitoring for gastrointestinal bleeding disorders such as colorectal cancer by laboratories and physician offices.

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology wherein the antigen-antibody complexes formed after processing the test sample with the detection buffer are captured while migrating through the test cartridge which is scanned by the *i*-CHROMA Reader to compute, convert and display the test result in a qualitative (positive or negative) manner.

2-2 Components of *i*-CHROMA iFOB:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer'.

- The test cartridge contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.

- The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each sample collection tube contains 1 mL detection buffer. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

2-3 *i*-CHROMA iFOB Test Cartridge Format and Structure:

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2-4 *i*-CHROMA iFOB Sample Collection Tube:

Sample Collection Tube is an essential component of *i*-CHROMA iFOB. A box containing 25 sample collection tubes, is delivered separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

The sample collection tube is a specially designed plastic container. Each sample collection tube contains 1mL Detection Buffer. Apart from being the container for the detection buffer, the sample collection tube serves the following purposes:

i) Proper sampling of the fecal sample
ii) Processing or thorough mixing of the fecal sample with the detection buffer for ensuring complete extraction of the fecal sample
iii) Application of precise quantity of the processed fecal sample into the 'Sample well' of the *i*-CHROMA iFOB test cartridge

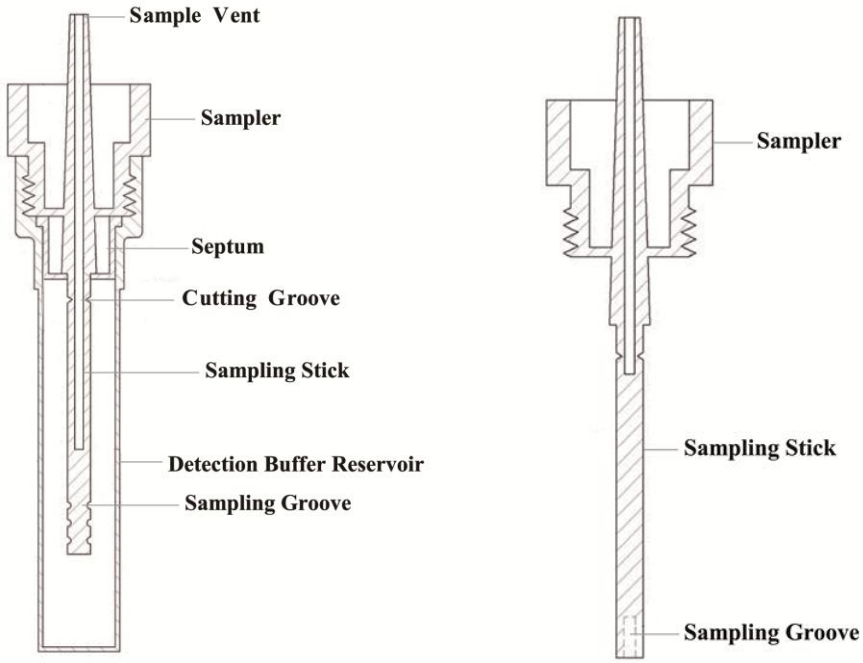

Figure 2: Diagram of *i*-CHROMA iFOB Sample Collection Tube

The sample collection tube is made up of two distinct and detachable components viz. the '**Detection Buffer Reservoir**' and the '**Sampler**'.

The **Detection Buffer Reservoir** is a cylindrical, near-transparent, plastic container similar in shape to a test tube which acts as the vessel for the detection buffer as well as its mixture with the fecal sample.

The open end of the detection buffer reservoir is enlarged and threaded on the inner surface so as to screw-in the sampler.

Just below the enlarged, and threaded open-end of the detection buffer reservoir, a '**Septum**' in the form of a small, cylindrical disc-like, plastic structure with a minute aperture at its center; has been fitted inside the detection buffer reservoir. This septum wipes the excess fecal material from the sampling stick when it passes through the aperture of the septum after sampling. Secondly, as the sampling stick exactly fits into

this aperture of the septum, it prevents the mixture of the fecal sample and the detection buffer from splashing out of sample collection tube during shaking/mixing.

The **Sampler** is somewhat an inverted umbrella-like plastic structure. The sampler is in the form of a long stalk called as the '**Sampling Stick**', the upper end of which passes through a '**Cap**' The lower portion of the cap is threaded. It is this threaded portion which screws-in the sampler into the detection buffer reservoir.

The upper $^{2}/_{3}^{rd}$ portion of the sampling stick has been actually made into a hollow tube while the basal $^{1}/_{3}^{rd}$ portion is non-hollow. The surface of the sampling stick in lowermost part of this basal portion is grooved which is called as '**Sampling Grooves**'.

For processing the fecal sample, the cap is unscrewed and the sampler/sampling stick is removed from the sample collection tube. While removing the sampling stick, the septum should remain fitted inside the detection buffer reservoir otherwise there is possibility of the detection buffer spilling out of the reservoir.

The grooved end of the sampling stick is inserted into the fecal sample at 5~6 different sites so as to ensure a representative sampling. Sampling grooves on the sampling stick should be covered with sufficient fecal sample while ensuring that the quantity is not too much.

The sample-ridden sampling stick is then inserted back into the sample collection tube and the cap of the sampler is screwed-in tightly. The excess fecal material is wiped off from the sampling stick when it passes though the septum of the detection buffer reservoir. At this stage, the sampling system of *i*-CHROMA iFOB delivers the fecal material into detection buffer already present in the sample collection tube.

Contents of the sample collection tube are shaken well and mixed thoroughly to yield a homogenous suspension for complete extraction of the fecal sample. Fecal sample mixture thus obtained; should be kept standing at least for 10 minutes. Fecal sample thus processed with the detection buffer in the sample collection tube is stable for 72 hours if stored at ambient temperature (up to 37℃) and for 96 hours if stored at 2~8℃ in a refrigerator. However it is strongly recommended that fecal sample should be processed and tested immediately or as early as possible after it is collected and submitted by the patient to the laboratory.

Before loading the processed fecal sample into the sample well of the *i*-CHROMA iFOB test cartridge, the sample collection tube is held in vertical position and the sampling stick is cut by bending it the 2-3 times just below the cap i.e. at the '**Cutting Groove**' which is the first designated point below the cap as shown in the figure above. The sample collection tube must be held in an upright position during this stick-cutting process.

After the stick-cutting process, the basal non-hollow portion of the sampling stick will remain suspended in the processed fecal sample mixture while its upper hollow tube-like portion will now open into the detection buffer reservoir.

The processed fecal sample mixture can now be squeezed out by inverting the sample collection tube. In this position, the processed fecal sample mixture will squeeze out from the '**Sample Vent**' of the sampler.

Three drops of the processed fecal sample are loaded into the sample well of the *i*-CHROMA iFOB test cartridge. The sample-loaded test cartridge is then immediately inserted in the cartridge holder of the *i*-CHROMA Reader which scans it after 10 minutes to compute and display the test result.

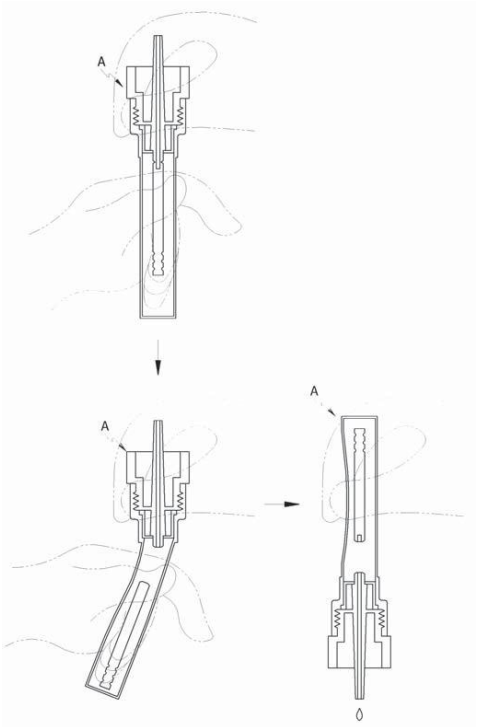

Figure 3: Using the *i*-CHROMA iFOB Sample Collection Tube

2-5 *i*-CHROMA iFOB Test Principle

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human fecal sample is processed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer bind with hemoglobin in the fecal occult blood (FOB).

When this processed fecal sample is loaded into the sample well on the test cartridge as per the prescribed test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, the fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, the more hemoglobin in the human fecal sample, the more complexes get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

i-CHROMA iFOB and *i*-CHROMA Reader are compatible only with each other.

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2-6 *i*-CHROMA iFOB Test Method

2-6-1 Sample Collection and Processing:

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2-6-2 Test Setup:

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2-5-3 Test Procedure:

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2-7 Production Process of *i*-CHROMA iFOB

2-7-1 Steps in Production Process

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3 *i*-CHROMA Reader

3-1 Introduction

i-CHROMA Reader is a custom-configured, portable, desktop, fluorescence-scanning instrument for qualitative detection of fecal occult blood (FOB) in human fecal samples; duly processed and tested by *i*-CHROMA iFOB. *i*-CHROMA Reader can also be used for quantitative determination of various other analytes/disease markers when used in conjunction with other *in vitro* diagnostic immunoassay tests manufactured by Boditech Med Inc. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other.

i-CHROMA Reader is intended to be used only in conjunction with *i*-CHROMA iFOB for *in vitro* diagnostic purpose by laboratories and physician offices. *i*-CHROMA Reader measures 250 mm (L) x 185 mm (W) x 80 mm (H) in size and weighs 1.2 Kg.

The *i*-CHROMA iFOB test cartridge is loaded with the human fecal sample which has been duly pre-processed as per the standard test procedure prescribed by Boditech Med Inc. This sample-loaded test cartridge is inserted in to the cartridge holder of the *i*-CHROMA Reader for the purpose of being scanned.

i-CHROMA Reader is designed to extract designated information off the *i*-CHROMA test cartridge (loaded with the test sample duly processed as per the recommended *i*-CHROMA test procedure) manufactured by Boditech Med Inc. *i*-CHROMA Reader includes specific components required to perform this task in a preprogrammed manner.

The *i*-CHROMA iFOB test cartridge contains a test line and a control line which have been tagged with the capture antibodies. Complexes of the capture antibody-analyte (FOB hemoglobin)-detector antibody accumulate at the test line on test cartridge membrane. One would need an external light source to excite these fluorochrome-labeled complexes accumulated at the test line so that they would emit characteristic radiation i.e. fluorescence. *i*-CHROMA Reader uses a semiconductor diode laser as the excitation light source.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin (accumulated at the test line). The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration. The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

The ‘ID Chip’ provided with *i*-CHROMA test cartridge(s) contains a memory device which contains encoded calibration data. An ID chip having a lot number matching with that of the test cartridge and the sample collection tube is inserted into the designated port of the *i*-CHROMA Reader which utilizes the calibration data for computing the test result(s). Hence the user is not required to perform routine calibration before performing the test.

i-CHROMA Reader automatically performs a preprogrammed ‘system self-check’ (displayed on the screen as ‘Self-test Mode’) each time upon turning the power switch ‘on’. The ‘system self-check’ includes a series of routine checks on key electronic components representing major functions of *i*-CHROMA Reader.

Successful completion of ‘system self-check’ indicates that key electronic components (representing major functions) of *i*-CHROMA Reader are working in order. Upon successful completion of ‘system self-check’, *i*-CHROMA Reader momentarily displays the message ‘OK’ followed by display of the default ‘MENU’ mode which readies the *i*-CHROMA Reader for performing the designated task further.

If any of the key electronic components of the *i*-CHROMA Reader is not working in order, ‘system self-check’ will not be completed successfully and the *i*-CHROMA Reader will display any of the error message alerts ‘Error 21 Turn Off the Power’- ‘Error 24 Turn Off the Power’ thereby disabling the *i*-CHROMA Reader for further use.

i-CHROMA Reader is also provided with a set of ‘System Check ID Chip’ and ‘System Check Cartridge’. ‘System Check’ is to be performed regularly as an additional tool to ascertain whether the *i*-CHROMA Reader would carry out the designated task as intended if *i*-CHROMA test is performed on clinical samples. It is also recommended to perform the system check particularly when using the *i*-CHROMA Reader after extended period(s) of non-use, after up-gradation of the software, after changing the settings and before performing the *i*-CHROMA test(s) using a new lot of test components.

‘System Check ID Chip’ and ‘System Check Cartridge’ are just like the replicas of ‘*i*-CHROMA Test ID Chip’ and ‘*i*-CHROMA Test Cartridge’ respectively. However, ‘System Check’ is to be performed without loading the processed sample into the sample well of the ‘System Check Cartridge’.

Unlike the ‘*i*-CHROMA test cartridge’, test line and control line in the ‘System Check Cartridge’ have been tagged with a fluorochrome. It is the same fluorochrome with which the detector antibodies (present in the detection buffer) have been labeled.

Upon inserting the ‘System Check Cartridge’ in the cartridge holder of *i*-CHROMA Reader, successful completion of the ‘System Check’ would display the result as ‘System Check System OK’ which further assures that key electronic components of *i*-CHROMA Reader are functioning in order and the *i*-CHROMA Reader is most likely to offer valid and accurate results of *i*-CHROMA test performed on clinical samples or controls.

If the ‘System Check’ is unsuccessful, it would display the error message alert ‘System Check Error S1’ or ‘System Check Error S2’ which indicates either some problem with physical or functional integrity of the inserted ‘System Check Cartridge’ or malfunctioning of key electronic component(s) of *i*-CHROMA Reader such that the *i*-CHROMA Reader may not offer valid or accurate result(s) of *i*-CHROMA tests performed on clinical samples or controls.

3-2 Components of *i*-CHROMA Reader

Since *i*-CHROMA Reader has been designed to be a stand-alone device (although network connectivity is also supported), users would use built-in input means only by default. Following is the itemized description of various functional and operational elements which are accessible by the user of *i*-CHROMA Reader.

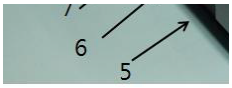
3-2-1 Function/Control Keys:

Operation of *i*-CHROMA Reader is based on five primary functions; each of which is controlled by one or more keys in the key pad provided on the front panel of the *i*-CHROMA Reader.

These keys are used to control the general settings and operation of the *i*-CHROMA Reader. One can adjust the settings, move the cartridge holder in and out of the main body of the instrument and initiate the measurement sequence. With proper combination of key sequences, one can gain access to system-level setting authority.

3-2-2 Display Screen:

The display screen consists of a LCD display device which is based on a black and white 4x18 character display module. Any pertinent information about proper operation of the system would be displayed on the display screen. These include, but not limited to, the test result, time, temperature, software version number, procedural and error message alert if any. When in setting mode, the user would interact with the system via the information shown on the display screen.



1. Set of ‘Function/Control Keys’
2. Display Screen
3. ID Chip Port
4. Test Cartridge Port
5. Power ‘On/Off’ Switch
6. RS 232C Port
7. Power Plug Socket

Figure 6: Functional and Operational Elements of *i*-CHROMA Reader

Figure 7: Top View of *i*-CHROMA Reader

Figure 8: Side View of *i*-CHROMA Reader

3-2-3 ID Chip Port:

In Vitro diagnostic test systems are inevitably susceptible to batch-to-batch variations. *i*-CHROMA tests counter this problem by providing means of compensating for the batch-to-batch variations. For this purpose, the *i*-CHROMA test cartridge(s) is supplemented with an ID-Chip having a matching lot number.

The ID chip contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot

under consideration and applies appropriate correction to the conversion formula while computing the test result.

3-2-4 Test Cartridge Port:

The test cartridge holder ejects out of the main body of *i*-CHROMA Reader from this port. After inserting the sample-loaded test cartridge into the cartridge holder, the 'Select' key is to be pressed for scanning the test cartridge by the *i*-CHROMA Reader. The cartridge holder along with the 'Test Cartridge' moves into the *i*-CHROMA Reader. After the test result is displayed on the display screen, the cartridge holder along with the test cartridge is ejected automatically and stays protruded outside the main body *i*-CHROMA Reader. Upon pressing the 'Select' key or 'In/Out' key (depending on the display message and/or stage of operation), the cartridge holder would retract into *i*-CHROMA Reader.

3-2-5 Power 'On/Off' Switch:

The power switch is provided on the right side of the *i*-CHROMA Reader.

3-2-6 RS 232C Port:

This port serves as both the input and the output port. The test result is by default routed through this port to the printer if attached. Without the printer being attached, the output is disregarded. One can utilize this feature to establish a network connection so that another device would capture the printer output for further processing and share the same with other networked system(s).
This port could also be used to facilitate the reception of incoming data. One would use this feature to accommodate external control of the system.

3-2-7 Power Plug Socket:

Power plug socket is provided on the right side of the *i*-CHROMA Reader adjacent to the RS232C Port and the power switch.

3-3 Regarding prior FDA clearance of *i*-CHROMA™ Reader:

i-CHROMA Reader has received prior clearance from FDA as the associated instrument of the ***i*-CHROMA CRP Test which has been cleared by FDA** vide **the 510(k) number k062981.**

Package Insert

i-CHROMA iFOB

CLIA Complexity Waived

- *i*-CHROMA iFOB is CLIA-waived for human fecal samples only.
- Laboratories performing this test must hold a 'Certificate of CLIA Waiver'.
- If the laboratory does not have a certificate of waiver, the application for certification (Form CMS 116) can be obtained online at www.cms.hhs.gov/clia/ or from the local state agency. Completed application should be forwarded to the local state agency for the state in which the laboratory is located.
- Laboratories with a 'Certificate of CLIA Complexity Waiver' must follow manufacturer's instructions for performing this test.
- If laboratory modifies the test or the manufacturer's instructions, the test will no longer be 'CLIA-waived' and will be classified as 'High Complexity'.
- For complete information, refer to the following additional instructional material:
  - Operation Manual of '*i*-CHROMA Reader'
  - Package Insert of '*i*-CHROMA iFOB Controls'

INTENDED USE

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

i-CHROMA iFOB is a rapid, convenient, sensitive and reliable in vitro diagnostic test intended for routine physical examination, screening and/or monitoring for gastrointestinal bleeding disorders such as colorectal cancer by laboratories and physician offices.

INTRODUCTION

Colorectal cancer (CRC) is the third most common malignant cancer worldwide and the second leading cause of cancer deaths in the United States. About 143,000 newly-diagnosed cases of CRC and about 52,000 deaths due to the same had been projected in the United States for the year 2012.

Fecal Occult Blood (FOB) is a widely accepted early marker for screening of colorectal cancer. Screening methods for colorectal cancer include the conventional guaiac-based fecal occult blood tests (FOBTs), immunochemical fecal occult blood tests (iFOBTs), barium enema, sigmoidoscopy and colonoscopy.

Conventional FOBTs use the chemical Guaiac, which detects hemoglobin by virtue of its sensitivity to hemoglobin peroxidase activity. Since the late 1970s, these guaiac-based FOBTs have been the primary screening method for colorectal cancer. These tests have a number of limitations such as diet restrictions because of interference from dietary plant peroxidase(s), low sensitivity to clinically significant colorectal neoplasis, non-specificity for human hemoglobin, sample handling and others.

An alternative to conventional guaiac-based FOBTs is immunochemical testing (iFOBTs), which detects only the specific portion of human hemoglobin rather than detecting hemoglobin peroxidase activity, which is prone to interference from dietary plant

peroxidase(s). iFOBTs use specific antibodies for capture and detection of FOB hemoglobin in the human fecal samples. iFOBTs thus overcome the critical limitations associated with the conventional guaiac-based FOBTs.

Large randomized controlled clinical trials have shown that iFOB screening can result in decreased colorectal cancer mortality. Over the years, iFOBTs have been slowly replacing the conventional guaiac-based FOBTs. *i*-CHROMA iFOB uses specific monoclonal antibodies for capture and detection of human hemoglobin.

PRINCIPLE

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human fecal sample is processed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer bind with hemoglobin in the fecal occult blood (FOB).

When this processed fecal sample is loaded into the sample well on the test cartridge as per the prescribed test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, more the hemoglobin in the human fecal sample, more the complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

Intensity of the fluorescence is scanned and converted into an electric signal which is proportional to intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample. The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

Computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative manner (very low, negative, positive or very high).

COMPONENTS AND REAGENTS

For performing *i*-CHROMA iFOB test, following items are needed

- *i*-CHROMA iFOB Test Cartridge
- *i*-CHROMA iFOB Sample Collection Tube (containing the detection buffer)
- *i*-CHROMA iFOB ID Chip

'*i*-CHROMA iFOB Test Cartridge' contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge

is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains the '*i*-CHROMA iFOB ID Chip'.

Each '*i*-CHROMA iFOB Sample Collection Tube' contains 1 mL '*i*-CHROMA iFOB Detection Buffer'. The detection buffer contains fluorochrome-labeled anti-hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

STORAGE AND STABILITY

***i*-CHROMA iFOB Sample Collection Tube(s)**:

- Must have been stored at 2~8°C/35.6~46.4°F in a refrigerator.
- Do not freeze.
- Do not use beyond expiration date.

***i*-CHROMA iFOB Test Cartridge(s):**

- Must have been stored in sealed condition at 4~30°C/39.2~86°F,
- Do not freeze.
- Do not use beyond expiration date.

WARNINGS AND PRECAUTIONS

A. General:

- Strictly follow the instructions and test procedure as recommended by the manufacturer; otherwise test results may be misleading or erroneous.
- It is recommended that laboratory should give the *i*-CHROMA iFOB Sample Collection Tube to the patient so that the patient can collect fecal sample and do the sampling.
- Occasionally, laboratory may receive fecal sample which has been collected and submitted in a specimen cup or similar container by the patient.
- Commonly available Sample Collection Paper and Specimen Cup must be provided to the patient for the purpose of sample collection. These items may also be ordered separately from supplier/distributor authorized by the manufacturer.

B. Technical:

- Test should be performed using Test Cartridge, Sample Collection Tube and ID Chip; all having exactly matching lot number. Never interchange test products from different lots.
- Do not use the test cartridge or sample collection tube if it has been already used, damaged or stored under improper conditions.
- Misleading or erroneous test result(s) may be obtained with test components which are past the expiration date or stored improperly or not matching with each other.
- Use *i*-CHROMA iFOB Test Cartridge and *i*-CHROMA Reader only with each other.
- It is strongly recommended that fecal sample should be processed and tested immediately or as early as possible after it is collected and submitted by the patient to the laboratory.

- Fecal sample submitted by the patient in specimen cup may be stored at ambient temperature (not exceeding 37° C/98.6° F) but must be processed and/or tested within 48 hours after collection.
- Fecal sample submitted by the patient in '*i*-CHROMA iFOB Sample Collection Tube' may be stored at ambient temperature (not exceeding 37° C/98.6° F) for up to 72 hours or at 2~8° C/35.6~46.4° F for up to 96 hours after collection but must be tested within these time limits.
- Test cartridge and sample collection tube (containing processed fecal sample or control) must be allowed to attain ambient temperature (15~37 °C/59~98.6 °F) before testing.
- A sample collection tube and test cartridge should be used for testing a sample or control only once and should never be reused.

C. Clinical:

- *i*-CHROMA iFOB is meant for *in vitro* diagnostic use only.
- The test should always be performed upon recommendation of attending physician.
- Test result should not be considered conclusive evidence of presence or absence of gastrointestinal bleeding or disorder.
- The test may yield false negative or false positive results owing to certain technical and clinical factors.

D. Patient Instructions:

- Provide appropriate instructions and guidance to the patient for properly collecting the fecal sample and submitting it to laboratory for testing.
- Patient must be instructed to observe following precautions:
  - Dietary restrictions if any; as advised by attending physician, must be followed by the patient before collecting and submitting fecal sample for testing.
  - Fecal sample should not be collected during or within three days after menstrual period, or if the patient suffers from bleeding hemorrhoids or urinary bleeding.
  - Fecal sample should not come in contact with toilet water and/or urine until collected.
  - After collecting fecal sample, it should be submitted to the laboratory as early as possible such that it can be tested within the stipulated time limits.

E. Handling and Disposal:

Fecal sample, used test cartridge and used sample collection tube should be considered as potentially infectious and hence must be disposed of in accordance with appropriate local, state or federal requirements.

MATERIALS SUPPLIED

Commercial '*i*-CHROMA iFOB' test product comprises:

1) ***i*-CHROMA iFOB Test Cartridge Box**
   Contains:
   - 25 Test Cartridges
   - 1 ID Chip
   - 1 Package Insert
   - 1 Quick Reference Instructions Guide

2) ***i*-CHROMA iFOB Sample Collection Tube Box**

Contains:

- 25 Sample Collection Tubes containing Detection Buffer

Sample collection tubes box is supplied separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items are also required for performing *i*-CHROMA iFOB tests. However, these items can be ordered separately from '*i*-CHROMA iFOB' as per requirement.
Contact the manufacturer or authorized supplier for more information.

1) *i*-CHROMA Reader
2) *i*-CHROMA iFOB Controls
3) Specimen Collection Papers & Specimen Cups

QUALITY CONTROL

External Control

Importance:

- Controls must be tested regularly if you are using *i*-CHROMA iFOB Test under CLIA-waived status.

Purpose:

- To verify whether *i*-CHROMA iFOB Test offers expected test results with *i*-CHROMA iFOB Controls.
- To assure and confirm acceptable performance of *i*-CHROMA iFOB Test System.

Items specially required:

- *i*-CHROMA iFOB Controls to be procured separately from the 'Test Cartridge Box & Sample Collection Tube Box'.

For details:

- Refer to the 'Package Insert' of *i*-CHROMA iFOB Controls.

Procedure:

- As described under 'Testing *i*-CHROMA iFOB Controls' in 'Test Procedure' section of this insert.

When to Perform:

- At least once weekly before testing fecal samples
- In case of any concern regarding functional integrity of the 'Test cartridge(s) and/or Detection Buffer in Sample Collection Tube(s)'
- In case of any question concerning validity or accuracy of test results
- Before performing the test using any new lot of test components or any new shipment even if it belonged to a previously received lot
- Once every month for routinely checking stability of stored test components.
- If the test is being performed by a new operator
- If the operator has not performed the test within last 7 days.

What the results indicate:

- Test results must be obtained as 'iFOB Test Negative' in case of the 'Negative Control' and 'iFOB Test Positive' in case of the 'Positive Control'.
- If observed under the 'Dual Display' mode of *i*-CHROMA Reader, the external control test results must be 'iFOB Test Negative 45.0~55.0 ng/mL' in case of the 'Negative Control' and 'iFOB Test Positive 135.0~165.0 ng/mL' in case of the 'Positive Control'.
- If expected results are obtained with the controls, then:
  - It assures acceptable performance of *i*-CHROMA iFOB Test system.
  - Test results with fecal samples are most likely to be accurate and valid.
  - You can proceed to test the fecal samples.
- If results obtained with any/both controls are not as expected, then:
  - It may be due to one of the following reasons:
    - Proper technique or correct procedure was not followed while testing the controls.
    - Quality/Functional integrity of the controls and /or other components of the test system might have been adversely affected due to improper storage and/or handling.
    - The test system being used may not be performing effectively and hence tests performed on clinical human fecal samples using this test system may yield results of questionable validity and/or accuracy.
  - Test the controls again after correcting any error that might have occurred.
  - If test results with the controls continue to be unacceptable; then:
    - Do not perform further tests on the fecal samples or do not report any result.
    - Contact the manufacturer for technical assistance.

Internal Control

What it is:

- 'Control line' of test cartridge functions as the quality control mechanism which fairly satisfies routine quality control requirement of '*i*-CHROMA iFOB Test(s)'.

How it is executed:

- It is executed automatically whenever a control or fecal sample is tested by *i*-CHROMA iFOB test.

What its normal functioning indicates:

- Internal control mechanism functioned optimally.
- Sufficient quantity of processed test sample was loaded into the sample well.
- The test sample migrated to the control line and test line as required.

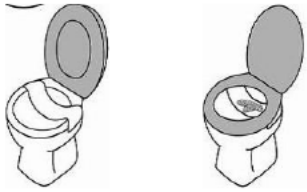
What if it malfunctions?

- In case of malfunction of the internal control due to any reason, *i*-CHROMA Reader displays any of the error message alerts viz. 'Caution! Error', 'iFOB Test Error 26' or 'iFOB Test Error 28' thereby terminating the test.
- Repeat the test using a new test cartridge following correct test procedure.
- If same error message alert(s) is displayed again, contact the manufacturer for technical assistance.

TEST PROCEDURE

Sample collection by patient

1) Lift toilet cover and toilet seat.
2) Position and fix the sample collection paper to the sides of toilet rim in rear half of the toilet bowl, allowing the paper to sag.
3) Make bowel movement on to the collection paper.
4) Do not remove the collection paper from the toilet bowl until fecal sample has been transferred to a specimen cup or into the 'Sample Collection Tube' as instructed by the laboratory.



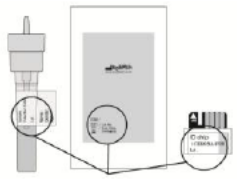
Sample processing by patient or operator

1) Enter Patient Identification Information on the label of '*i*-CHROMA iFOB Sample Collection Tube'.
2) Unscrew the cap of sample collection tube and remove the sampler.
3) Insert the sampling stick of sampler into the human fecal sample at 5-6 different sites.
4) Re-apply the sampler back into sample collection tube and tighten its cap.
5) Shake the sample collection tube 10 times and allow it to stand for 10 minutes before testing.

Arranging test setup

1) Arrange following test components:
   - *i*-CHROMA iFOB Test Cartridge & ID Chip
   - *i*-CHROMA iFOB Sample Collection Tube (containing processed human fecal sample)
   - *i*-CHROMA Reader
2) All these test components must have been stored properly under recommended storage conditions.
3) Check whether lot number of the ID chip is exactly same as lot numbers of the test cartridge and the sample collection tube.

4) Ensure that test cartridge and sample collection tubes have not passed respective expiration dates.
5) Allow the test components to attain ambient temperature (15~37º C/59~98.6º F) for about 30 min.



Performing 'System Check' on *i*-CHROMA Reader

1) Arrange System Check ID Chip and System Check Cartridge.
2) Turn power switch of *i*-CHROMA Reader 'On'. It will automatically display the default 'MENU'.
3) Select 'Test Mode' and insert 'System Check ID Chip' in the ID chip port.
4) *i*-CHROMA Reader ejects the cartridge holder.
5) Insert System Check Cartridge and press 'Select'.
6) *i*-CHROMA Reader should display 'System Check System OK' indicating overall normal functioning.

Testing processed human fecal sample

(b)(4)Trade Secret Process - Testing Report

[redacted]

(b)(4)Trade Secret Process - Testing Report

[redacted]

INTERPRETATION OF TEST RESULTS

- Cut-off of *i*-CHROMA iFOB is 100 ng/mL (hemoglobin in fecal sample)
- Reportable range of the test is 25-1000 ng/mL
- *i*-CHROMA Reader displays the test result as follows:
  - 'iFOB Test Very Low' (if < 25.0 ng/mL)
  - 'iFOB Test Negative' (if < 100.0 ng/mL)
  - 'iFOB Test Positive' (if 100.0~1000 ng/mL)
  - 'iFOB Test Very High' (if > 1000 ng/mL)
- Report the test result to the attending physician for correct interpretation and appropriate medical intervention.

PERFORMANCE CHARACTERISTICS

1. **Analytical sensitivity:** Analytical sensitivity (lower limit of detection) of *i*-CHROMA iFOB is 25.0 ng/mL (hemoglobin in human fecal sample).
2. **Cut-off:** Cut-off of *i*-CHROMA iFOB is 100.0 ng/mL (hemoglobin in human fecal sample).
3. **Measuring range**: Measuring/reportable range of *i*-CHROMA iFOB is 25.0-1000.0 ng/mL (hemoglobin in human fecal).
4. **Prozone effect:** *i*-CHROMA iFOB showed no prozone effect upto 1500.0 ng/mL (hemoglobin in test sample)**.**
5. **Sensitivity to human hemoglobin variant:** *i*-CHROM iFOB has been found to be equally sensitive to 'Hemoglobin S' as the human hemoglobin variant associated with sickle cell anemia.
6. **Interference:** *i*-CHROMA iFOB showed no significant interference from animal hemoglobin (bovine, chicken, fish, equine, goat, swine, rabbit, and sheep origin) as well as endogenous substances (Ascorbic Acid, Bilirubin, Albumin and Myoglobin).
7. **Precision:** *i*-CHROMA iFOB test results showed high degree of repeatability as well as reproducibility under different variability conditions.
8. **Comparability:** Test results of a method comparison study performed on several clinical human fecal samples showed acceptable level of agreement between *i*-CHROMA iFOB and the predicate method OC Auto Micro FOB Test (Polymedco Inc., USA).

LIMITATIONS OF THE TEST SYSTEM

i-CHROMA iFOB provides accurate and reliable test results subject to the following constraints:

- Accuracy and reliability of test results is highly dependent on proper handling/storage of test components and test samples as well as strict adherence to the correct testing and quality control procedures described in this insert.
- The test may yield false positive result(s) due to cross-reactions of some components of the fecal sample or the fecal occult blood with the capture/detector antibodies and/or non-specific adhesion of certain components (having similar epitopes) with these antibodies.
- The test may also yield false negative results; the most common factor being non-responsiveness of the antigen to the capture/detector antibodies due to its epitopes being masked by some unknown components such that the antigen cannot be detected or captured by the antibodies. False negative results may also be obtained due to instability or degradation of the hemoglobin antigen with time and/or temperature making it unrecognizable by the antibodies.
- Other factors causing erroneous/misleading results include technical/procedural errors, degradation of the test components/reagents as well as presence of interfering substances in the test samples.
- The user should neither arrive at any conclusion nor take any decision of medical/therapeutic importance after knowing the test result without first consulting the attending physician.
- Any clinical diagnosis and consequent decision of medical/therapeutic importance based on the test result(s) must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

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Note: Please refer to the table below to identify various symbols on the product labels

	Read instructions for use
	Use by
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
IVD	*In vitro* diagnostic medical device
	Temperature limitation
	Do not Reuse

For technical assistance please contact:
Boditech Med Inc.'s Technical Services
Phone: + 82 33 243 1400
E-mail: support@boditech.co.kr

Boditech Med Incorporated
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPIUBLIC OF KOREA.

Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr

Website: www.boditech.co.kr

Quick Reference Instructions

i-CHROMA iFOB

CLIA Complexity Waived

- ***i*-CHROMA iFOB** is CLIA-waived for human fecal samples only.
- Laboratories performing this test must hold a 'Certificate of CLIA Waiver'.
- Laboratories with a 'Certificate of CLIA Complexity Waiver' must follow manufacturer's instructions for performing this test.
- If laboratory modifies the test or the manufacturer's instructions, the test will no longer be 'CLIA-waived' and will be classified as 'High Complexity'.
- For complete information, refer to the following instructional material.

  - Package Insert of *i*-CHROMA iFOB
  - Package Insert of *i*-CHROMA iFOB Controls
  - Operation Manual of *i*-CHROMA Reader

Which items you need for the test

- *i*-CHROMA iFOB
- *i*-CHROMA Reader

How you may receive and store the test sample(s)

Fecal sample submitted in *i*-CHROMA iFOB Sample Collection Tube:

- May be stored at ambient temperature (≤ 37º C/98.6º F) up to 72 hours or at 2~8º C/ 35.6~46.4º F in a refrigerator up to 96 hours before testing.
- Do not freeze.

Fecal sample submitted in a specimen cup:

- May be stored at ambient temperature (≤ 37º C/98.6º F) up to 48 hours after collection.
- Must be processed or tested within 48 hours after collection.
- Do not freeze.

How you should store the test products

***i*-CHROMA iFOB Sample Collection Tubes**:

- Must have been stored at 2~8°C/35.6~46.4°F in a refrigerator. Do not freeze.
- Do not use beyond expiration date.
- Use for processing a fecal sample or a control only once. Never reuse.

***i*-CHROMA iFOB Test Cartridges:**

- Must have been stored in sealed condition at 4~30°C/39.2~86°F. Do not freeze.
- Do not use beyond expiration date.
- Use for testing a fecal sample or a control only once. Never reuse.

***i*-CHROMA iFOB Controls**:

- Vials of Negative and Positive controls must have been stored at 2~8°C/ 35.6~46.4°F in a refrigerator. Do not freeze.
- Do not use beyond one month after the vials are opened for the first time.
- Do not use beyond expiration date.

***i*-CHROMA iFOB ID Chip and *i*-CHROMA Reader**:

- Always store and use at ambient temperature (15~37°C/59~98.6°F).
- Store properly and handle gently to avoid any physical damage.
- Keep away from moisture, heat, direct sunlight, vibrations and magnetic field.

Warnings and Precautions

A. General:

- Strictly follow the instructions and test procedure as recommended by the manufacturer; otherwise test results may be misleading or erroneous.
- It is recommended that laboratory should give *i*-CHROMA iFOB Sample Collection Tube to the patient so that the patient can collect fecal sample and do the sampling himself/herself.
- Occasionally, laboratory may receive fecal sample which has been collected and submitted in a specimen cup or similar container by the patient.
- Commonly available Specimen Collection Paper and Specimen Cup must be provided to the patient for the purpose of sample collection. These items may also be ordered separately from supplier/distributor authorized by the manufacturer.

B. Technical:

- Test should be performed using Test Cartridge, Sample Collection Tube and ID Chip; all having exactly matching lot number. Never interchange test products from different lots.

- Do not use the test cartridge or sample collection tube if it has been already used, damaged or stored under improper conditions.
- Misleading or erroneous test result(s) may be obtained with test components which are past the expiration date or stored improperly or not matching with each other.
- Use *i*-CHROMA iFOB Test Cartridge and *i*-CHROMA Reader only with each other.
- Test cartridge and sample collection tube (containing processed fecal sample or control) must be allowed to attain ambient temperature (15~37º C/59~98.6º F) before testing.

C. Clinical:

- This test is meant for *in vitro* diagnostic use only.
- The test should always be performed upon recommendation of attending physician.
- Test result should not be considered conclusive evidence of presence or absence of gastrointestinal bleeding or disorder.
- The test may yield false negative or false positive results owing to certain technical and clinical factors.

D. Patient Instructions:

- Provide appropriate instructions and guidance to the patient for properly collecting the fecal sample and submitting it to laboratory for testing.
- Patient must be instructed to observe following precautions:
- Dietary restrictions if any; as advised by attending physician, must be followed by the patient before collecting and submitting fecal sample for testing.
- Fecal sample should not be collected during or within three days after menstrual period, or if the patient suffers from bleeding hemorrhoids or urinary bleeding.
- Fecal sample should not come in contact with toilet water and/or urine until collected.
- After collecting fecal sample, it should be submitted to the laboratory as early as possible such that it can be tested within the stipulated time limits.

E. Handling and Disposal:

Fecal sample, used test cartridge and used sample collection tube should be considered as potentially infectious and hence must be disposed of in accordance with appropriate local, state or federal requirements.

Quality Control

A. Performing 'System Check' on *i*-CHROMA Reader:

Importance

- System Check of *i*-CHROMA Reader must be performed regularly.

Purpose

- To ascertain overall normal functioning of the *i*-CHROMA Reader
- To ascertain whether it would carry out the designated task as intended.

Items specially required

- A set of *i*-CHROMA System Check Cartridge and its ID Chip is provided with the *i*-CHROMA Reader.

For details

- Refer to the Operation Manual of *i*-CHROMA Reader.

Procedure

- As described under 'Performing System Check on *i*-CHROMA Reader' in the 'Test Procedure section of this Quick Reference Instructions'.

When to Perform

- In case of installing the *i*-CHROMA Reader for the first time.
- In case of any concern regarding physical/functional integrity of the Reader
- In case of any question concerning validity or accuracy of test results.
- Before performing the test using *i*-CHROMA Reader after extended period of non-use, changing its operational settings or up-gradation of software.

What the result indicates

- If the result is 'System Check System OK', then:

  - It confirms overall normal functioning of the *i*-CHROMA Reader.
  - *i*-CHROMA iFOB Test results are most likely to be accurate and valid.
  - Proceed for testing the controls or fecal samples.

- If the result is 'System Check Error S1' or 'System Check Error S2', then:

  - Discontinue using the *i*-CHROMA Reader or do not report any test result.
  - Contact the manufacturer for technical assistance.

B. Testing '*i*-CHROMA iFOB Controls':

Importance

- Controls must be tested regularly if you are using *i*-CHROMA iFOB Test under CLIA-waived status.

Purpose

- To verify whether *i*-CHROMA iFOB Test offers expected test results with *i*-CHROMA iFOB Controls.
- To assure and confirm acceptable performance of *i*-CHROMA iFOB Test System.

Items specially required

- *i*-CHROMA iFOB 'Negative & Positive Controls' to be procured separately from the 'Test Cartridge Box & Sample Collection Tube Box'.

For details

- Refer to the Package Insert of *i*-CHROMA iFOB Controls.

Procedure

- As described under 'Testing *i*-CHROMA iFOB Controls' in 'Test Procedure section of this Quick Reference Instruction Guide'.

When to Perform

- At least once weekly before testing fecal samples
- In case of any concern regarding functional integrity of the Test cartridges and/or Detection Buffer in Sample Collection Tubes
- In case of any question concerning validity or accuracy of test results
- Before performing *i*-CHROMA iFOB Test using any new lot of test components or any new shipment even if it belonged to a previously received lot
- Once every month for routinely checking stability of stored test components
- If the test is being performed by a new operator
- If the operator has not performed the test within last 7 days.

What the results indicate

- Test results must be obtained as 'iFOB Test Negative' in case of the 'Negative Control' and 'iFOB Test Positive' in case of the 'Positive Control'.
- If observed under the 'Dual Display' mode of *i*-CHROMA Reader, the external control test results must be 'iFOB Test Negative 45.0~55.0 ng/mL' in case of the 'Negative Control' and 'iFOB Test Positive 135.0~165.0 ng/mL' in case of the 'Positive Control'.
- If expected results are obtained with the controls, then:

  - It assures acceptable performance of *i*-CHROMA iFOB Test system.
  - Test results with fecal samples are most likely to be accurate and valid.
  - You can proceed to test the fecal samples.

- If results obtained with any/both controls are not as expected, then:

  - It may be due to one of the following reasons:

    - Proper technique or correct procedure was not followed while testing the controls.
    - Quality/Functional integrity of the controls and /or other components of the test system might have been adversely affected due to improper storage and/or handling.
    - The test system being used may not be performing effectively and hence tests performed on clinical human fecal samples using this test system may yield results of questionable validity and/or accuracy.
  - Test the controls again after correcting any error that might have occurred.
  - If test results with the controls continue to be unacceptable; then:

    - Do not perform further tests on the fecal samples or do not report any result.
    - Contact the manufacturer for technical assistance.

C. Built-in Procedural Controls:

1. Preprogrammed 'System Self-check' of *i*-CHROMA Reader:

What it is

- It is a mechanism which routinely checks whether key electronic components representing major functions of the *i*-CHROMA Reader are working in order.

How it is executed

- It is executed automatically whenever the power switch of *i*-CHROMA Reader is turned 'ON'.

What it normally indicates

- Up on turning the power switch on, *i*-CHROMA Reader displays 'Self-test Mode' and then momentarily displays 'OK' and comes in 'MENU' mode.
- This indicates that key electronic components representing major functions of the *i*-CHROMA Reader are working in order.
- You can proceed to perform the tests.

What if it malfunctions?

- If one or more of the key electronic components malfunctions, *i*-CHROMA Reader displays any of the error message alerts 'Error 21 Turn Off the Power'-'Error 24 Turn Off the Power' thereby disabling it from further use.
- Contact the manufacturer for technical assistance.

2. Internal Control of *i*-CHROMA iFOB Test Cartridge:

What it is

- ‘Control line’ of test cartridge functions as the quality control mechanism which fairly satisfies routine quality control requirement of *i*-CHROMA iFOB Tests.

How it is executed

- It is executed automatically whenever an external control reagent or fecal sample is tested by *i*-CHROMA iFOB test.

What it normally indicates

- Internal control mechanism functioned optimally.
- Sufficient quantity of processed test sample was loaded into the sample well.
- The test sample migrated to the control line and test line as required.

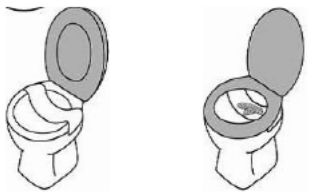
What if it malfunctions?

- In case of malfunction of the internal control due to any reason, *i*-CHROMA Reader displays any of the error message alerts viz. ‘Caution! Error’, ‘iFOB Test Error 26’ or ‘iFOB Test Error 28’ thereby terminating the test.
- Repeat the test using a new test cartridge following correct test procedure.
- If same error message alert(s) is displayed again, contact the manufacturer for technical assistance.

Test Procedure

Sample collection by patient:

1. Lift toilet cover and toilet seat.
2. Position and fix the ‘collection paper’ to the sides of toilet rim in rear half of toilet bowl, allowing the paper to sag.
3. Make bowel movement on to the collection paper.
4. Do not remove the collection paper from the toilet bowl until fecal sample has been transferred to a ‘specimen cup’ or into the ‘*i*-CHROMA iFOB Sample Collection Tube’ as instructed by laboratory.



Sample processing by patient or operator:

1. Enter 'Patient Identification Information' on the label of '*i*-CHROMA iFOB Sample Collection Tube'.
2. Unscrew the 'cap' of 'sample collection tube' and remove the 'sampler'.
3. Insert the 'sampling stick' of 'sampler' into the human fecal sample at 5-6 different sites.
4. Re-apply the 'sampler' back into 'sample collection tube' and tighten its 'cap'.
5. Shake the 'sample collection tube' 10 times and allow it to stand for 10 minutes before testing.

Arranging test setup:

1. Arrange following test components:
   - *i*-CHROMA iFOB ID Chip
   - Sealed *i*-CHROMA iFOB Test Cartridge
   - *i*-CHROMA iFOB Sample Collection Tube (containing processed human fecal sample)
   - *i*-CHROMA Reader

2. All these test components must have been stored properly under recommended storage conditions.
3. Check whether lot number of the ID chip is exactly same as lot numbers of the test cartridge and the sample collection tube.
4. Ensure that test cartridge and sample collection tubes have not passed respective expiration dates.
5. Allow the test components to attain ambient temperature (15~37º C/59~98.6º F) for about 30 min.

Performing 'System Check' on *i*-CHROMA Reader:

1. Arrange '*i*-CHROMA System Check ID Chip' and '*i*-CHROMA System Check Cartridge'.
2. Turn power switch of *i*-CHROMA Reader 'On'. It will automatically display the default 'MENU'.
3. Select 'Test Mode' and insert 'System Check ID Chip' in the 'ID chip port'.
4. *i*-CHROMA Reader ejects the cartridge holder.
5. Insert 'System Check Cartridge' and press 'Select'.
6. *i*-CHROMA Reader should display 'System Check System OK' indicating overall normal functioning.

Testing '*i*-CHROMA iFOB Controls':

(b)(4)Trade Secret Process - Testing Report

[redacted]

(b)(4)Trade Secret Process - Testing Report

[redacted]

Testing processed human fecal sample:

(b)(4)Trade Secret Process - Testing Report

[redacted]

Interpretation of Test Results

- Cut-off value is 100 ng/mL (hemoglobin in fecal sample)
- Reportable range of the test is 25-1000 ng/mL
- *i*-CHROMA Reader displays the test result as follows:

  - ‘iFOB Test Very Low’ (if < 25.0 ng/mL)
  - ‘iFOB Test Negative’ (if < 100.0 ng/mL)
  - ‘iFOB Test Positive’ (if 100.0~1000 ng/mL)
  - ‘iFOB Test Very High’ (if > 1000 ng/mL)

- Report the test result to the attending physician for correct interpretation and appropriate medical intervention.

For technical assistance, please contact:

Boditech Med Inc.'s Technical Services

Phone: + 82 33 243 1400

E-mail: support@boditech.co.kr

Submitter:
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Boditech Med Inc.
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March 4, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Attn: eSubmitter Team
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Sir or Madam:

This submission dated March 4, 2014, is filed pursuant to the In Vitro Diagnostic Device Evaluation and Safety program's Electronic Review (eReview).

The submission is a Supplement to K132167. This submission includes a **CLIA Waiver**.

Truth and Accuracy Statement
To the best of my knowledge, the data and information submitted in this premarket notification are truthful and accurate, and no material fact has been omitted (as required by 21 CFR 807.87).

Sincerely,

Sang Yeol Park
Senior Director
Boditech Med Inc.

Submission Report

Admin

1.0 Type of Submission

Introduction

Department of Health and Human Services
Food and Drug Administration

CDRH PreMarket Review Submission Cover Sheet

Form Approval
OMB No. 0910-0120

Note:	*Please be advised that: 1) under 21 CFR 807.7(1), we may request any additional information that is necessary to reach a determination regarding substantial equivalence and 2) supportive raw data may be provided as attachments to this submission.*
Information:	*Whenever possible, please enter descriptions in executive summary format because this information will be used to generate the FDA Decision summary. If additional information is needed, please attach the appropriate file.*

Section A	**Type of Submission**

Submission Type	*	510(k) and CLIA Waiver Combination
. Submission Sub-Type	*	Supplement
- Submission Sub-Sub-Type		
Enter the original submission number.	*	K132167
Is this a bundled submission?		

User Fee Payment ID Number	

MDUFMA Cover Sheet

Please attach the completed MDUFMA Cover Sheet.

2.0 Contact Information

Section B	**Primary Contact (Submitter, Applicant, or Sponsor)**

Primary Contact Information *

Contact Information:	
Contact Name	Dr. Sang Yeol Park
Occupation Title	Senior Director
Email Address	psy@boditech.co.kr
Address	
Establishment Name	Boditech Med Inc.
Division Name	Quality Assurance & Regulatory Affairs
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Telephone Number	82-33-2431400
Fax Number	82-33-2439373

Section C	**Secondary Contact (Applicant Correspondent, US Agent, or Consultant)**

Secondary Contact Information	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Address	
Establishment Name	
Division Name	
Address	
Telephone Number	
Fax Number	

Who should be contacted for issues related to this submission? *	Primary Contact

Section D	**Manufacturing Location (Physical Location of the Manufacturing Plant)**

Manufacturing Location (Optional)	
Establishment Information:	
Establishment Name	
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
D&B D-U-N-S Number	
Physical Location:	
Address	
Telephone Number	
Fax Number	

CLIA Waiver

Introduction

CLIA Waiver Application	
Note:	*CLIA requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services before accepting materials derived from the human body for laboratory tests. 42U.S.C § 263a(b). Laboratories that perform only tests that are "simple" and that have an "insignificant risk of an erroneous result" may obtain a certificate of waiver. The Secretary has delegated to FDA the authority to determine whether particular tests (waived tests) are "simple" and have "insignificant risk of an erroneous result" under CLIA 69 FR 22849.*

Note:	*To demonstrate that your device is simple and has an insignificant risk of erroneous result, the following items should be included in your waiver application: a description of your device that demonstrates it is simple to use; a hazard analysis, including flex studies that identify potential sources of error for your device and a description of methods you have implemented to mitigate the risk of these errors; validation studies to demonstrate the ability of the failure alert and fail-safe mechanisms to mitigate the risk of errors (under conditions of stress); a description of the design and results of the clinical studies you conducted to demonstrate that the device has an insignificant risk of erroneous results in the hands of the intended user; and proposed labeling with instructions for use that are consistent with a device that is "simple."*

Refer to the "Draft Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications" for more information.

1.0 Type of Product

Select device type:	*	Qualitative
Select device technology:	*	Rapid Immunochromatographicassay, Lateral Flow

Enter the device technology if you chose "Other."

2.0 Test Principle

Enter a brief description of the technology/methodology utilized in the device (i.e., describe how the device works). Describe the principles of the device methodology and whether it is well established or new for the intended use (provide references). Include relevant technical specifications of material and methods not included in the draft package insert (e.g., description of antibodies and epitopes). Also describe the traceability of the method. *
Intended Use: *i*-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples. *i*-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected. **Components of *i*-CHROMA iFOB:** *i*-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer' and *i*-CHROMA Reader - The test cartridge contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip. - The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each sample collection tube contains 1 mL detection buffer. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

- Additionally, 'Patient Packs' are provided along with the test cartridge box and also separately on demand.

Each 'Patient Pack' contains following items:

§ 1 Patient Instructions Leaflet (for sampling instructions)

§ 1 Sample Collection Paper (for fixing onto the toilet bowl)

§ 1 Sample Sac containing an absorption pad (for enclosing the sample collection tube after sampling)

§ 1 Return Envelop (for submitting the sample collection tube to the laboratory/physician office for testing)

- *i*-CHROMA Reader is a fluorometer instrument which scans the sample-loaded *i*-CHROMA iFOB test cartridge and displays the test result. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other. *i*-CHROMA Reader is marketed/supplied separately on demand.
- The ID chip contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

Test Principle:

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human fecal sample is mixed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer binds with hemoglobin in the fecal occult blood (FOB).

When the fecal sample mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, the fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, more the hemoglobin in the human fecal sample, more the complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROM Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

i-CHROMA iFOB and *i*-CHROMA Reader are compatible only with each other.

Traceability

- *i*-CHROMA iFOB Test as well as the Controls are traceable to the 'IRMM/IFCC-467 Human Hemoglobin Reference Standard' and 'OC-Standard V-IX50'.

- **Product Name:** IRMM/IFCC-467

  Chemical Nature: Highly purified non-glycated haemoglobin (HbA0) obtained from human blood

  Source: **I**nstitute for **R**eference **M**aterials and **M**easurement, Joint Research Centre, European Commission

  IRMM/IFCC-467 is certified to contain > 976 millimole HbA0 per mole (HbA1c+HbA0) corresponding to total hemoglobin mass fraction value of 119.7±3.7 mg/g (hemoglobin per gram of the reference standard solution).

  HbA0 is defined as the non-glycated haemoglobin while HbA1c is defined as the beta-N-(1-deoxyfructos-1-yl) haemoglobin.

- 'OC-Standard V-IX50' is supplied by Eiken Chemical Co. Ltd., Japan.

Calibration

- *i*-CHROMA iFOB test has been designed to possess an auto-calibration feature.
- *i*-CHROMA iFOB ID Chip (supplied in the test cartridge box) contains encoded calibration data/information correlating with the lot to lot manufacturing variation with respect to *i*-CHROMA iFOB test.
- For performing the test, *i*-CHROMA iFOB ID Chip having a lot number exactly matching with the lot number of the test cartridge (and also the sample collection tube containing detection buffer) being used for the test; is inserted in the 'ID Chip Port' of the *i*-CHROMA Reader.
- The *i*-CHROMA Reader which utilizes the calibration data while computing and converting the test result.
- Hence the operator is not required to carry out any procedure for routine calibration before perfo ming the test.

Internal/Procedural Control of *i*-CHROMA iFOB:

In addition to the test line, *i*-CHROMA iFOB test cartridge also contains a 'control line' on which 'rabbit immunoglobulin-G antibodies' have been immobilized.

As the human fecal sample (duly mixed with *i*-CHROMA FOB detection buffer and loaded into the sample well) migrates through the test cartridge, fluorochrome-labeled anti-rabbit immunoglobulin-G antibodies in the detection buffer get captured on to the rabbit immunoglobulin-G antibodies immobilized on the control line of the test cartridge.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes accumulated at the test line as well as the control line.

While computing the test result, *i*-CHROMA Reader takes into account the ratio of fluorescence generated at the test line and the control line of the inserted cartridge.

If the control line mechanism is either non-functional or does not function optimally due to any reason, *i*-CHROMA Reader will not display any test result after the sample-loaded *i*-CHROMA iFOB test cartridge is inserted in its test cartridge holder.

In that case *i*-CHROMA Reader will display any of the error message alerts viz. 'Caution! Error', 'iFOB Te st Error 26' and 'iFOB Test Error 28' thereby terminating the test and necessitating to repeat the test using a new *i*-CHROMA iFOB test cartridge.

Thus the control line of *i*-CHROMA iFOB test cartridge functions as the built-in procedural control which fairly satisfies the routine quality control requirement of *i*-CHROMA iFOB test(s).

This internal control is executed automatically each time a human fecal sample (mixed with detection buffer in the *i*-CHROMA iFOB sample collection tube) or *i*-CHROMA iFOB Control is being tested with *i*-CHROMA iFOB test.

If none of the above error message alerts is displayed by *i*-CHROMA Reader (after a 'sample-loaded *i*-CHROMA iFOB test cartridge' has been inserted in it) and a valid '*i*-CHROMA iFOB test' result is displayed, the operator can be sure that:

a) The control line mechanism of the test cartridge was optimally functional.
b) Sufficient quantity of test sample (mixed with the detection buffer) was loaded into the sample well of the test cartridge.
c) Test sample mixture loaded into the 'sample well' has migrated to the control line and test line of the test cartridge as required.
d) All the components of *i*-CHROMA iFOB test functioned properly.
e) Correct procedural technique for the *i*-CHROMA FOB test was followed.

3.0 Demonstrating Simple

Note:	*The following characteristics are used to determine if the device is simple.*

Select the test system: *	Self-contained test (test kit with reagents)

Enter a brief description on how the device meets this criterion. *

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

The antigen-antibody complexes fo med after mixing the human fecal sample with the detection buffer are captured onto the capture antibodies immobilized at the test line and the control line of the test cartridge upon loading the sample mixture into the its sample well.

The sample-loaded test cartridge is further scanned by the *i*-CHROMA Reader which computes, converts, and displays the test result in a qualitative (positive or negative) manner.

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip', a 'Sample Collection Tube' containing the 'Detection Buffer' and '*i*-CHROMA Reader'

Thus *i*-CHROMA iFOB is a self-contained semi-automated test because the user does not require any reagent(s) and/or instrument other than those provided by

the manufacturer.

The device uses unprocessed specimens. *	Yes

Enter a brief description on how the sample meets this criterion.

i-CHROMAiFOB in conjunction with *i*-CHROMAReader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

i-CHROMA iFOB is based on antigen-antibody reaction and fluorescence technology wherein the antigen-antibody complexes fo med after mixing the test sample with the detection buffer are captured while migrating through the test cartridge which is scanned by the *i*-CHROMA Reader to compute, convert and display the test result in a qualitative (positive or negative) manner.

Sample preparation for *i*-CHROMA iFOB comprises two simple steps as follows:

i) Sampling/Transferring the fecal sample into the detection buffer tube by patient or operator **&**

ii) Mixing the fecal sample with the detection buffer by simply shaking the sample collection tube before performing the test

Thus *i*-CHROMA iFOB is a simple test which does not involve any specialized processing of the test sample other than simply transferring and mixing the fecal sample with the detection buffer in the sample collection tube.

Select the sample type the device uses for testing. *	Other

Enter the device's sample type if you chose "Other." *

Human fecal sample mixed with the detection buffer in i-CHROMA iFOB sample collection tube

The device needs only basic, non-technique specimen manipulation, for any decontamination. *	Yes

Enter a brief description on how the device meets this criterion.

It is recommended that the laboratory/physician office should put one '*i*-CHROMA iFOB Sample Collection Tube' into the 'Sample Sac' contained in the 'Patient Pack' before handing over the 'Patient Pack' to the patient.

The patient is supposed to transfer fecal sample into the *i*-CHROMA iFOB sample collection tube at home and returns it to the laboratory for testing.

Sample collection/Sampling procedure and other relevant instructions have been illustrated with help of suitable diagrams in the 'Patient Information Leaflet' provided in the patient pack.

The patient returns the sample collection tube to the physician office/laboratory where this fecal sample mixture (in the sample collection tube) is used for the test without any processing.

Thus *i*-CHROMA iFOB involves only basic, non-technique-dependent specimen manipulation without any need for decontamination of the test sample.

The device needs only basic, non-technique reagent manipulation. *	Yes

Enter a brief description on how the device meets this criterion.

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer'.

None of these test components needs any modification or processing. The sample collection tube needs to be simply shaken to m ix the fecal sample with the detection buffer.

Thus *i*-CHROMA iFOB involves only basic, non-technique-dependent reagent manipulation.

The device needs no operator intervention during the analysis steps. *	Yes

Enter a brief description on how the device meets this criterion.

Upon inserting the sample-loaded test cartridge in the cartridge holder, the *i*-CHROMA Reader scans the inserted test cartridge to automatically compute and convert the test result based on a pre-programed calibration.

i-CHROMA Reader then displays the test result in a qualitative (positive or negative) manner.

The test result is to be reported to the attending physician for valid interpretation and appropriate medical intervention.

Thus *i*-CHROMA iFOB test does not require any operator intervention during the analysis steps.

The device needs no technical or specialized training with respect to troubleshooting or interpretation of multiple or complex error codes. *	Yes

Enter a brief description on how the device meets this criterion.

i-CHROMA Reader is meant for scanning the sample-loaded test cartridge for automatic computation, conversion and display of test result.

i-CHROMA Reader has been designed to perfo m these tasks in a preprogrammed manner.

Error message alerts/codes if any; are also displayed by the *i*-CHROMA Reader.

'*i*-CHROMA Reader Operation Manual' contains all the information on interpretation and preventive or corrective actions required for troubleshooting in case any error code is displayed by the *i*-CHROMA Reader.

This information has been provided in a simple and easily understandable manner.

Most of the error codes have been inco porated into test system as the 'fail-safe mechanisms' whereby the test is terminated without any test result and the operator has to repeat the test using another test cartridge.

'*i*-CHROMA iFOB Quick Reference Instructions' and '*i*-CHROMA iFOB Package Insert' also contain the relevant information.

Thus the system operator does not require any technical knowledge or specialized training for the purpose of the test with respect to troubleshooting or interpretation of multiple or complex error codes.

The device needs no electronic or mechanical maintenance beyond simple tasks (e.g., changing a battery). *	Yes

Enter a brief description on how the device meets this criterion.

The laboratory or physician office does not need to carry out any electronic or mechanical maintenance of any *i*-CHROMA iFOB test component including the *i*-CHROMA Reader.

The 'Test Cartridge', 'ID Chip' and 'Sample Collection Tube' just need to be stored i n appropriate conditions as mentioned in the instructional material.

The operator has to simply arrange the power connection for the *i*-CHROMA Reader. Only periodic cleaning of the exterior of *i*-CHROMA Reader is required no mally.

The manufacturer strongly discourages any electronic or mechanical maintenance and/or repair of the system at the user level. If warranted, the manufacture offers authorized repair or replacement services.

Instructions to this effect have been included in the instructional material.

The device provides direct readout of results (i.e., requires no calculation or conversions). *	Yes

Enter a brief description on how the device meets this criterion.

'ID Chip' is an essential component of *i*-CHROMA iFOB. A matching ID Chip needs to be inserted in the 'ID Chip Port' of the *i*-CHROMA Reader before inserting the sample-loaded test cartridge in the cartridge holder. The ID chip contains a memory device encoding the calibration data/information.

i-CHROMA Reader scans the inserted test cartridge to automatically compute, convert and display the test result in a qualitative i.e. 'Negative' or 'Positive' manner based on a pre-programed calibration presented by the already inserted ID chip.

The test result is to be reported to the attending physician for valid interpretation and appropriate medical intervention.

Thus as *i*-CHROMA iFOB provides direct read-out of test results, the operator has no role in calibration, calculation and interpretation with respect to the test result.

The Quick Reference Instructions and/or Instrument Manual are written at no higher than a seventh grade reading level. *	Yes

Enter a brief description on how the reading level was determined. *

'*i*-CHROMA iFOB Quick Rererence Instructions (QRI)' guide has been written at no higher than a 7th grade reading level.

In the clinical study, *i*-CHROMA iFOB testing was performed by operators who had minimum or no qualifications and/or previous training/experience relevant to laboratory clinical testing.

Written feedback obtained from the each operator participated in the clinical studies of *i*-CHROMA iFOB revealed that *i*-CHROMA iFOB Quick Rererence Instructions (QRI) guide had been written at no higher than a 7th grade reading level.

A 'Patient Instruction Leaflet' has also been included in the 'Patient Pack' for assisting the patient with sampling/transferring the fecal sample to the sample collection tube.

Other instructional material such as '*i*-CHROMA iFOB Package Insert', '*i*-CHROMA iFOB Control Insert' and '*i*-CHROMA Reader Operation Manual' also explain all the information required for performing the test in the simplest possible manner easily understandable by the intended operator.

4.0 Demonstrating Insignificant Risk of an Erroneous Result

4.1 Tier 1 Risk Analysis and Flex Studies

Note:	*Include a report of the risk analysis results that identifies all potential sources of error, including test system failures and operator errors for your device.*

4.1.1 Design and Results

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

4.1.2 Flex Studies Conclusions

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Item: 2

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Item: 3

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

4.2 Tier 2 Fail-Safe and Failure Alert Mechanisms

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Describe the calibration procedure of the device. *

(b)(4)Trade Secret Process

[redacted]

Describe the specimen identification used, if any, for your device. *

(b)(4)Trade Secret Process

[redacted]

External Control Information

Describe the external controls, manufacturer, and if they are included with the device. *

'*i*-CHROMA iFOB Negative Control' and '*i*-CHROMA iFOB Positive Control' are the two external control reagents recommended as essential components of *i*-CHROMA iFOB test.

Both external controls are intended for monitoring and ensuring acceptable perfo mance of the test system and hence they are invariably important for routine quality control of CHROMA iFOB.

These controls must be tested regularly if '*i*-CHROMA iFOB Test' is being used under CLIA-waived status.

i-CHROMA iFOB test results of human fecal samples should not be considered valid and accurate unless supported or corroborated with valid/acceptable test results of these controls tested by the same test system.

i-CHROMA iFOB Controls represent assayed test material containing 'Human Hemoglobin A0' as the analyte dissolved in a buffered liquid medium containing preservative.

i-CHROMA iFOB 'Negative' & 'Positive' Controls contain different levels of the analyte 'Human Hemoglobin A_0' as follows:

No.	Control Reagent		Assigned Target Value	Valid/Acceptable Test Result
1	Low	*i*-CHROMA iFOB	50 ng/mL	iFOB Test Negative

		Negative Control		
2	High	*i*-CHROMA iFOB Positive Control	150 ng/mL	iFOB Test Positive

i-CHROMA iFOB Controls are manufactured and marketed by Boditech Med Inc., 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 200-883, REPUBLIC OF KOREA which also manufactures and markets other components of *i*-CHROMA iFOB test including the *i*-CHROMA Reader

The 'Negative' and 'Positive' controls are presented in separate plastic vials containing 1 mL of the external control reagent.

For offering customized commercial '*i*-CHROMA iFOB Test Product(s)' to ensure better management of user resources, the '*i*-CHROMA iFOB Controls' are marketed separately from '*i*-CHROMA iFOB Test Cartridge Box' and '*i*-CHROMA iFOB Sample Collection Tube Box'.

Describe the frequency the controls should be assayed. *

Quality control of '*i*-CHROMA iFOB test system' using *i*-CHROMA iFOB external controls is intended to assure and confirm acceptable performance of the test system by verifying whether the test system yields expected/acceptable test results with the controls.

Accordingly, *i*-CHROMA iFOB controls should normally be assayed by '*i*-CHROMA iFOB test' at least once daily before performing the *i*-CHROMA iFOB tests on fecal samples.

However, it is further recommended that *i*-CHROMA iFOB controls should also be assayed by '*i*-CHROMA iFOB test' if any of the following special circumstances is encountered:

- In case of any concern regarding functional integrity of the test cartridges and/or detection buffer in sample collection tubes
- In case of any question concerning validity or accuracy of test results
- Before performing *i*-CHROMA iFOB test using:
  - § Any new lot of test components
  - § Any new shipment even if it belonged to a previously received lot
- Once every month for routinely checking stability of the stored test components
- If the test is being performed by a new operator
- If the operator has not perfo med the test within last 7 days

Describe the storage and stability that may refer to the 510(k). *

(b)(4)Trade Secret Process

[redacted]

Provide the number of control levels required, matrix, and simple preparation steps, if any. *

(b)(4)Trade Secret Process

[redacted]

Validating Fail-safe and Failure Alert Mechanisms, Including External Control Procedures

Describe if any, the fail-safe mechanism that renders no result when the test system malfunctions, such as error codes. *

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Describe the fail-safe mechanism used when results exceed the reportable range (very high or low). Note: If the result is a critical value, for example: glucose, then describe how users are alerted that the glucose value is critical (too low or too high). Describe how the result would be reported (for example, greater than 600 mg/dl or less than 30 mg/dl). *

(b)(4)Trade Secret Process

[redacted]

4.2.1 Risk Identification and Risk Control Measures

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

message alerts were obtained:

'iFOB Test Error 26'

'iFOB Test Error 27'

'iFOB Test Error 28'

'iFOB Test Error 29'

4.3 Accuracy

Note:	*The following questions in the Accuracy section demonstrate that your device is "accurate" in the hands of the intended operators. Please attach the data from the studies in an Excel file when applicable.*

4.3.1 Testing Sites and Participants

Note:	*Report the results of the clinical study by each site overall (pooled). The report should include protocol description, number of subjects studied, procedures for subject inclusion and exclusion, description of subject population, description of how specimens were collected and stored, sites that discontinued and the reasons for the discontinuation, and the number of device failures and replacements. Include any invalid results and how these were handled, information about QC procedures that were performed by the users, pertinent tabulations, annotated line listing of results, and clear descriptions and presentations of the statistical analyses.*

Provide the number of sites used and include a description of each site (i.e. physician's office). *

Clinical testing sites:

- Clinical testing of *i*-CHROMA iFOB was conducted at following three sites at different demographic locations:

(b)(4)Trade Secret Process [redacted]

- These sites were selected to closely replicate the clinical setting actually intended for proposed clinical use of *i*-CHROMA iFOB.
- Details of these clinical testing sites are as follows:

Study site 1:

Site Number: CSS-1

(b)(4)Trade Secret Process [redacted]

Study site 2:

Site Number: CSS-2

(b)(4)Trade Secret Process [redacted]

Study site 3:

Site Number: CSS-3

(b)(4)Trade Secret [redacted]

(b)(4)Trade Secret Process [redacted]

Clinical investigators:

- Clinical investigators were not involved in the clinical testing of *i*-CHROMA iFOB conducted at the three testing sites.

Provide the number and demographics of the operators at each site and combined ((i.e. education) (including experience and training), and occupation)). *

- It was aimed to enroll 3 operators at each testing site so as to have the participation of a minimum of 9 operators in total over the three clinical testing sites.
- At the two Korean sites (Study Site No. CSS-1 & CSS-2), special arrangements were made to ensure that *i*-CHROMA iFOB testing was performed by operators other than the regular laboratory technical staff performing routine clinical laboratory tests at these sites.
- These new operators were either biomedical laboratory science or clinical pathology undergraduate students doing internship at these hospitals or the staff serving in other support functions like administration, office assistance, nursing/patient counselling etc. at these hospitals.
- At the (b)(4)Trade Secret [redacted] (Study Site No. CSS-1), eight laboratory technicians were available which included two biomedical laboratory science interns. These two intern students and one person from amongst the support staff were enrolled as *i*-CHROMA iFOB operators.
- At the (b)(4)Trade Secret Process [redacted] (Study Site No. CSS-2), four laboratory technicians were available which included one clinical pathology intern student. The intern student and two persons from amongst the support staff were enrolled as *i*-CHROMA iFOB operator.
- Thus, these new operators had minimum or no qualifications and/or previous training/experience relevant to laboratory clinical testing.
- At the US study site (Site No. CSS-3), operators with least level of academic qualifications and professional training/experience from amongst the operators available at the site, were enrolled to participate in the study.
- However, OC Auto Micro FOB testing was performed by the technician/professional-in-charge of the analyzer at the respective sites.

Table VI.3.A: Site-wise availability, enrolment and participation of operators for the clinical testing study of *i*-CHROMA iFOB

Site No.	Clinical testing site	Number of operators at the testing site	
		Available	Chosen to enroll & participate in the clinical testing
CSS-1	(b)(4)Trade Secret Process [redacted]	06 + 2*	**2*** (CSS1-O1 & CSS1-O2) + **1Δ** (CSS1-O3)
CSS-2		03 + 1*	**1*** (CSS2-O1) + **2Δ** (CSS2-O2 & CSS2-O3)
CSS-3		04	**03** (CSS3-O1, CSS3-O2 & CSS3-O3)
	Total	**16**	**09**

* *These operators were either biomedical laboratory science or clinical pathology undergraduate students doing internship at these hospitals.*

Δ *These operators were the staff serving in other support functions like nursing, administration, office assistance, patient counselling etc. at these hospitals.*

Details of education, occupation, training/experience etc. of the enrolled operators have been provided in the following Table:

Study site	Information	Operators enrolled for & participated in the clinical study		
		Operator CSS1-O1	Operator CSS1-O2	Operator CSS1-O3
CSS-1: (b)(4)Trade [redacted]	Education	Biomedical Laboratory Science Undergraduate	Biomedical Laboratory Science Undergraduate	Bachelor in Physics

(b)(4)Trade Secret Process Republic of Korea		student	student	
	Occupation	Medical Laboratory Intern	Medical Laboratory Intern	Hospital General Support Staff
	Training and/ or Experience	Very little professional experience of clinical laboratory testing	Very little professional experience of clinical laboratory testing	No professional experience of clinical laboratory testing
CSS-2: (b)(4)Trade Secret Process Republic of Korea	**Education**	Clinical Pathology Undergraduate student	Diploma in Nursing	Bachelor of Hospital Administration
	Occupation	Medical Laboratory Intern	Hospital Nurse	Hospital Assistant
	Training and/ or Experience	Very little professional experience of clinical laboratory testing	No professional experience of clinical laboratory testing	No professional experience of clinical laboratory testing
CSS-3: (b)(4)Trade Secret P (b)(4)Trade (b), USA	**Education**	Bachelor in Bioscience	Two year college education	Bachelor in Bioscience
	Occupation	Medical Technician	Medical Technician	Medical Technician
	Training and/or Experience	ASCP certification with three years professional experience	ASCP certification with one year professional experience	ASCP certification

Provide the education (including experience and training) and occupation information on operators that were available at the testing site but were not chosen. *

Details of education, occupation, training/experience etc. of the operators that were available at the testing sites but not enrolled for the study, have been provided in the following Table:

Study site	Information	Operators enrolled for & participated in the clinical study		
		Operator CSS1-O4	**Operator CSS1-O5**	**Operator CSS1-O6**
CSS-1: (b)(4)Trade Secret Process Republic of Korea	**Education**	Bachelor in Biomedical Laboratory Science	Bachelor in Clinical Pathology	Bachelor in Clinical Pathology
	Occupation	Senior Medical Laboratory Technician	Senior Medical Laboratory Technician	Medical Laboratory Technician
	Training and/ or Experience	12 years professional experience	7 years professional experience	5 years professional
CSS-1: (b)(4)Trade Secret Process Republic of		**Operator CSS1-O7**	**Operator CSS1-O8**	**Operator CSS1-O9**
	Education	Bachelor in Clinical Pathology	Bachelor in Clinical Pathology	Bachelor in Biomedical Laboratory Science
	Occupation	Medical Laboratory Technician	Medical Laboratory Technician	Medical Laboratory Technician

Korea	**Training and/ or Experience**	5 years professional experience	2 years professional experience	4 years professional experience
CSS-2: (b)(4)Trade Secret Process [redacted] Republic of Korea		**Operator CSS2-O4**	**Operator SS2-O5**	**Operator CSS2-O6**
	Education	Bachelor in Clinical Pathology	Bachelor in Clinical Pathology	Bachelor in Biomedical Laboratory Science
	Occupation	Medical Laboratory Technician	Medical Laboratory Technician	Medical Laboratory Technician
	Training and/ or Experience	6 years professional experience	2 years professional experience	5 years professional experience
CSS-3: (b)(4)Trade Secret Process [redacted] (b) USA		**Operator CSS3-O4**	--	--
	Education	Bachelor Degree	--	--
	Occupation	Medical Technician	--	--
	Training and/or Experience	ASCP certification with five years professional experience	--	--

Describe what instructional material was provided to the test operator. *

- Test operators who participated in the clinical testing study (conducted at the two Korean sites) were provided with Korean language versions of following instructional materials:
  1. List of 'Do's and Don'ts for Test Operators'
  2. Draft of proposed 'Quick Reference Instructions of *i*-CHROMA iFOB'
  3. Draft of proposed 'Package Insert of *i*-CHROMA iFOB'
  4. Draft of proposed 'Package Insert of *i*-CHROMA iFOB Controls'
  5. Draft of proposed 'Operation Manual of *i*-CHROMA Reader'
- Test operators who participated in the clinical study conducted at the USA site were provided with proper English drafts of the above instructional materials.
- At each testing site, the technician operating the 'OC Auto Micro FOB' referred the relevant instructional material.

Provide the results of the operator questionnaire from each site and combined. *

Content of the operator questionnaire as well as site-wise/operator-wise and combined feedback have been shown in the following Tables:

Que. No.	Question with Options	Clinical Study Sites			Combined Responses
		Site CSS-1	Site CSS-2	Site CSS-3	
		3 Operators	3 Operators	3 Operators	9 Operators
1	**How it was to understand the test instructions.**				
a	Very easy	02	03	03	**08**
b	Easy	01	00	00	**01**
c	Somewhat difficult	--	--	--	--

d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
2	**How it was to follow the test instructions.**				
a	Very easy	02	03	03	**08**
b	Easy	01	00	00	**01**
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
3	**How it was to apply the fecal sample mixture into 'sample well' of the test cartridge correctly.**				
a	Very easy	03	03	03	**09**
b	Easy	--	--	--	--
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
4	**How it was to test the i-CHROMA iFOB external controls.**				
a	Very easy	01	02	02	**05**
b	Easy	02	01	01	**04**
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
5	**How it was to operate the *i*-CHROMA Reader.**				
a	Very easy	02	02	03	**07**
b	Easy	01	01	00	**02**
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--

Que. No.	**Question with Options**	**Clinical Study Sites**			**Combined Responses**
		Site CSS-1	**Site CSS-2**	**Site CSS-3**	
		3 Operators	**3 Operators**	**3 Operators**	**9 Operators**
6	**How it was to read/understand the normal procedural message alerts displayed by *i*-**				

	CHROMA Reader.				
a	Very easy	03	03	03	**09**
b	Easy	--	--	--	--
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
7	**How it was to read and understand the test results displayed by *i*-CHROMA Reader.**				
a	Very easy	03	03	03	**09**
b	Easy	--	--	--	--
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
8	**How it was to read and understand the error message alerts; if any displayed by *i*-CHROMA Reader.**				
a	Very easy	--	--	--	--
b	Easy	--	--	--	--
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
f	I did not encounter any error message alert	03	03	03	**09**
9	**How it was to perform the overall testing process.**				
a	Very simple	01	02	02	**05**
b	Simple	02	01	01	**04**
c	Somewhat complex	--	--	--	--
d	Complex	--	--	--	--
e	Highly complex	--	--	--	--
10	**How the instructional material explains what to do if a test result is invalid?**				
a	Very clearly	02	02	03	**07**
b	Clearly	01	01	00	**02**
c	Ambiguously	--	--	--	--
d	Vaguely	--	--	--	--
e	Not at all	--	--	--	--

Que. No.	**Question with Options**	**Clinical Study Sites**			**Combined Responses**
		Site CSS-1	**Site CSS-2**	**Site CSS-3**	
		3 Operators	**3 Operators**	**3 Operators**	**9 Operators**

11	**How the instructional material explains what to do if any error message alert is displayed by the *i*-CHROMA Reader?**				
a	Very clearly	02	02	03	**07**
b	Clearly	01	01	00	**02**
c	Ambiguously	--	--	--	--
d	Vaguely	--	--	--	--
e	Not at all	--	--	--	--
12	**You could perform the test properly the first time after …..**				
a	Merely reading the instructional material	02	03	03	**08**
b	Reading the instructional material as well as contacting the technical assistance services of the manufacturer	01	00	00	**01**
c	Discussing the test with other test operator(s)	--	--	--	--
d	Taking help from other test operator(s)	--	--	--	--

4.3.3 Clinical Studies for Tests with Qualitative Results

Documentation of Comparative Method

Provide the name of the method and type of comparative method (A, B, C, D, or E). Link to Guidance Doc/specific section. *

- **Selection of comparative method (CM):**
  - Fecal samples of individuals comprising asymptomatic/low risk (negative diagnoses) and high risk (positive diagnoses) subjects were tested with *i*-CHROMA iFOB in order to compare the test results (iFOB Test Negative/ Positive) with the clinical/ colonoscopic status of the subject.
  - However, in order to ensure that clinical samples having near-cutoff analyte concentrations were also included/tested in the method comparison study, 'OC Auto Micro FOB' test was selected as the predicate/comparative method for the purpose of clinical testing of *i*-CHROMA iFOB.
  - 'OC Auto Micro FOB' has been cleared by the USFDA as a qualitative *in vitro* diagnostic test **(k041408)** but it can present the test results in qualitative as well as quantitative manner.
  - Hence 'OC Auto Micro FOB' has been considered as the 'Type-A Comparative Method' (quantitative reference method) as per the USDFA guidance document **'Recommendations for CLIA Waiver Applications for Manufacturers of In Vitro Diagnostic Devices'**.
  - OC Auto Micro FOB Test (in conjunction with OC Auto Micro 80 Analyzer) is marketed by Polymedco Inc., USA. It is an immunological test system intended for detection of human hemoglobin in human feces by professional laboratories.
  - OC Auto Micro FOB test is intended for determination of gastrointestinal bleeding found in a number of gastrointestinal disorders e.g. colitis, polyps, and colorectal cancer.
  - It is recommended for use in routine physical examinations, monitoring and screening for colorectal cancer or gastrointestinal bleeding.
  - The test cut-off of OC Auto Micro FOB test is 100 ng/mL (FOB hemoglobin in the fecal sample in the extraction buffer).

Provide a description of the Comparative Method, which includes intended use population/target population, condition of interest/target condition, reference standard for establishing the presence or absence of the condition or characteristic of interest, and diagnostic accuracy of the test. For CMs C *

and D, provide information supporting traceability.

- 'OC Auto Micro FOB' has been cleared by the USFDA as a qualitative *in vitro* diagnostic test **(k041408)** but it can present the test results in qualitative as well as quantitative manner.
- Hence 'OC Auto Micro FOB' has been considered as the 'Type-A Comparative Method' (quantitative reference method) as per the USDFA guidance document **'Recommendations for CLIA Waiver Applications for Manufacturers of In Vitro Diagnostic Devices'**.
- OC Auto Micro FOB Test (in conjunction with OC Auto Micro 80 Analyzer) is marketed by Polymedco Inc., USA. It is an immunological test system intended for detection of human hemoglobin in human feces by professional laboratories.
- OC Auto Micro FOB test is intended for determination of gastrointestinal bleeding found in a number of gastrointestinal disorders e.g. colitis, polyps, and colorectal cancer.
- It is recommended for use in routine physical examinations, monitoring and screening for colorectal cancer or gastrointestinal bleeding.
- The test cut-off of OC Auto Micro FOB test is 100 ng/mL (FOB hemoglobin in the fecal sample in the extraction buffer).

Statistical Analysis

Note: *Provide the following information based on each site as well as a combined analysis over all sites.*

Method Comparison

Provide the calculated percent agreement estimates along with one sided 97.5% lower confidence bounds for the positive and negative result. Note: The positive and negative samples are dete mined by the comparative method. *

Study site	Waiver Method (WM)	Comparative Method (CM)			Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreeme (95% CI
		OC Auto Micro FOB					
	i-CHROMA iFOB	Positive Results	Negative Results	Total Results			
CSS-1	Positive Results	54	01	55	98.29%	98.18% (90.40% - 99.68%)	98.39% (91.41% - 99.72%)
	Negative Results	01	61	62			
	Total Results	55	62	117			
CSS-2	Positive Results	57	02	59	97.56%	98.3% (90.86% - 99.70%)	96.9% (89.46% - 99.15%)
	Negative Results	01	63	64			
	Total Results	58	65	123			
CSS-3	Positive Results	32	01	33	98.80%	100% (89.28% - 100%)	98.04% (89.70% - 99.65%)
	Negative Results	00	50	50			
	Total Results	32	51	83			
CSS-1+CSS-2 +CSS-3	Positive Results	143	04	147	98.14%	98.6% (95.18% - 99.63%)	97.8% (94.43% - 99.13%)
	Negative Results	02	174	176			
	Total Results	145	178	323			

Test Performance of Qualitative Tests

Provide in tabular format all invalid results obtained. It should capture the number of times a sample and/or specimen needed to be tested in order to obtain a valid result. *

No invalid and/or indeterminate i-CHROMA iFOB test result was obtained at any of the three testing sites during the course of clinical testing of i-CHROMA iFOB.

Provide information that shows the percent agreement of the positive and negative results between the waiver method and comparative method is 95% or greater. *

Study site	Waiver Method (WM)	Comparative Method (CM)			Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreeme (95% CI
		OC Auto Micro FOB					
	i-CHROMA iFOB	Positive Results	Negative Results	Total Results			
CSS-1	Positive Results	**54**	01	55	98.29%	**98.18%** (90.40% - 99.68%)	**98.39%** (91.41% - 99.72%)
	Negative Results	01	**61**	62			
	Total Results	**55**	**62**	**117**			
CSS-2	Positive Results	**57**	02	59	97.56%	**98.3%** (90.86% - 99.70%)	**96.9%** (89.46% - 99.15%)
	Negative Results	01	**63**	64			
	Total Results	**58**	**65**	**123**			
CSS-3	Positive Results	**32**	01	33	98.80%	**100%** (89.28% - 100%)	**98.04%** (89.70% - 99.65%)
	Negative Results	00	**50**	50			
	Total Results	**32**	**51**	**83**			
CSS-1+CSS-2 +CSS-3	Positive Results	**143**	04	147	98.14%	**98.6%** (95.18% - 99.63%)	**97.8%** (94.43% - 99.13%)
	Negative Results	02	**174**	176			
	Total Results	**145**	**178**	**323**			

Provide information that shows the percent of positive and negative results should be close to 95%. *

Site-wise as well as combined information regarding the percent of the positive and negative results obtained with 60 aliquots of the weak positive sample and 60 aliquots of the weak negative sample tested by *i*-CHROMA iFOB have been shown in the following Table:

Table: *i*-CHROMA iFOB Test Results of 60 aliquots of the Weak Positive Sample and 60 aliqouts of the Weak Negative Sample tested at each study site of clinical method comparison study of *i*-CHROMA iFOB

Number and Name of Testing Site	Operator	Number of Aliquots Tested		*i*-CHROMA iFOB (WM) Test Results			
				Aliquots of the Weak Positive Sample		Aliquots of the Weak Negative Samples	
		Aliquots of Weak Positive Sample	Aliquotsof Weak Negative Sample	True Positive Results	False Negative Results	True Negative Results	False Positive Results
CSS-1 (b)(4)Trade (b)	Operator CSS1-O1	20	20	20	00	20	00
	Operator	20	20	19	01	20	00

(b)(4)Trade Secret Republic of Korea	CSS1-O2						
	Operator CSS1-O3	20	20	19	01	19	01
	Total	**60**	**60**	**58 (96.66%)**	**02 (3.33%)**	**59 (98.33%)**	**01 (1.66%)**
CSS-2 (b)(4)Trade (b)(4)Trade Secret Process Republic of Korea	Operator CSS2-O1	20	20	19	01	18	02
	Operator CSS2-O2	20	20	18	02	20	00
	Operator CSS2-O3	20	20	20	00	20	00
	Total	**60**	**60**	**57 (95%)**	**03 (5%)**	**58 (96.66%)**	**02 (3.33%)**
CSS-3 (b)(4)Trade (b), (b)(4)Trade (b) USA	Operator CSS3-O1	20	20	20	00	19	01
	Operator CSS3-O2	20	20	20	00	20	00
	Operator CSS3-O3	20	20	19	01	18	02
	Total	**60**	**60**	**59 (98.33%)**	**01 (1.66%)**	**57 (95%)**	**03 (5%)**
Testing Sites CSS-1 + CSS-2 + CSS-3	**Grand Total**	**180**	**180**	**174 (96.66%)**	**06 (3.33%)**	**174 (96.66%)**	**06 (3.33%)**

Provide information that shows the difference in percents of the positive results and negative results among the three sites (should not be clinically or statistically significant at alpha = 0 05). *

Site-wise as well as combined estimates of percent of positive results (obtained with aliquots of the weak positive sample) and percent of negative results (obtained with aliquots of the weak negative sample) along with respective two-sided 95% confidence intervals have been shown in the following Table:

Table: Site-wise as well as combined estimates of percent of positive results (obtained with aliquots of the weak positive sample) and percent of negative results (obtained with aliquots of the weak negative sample) along with respective two-sided 95% confidence intervals tested with *i*-CHROMA iFOB

Type of Weak Sample Tested	Percent of positive and negative Results (along with 95% confidence intervals) obtained with *i*-CHROMA iFOB

by *i*-CHROMA iFOB	Site CSS-1 (b)(4)Trade Secret Process Republic of Korea	Site CSS-2 (b)(4)Trade Secret Process Republic of Korea	Site CSS-3 (b)(4)Trade Secret P (b)(4)Trade USA	Site CSS-1 + Site CSS-2 + Site CSS-3
60 Aliquots of Weak Positive Sample	**96.67%** (88.64%-99.08%)	**95%** (86.30%-98.29%)	**98.33%** (91.15%-99.71%)	**96.67%** (92.92%-98.46%)
60 Aliquots of Weak Negative Sample	**98.33%** (91.15%-99.71%)	**96.67%** (88.64%-99.08%)	**95%** (86.30%-98.29%)	**96.67%** (92.92%-98.46%)

- The differences in percent of positive results (for the weak positive sample) among the three sites and also the differences in percent of negative results (for the weak negative sample) among the three testing sites were not found to be statistically significant at alpha = 0 05.

5.0 Labeling

Provide proposed package labeling to demonstrate conformance to 21 CFR 809.10. Include the Quick Reference Instructions, Quality Control Package Insert, and the Instrument Manual. *

Labels of various components of *i*-CHROMA iFOB test system have been outlined in 'Section 13: Proposed Labelling'.

Appropriate instructional materials consistent with the proposed 'CLIA Waiver' application of *i*-CHROMA iFOB test system, have been included in Appendix II – V as per following details:

Appendix II: *i*-CHROMA iFOB Test Package Insert

Appendix III: *i*-CHROMA iFOB Test Quick Reference Instructions (QRI)

Appendix IV: *i*-CHROMA iFOB Control Package Insert

Appendix V: *i*-CHROMA Reader Operational Manual

6.0 Other Supportive Information

Enter any additional supporting information for this submission. *

There is no additional supportive information.

File Attachment	Sections and Appendices for Additional Info mation to K132167

Supplement

1.0 Deficiencies and Responses

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process - Product Specs

[redacted]

(b)(4)Trade Secret Process - Product Specs

[redacted]

(b)(4)Trade Secret Process - Product Specs

[redacted]

(b)(4)Trade Secret Process - Product Specs

[redacted]

(b)(4)Trade Secret Process - Product Specs

[redacted]

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February 28, 2014

To
Food and Drug Administration,
Center for Devices and Radiological Health,
Document Mail Center - WO66-G609,
10903 New Hampshire Avenue,
Silver Spring, Maryland 20993-0002,
USA.

510(k) Notification

21 CFR 807.90(e)

To whom it may concern

Dear Sir/Madam,

This is to notify you of the intention of Boditech Med Inc. to manufacture and market the following device:

Device Type/Common Name: Fecal Occult Blood Test

Trade/Proprietary Name : *i*-CHROMA iFOB with *i*-CHROMA Reader

Type of Submission : Traditional 510(k) Submission

Basis for Submission : Additional Information to 510(k) Hold Letter for a New Device

Submitter : **Boditech Med Inc.**
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: psy@boditech.co.kr
Website: www.boditech.co.kr

Contact Person : **Sang Yeol Park**/ Senior Director/ Ph.D.

Establishment Registration Number : Establishment will be registered following FDA clearance

Name(s) and Address(es) of Manufacturing Facility : **Boditech Med Inc.**
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.

Boditech Med Inc. www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 200-883, Korea
바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

Classification Regulation : 21 CFR § 864.6550

Class : II

Panel : Hematology

Product Code : OOX; Automated Occult Blood Analyzer

Prior FDA Document Numbers:

(1) **USFDA 510(k) No. k062981** accorded to the clearance of *i*-Chroma CRP Test of which *i*-CHROMA Reader is an associated device

(2) **FDA's Memo** dated **October 27, 2011** regarding **Pre-IDE Submission No. I110619** for *i*-Chroma iFOB

(3) **K132167 Hold Letter** dated **September 9, 2013** regarding *i*-CHROMA iFOB 510k Submission

(4) **Q131368 Final Review Memo** dated **December 11, 2013** and **E-mail Response** dated **December 24, 2013**

Predicate Device : OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer

Predicate Device 'K' Number : K041408

Predicate Device Product Code : KHE-Reagent, Occult Blood

Compliance with any special control : Not Applicable

Preference for continued confidentiality (21 CFR 807.95) : Not Applicable

Table 3.1: Design and Use of the Device

No.	Question	Yes/No
1	Is the device intended for prescription use (21 CFR 801 Subpart D)?	**Yes**
2	Is the device intended for over-the-counter use (21 CFR 807 Subpart C)	**No**
3	Does the device contain components derived from a tissue or other biologic source?	**Yes**
4	Is the device provided sterile?	**No**
5	Is the device intended for single use?	**Yes***
6	Is the device a reprocessed single use device?	**No**

Boditech Med Inc. www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 200-883, Korea
바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

7	If yes, does this device type require reprocessed validation data?	**Not Applicable**
8	Does the device contain a drug?	**No**
9	Does the device contain a biologic?	**Yes**
10	Does the device use software?	**Yes**[Δ]
11	Does the submission include clinical information?	**No**
12	Is the device implanted?	**No**

* *i*-CHROMA iFOB is intended for single use while *i*-CHROMA Reader is intended for scanning the sample-loaded *i*-CHROMA iFOB Test Cartridges as well as for being used in conjunction with other *in vitro* diagnostic tests manufactured by Boditech Med Inc.

[Δ] Functioning of *i*-CHROMA Reader is based on the use of software.

Standard procedure prescribed by the USFDA has been followed and required documentation has been enclosed.

Thank you in advance for your consideration of our application.

Please feel free to contact us in case of any question or comment about this submission.

Sincerely yours,

Sang Yeol Park
Director of Quality Assurance
& Regulatory Affairs

Boditech Med Inc. www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 200-883, Korea
바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

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Section 4: Indications for Use

510(k) Number (if known): K132167

Device Name: *i*-CHROMA iFOB with *i*-CHROMA Reader

Indications for Use:

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

i-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Prescription Use ____ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of _____

Section 5: 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR, Section 807.92 (c).

Submitter Information: Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: psy@boditech.co.kr
Website: www.boditech.co.kr

Contact Person: **Sang Yeol Park**/ Senior Director/ Ph.D.

Date: **March 03, 2014**

Device Information:

Trade Name: *i*-CHROMA iFOB with *i*-CHROMA Reader
Common Name: *i*-CHROMA iFOB
Classification Name: Automated Occult Blood Analyzer
Class: II
Panel: Hematology
Product Code: OOX
Regulation: 21 CFR § 864.6550

Predicate Device: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer
Predicate K Number: K041408

Device Description:

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

Intended Use(s):

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples. *i*-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Indications for Use(s):

i-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Components of *i*-CHROMA iFOB:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer' and *i*-CHROMA Reader

- The test cartridge contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.

- The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each sample collection tube contains 1 mL detection buffer. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

- Additionally, 'Patient Packs' are provided along with the test cartridge box and also separately on demand.

  Each 'Patient Pack' contains following items:
  - 1 Patient Instructions Leaflet (for sampling instructions)
  - 1 Sample Collection Paper (for fixing onto the toilet bowl)
  - 1 Sample Sac (for enclosing the sample collection tube after sampling)
  - 1 Return Envelop (for submitting the sample collection tube to the laboratory/physician office for testing)

- *i*-CHROMA Reader is a fluorometer instrument which scans the sample-loaded *i*-CHROMA iFOB test cartridge and displays the test result. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other. *i*-CHROMA Reader is marketed/supplied separately on demand.

- The ID chip contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

***i*-CHROMA iFOB Test Cartridge:**

i-CHROMA iFOB Test Cartridge is composed of a test strip enclosed in a disposable plastic housing.

The components of the test strip are:

- An antibody-immobilized nitrocellulose membrane
- A sample pad
- An absorption pad (also called absorbing pad or absorbent pad)
- A plastic backing

***i*-CHROMA iFOB Sample Collection Tube:**

'Sample Collection Tube' is an essential component of *i*-CHROMA iFOB. A box containing 25 pre-filled sample collection tubes, is delivered separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

The sample collection tube is a specially designed plastic container. Each sample collection tube contains 1mL Detection Buffer. Apart from being the container for the detection buffer, the sample collection tube serves the following purposes:

i) Proper sampling of the fecal sample

ii) Thorough mixing of the fecal sample with the detection buffer for ensuring complete extraction of the fecal sample

iii) Application of precise quantity of the sample mixture into the 'Sample well' of the *i*-CHROMA iFOB test cartridge

***i*-CHROMA Reader:**

i-CHROMA Reader is a custom-configured, portable, desktop, fluorescence-scanning instrument for qualitative detection of fecal occult blood (FOB) in human fecal samples; duly mixed with the detection buffer and tested by *i*-CHROMA iFOB. Up on upgrading the software, *i*-CHROMA Reader can also be used for quantitative determination of various other analytes/disease markers when used in conjunction with other *in vitro* diagnostic immunoassay tests manufactured by Boditech Med Inc. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other.

i-CHROMA Reader is intended to be used only in conjunction with *i*-CHROMA iFOB for *in vitro* diagnostic purpose by laboratories and physician offices. *i*-CHROMA Reader measures 250 mm (L) x 185 mm (W) x 80 mm (H) in size and weighs 1.2 Kg.

The *i*-CHROMA iFOB test cartridge is loaded with the human fecal sample which has been duly mixed with the detection buffer in *i*-CHROMA iFOB Sample Collection Tube as per the standard test procedure recommended by Boditech Med Inc. This sample-loaded test cartridge is inserted in to the cartridge holder of the *i*-CHROMA Reader for the purpose of being scanned.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin (accumulated at the test line). The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration. The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

Test Principle:

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human fecal sample is mixed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer binds with hemoglobin in the fecal occult blood (FOB).

When the fecal sample mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, the fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, more the hemoglobin in the human fecal sample, more the complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which is correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

i-CHROMA iFOB and *i*-CHROMA Reader are compatible only with each other.

Substantial Equivalence Information:

Predicate Device: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer

Predicate K Number: K041408

Comparison with the Predicate Device:

Following table summarizes similarities and difference between the test device *i*-CHROMA iFOB and the predicate device OC Auto Micro FOB Test.

SIMILARITIES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Principle	Immunological test system using antigen-antibody reaction for detection of human hemoglobin in human fecal samples.	Immunological test system intended for qualitative detection of fecal occult blood in feces
2	Intended Use	Qualitative detection of fecal occult blood (FOB) in human fecal samples by laboratories and physician offices	Qualitative detection of fecal occult blood in feces by professional laboratories
3	Test Sample	Human fecal sample mixed with detection buffer in the sample collection tube	Feces in an extraction buffer
4	Test Cut-off	100 ng/mL (Human hemoglobin in human fecal sample mixed with detection buffer)	100 ng/mL (Human hemoglobin in feces processed in extraction buffer)
DIFFERENCES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Platform	Fluorescence immunoassay using lateral flow technology	Automated immunoassay using latex fixation
2	Test Time	10 minutes	5~10 minutes
3	Detection Mechanism	Involves scanning/measurement of intensity of fluorescence on the test cartridge membrane	Involves optical measurement of agglutination of latex particles

Standard/Guidance Document Referenced:

USFDA guidance document for industry and FDA staff:
'Review Criteria for Assessment of Qualitative Fecal Occult Blood In Vitro Diagnostic Devices' (Issue date: August 8, 2007**)**

Summary of Performance Testing (Bench):

- *i*-CHROMA iFOB showed **no prozone/hook effect up to** analyte concentration **2000 ng/mL**.
- *i*-CHROMA iFOB was found to be **equally sensitive to** 'Hemoglobin S' as the **abnormal hemoglobin** associated with sickle cell anemia.
- *i*-CHROMA iFOB showed **no significant cross-reactivity with** any of the eight **animal hemoglobin** (i.e. bovine, chicken, fish, horse/equine, goat, pig/swine, rabbit, and sheep origin) **and no significant interference from** any of the four **endogenous substances** (Ascorbic acid, Bilirubin, Albumin and Myoglobin).
- *i*-CHROMA iFOB **showed high degree of repeatability as well as** between-run, lot-to-lot, instrument-to-instrument and site-site **reproducibility.**
- **Analytical method comparison** study at three US sites performed on spiked human fecal samples **showed high degree** (more than 96% in each case) **of overall percent agreement** as well as **positive** percent agreement **and negative percent agreement between** test results obtained with ***i*-CHROMA iFOB** and the predicate method **OC Auto Micro FOB**.
- **Clinical testing study** at two Korean and one US site involving prospective testing of clinical human fecal samples showed:
  - **More than 96% positive and negative percent agreements** in test results when compared **with** the predicate method **OC Auto Micro FOB**
  - **95-99.66% accuracy** in test results **with weak positive and weak negative samples.**

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February 28, 2014

Premarket Notification
Truthful and Accurate Statement
[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Director of Quality Assurance & Regulatory Affairs of Boditech Med Inc., I believe to the best of my knowledge, that all data and information submitted in the pre-market notification are truthful and accurate and that no material fact has been omitted.

Sang Yeol Park
Director
Quality Assurance &
Regulatory Affairs

Boditech Med Inc. www.boditech.co.kr
43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 200-883, Korea
바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

Section 10: Executive Summary

Submitter's Information:

Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: psy@boditech.co.kr
Website: www.boditech.co.kr

Device Information:

Trade Name: *i*-CHROMA iFOB with *i*-CHROMA Reader
Common Name: *i*-CHROMA iFOB
Classification Name: Automated Occult Blood Analyzer
Class: II
Panel: Hematology
Product Code: OOX
Regulation: 21 CFR § 864.6550

Predicate Device: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer
Predicate K Number: K041408

Intended Use(s):

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples. *i*-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Indications for Use(s):

i-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Device Description:

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

Components of *i*-CHROMA iFOB:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer' and *i*-CHROMA Reader

- The test cartridge contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.

- The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each sample collection tube contains 1 mL detection buffer. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

- Additionally, 'Patient Packs' are provided along with the test cartridge box and also separately on demand.

  Each 'Patient Pack' contains following items:
  - 1 Patient Instructions Leaflet (for sampling instructions)
  - 1 Sample Collection Paper (for fixing onto the toilet bowl)
  - 1 Sample Sac containing an absorption pad (for enclosing the sample collection tube after sampling)
  - 1 Return Envelop (for submitting the sample collection tube to the laboratory/physician office for testing)

- *i*-CHROMA Reader is a fluorometer instrument which scans the sample-loaded *i*-CHROMA iFOB test cartridge and displays the test result. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other. *i*-CHROMA Reader is marketed/supplied separately on demand.

- The ID chip contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

***i*-CHROMA iFOB Test Cartridge:**

i-CHROMA iFOB Test Cartridge is composed of a test strip enclosed in a disposable plastic housing.

The components of the test strip are:

- An antibody-immobilized nitrocellulose membrane
- A sample pad
- An absorption pad (also called absorbing pad or absorbent pad)
- A plastic backing

***i*-CHROMA iFOB Sample Collection Tube:**

'Sample Collection Tube' is an essential component of *i*-CHROMA iFOB. A box containing 25 pre-filled sample collection tubes, is delivered separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

The sample collection tube is a specially designed plastic container. Each sample collection tube contains 1mL Detection Buffer. Apart from being the container for the detection buffer, the sample collection tube serves the following purposes:

i) Proper sampling of the fecal sample
ii) Thorough mixing of the fecal sample with the detection buffer for ensuring complete extraction of the fecal sample
iii) Application of precise quantity of the sample mixture into the 'Sample well' of the *i*-CHROMA iFOB test cartridge

***i*-CHROMA Reader:**

i-CHROMA Reader is a custom-configured, portable, desktop, fluorescence-scanning instrument for qualitative detection of fecal occult blood (FOB) in human fecal samples; duly mixed with the detection buffer and tested by *i*-CHROMA iFOB. Up on upgrading the software, *i*-CHROMA Reader can also be used for quantitative determination of various other analytes/disease markers when used in conjunction with other *in vitro* diagnostic immunoassay tests manufactured by Boditech Med Inc. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other.

i-CHROMA Reader is intended to be used only in conjunction with *i*-CHROMA iFOB for *in vitro* diagnostic purpose by laboratories and physician offices. *i*-CHROMA Reader measures 250 mm (L) x 185 mm (W) x 80 mm (H) in size and weighs 1.2 Kg.

The *i*-CHROMA iFOB test cartridge is loaded with the human fecal sample which has been duly mixed with the detection buffer in *i*-CHROMA iFOB Sample Collection Tube as per the standard test procedure recommended by Boditech Med Inc. This sample-loaded test cartridge is inserted in to the cartridge holder of the *i*-CHROMA Reader for the purpose of being scanned.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin (accumulated at the test line). The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration. The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

Test Principle:

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human fecal sample is mixed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer binds with hemoglobin in the fecal occult blood (FOB).

When the fecal sample mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, the fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, more the hemoglobin in the human fecal sample, more the complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROM Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

i-CHROMA iFOB and *i*-CHROMA Reader are compatible only with each other.

Comparison with the Predicate Device:

Following table summarizes similarities and difference between the test device *i*-CHROMA iFOB and the predicate device OC Auto Micro FOB Test.

SIMILARITIES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Nature of the Test	Rapid, convenient, sensitive and reliable *in vitro* diagnostic test	Rapid, convenient, sensitive and reliable *in vitro* diagnostic test
2	Intended Use	Qualitative detection of fecal occult blood (FOB) in human fecal samples by laboratories and physician offices	Qualitative detection of fecal occult blood in feces by professional laboratories
3	Indications for Use(s)	Routine physical examination when gastrointestinal bleeding may be suspected	(1) Routine physical examinations (2) Monitoring for bleeding in patients and (3) Screening for colorectal cancer or gastrointestinal bleeding.
4	User(s)	Laboratories and physician offices	Professional laboratories
5	Test Sample	Human fecal sample mixed with detection buffer in the sample collection tube	Feces in an extraction buffer
6	Test Principle	Immunological test system based on fluorescence technology for qualitative detection of human hemoglobin in human fecal samples.	Immunological test system intended for qualitative detection of fecal occult blood in feces
7	Special Instrument Requirement	'*i*-CHROMA Reader' for scanning the *i*-CHROMA iFOB test cartridge which has been loaded with the fecal sample mixed with the detection buffer	'Polymedco OC Auto Micro 80 Analyzer' on which the 'OC Auto Sampling Bottle(s)' containing the fecal sample(s) are placed for performing the automated test
8	Work Flow	Normally, patient receives 'Patient Pack' and the sample collection tube from the laboratory/ physician office. Patient collects/transfers fecal sample in to the sample collection tube and submits it to the laboratory/physician office for testing. Occasionally, the physician office / laboratory may receive fecal sample which has been submitted by the patient in a specimen cup or other suitable container.	Fecal sample is collected/transferred by the patient in to the sampling bottle which is sent to the professional laboratory for testing.

9	Sampling / Mixing the sample with detection buffer	Sampling is done with the help of the 'Sampling Stick' / 'Sampler' which is a part of the sample collection tube. The fecal sample is thus delivered into the sample collection tube containing the detection buffer which extracts it.	Sampling is done with the help of the 'Sampling Probe' which is a part of the 'OC-Auto Sampling Bottle'. The fecal sample is thus delivered into the sampling bottle containing the buffer which extracts it.
10	Test Cut-off	100 ng/mL (human hemoglobin in the human fecal sample mixed with detection buffer)	100 ng/mL (human hemoglobin in processed feces)
11	Presentation of Test Results	Qualitative (Positive if ≥ 100 ng/mL and Negative if <100 ng/mL)	Qualitative (Positive if ≥ 100 ng/mL and Negative if <100 ng/mL)
12	Biohazard and Compatibility with Environment	➢ Used test cartridges and sample collection tubes should be considered as a biohazard. ➢ Test components should be handled strictly as per the instructions given in the package insert and the operation manual. ➢ Used test cartridges and sample collection tubes should be disposed of in accordance with relevant local, state or federal regulations. ➢ If needed, the *i*-CHROMA Reader should be disposed of in accordance with applicable regulations.	➢ Similar handling precautions and disposal directives are prescribed by the manufacturer.
13	Compatibility with other Devices	➢ '*i*-CHROMA iFOB' and the '*i*-CHROMA Reader' are compatible only with each other for the purpose of this test. ➢ Up on upgrading the software, *i*-CHROMA Reader can also be used for measurement of various analytes/ disease markers when used in conjunction with other *in vitro* diagnostic tests manufactured by Boditech Med Inc.	➢ 'OC Auto Micro FOB Test' and 'Polymedco OC Auto Micro 80 Analyzer' are designed to be used together for the purpose of this test system.
14	Chemical Safety	If used in accordance with the warnings, precautions, instructions and procedure prescribed in the package insert, '*i*-CHROMA iFOB' has assured chemical safety profile.	'OC Auto Micro FOB Test' is reportedly safe on this count

Discussion of Similarities:

As evident from the table above *i*-CHROMA iFOB (along with *i*-CHROMA Reader) shares a very close similarity with the predicate device OC Auto Micro FOB Test (along with OC Auto Micro 80 Analyzer) when compared on different parameters related to scientific rationale, test principle, intended use(s), indications for use(s), user(s) profile, work flow, performance characteristics, effectiveness, energy used, bio-hazard and environmental compatibility, safety profile etc. This explicit similarity forms a robust foundation for substantial equivalence of *i*-CHROMA iFOB (along with *i*-CHROMA Reader) to the predicate device.

DIFFERENCES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Platform/ Format	Lateral flow chromatographic fluorescence immunoassay	Automated immunoassay using latex fixation
2	Test Components	➢ *i*-CHROMA iFOB Test Cartridge ➢ *i*-CHROMA iFOB Sample Collection Tube containing the Detection Buffer ➢ *i*-CHROMA iFOB ID Chip which contains encoded calibration data **&** ➢ *i*-CHROMA Reader	➢ Closed tube-type Sampling Bottle containing the Extraction Buffer ➢ Test Reagents (Latex reagent, Buffer, Negative & Positive Controls, Wash Concentrate, and Calibrator) **&** ➢ OC Auto Micro 80 Analyzer
3	Test Device	Test Cartridge (Test strip enclosed in a plastic housing)	Sampling Bottle containing an extraction buffer
4	Detection Mechanism	Involves scanning/measurement of intensity of fluorescence on the processed sample-loaded test cartridge membrane	Involves optical measurement of agglutination of latex particles

Discussion of Differences:

i-CHROMA iFOB (along with *i*-CHROMA Reader) differs from the predicate device OC Auto Micro FOB Test (along with OC Auto Micro 80 Analyzer) with respect to the test platform/format, test device & components and detection mechanism.

However, these differences are in accordance with the respective technology platforms on which the test device and the predicate device are based.

i-CHROMA iFOB is a fluorescence immuno-chromatographic assay based on lateral flow format while OC Auto Micro FOB Test is an automated immunoassay using latex fixation. The lateral flow technology is a quite well-established and proven platform for

development of modern rapid, sensitive, reliable and user-friendly *in vitro* diagnostic tests.

i-CHROMA iFOB differs from the predicate device in terms of test components. In *i*-CHROMA iFOB, the test components are viz. a 'Test Cartridge', a 'Sample Collection Tube containing Detection Buffer', an 'ID Chip' and the '*i*-CHROMA Reader' while in OC Auto Micro FOB test, the test components are: a closed tube-type 'OC-Auto Sampling Bottle containing Extraction Buffer', 'Test Reagents' (Latex Reagent, Buffer, Negative & Positive Controls, Wash Concentrate, and Calibrator) and the 'OC Auto Micro 80 Analyzer'.

i-CHROMA iFOB test cartridge and the sample collection tube (containing the detection buffer) collectively carry out the function which is analogous to the role of OC-auto sampling bottle (containing the extraction buffer) and the latex & buffer reagent provided as a part of the predicate test.

In case of *i*-CHROMA iFOB, the ID chip contains encoded calibration data. An ID chip having a lot number matching with that of the test cartridge and the sample collection tube; is inserted into the designated port of the *i*-CHROMA Reader which utilizes the calibration data for computing and converting the test result. In case of OC Auto Micro FOB test, calibration curve needs to be plotted for each measurement by serially diluting the primary calibrator and plotting the known concentrations of human hemoglobin in the control dilutions against the corresponding absorbance values.

i-CHROMA iFOB Control reagents are supplied on demand separately from the test components while negative & positive controls are supplied as components of the OC Auto Micro FOB test.

i-CHROMA iFOB test cartridge (loaded with a test sample mixed with the detection buffer) is to be inserted in the *i*-CHROMA Reader which scans it and automatically displays the test result. In case of the predicate device, similar role is played by the OC Auto Micro 80 Analyzer. OC-auto sampling bottle(s) containing the extracted fecal sample(s) is placed on the rack(s) of the OC Auto Micro 80 Analyzer which performs the automated immunoassay and displays the test result.

Thus it is undoubtedly established that above differences neither deviate *i*-CHROMA iFOB from being substantially equivalent to the predicate device nor adversely affect the performance, effectiveness and safety of *i*-CHROMA iFOB in any manner.

Summary of Performance Testing (Bench):

1) Cut-off:

- Analytical characterization of cut-off of *i*-CHROMA iFOB involved testing of 219 human fecal samples comprising 125 normal/negative samples and 94 positive samples as confirmed with the predicate test OC Auto Micro FOB.

- Test results were statistically analyzed by ROC Analysis and analyte concentration corresponding to maximum sensitivity as well as maximum specificity of *i*-CHROMA iFOB was taken as the cut-off.
- Cut-off of *i*-CHROMA iFOB was determined to be 100 ng/mL.

2) Prozone (hook) effect:

- Susceptibility of *i*-CHROMA iFOB to prozone effect was evaluated by testing 20 replicates of fecal samples spiked with human blood so as to obtain test samples containing human hemoglobin levels up to 2000 ng/mL.
- *i*-CHROMA iFOB was not found susceptible to prozone/hook effect as it would display positive test results with fecal samples containing hemoglobin concentration up to 2000 ng/mL.

3) Analytical specificity:

A) Sensitivity to human hemoglobin variant:

- Sensitivity of *i*-CHROMA iFOB to 'Hemoglobin S' as the human hemoglobin variant associated with sickle cell anemia was evaluated by testing 20 replicates of fecal samples spiked with blood of a sickle cell anemia patient so as to obtain test samples with five different concentrations of 'Hemoglobin S' (50 ng/mL, 85 ng/mL, 100 ng/mL, 115 ng/mL & 150 ng/mL).
- *i*-CHROMA iFOB was found to be equally sensitive to 'Hemoglobin S' as the human hemoglobin variant associated with sickle cell anemia.

B) Interference from animal hemoglobin:

- Cross-reactivity of *i*-CHROMA iFOB with animal hemoglobin was evaluated by testing 20 replicates of fecal samples spiked with human blood so as to obtain samples with 0 ng/mL, 50 ng/mL, 85 ng/mL, 100 ng/mL, 115 ng/mL & 150 ng/mL concentrations of human hemoglobin and further spiking them with blood of eight different animal species.
- Separate samples were prepared to obtain test samples containing intended level of respective animal hemoglobin such as bovine (2000 µg/mL), chicken (500 µg/mL), fish (100 µg/mL), horse/equine (500 µg/mL), goat (500 µg/mL), pig/swine (500 µg/mL), rabbit , (500 µg/mL) and sheep (500 µg/mL).
- *i*-CHROMA iFOB did not show significant cross-reactivity with any of the animal hemoglobin tested.

C) Interference from endogenous substances:

- Susceptibility of *i*-CHROMA iFOB to interference from endogenous substances was evaluated by testing 20 replicates of fecal samples spiked with human blood so as to obtain samples with 0 ng/mL, 50 ng/mL, 85 ng/mL, 100 ng/mL, 115 ng/mL & 150 ng/mL concentrations of human hemoglobin and further spiking them with solutions containing intended concentrations of four endogenous substances Ascorbic acid, Bilirubin, Albumin and Myoglobin.

- Separate samples were prepared to obtain test samples containing intended concentrations of the respective endogenous substance i.e. Ascorbic acid (30 µg/mL), Bilirubin (200 µg/mL), Albumin (60 mg/mL) and Myoglobin (2000 µg/mL).
- *i*-CHROMA iFOB did not show significant interference from any of the four endogenous substances which were tested.

4. Precision (Repeatability/Reproducibility):

- Imprecision (repeatability and reproducibility) of *i*-CHROMA iFOB was evaluated by testing 20 replicates of fecal samples spiked with human blood so as to obtain test samples containing seven different concentrations of human hemoglobin such as 50 ng/mL, 85 ng/mL, 90 ng/mL, 100 ng/mL, 110 ng/mL, 115 ng/mL and 1000 ng/mL under specific variability conditions with respect to device lots, instruments, operators, testing sites etc.
- Repeatability (within-run variability), between-run reproducibility, instrument-to-instrument reproducibility and lot-to-lot reproducibility studies were conducted at a hospital site in Republic of Korea. These studies involved three *i*-CHROMA iFOB lots, three *i*-CHROMA Readers, three operators etc. as appropriate.
- Site-to-site reproducibility study was conducted at three intended use sites in USA using three different lots of *i*-CHROMA iFOB i.e. different lot for each site using same/common test samples.
- *i*-CHROMA iFOB showed high degree of repeatability as well as between-run reproducibility, instrument-to-instrument reproducibility, lot-to-lot reproducibility and site-to-site reproducibility.

5. Analytical method comparison:

- Analytical method comparison study of *i*-CHROMA iFOB was conducted at three intended use sites in USA. However, it was independent from the site-to-site reproducibility study conducted at the same sites on different dates.
- 20 replicates of fecal samples spiked with human blood so as to obtain test samples containing seven different concentrations of human hemoglobin (such as 50 ng/mL, 85 ng/mL, 90 ng/mL, 100 ng/mL, 110 ng/mL, 115 ng/mL and 1000 ng/mL) were prepared separately for each site but were tested using same lot of *i*-CHROMA iFOB across the three sites.
- After testing with *i*-CHROMA iFOB, test samples from each site were tested with the predicate test OC Auto Micro FOB installed at one of the three sites.
- Site-wise as well as combined analysis of the study results showed that *i*-CHROMA iFOB test results had high degree (more than 96 % in each case) of overall percent agreement as well as positive percent agreement and negative percent agreement with OC Auto Micro FOB test results.

7. Clinical testing for CLIA-waiver application:

- The study was conducted at two hospitals in Korea and one laboratory in USA through prospective testing of clinical human fecal samples obtained from asymptomatic as

well as high-risk individuals who had already been screened with colonoscopy in the past.

- Clinical method comparison study was performed on total 323 clinical fecal samples comprising 146 positive samples and 177 negative samples (as tested by the comparative method OC Auto Micro FOB).
- Performance of *i*-CHROMA iFOB at analyte concentrations near the cutoff was evaluated by testing 60 aliquots each of a weak positive and a weak negative clinical sample at each of the three sites.
- Site-wise as well as combined analysis of results of clinical testing study showed:
  - High degree (more than 96% in each case) of overall percent agreement as well as positive percent agreement and negative percent agreements between test results obtained with *i*-CHROMA iFOB and OC Auto Micro FOB.
  - 95-99.66% positive and negative results with 60 aliquots each of the weak positive sample and the weak negative sample respectively at each of the three sites.

Conclusions:

In view of the matter mentioned above, it can be positively concluded that *i*-CHROMA iFOB is substantially equivalent to the predicate device OC Auto Micro FOB Test.

Section 11: Device Description

Device Information:

Trade Name: *i*-CHROMA iFOB with *i*-CHROMA Reader
Common Name: *i*-CHROMA iFOB
Classification Name: Automated Occult Blood Analyzer
Class: II
Panel: Hematology
Product Code: OOX
Regulation: 21 CFR § 864.6550

Intended Use(s):

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples. *i*-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Indications for Use(s):

i-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Introduction

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology wherein the antigen-antibody complexes formed after mixing the test sample with the detection buffer, are captured while migrating through the test cartridge which is scanned by the *i*-CHROMA Reader to compute, convert and display the test result in a qualitative (positive or negative) manner.

i-CHROMA iFOB:

Components of *i*-CHROMA iFOB:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer' and *i*-CHROMA Reader

- The test cartridge contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.

- The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each sample collection tube contains 1 mL detection buffer. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

- Additionally, 'Patient Packs' are provided along with the test cartridge box and also separately on demand.

  Each 'Patient Pack' contains following items:

  - 1 Patient Instructions Leaflet (for sampling instructions)
  - 1 Sample Collection Paper (for fixing onto the toilet bowl)
  - 1 Sample Sac containing an absorption pad (for enclosing the sample collection tube after sampling)
  - 1 Return Envelop (for submitting the sample collection tube to the laboratory/physician office for testing)

- *i*-CHROMA Reader is a fluorometer instrument which scans the sample-loaded *i*-CHROMA iFOB test cartridge and displays the test result. *i*-CHROMA Reader and *i*-CHROMA iFOB test cartridge are compatible only with each other. *i*-CHROMA Reader is marketed/supplied separately on demand.

- The ID chip contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

i-CHROMA iFOB Test Cartridge Format and Structure:

i-CHROMA iFOB test cartridge is composed of a test strip enclosed in a disposable plastic housing as shown in **Figure 11.1**.

The components of the test strip are:

- An antibody-immobilized nitrocellulose membrane
- A sample pad
- An absorption pad (also called absorbing pad or absorbent pad)
- A plastic backing

(b)(4)Trade Secret Process - Product Specs

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i-CHROMA iFOB Sample Collection Tube:

Sample Collection Tube is an essential component of *i*-CHROMA iFOB. A box containing 25 pre-filled sample collection tubes is delivered separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

The sample collection tube is a specially designed plastic container. Each sample collection tube contains 1mL Detection Buffer. Apart from being the container for the detection buffer, the sample collection tube serves the following purposes:

i) Proper sampling of the fecal sample

ii) Thorough mixing of the fecal sample with the detection buffer for ensuring complete extraction of the fecal sample

iii) Application of precise quantity of the fecal sample mixture into the 'Sample well' of the *i*-CHROMA iFOB test cartridge

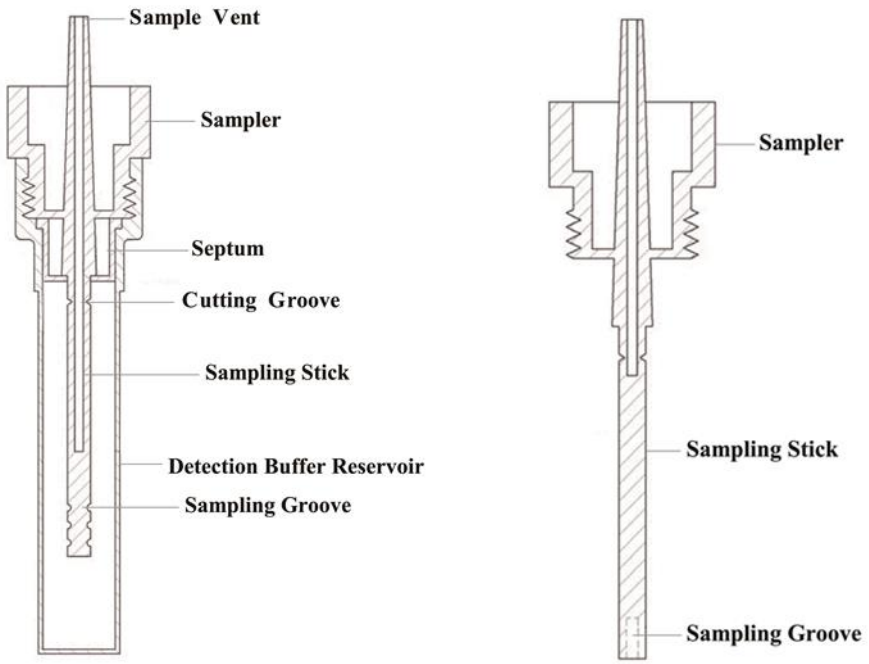


Figure 11.2: Diagram of *i*-CHROMA iFOB Sample Collection Tube

The sample collection tube is made up of two distinct and detachable components viz. the '**Detection Buffer Reservoir**' and the '**Sampler**'.

The **Detection Buffer Reservoir** is a cylindrical, near-transparent, plastic container similar in shape to a test tube which acts as the vessel for the detection buffer as well as its mixture with the fecal sample.

The open end of the detection buffer reservoir is enlarged and threaded on the inner surface so as to screw-in the sampler.

Just below the enlarged, and threaded open-end of the detection buffer reservoir, a '**Septum**' in the form of a small, cylindrical disc-like, plastic structure with a minute aperture at its center; has been fitted inside the detection buffer reservoir. This septum wipes the excess fecal material from the sampling stick when it passes through the aperture of the septum after sampling. Secondly, as the sampling stick exactly fits into this aperture of the septum, it prevents the mixture of the fecal sample and the detection buffer from splashing out of sample collection tube during shaking/mixing.

The **Sampler** is somewhat an inverted umbrella-like plastic structure. The sampler is in the form of a long stalk called as the '**Sampling Stick**', the upper end of which passes through a '**Cap**' The lower portion of the cap is threaded. It is this threaded portion which screws-in the sampler into the detection buffer reservoir.

The upper $^{2}/_{3}^{rd}$ portion of the sampling stick has been actually made into a hollow tube while the basal $^{1}/_{3}^{rd}$ portion is non-hollow. The surface of the sampling stick in lowermost part of this basal portion is grooved which is called as '**Sampling Grooves**'.

For sampling, the cap is unscrewed and the sampler/sampling stick is removed from the sample collection tube. While removing the sampling stick, the septum remains fitted inside the detection buffer reservoir otherwise there is possibility of the detection buffer spilling out of the reservoir.

The grooved end of the sampling stick is inserted into the fecal sample at 5~6 different sites so as to ensure a representative sampling. Sampling grooves on the sampling stick should be covered with sufficient fecal sample while ensuring that the quantity is not too much.

The sample-ridden sampling stick is then inserted back into the sample collection tube and the cap of the sampler is screwed-in tightly. The excess fecal material is wiped off from the sampling stick when it passes though the septum of the detection buffer reservoir. At this stage, the sampling system of *i*-CHROMA iFOB delivers the fecal material into detection buffer already present in the sample collection tube.

Contents of the sample collection tube are shaken well and mixed thoroughly to yield a homogenous suspension for complete extraction of the fecal sample. Fecal sample mixture thus obtained; should be kept standing at least for 10 minutes. Fecal sample thus mixed with the detection buffer in the sample collection tube is stable for 72 hours if stored at ambient temperature (up to 37° C) and for 96 hours if stored at 2~8 °C in a refrigerator. However it is strongly recommended that fecal sample mixture should be tested immediately or as early as possible after it is collected and submitted by the patient to the laboratory.

Before loading the fecal sample mixture into the sample well of the *i*-CHROMA iFOB test cartridge, the sample collection tube is held in vertical position and the sampling stick is cut by bending it the 2-3 times just below the cap i.e. at the '**Cutting Groove**' which is the first designated point below the cap as shown in the figure above. The sample collection tube must be held in an upright position during this stick-cutting process.

After the stick-cutting process, the basal non-hollow portion of the sampling stick will remain suspended in the fecal sample mixture while its upper hollow tube-like portion will now open into the detection buffer reservoir.

The fecal sample mixture can now be squeezed out by inverting the sample collection tube. In this position, the fecal sample mixture will squeeze out from the '**Sample Vent**' of the sampler.

Three drops of the fecal sample mixture are loaded into the sample well of the *i*-CHROMA iFOB test cartridge. The sample-loaded test cartridge is then immediately inserted in the cartridge holder of the *i*-CHROMA Reader which scans it after 10 minutes (as per the default reaction time setting i.e. Single Mode) to compute and display the test result.

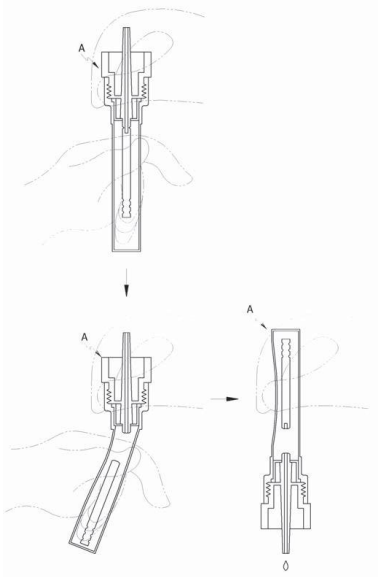


Figure 11.3: Using the *i*-CHROMA iFOB Sample Collection Tube

i-CHROMA iFOB Test Principle:

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology as depicted in **Figure 11.4**.

When a human fecal sample is mixed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer bind with hemoglobin in the fecal occult blood (FOB).

When the fecal sample mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, the fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, the more hemoglobin in the human fecal sample, the more complexes get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the

intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

i-CHROMA iFOB and *i*-CHROMA Reader are compatible only with each other.

(b)(4)Trade Secret Process - Product Specs

[redacted]

Figure 11.4: Principle of *i*-CHROMA iFOB

i-CHROMA Reader:

Introduction:

i-CHROMA Reader is a custom-configured, portable, desktop, fluorescence-scanning instrument for qualitative detection of fecal occult blood (FOB) in human fecal samples; duly processed and tested by *i*-CHROMA iFOB. Upon upgrading the software, *i*-CHROMA Reader can also be used for quantitative determination of various other analytes/disease markers when used in conjunction with other *in vitro* diagnostic immunoassay tests manufactured by Boditech Med Inc. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other.

i-CHROMA Reader is intended to be used only in conjunction with *i*-CHROMA iFOB for *in vitro* diagnostic purpose by laboratories and physician offices. *i*-CHROMA Reader measures 250 mm (L) x 185 mm (W) x 80 mm (H) in size and weighs 1.2 Kg.

i-CHROMA iFOB test cartridge is loaded with human fecal sample which has been duly mixed with the detection buffer in the '*i*-CHROMA iFOB sample collection tube' as per the standard test procedure recommended by Boditech Med Inc. This sample-loaded test cartridge is inserted in to the cartridge holder of *i*-CHROMA Reader for the purpose of being scanned.

i-CHROMA Reader is designed to extract designated information off the sample-loaded *i*-CHROMA iFOB test cartridge (manufactured by Boditech Med Inc.). *i*-CHROMA Reader includes specific components required to perform this task in a preprogrammed manner.

The *i*-CHROMA iFOB test cartridge contains a test line and a control line which have been tagged with the capture antibodies. Complexes of the capture antibody-analyte (FOB hemoglobin)-detector antibody accumulate at the test line on test cartridge membrane. One would need an external light source to excite these fluorochrome-labeled complexes accumulated at the test line so that they would emit characteristic radiation i.e. fluorescence. *i*-CHROMA Reader uses a semiconductor diode laser as the excitation light source.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin (accumulated at the test line). The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration. The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

The 'ID Chip' provided with *i*-CHROMA test cartridge(s) contains a memory device which contains encoded calibration data. An ID chip having a lot number matching with that of the test cartridge and the sample collection tube is inserted into the designated port of the *i*-CHROMA Reader which utilizes the calibration data for computing the test result(s). Hence the user is not required to perform routine calibration before performing the test.

Regarding prior FDA clearance of *i*-CHROMA Reader:

i-CHROMA Reader has received prior clearance from FDA as the associated instrument of the ***i*-CHROMA CRP Test which has been cleared by FDA** vide **the 510(k) number k062981**

Risk Control Measures Incorporated in *i*-CHROMA iFOB Test System

Risk management has been used for proper identification and effective control of error sources which may be associated with the intended use of *i*-CHROMA iFOB.

Appropriate risk control measures in the form of fail-safe and/or failure alert mechanisms have been incorporated in *i*-CHROMA iFOB test system.

These fail-safe and failure alert mechanisms help assure that *i*-CHROMA iFOB test has an insignificant risk of an erroneous result.

Various fail-safe and/or failure alert mechanisms incorporated in *i*-CHROMA iFOB test system can be broadly classified as follows:

- Appropriate design and physical features to prevent operator errors
- Electronic controls in *i*-CHROMA Reader
- Mechanism for identification and validation of *i*-CHROMA iFOB ID chip
- Unique barcode and mechanism for identification/validation of *i*-CHROMA iFOB test cartridge
- Procedural/Internal control of *i*-CHROMA iFOB
- *i*-CHROMA iFOB external controls

Various fail-safe & failure alert mechanisms and other risk control measures incorporated in the *i*-CHROMA iFOB test system have been described in detail in following appendices:

Appendix VI: System Information and Clinical Testing for CLIA Waiver Application of *i*-CHROMA iFOB

Appendix VII: Risk Analysis of *i*-CHROMA iFOB Test System

Section 12: Substantial Equivalence Discussion

Device Information:

Trade Name: *i*-CHROMA iFOB with *i*-CHROMA Reader
Common Name: *i*-CHROMA iFOB
Manufacturer: **Boditech Med Inc.**
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: psy@boditech.co.kr
Website: www.boditech.co.kr

Predicate Information:

Trade Name: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer
510(k) Number: **K041408**
510(k) Holder: **Polymedco Inc.**
510 Furnace Dock Rd,
Cortlandt Manor, NY 10567,
USA.
Phone: 1-800-431-2123 or 914-739-5400
Fax: 914-739-5890

Comparison with the Predicate Device:

Following table summarizes similarities and difference between the test device *i*-CHROMA iFOB and the predicate device OC Auto Micro FOB Test.

SIMILARITIES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Nature of the Test	Rapid, convenient, sensitive and reliable *in vitro* diagnostic test	Rapid, convenient, sensitive and reliable *in vitro* diagnostic test
2	Intended Use	Qualitative detection of fecal occult blood (FOB) in human fecal samples by laboratories and physician offices	Qualitative detection of fecal occult blood in feces by professional laboratories
3	Indications for Use(s)	Routine physical examination when gastrointestinal bleeding may be suspected	(1) Routine physical examinations, (2) Monitoring for bleeding in patients, and (3) Screening for colorectal cancer or gastrointestinal bleeding.

4	User(s)	Laboratories and physician offices	Professional laboratories
5	Test Sample	Human fecal sample mixed with detection buffer in the sample collection tube	Feces in an extraction buffer
6	Test Principle	Immunological test system based on fluorescence technology for qualitative detection of human hemoglobin in human fecal samples.	Immunological test system intended for qualitative detection of fecal occult blood in feces
7	Special Instrument Requirement	'*i*-CHROMA Reader' for scanning the *i*-CHROMA iFOB test cartridge which has been loaded with the fecal sample mixed with the detection buffer	'Polymedco OC Auto Micro 80 Analyzer' on which the 'OC Auto Sampling Bottle(s)' containing the fecal sample(s) are placed for performing the automated test
8	Work Flow	Normally, patient receives 'Patient Pack' and the sample collection tube from the laboratory/ physician office. Patient collects/transfers fecal sample in to the sample collection tube and submits it to the laboratory/physician office for testing. Occasionally, the physician office / laboratory may receive fecal sample which has been submitted by the patient in a specimen cup or other suitable container.	Fecal sample is collected/transferred by the patient in to the sampling bottle which is sent to the professional laboratory for testing.
9	Sampling / Mixing the sample with detection buffer	Sampling is done with the help of the 'Sampling Stick' / 'Sampler' which is a part of the sample collection tube. The fecal sample is thus delivered into the sample collection tube containing the detection buffer which extracts it.	Sampling is done with the help of the 'Sampling Probe' which is a part of the 'OC-Auto Sampling Bottle'. The fecal sample is thus delivered into the sampling bottle containing the buffer which extracts it.
10	Test Cut-off	100 ng/mL (human hemoglobin in the human fecal sample mixed with detection buffer)	100 ng/mL (human hemoglobin in processed feces)
11	Presentation of Test Results	Qualitative (Positive if ≥ 100 ng/mL and Negative if < 100 ng/mL)	Qualitative (Positive if ≥ 100 ng/mL and Negative if <100 ng/mL)
12	Biohazard and Compatibility with Environment	➢ Used test cartridges and sample collection tubes should be considered as a biohazard. ➢ Test components should be handled strictly as per the instructions given in the package insert and the operation manual. ➢ Used test cartridges and sample collection tubes should be disposed of	➢ Similar handling precautions and disposal directives are prescribed

		in accordance with relevant local, state or federal regulations. ➢ If needed, the *i*-CHROMA Reader should be disposed of in accordance with applicable regulations.	by the manufacturer.
13	Compatibility with other Devices	➢ '*i*-CHROMA iFOB' and the '*i*-CHROMA Reader' are compatible only with each other for the purpose of this test system. ➢ Up on upgrading the software, *i*-CHROMA Reader can also be used for measurement of various analytes/disease markers when used in conjunction with other *in vitro* diagnostic tests manufactured by Boditech Med Inc.	➢ 'OC Auto Micro FOB Test' and 'Polymedco OC Auto Micro 80 Analyzer' are designed to be used together for the purpose of this test system.
14	Chemical Safety	If used in accordance with the warnings, precautions, instructions and procedure prescribed in the package insert, '*i*-CHROMA iFOB' has assured chemical safety profile.	'OC Auto Micro FOB Test' is reportedly safe on this count

Discussion of Similarities:

As evident from the table above *i*-CHROMA iFOB (along with *i*-CHROMA Reader) shares a very close similarity with the predicate device OC Auto Micro FOB Test (along with OC Auto Micro 80 Analyzer) when compared on different parameters related to scientific rationale, test principle, intended use(s), indications for use(s), user(s) profile, work flow, performance characteristics, effectiveness, energy used, bio-hazard and environmental compatibility, safety profile etc. This explicit similarity forms a robust foundation for substantial equivalence of *i*-CHROMA iFOB (along with *i*-CHROMA Reader) to the predicate device.

DIFFERENCES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Platform/ Format	Lateral flow chromatographic fluorescence immunoassay	Automated immunoassay using latex fixation
2	Test Components	➢ *i*-CHROMA iFOB Test Cartridge ➢ *i*-CHROMA iFOB Sample Collection Tube containing the Detection Buffer ➢ *i*-CHROMA iFOB ID Chip which	➢ Closed tube-type Sampling Bottle containing the Extraction Buffer ➢ Test Reagents (Latex reagent, Buffer, Negative & Positive Controls, Wash Concentrate, and

		contains encoded calibration data **&** ➢ *i*-CHROMA Reader	Calibrator) **&** ➢ OC Auto Micro 80 Analyzer
3	Test Device	Test Cartridge (Test strip enclosed in a plastic housing)	Sampling Bottle containing an extraction buffer
4	Detection Mechanism	Involves scanning/measurement of intensity of fluorescence on the processed sample-loaded test cartridge membrane	Involves optical measurement of agglutination of latex particles

Discussion of Differences:

i-CHROMA iFOB (along with *i*-CHROMA Reader) differs from the predicate device OC Auto Micro FOB Test (along with OC Auto Micro 80 Analyzer) with respect to the test platform/format, test device & components and detection mechanism.

However, these differences are in accordance with the respective technology platforms on which the test device and the predicate device are based.

i-CHROMA iFOB is a fluorescence immuno-chromatographic assay based on lateral flow format while OC Auto Micro FOB Test is an automated immunoassay using latex fixation. The lateral flow technology is a quite well-established and proven platform for development of modern rapid, sensitive, reliable and user-friendly *in vitro* diagnostic tests.

i-CHROMA iFOB differs from the predicate device in terms of test components. In *i*-CHROMA iFOB, the test components are viz. a 'Test Cartridge', a 'Sample Collection Tube containing Detection Buffer', an 'ID Chip' and the '*i*-CHROMA Reader' while in OC Auto Micro FOB test, the test components are: a closed tube-type 'OC-Auto Sampling Bottle containing Extraction Buffer', 'Test Reagents' (Latex Reagent, Buffer, Negative & Positive Controls, Wash Concentrate, and Calibrator) and the 'OC Auto Micro 80 Analyzer'.

i-CHROMA iFOB test cartridge and the sample collection tube (containing the detection buffer) collectively carry out the function which is analogous to the role of OC-auto sampling bottle (containing the extraction buffer) and the latex & buffer reagent provided as a part of the predicate test.

In case of *i*-CHROMA iFOB, the ID chip contains encoded calibration data. An ID chip having a lot number matching with that of the test cartridge and the sample collection tube; is inserted into the designated port of the *i*-CHROMA Reader which utilizes the calibration data for computing and converting the test result. In case of OC Auto Micro FOB test, calibration curve needs to be plotted for each measurement by serially diluting the primary calibrator and plotting the known concentrations of human hemoglobin in the control dilutions against the corresponding absorbance values.

i-CHROMA iFOB Control reagents are supplied on demand separately from the test components while negative & positive controls are supplied as components of the OC Auto Micro FOB test.

i-CHROMA iFOB test cartridge (loaded with a test sample processed with the detection buffer) is to be inserted in the *i*-CHROMA Reader which scans it and automatically displays the test result. In case of the predicate device, similar role is played by the OC Auto Micro 80 Analyzer. OC-auto sampling bottle(s) containing the extracted fecal sample(s) is placed on the rack(s) of the OC Auto Micro 80 Analyzer which performs the automated immunoassay and displays the test result.

Thus it is undoubtedly established that above differences neither deviate *i*-CHROMA iFOB from being substantially equivalent to the predicate device nor adversely affect the performance, effectiveness and safety of *i*-CHROMA iFOB in any manner.

Conclusions:

In view of the matter mentioned above, it can be positively concluded that *i*-CHROMA iFOB is substantially equivalent to the predicate device OC Auto Micro FOB Test.

Section 13: Proposed Labeling

A. Labels of Test Components and Accessories

1) Test Cartridge Box Label:

(Outer packaging label)

i-CHROMA iFOB

Intended Use: Fluorescence immunochromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples by laboratories and physician offices

This box contains:

Item	Quantity
i-CHROMA iFOB Test Cartridges	25
i-CHROMA iFOB ID Chip	1
Package Insert	1
Quick Reference Instructions Sheet	1

Lot No.: FOXGA06 (Example)
Expiration Date: 06.05.2015 (Example)
(Date. Month.Year **)**

- For *in vitro* diagnostic use only
- Store sealed test cartridges at 4ºC~30ºC.
- Read the package insert carefully and follow the instructions and procedure mentioned therein before performing the test.

Test results should not be considered valid and accurate unless supported or corroborated with acceptable tests results with *i*-CHROMA iFOB Controls.

Manufactured by:

Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr
Website: www.boditech.co.kr

2) Test Cartridge Pouch Label:

(Immediate packaging label)

i-CHROMA iFOB Test Cartridge

- For *in vitro* diagnostic use only
- Store sealed test cartridge at 4 ~ 30°C.
- If stored in a refrigerator, allow a minimum of 30 minutes for the sealed test cartridge to attain room temperature prior to performing the test.
- Do not unseal the test cartridge until just prior to performing the test.

Lot No.: FOXGA06 (Example)
Expiration Date: 06.05.2015 (Example)
(Date. Month.Year **)**

Manufactured by:
Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr
Website: www.boditech.co.kr

3) ID Chip Label:

	ID Chip
Face	**iFOB**
	LOT: FOXGA06 (Example)
	***i*-CHROMA™**
Back	**ID Chip**

4) Sample Collection Tube Box Label:

(Outer packaging label)

i-CHROMA iFOB
Sample Collection Tube

This box contains:

Item	Quantity
i-CHROMA iFOB Sample Collection Tubes (Each containing 1 mL Detection Buffer)	25

Lot No.: FOXGA06 (Example)

Expiration Date: 06.05.2015 (Example)

(Date. Month.Year **)**

- For *in vitro* diagnostic use only
- A sample collection tube is meant for mixing the fecal sample with detection buffer.
- Store the sample collection tubes in a refrigerator at 2ºC~8ºC
- Allow a minimum of 30 minutes for the sample collection tube to attain room temperature prior to performing the test.
- Please read the package insert carefully and follow the instructions and procedure mentioned therein before performing the test.

Manufactured by:

Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr
Website: www.boditech.co.kr

5) Sample Collection Tube Label:

(Immediate container label)

i-CHROMA iFOB

Sample Collection Tube

Lot No.: FOXGA06 (Example)
Exp. Date: 06.05.2015 (Example)
(Date. Month.Year **)**

Patient Name: …….
Date of Birth: ……..(MMDDYY)
Gender: …….
Time of Collection: …… (Hour: Minute am/pm)
Date of Collection: ……(MMDDYYY)

6) *i*-CHROMA iFOB Patient Pack Label

(Outer packaging label)

CHROMA iFOB Patient Pack

This patient pack contains:

- 1 Patient Instructions Leaflet (for sampling instructions)
- 1 Sample Collection Paper (for fixing onto the toilet bowl)
- 1 Sample Sac containing an absorption pad (for enclosing the sample collection tube after sampling)
- 1 Return Envelop (for submitting the sample collection tube to the laboratory/physician office for testing)

Important:

- Laboratory/Physician office should place one '*i*-CHROMA iFOB Sample Collection Tube' inside the 'Sample Sac' before handing over this patient pack to the patient.
- Do not remove the absorbent strip from the sample sac.

7) Sample Sac Label

SAMPLE SACK

Have you entered 'Patient Information' on the label of Sample Collection Tube?

- Place sample collection tube into this sack.
- Remove blue colored tape from the nick area.
- Fold at the dashed line marked along the nick.
- Press firmly to seal.

Do not remove the absorbent strip from this sample sack.

Clinical Specimen
(Human Fecal Sample)

8) Return Envelope Label

From: _____

_____

_____

Apply 1st Class Postage	Apply 1st Class Postage	Apply 1st Class Postage	Apply 1st Class Postage

Contents: Diagnostic Test Sample

Date of Collection: _____

Time of Collection: _____

Return To: _____

_____

_____

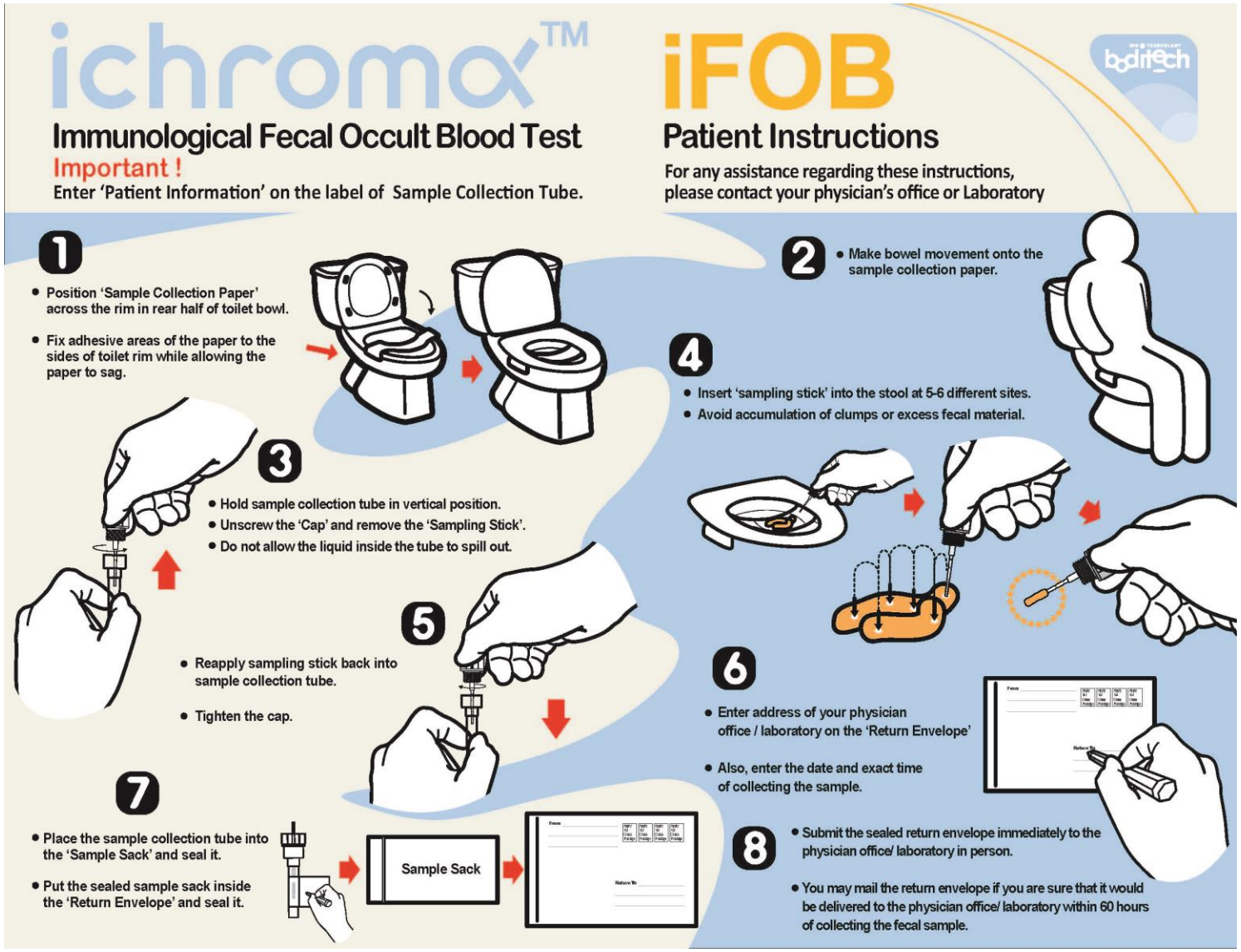
Instructions:

1. Put the sealed sample sack inside this return envelope.
2. Remove the green colored tape.
3. Fold at the dashed line.
4. Press firmly to seal.
5. Submit immediately to the physician office/laboratory in person.
6. You may mail this envelope if you are sure that it would be delivered to the physician office/laboratory within 60 hours of collecting the fecal sample.

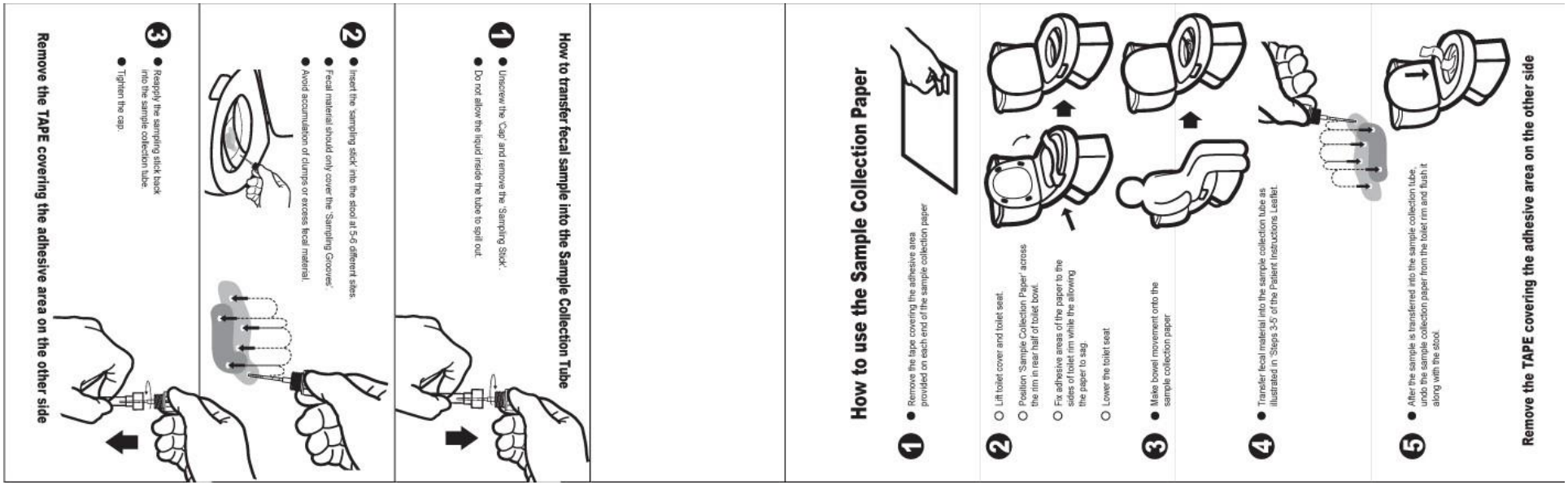
Note: Use of paper envelopes for mailing diagnostic test samples is prohibited by US Postal Service regulations. Hence, use only this envelope approved by US Postal service, for mailing the test sample.

B. Instructional Materials

1) Patient Instructions Leaflet:



2) Sample Collection Paper:



3) *i*-CHROMA iFOB Package Insert:

Please refer to '**Appendix II**: *i*-CHROMA iFOB Package Insert'

4) *i*-CHROMA iFOB Quick Reference Instructions:

Please refer to '**Appendix III**: *i*-CHROMA iFOB Quick Reference Instructions'

5) *i*-CHROMA iFOB Controls Package Insert:

Please refer to '**Appendix IV**: *i*-CHROMA iFOB Controls Package Insert '

6) *i*-CHROMA Reader Operation Manual:

Please refer to '**Appendix V**: *i*-CHROMA Reader Operation Manual '

Section 14: Sterilization and Shelf Life

Sterilization:

(b)(4)Trade Secret Process - Product Specs

[redacted]

(b)(4)Trade Secret Process - Product Specs

[redacted]

Software Validation Report

Report No. : SF.VL.01 (Rev.4)

Prepared by: 2013.12.27

Approved by: 2013.12.30

Boditech Med Inc.

(b)(4)Trade Secret Process - Software Validation Report

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Appendix I: *i*-CHROMA iFOB System Information

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1. Background

1.1 Lateral Flow Assay

Immunoassays have been widely used in many important areas of medical practice and pharmaceutical industry such as diagnosis of diseases, therapeutic drug monitoring, clinical pharmacokinetic and bioequivalence studies in drug discovery since the mid-1960s. Clinical immunoassays in connection with medical diagnosis are usually performed either in central laboratorie(s) of hospitals or clinics using a variety of instrument-based technologies or on-site/near-patient (also known as point-of-care/POC) using rapid test techniques.

Rapid immunoassays are commonly designed in two configurations. First type is the 'Flow-through System', which involves multiple steps. The test device based on flow-through mechanism generally uses a reagent-containing matrix layered on a porous material. Test sample is applied to and flows through the porous material, and analyte in the sample reacts with the reagent(s) to produce a detectable signal on the porous material. These devices are generally encased in a plastic housing or casing with calibrations to aid in the detection of the particular analyte. The test procedure may take as long as 20 minutes. One sample is tested per test device.

The second type of rapid immunoassays is the 'Lateral Flow System' which is a single step technique. The test device based on lateral flow mechanism also uses a porous membrane for performing analyte detection. However, instead of drawing the sample through the membrane perpendicularly, the sample is permitted to flow laterally from an application zone to a reaction zone on the membrane surface. The capture reagent is present in the reaction zone, and the captured analyte can be detected by a variety of protocols, including direct visualization of visible moieties associated with the captured analyte. Tests results are obtained in 10-30 minutes after loading the test device with the sample. Lateral flow test devices can be designed so as to test for a single or multiple analyte(s).

As the flow-through type immunoassay involves multiple steps and requires greater operational skill, this format is less commonly used as compared to the lateral flow type.
Lateral flow tests; also known as immunochromatographic strip tests have been a popular tool for performing rapid immunoassays since their introduction in the mid-1980s. Lateral flow tests have been developed using combinations of various features. Hence it is customary to accept a broad definition of lateral flow tests to include any immunochromatographic strip test/device based on fluid migration or flow technology using a paper, nitrocellulose or similar support material with or without being enclosed in a housing/casing. Further, it may be used for testing a single or multiple analyte(s) and the test device may be read either manually or by using an instrument or reader. The lateral flow format is thus so versatile that rapid immunoassay test manufacturers have developed these tests for variety of situations requiring rapid testing.

At present, lateral flow tests are widely used for diagnostic purposes in hospitals, clinics,

physician offices, and clinical laboratories. They are meant for the qualitative and quantitative detection of a wide variety of antigens and antibodies in various biological samples including whole blood, plasma, serum, urine, saliva, sweat, tears, biopsied tissue and fluids. They are also used in veterinary medicine. Apart from diagnostic purposes, lateral flow tests offer an important tool in manufacturing, quality control and product safety assurance in pharmaceutical, biologics and food production. These tests also find important applications in water safety evaluation and environmental testing. More recently lateral flow tests are being developed to measure the products of nucleic acid amplification.

Lateral flow immunochromatographic tests have proved to be an ideal tool for variety of applications by virtue of their following features:

- Simple and user-friendly design/format which enables use by non-technical or non-laboratory personnel and thus supporting point-of-care/home testing
- Minimal operator-dependent steps and easy interpretation of test results
- Short processing time (5-30 minutes to get the results) offers rapid testing
- High sensitivity, specificity and accuracy
- Good stability with shelf-lives of 12-24 months mostly without necessitating refrigeration
- Requires very small volumes of test samples
- Amenable to various types of test samples
- Versatility of applications

Favorable technological and commercial aspects of the lateral flow tests include:

- Established technology which can be integrated with on-board electronics, reading instrument system and information systems
- Relative ease of manufacture because of already developed equipment and processes
- Prospects of easy scale-up to high-volume production
- Relatively low cost and short timeline of product development and regulatory approval
- Huge market potential

Combined with the principles of thin layer and paper chromatography, the development of lateral flow immunoassays is the result of convergence of several technological landmarks tracing back to the 1950s with the invention of first antigen-antibody radioimmunoassay (RIA) reaction by Burson and Yallow. The enzyme immunoassays (EIA) introduced in the 1960s offered significant advantages over the radioimmunoassay in respect of replacement of radioisotopes with enzymes, higher specificities, faster reaction times and longer shelf-lives. The lateral flow technology continued to be refined over the years and established firmly in the late 1980s with the filing of several patents on the lateral flow technology platform. Significant amongst them were those filed by Becton Dickinson & Co, Uniliver and Carter Wallace. Since then over 500 patents have been filed on various aspects of this technology.

The trend towards more decentralized healthcare delivery obviously resulted in the decentralization of laboratory diagnostic services as well. Immunoassays account for approximately 30% of all marketed diagnostic tests. Technological innovations in lateral flow tests have facilitated the move to bring diagnostic testing closer to the patient—be it at home, at work place, in the hospital bedside or the pharmacy. The pharmacies and retail shopping malls are rapidly becoming the focal point for Over-the-Counter (OTC) testing and screening related to heart diseases and diabetes. In current scenario, most of the marketed Point-Of-Care Testing (POCT) systems cover infectious diseases, life style-related conditions like cardiac diseases and diabetes, fertility issues like pregnancy detection and drug abuse detection/monitoring.

Furthermore, the noteworthy aspect of almost all of these lateral flow immunoassays tests is the use of single-use test devices. It is not realistic to expect that any medical practice or clinic would have the storage space, inventory control system and inclination to keep some 20 to 30 different test devices on hand. Therefore considerable research has been ongoing for the past 15 years for a multipurpose POCT platform for lateral flow immunoassays.

Remote monitoring and testing of patients-at-risk; both at home and in hospitals or clinics; is fast-emerging as a primary proactive strategy to keep individuals out of hospital emergency and acute care wards. Point-of-Care testing as the new frontier of health care delivery promises to achieve this objective. Patients with diabetes and many other chronic diseases or conditions as well as the elderly and those suffering from HIV/AIDS are being increasingly targeted for such near-patient testing.

Advances in functional genomics, bioinformatics, microelectronics and miniaturization have dramatically changed the diagnostic test technology in recent years. Improvements in the biomedical engineering-based clinical devices with inputs derived from the information and computer technologies have been opening up new markets for rapid diagnostic test products. Global economic instability and rising healthcare costs coupled with increasing demand for rapid test results to reduce the need and duration of hospitalization has further influenced the development of rapid diagnostic test products. Near-patient testing is one of the most rapidly growing segments as the tests that were once carried out in central laboratories; are now available as near-patient tests. All these factors would have a further positive impact on research, development and commerce of POCT segment.

Though the market is witnessing commercial unveiling of newer and newer near-patient, rapid diagnostic test products based on advanced lateral flow technologies, POC testing has still a long way to go so far its worldwide coverage is concerned. Globally about 10% of the immunoassay-based diagnostic tests are performed in settings other than a hospital or commercial laboratory. In the U.S. alone, there are approximately 41,000 small to medium-sized physician office practices and freestanding alternate-site laboratories, which are licensed under Clinical Laboratory Improvement Amendments (CLIA) for high or moderate complexity testing. Most of these sites do not currently have

immunodiagnostic testing capability. The potential for POC testing and lateral flow immunoassays is enormous and new hope has been placed in microchip and miniaturized systems in this context.

All these terms such as decentralized, rapid, near-patient, point-of-care testing etc. refer to an approach to diagnostic testing that uses light weight, readily portable and easy-to-use devices; designed to perform complex biological tests at the site where they are needed most. Traditionally these tests are usually performed in laboratories equipped with large instruments. The main market-driving force behind the POCT diagnostic products is the enhanced portability and networking capabilities that allow rapid immediate patient care. So far, the commercialization such portable diagnostic devices for POC testing has been restrained by the lack of suitable miniaturized, low power consuming, optical detection systems.

Membrane lateral flow is the technology most commonly adopted in rapid disposable POCT systems. This technology lacks desired sensitivity and in most cases provides only qualitative or Yes/No type test results. Testing of new analytes will not be shifted to POC settings until the results are comparable with those obtained with the tests performed in the central laboratory systems. This would obviously require quantitative measurement of analyte(s) in the test samples. Membrane lateral flow is generally appropriate for qualitative assays, but for technical reasons it does not lend itself to quantitative assays.

The success of lateral flow technology-based POCT techniques depends on the evolution of the technology but is also influenced by how POCT market unfolds. Miniaturization of traditional diagnostic techniques has led to the introduction of a number of innovative point-of-care tests and devices. *In vitro* diagnostics manufacturers have developed and are designing technological innovations that provide more patient-friendly, cost-effective, multiplexed POC testing platforms coupled with high-end software capabilities. Decentralized testing directives aimed at nearer-the-patient testing coupled with newer healthcare trends and novel therapeutics are set to redefine and refocus the role of laboratory diagnostic services in healthcare.

Though development of new age microchip-based diagnostic POCT systems has been a considerably challenging issue, miniaturization of conventional laboratory tests is not new as best exemplified by the Glucose Meter for self-testing of blood glucose by patients and individuals. Such miniaturized versions of conventional laboratory tests are already available for about 70 analytes and there are at least 50 companies selling these miniaturized test products around the world. Development of molecular biology-based tests, decentralization of out-patient testing, increased self-testing and trend towards home-patient testing are fuelling the demand for miniaturization of POCT products and thereby for the next generation of more sophisticated diagnostic devices commonly referred to as chips.

Modern medicine is entering an era characterized by emergence of biomedical therapeutics and devices utilizing the principles of genomics, bioinformatics and miniaturization/ portability of medical devices. These frontiers of medical science are set to revolutionize the diagnosis, treatment and monitoring of diseases such as Alzheimer's

disease, rheumatoid arthritis, cancer, heart diseases, HIV/AIDS, hepatitis C, other contagious and hereditary diseases. Clinical/laboratory testing play a critical role in post-genomic medicine. Molecular immunoassays and cell-based tests are beginning to prove their role in the earlier diagnosis of diseases, improvement in drug efficacy and physicians' ability to monitor the success of the chosen intervention.

Newer diagnostic test methodologies mainly include the DNA probe tests for viruses, bacteria, genetic markers etc. as well as blood and cell-based tests for disease-specific markers such as those for diabetes, cancer, osteoporosis, arthritic conditions and cardiac disease. These new tests would allow physicians to tailor therapeutics derived from combinatorial chemistry, antisense therapy and gene therapies for specific patient and disease. Increased knowledge of disease physiology derived from molecular biology and human genome studies will enhance the position of analytes used in chronic conditions such as cardiovascular disease, autoimmune disorders and diabetes. The function of genes is measured by presence of tangible products - proteins of every size and molecular structure. Thus immunoassays combined with DNA probe studies will have an important place in the new era of disease-based medicine.

For POC tests to become more meaningful and more acceptable to healthcare professionals, they must combine the benefits of new miniaturized technologies with digital capture of test results which are then correlated to algorithms embedded in the device chips which further transform a unique set of test data into an actionable piece of information. A step further would be to make home-testing for chronic diseases interactive so that the patient can be advised to take action when necessary. Similarly, POC information systems can aid the physicians in determining the significance of a laboratory test result. However, all new immunoassays and especially those designed for rapid testing will have to prove themselves on the parameters of medical research, health economics and improved patient outcomes.

1.2 Fecal Occult Blood test

(b)(4)Trade Secret Process - Software Validation Report

[redacted]

(b)(4)Trade Secret Process - Software Validation Report

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2. *i*-CHROMA iFOB

2-1 Introduction

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

i-CHROMA iFOB is an *in vitro* diagnostic test intended to be used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology wherein the antigen-antibody complexes formed after mixing the test sample with the detection buffer are captured while migrating through the test cartridge which is scanned by the *i*-CHROMA Reader to compute, convert and display the test result in a qualitative (positive or negative) manner.

2-2 Components of *i*-CHROMA iFOB:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer' and *i*-CHROMA Reader.

- The test cartridge contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.

- The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each sample collection tube contains 1 mL detection buffer. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

- *i*-CHROMA Reader is a fluorometer instrument which scans the sample-loaded *i*-CHROMA iFOB test cartridge and displays the test result. *i*-CHROMA Reader and *i*-CHROMA iFOB test cartridge are compatible only with each other. *i*-CHROMA Reader is marketed/supplied separately on demand.

- The ID chip contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

- Additionally, 'Patient Packs' are provided along with the test cartridge box and also separately on demand.

  Each 'Patient Pack' contains following items:

  - 1 Patient Instructions Leaflet (for sampling instructions)
  - 1 Sample Collection Paper (for fixing onto the toilet bowl)
  - 1 Sample Sac containing an absorption pad (for enclosing the sample collection tube after sampling)
  - 1 Return Envelop (for submitting the sample collection tube to the laboratory/ physician office for testing)

2-3 *i*-CHROMA iFOB Test Cartridge Format and Structure:

i-CHROMA iFOB test cartridge is composed of a test strip enclosed in a disposable plastic housing.

The components of the test strip are:

- An antibody-immobilized nitrocellulose membrane
- A sample pad
- An absorption pad (also called absorbing pad or absorbent pad)
- A plastic backing

(b)(4)Trade Secret Process

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(b)(4)Trade Secret Process

[redacted]

Figure 1:Structure and Format of *i*-CHROMA iFOB Test Cartridge

2-4 *i*-CHROMA iFOB Sample Collection Tube:

Sample Collection Tube is an essential component of *i*-CHROMA iFOB. A box containing 25 pre-filled sample collection tubes is delivered separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

The sample collection tube is a specially designed plastic container. Each sample collection tube contains 1mL Detection Buffer. Apart from being the container for the detection buffer, the sample collection tube serves the following purposes:

i) Proper sampling of the fecal sample
ii) Thorough mixing of the fecal sample with the detection buffer for ensuring complete extraction of the fecal sample
iii) Application of precise quantity of the fecal sample mixture into the 'Sample well' of the *i*-CHROMA iFOB test cartridge

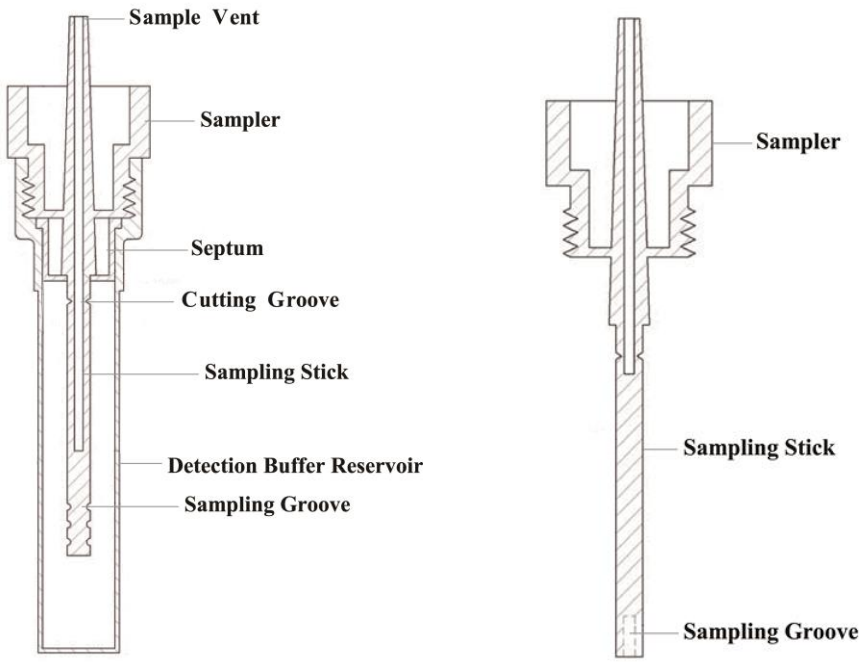

Figure 2: Diagram of *i*-CHROMA iFOB Sample Collection Tube

The sample collection tube is made up of two distinct and detachable components viz. the '**Detection Buffer Reservoir**' and the '**Sampler**'.

The **Detection Buffer Reservoir** is a cylindrical, near-transparent, plastic container similar in shape to a test tube which acts as the vessel for the detection buffer as well as its mixture with the fecal sample.

The open end of the detection buffer reservoir is enlarged and threaded on the inner surface so as to screw-in the sampler.

Just below the enlarged, and threaded open-end of the detection buffer reservoir, a '**Septum**' in the form of a small, cylindrical disc-like, plastic structure with a minute aperture at its center; has been fitted inside the detection buffer reservoir. This septum wipes the excess fecal material from the sampling stick when it passes through the aperture of the septum after sampling. Secondly, as the sampling stick exactly fits into this aperture of the septum, it prevents the mixture of the fecal sample and the detection buffer from splashing out of sample collection tube during shaking/mixing.

The **Sampler** is somewhat an inverted umbrella-like plastic structure. The sampler is in the form of a long stalk called as the '**Sampling Stick**', the upper end of which passes through a '**Cap**' The lower portion of the cap is threaded. It is this threaded portion which screws-in the sampler into the detection buffer reservoir.

The upper $^{2}/_{3}^{rd}$ portion of the sampling stick has been actually made into a hollow tube while the basal $^{1}/_{3}^{rd}$ portion is non-hollow. The surface of the sampling stick in lowermost part of this basal portion is grooved which is called as '**Sampling Grooves**'.

For sampling, the cap is unscrewed and the sampler/sampling stick is removed from the sample collection tube. While removing the sampling stick, the septum remains fitted inside the detection buffer reservoir otherwise there is possibility of the detection buffer spilling out of the reservoir.

The grooved end of the sampling stick is inserted into the fecal sample at 5~6 different sites so as to ensure a representative sampling. Sampling grooves on the sampling stick should be covered with sufficient fecal sample while ensuring that the quantity is not too much.

The sample-ridden sampling stick is then inserted back into the sample collection tube and the cap of the sampler is screwed-in tightly. The excess fecal material is wiped off from the sampling stick when it passes though the septum of the detection buffer reservoir. At this stage, the sampling system of *i*-CHROMA iFOB delivers the fecal material into detection buffer already present in the sample collection tube.

Contents of the sample collection tube are shaken well and mixed thoroughly to yield a homogenous suspension for complete extraction of the fecal sample. Fecal sample mixture thus obtained; should be kept standing at least for 10 minutes. Fecal sample thus

mixed with the detection buffer in the sample collection tube is stable for 72 hours if stored at ambient temperature (up to 37° C) and for 96 hours if stored at 2~8 °C in a refrigerator. However it is strongly recommended that fecal sample mixture should be tested immediately or as early as possible after it is collected and submitted by the patient to the laboratory.

Before loading the fecal sample mixture into the sample well of the *i*-CHROMA iFOB test cartridge, the sample collection tube is held in vertical position and the sampling stick is cut by bending it the 2-3 times just below the cap i.e. at the '**Cutting Groove**' which is the first designated point below the cap as shown in the figure above. The sample collection tube must be held in an upright position during this stick-cutting process.

After the stick-cutting process, the basal non-hollow portion of the sampling stick will remain suspended in the processed fecal sample mixture while its upper hollow tube-like portion will now open into the detection buffer reservoir.

The fecal sample mixture can now be squeezed out by inverting the sample collection tube. In this position, the fecal sample mixture will squeeze out from the '**Sample Vent**' of the sampler.

Three drops of the fecal sample mixture are loaded into the sample well of the *i*-CHROMA iFOB test cartridge. The sample-loaded test cartridge is then immediately inserted in the cartridge holder of the *i*-CHROMA Reader which scans it after 10 minutes (as per the default reaction time setting i.e. Single Mode) to compute and display the test result.

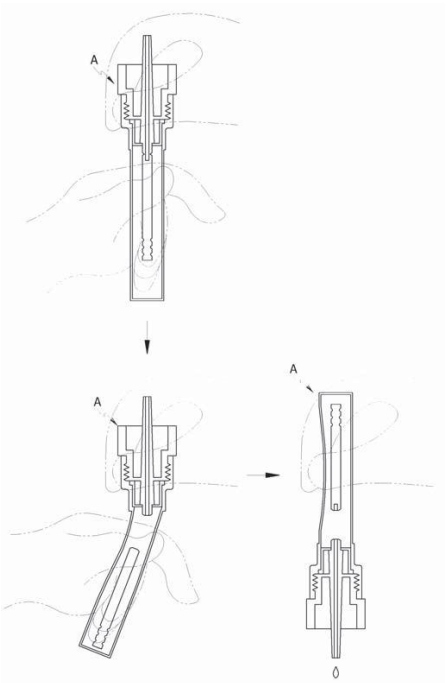

Figure 3: Using the *i*-CHROMA iFOB Sample Collection Tube

2-5 *i*-CHROMA iFOB Test Principle

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(b)(4)Trade Secret Process

[redacted]

Figure 4: Principle of *i*-CHROMA iFOB

2.6 *i*-CHROMA iFOB Test Method:

'Patient Packs' are supplied along with *i*-CHROMA iFOB test cartridge box and also separately on demand. It is recommended that the laboratory/physician office should put one '*i*-CHROMA iFOB Sample Collection Tube' into the 'Sample Sac' contained in the 'Patient Pack' before handing over the 'Patient Pack' to the patient. Patient is supposed to transfer fecal sample into the *i*-CHROMA iFOB sample collection tube at home and return it to the laboratory for testing.

Sample collection/Sampling procedure and other relevant instructions have been illustrated with help of suitable diagrams in the 'Patient Information Leaflet' provided in the patient pack.

Laboratory/physician office should also give appropriate instructions to the patient regarding sample collection/sampling procedure, entering required information on the label of sample collection tube and returning the sample collection tube to the laboratory for testing within recommended time limits.

Fecal sample thus mixed with the detection buffer in the sample collection tube is stable for 72 hours if stored at ambient temperature (up to 37° C) and for 96 hours if stored at 2° C ~8° C in a refrigerator.

Occasionally, laboratory may receive fecal samples which have been collected and submitted in specimen cups or similar containers by the patients. Such fecal samples may are stable for 48 hours if stored at ambient temperature (up to 37º C) after collection.

However, it is strongly recommended that laboratory/physician office should test the fecal sample immediately or as early as possible within the recommended time limits after it is received from the patient.

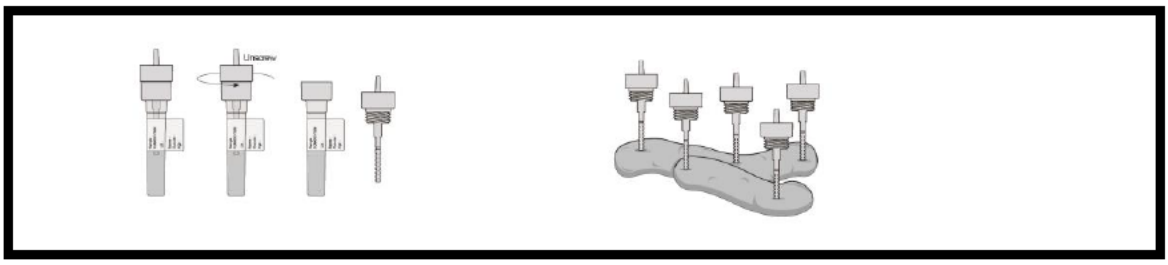
General procedure of *i*-CHROMA iFOB test is as follows:

A. Sample collection by patient:

1) Lift toilet cover and toilet seat.
2) Position and fix sample collection paper to the sides of rim in rear half of toilet bowl, allowing the paper to sag.
3) Make bowel movement on to the collection paper.
4) Do not remove the collection paper from toilet bowl until fecal sample has been transferred into the '*i*-CHROMA iFOB Sample Collection Tube' or a specimen cup.

B. Sampling by patient or test operator:

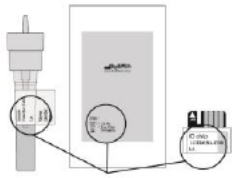
1) Enter required 'Patient Information' on the label of '*i*-CHROMA iFOB Sample Collection Tube'.
2) Unscrew the cap of sample collection tube and remove the sampler.
3) Insert sampling stick of sampler into the stool at 5-6 different sites.
4) Re-apply sampler back into sample collection tube and tighten its cap.



C. Arranging test setup:

1) Arrange following test components:
   - *i*-CHROMA iFOB Test Cartridge & ID Chip
   - *i*-CHROMA iFOB Sample Collection Tube (containing the fecal sample)
   - *i*-CHROMA Reader (attached with key pad and serial printer)

2) All these test components must have been stored properly under recommended storage conditions.
3) Check whether lot number of the ID chip is exactly same as lot numbers of the test cartridge and the sample collection tube.
4) Ensure that test cartridge and sample collection tube has not passed respective expiration dates.
5) Allow the test components to attain ambient temperature (15~37º C/59~98.6º F) for about 30 min.



D. Performing 'System Check' on *i*-CHROMA Reader:

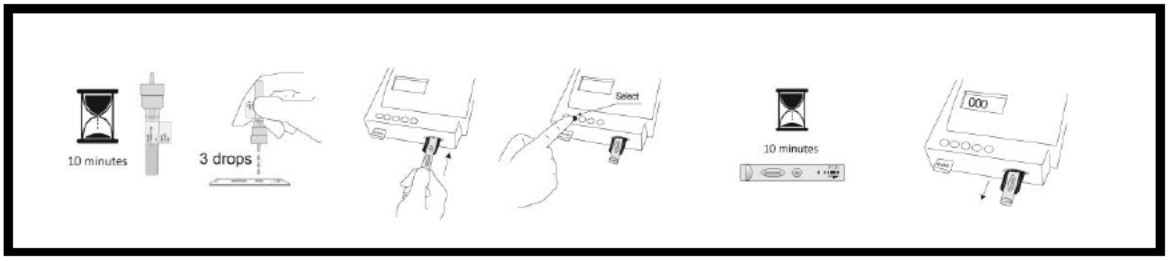
1) Arrange '*i*-CHROMA System Check ID Chip & System Check Cartridge'.
2) Turn power switch of *i*-CHROMA Reader 'On'. It will automatically display the default 'MENU'.
3) Select 'Test Mode' and insert 'System Check ID Chip' in the ID chip port.
4) *i*-CHROMA Reader ejects cartridge holder and displays the message alert 'Input Patient ID'.
5) Press 'Select' to skip inputting 'Patient ID'. Message alert 'Insert System Check Cartridge' is displayed.
6) Insert System Check Cartridge in the cartridge holder and press 'Select'.
7) *i*-CHROMA Reader should display 'System Check System OK' indicating overall normal functioning.

E. Testing the patient sample:

1) Shake the sample collection tube (containing fecal sample) about 10 times.
2) Hold it in vertical position and cut the sampling stick by bending the tube 2-3 times just below the cap.
3) Allow the sample collection tube to stand for 10 minutes in vertical position.
4) Turn power switch of *i*-CHROMA Reader 'On'. It automatically displays the default 'MENU'.
5) Select 'Test Mode' and insert '*i*-CHROMA iFOB ID Chip' in the ID chip port.
6) *i*-CHROMA Reader ejects cartridge holder and displays message alert 'Input Patient ID'.
7) Input an 11-digit patient ID correctly based on the patient information and laboratory record system in the following manner:

- First six digits for patient's date of birth e.g. enter March 9, 2014 as 030914
- Next two digits for patient's gender e.g. 01 for male and 02 for female
- Last three digits for serial number of the test as entered/to be entered in record/information management system of the laboratory e.g. enter 'Serial No. 1' as '001'

8) After inputting the patient ID, press 'Select'. Message alert 'Insert iFOB Test Cartridge' is displayed.
9) Remove the '*i*-CHROMA iFOB Test Cartridge' from its original pouch and place it on a flat surface.
10) Invert the sample collection tube and squeeze out precisely three drops of fecal sample mixture into 'Sample Well' of the test cartridge.
11) Immediately insert the sample-loaded test cartridge in the cartridge holder and press 'Select'.
12) *i*-CHROMA Reader will automatically scan the inserted test cartridge after 10 minutes and display test result.
13) If *i*- CHROMA Reader has been set to 'Multi Mode', allow the sample-loaded test cartridge to stand for exactly 10 minutes outside the *i*-CHROMA Reader.
14) After 10 minutes, insert the sample-loaded test cartridge in the cartridge holder and press 'Select'.
15) *i*-CHROMA Reader immediately scans the inserted test cartridge and displays test result.



Details of *i*-CHROMA iFOB test procedure have been described in **Appendix II:** *i*-CHROMA iFOB Package Insert and **Appendix III:** *i*-CHROMA iFOB Quick Reference Instructions

Detail information regarding operation of *i*-CHROMA Reader has been included in **Appendix IV:** *i*-CHROMA Reader Operation Manual.

Detail information regarding of *i*-CHROMA iFOB Negative & Positive Controls along with the control test procedure has been included in **Appendix V:** *i*-CHROMA iFOB Control Package Insert.

2.7 Production Process of *i*-CHROMA iFOB

(b)(4)Trade Secret Process

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[redacted]

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(b)(4)Trade Secret Process

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3 *i*-CHROMA Reader

3-1 Introduction

i-CHROMA Reader is a custom-configured, portable, desktop, fluorescence-scanning instrument for qualitative detection of fecal occult blood (FOB) in human fecal samples; duly processed and tested by *i*-CHROMA iFOB. Upon upgrading the software, *i*-CHROMA Reader can also be used for quantitative determination of various other analytes/disease markers when used in conjunction with other *in vitro* diagnostic immunoassay tests manufactured by Boditech Med Inc. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other.

i-CHROMA Reader is intended to be used only in conjunction with *i*-CHROMA iFOB for *in vitro* diagnostic purpose by laboratories and physician offices. *i*-CHROMA Reader measures 250 mm (L) x 185 mm (W) x 80 mm (H) in size and weighs 1.2 Kg.

i-CHROMA iFOB test cartridge is loaded with human fecal sample which has been duly mixed with the detection buffer in the '*i*-CHROMA iFOB sample collection tube' as per the standard test procedure recommended by Boditech Med Inc. This sample-loaded test cartridge is inserted in to the cartridge holder of *i*-CHROMA Reader for the purpose of being scanned.

i-CHROMA Reader is designed to extract designated information off the sample-loaded *i*-CHROMA iFOB test cartridge (manufactured by Boditech Med Inc.). *i*-CHROMA Reader includes specific components required to perform this task in a preprogrammed manner.

The *i*-CHROMA iFOB test cartridge contains a test line and a control line which have been tagged with the capture antibodies. Complexes of the capture antibody-analyte (FOB hemoglobin)-detector antibody accumulate at the test line on test cartridge membrane. One would need an external light source to excite these fluorochrome-labeled complexes accumulated at the test line so that they would emit characteristic radiation i.e. fluorescence. *i*-CHROMA Reader uses a semiconductor diode laser as the excitation light source.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin (accumulated at the test line). The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration. The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

The 'ID Chip' provided with *i*-CHROMA test cartridge(s) contains a memory device which contains encoded calibration data. An ID chip having a lot number matching with that of the test cartridge and the sample collection tube is inserted into the designated port of the *i*-CHROMA Reader which utilizes the calibration data for computing the test result(s). Hence the user is not required to perform routine calibration before performing the test.

3-2 Components of *i*-CHROMA Reader

Since *i*-CHROMA Reader has been designed to be a stand-alone device (although network connectivity is also supported), users would use built-in input means only by default. Following is the itemized description of various functional and operational elements which are accessible by the user of *i*-CHROMA Reader.

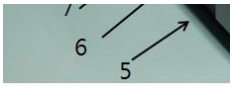
3-2-1 Function/Control Keys:

Operation of *i*-CHROMA Reader is based on five primary functions; each of which is controlled by one or more keys in the key pad provided on the front panel of the *i*-CHROMA Reader.

These keys are used to control the general settings and operation of the *i*-CHROMA Reader. One can adjust the settings, move the cartridge holder in and out of the main body of the instrument and initiate the measurement sequence. With proper combination of key sequences, one can gain access to system-level setting authority.

3-2-2 Display Screen:

The display screen consists of a LCD display device which is based on a black and white 4x18 character display module. Any pertinent information about proper operation of the system would be displayed on the display screen. These include, but not limited to, the patient ID, test result, time, temperature, software version number, procedural and error message alert if any. When in setting mode, the user would interact with the system via the information shown on the display screen.



1. Set of ‘Function/Control Keys’
2. Display Screen
3. ID Chip Port
4. Test Cartridge Port
5. Power ‘On/Off’ Switch
6. RS 232C Port
7. Power Plug Socket

Figure 6: Functional and Operational Elements of *i*-CHROMA Reader

Figure 7: Top View of *i*-CHROMA Reader

Figure 8: Side View of *i*-CHROMA Reader

3-2-3 ID Chip Port:

In Vitro diagnostic test systems are inevitably susceptible to batch-to-batch variations. *i*-CHROMA tests counter this problem by providing means of compensating for the batch-to-batch variations. For this purpose, the *i*-CHROMA test cartridge(s) is supplemented with an ID-Chip having a matching lot number.

The ID chip contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

3-2-4 Test Cartridge Port:

The test cartridge holder ejects out of the main body of *i*-CHROMA Reader from this port. After inserting the sample-loaded test cartridge into the cartridge holder, the 'Select' key is to be pressed for scanning the test cartridge by the *i*-CHROMA Reader. The cartridge holder along with the 'Test Cartridge' moves into the *i*-CHROMA Reader. After the test result is displayed on the display screen, the cartridge holder along with the test cartridge is ejected automatically and stays protruded outside the main body *i*-CHROMA Reader. Upon pressing the 'Select' key or 'In/Out' key (depending on the display message and/or stage of operation), the cartridge holder would retract into *i*-CHROMA Reader.

3-2-5 Power 'On/Off' Switch:

The power switch is provided on the right side of the *i*-CHROMA Reader.

3-2-6 RS 232C Port:

This port serves as both the input and the output port. A keypad is attached to the reader through this port for inputting an 11-digit 'Patient ID' before testing a patient sample. The test result is by default routed through this port to the printer if attached. Without the printer being attached, the output is disregarded. A 'Y' cable is provided to attach the keypad as well as the printer to the **i**-CHROMA Reader through this port. One can utilize this feature to establish a network connection so that another device would capture the printer output for further processing and share the same with other networked system(s). This port could also be used to facilitate the reception of incoming data. One would use this feature to accommodate external control of the system.

3-2-7 Power Plug Socket:

Power plug socket is provided on the right side of the *i*-CHROMA Reader adjacent to the RS232C Port and the power switch.

3-3 Regarding prior FDA clearance of *i*-CHROMA™ Reader:

i-CHROMA Reader has received prior clearance from FDA as the associated instrument of the ***i*-CHROMA CRP Test which has been cleared by FDA** vide **the 510(k) number k062981.**

4. Risk Control Measures Incorporated in *i*-CHROMA iFOB Test System

Risk management has been used for proper identification and effective control of error sources which may be associated with the intended use of *i*-CHROMA iFOB.

Appropriate risk control measures in the form of fail-safe and/or failure alert mechanisms have been incorporated in *i*-CHROMA iFOB test system.

These fail-safe and failure alert mechanisms help assure that *i*-CHROMA iFOB test has an insignificant risk of an erroneous result.

Various fail-safe and/or failure alert mechanisms incorporated in *i*-CHROMA iFOB test system can be broadly classified as follows:

- Appropriate design and physical features to prevent operator errors
- Electronic controls in *i*-CHROMA Reader
- Mechanism for identification and validation of *i*-CHROMA iFOB ID chip
- Unique barcode and mechanism for identification/validation of *i*-CHROMA iFOB test cartridge
- Procedural/Internal control of *i*-CHROMA iFOB
- *i*-CHROMA iFOB external controls

Various fail-safe & failure alert mechanisms and other risk control measures incorporated in the *i*-CHROMA iFOB test system have been described in detail in following appendices:

Appendix VI: System Information and Clinical Testing for CLIA Waiver Application of *i*-CHROMA iFOB

Appendix VII: Risk Analysis of *i*-CHROMA iFOB Test System

i-CHROMA iFOB

CLIA Complexity Waived

- *i*-CHROMA iFOB is CLIA-waived for human fecal samples only.
- Laboratories performing this test must hold a 'Certificate of CLIA Waiver'.
- If the laboratory does not have a certificate of waiver, the application for certification (Form CMS 116) can be obtained online at www.cms.hhs.gov/clia/ or from the local state agency. Completed application should be forwarded to the local state agency for the state in which the laboratory is located.
- Laboratories with a 'Certificate of CLIA Complexity Waiver' must follow manufacturer's instructions for performing this test.
- If laboratory modifies the test or the manufacturer's instructions, the test will no longer be 'CLIA-waived' and will be classified as 'High Complexity'.
- For complete information, refer to the following additional instructional materials:
  - Operation Manual of '*i*-CHROMA Reader'
  - Package Insert of '*i*-CHROMA iFOB Controls'

INTENDED USE

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

i-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

INTRODUCTION

Colorectal cancer (CRC) is the third most common malignant cancer worldwide and the second leading cause of cancer deaths in the United States. About 143,000 newly-diagnosed cases of CRC and about 52,000 deaths due to the same had been projected in the United States for the year 2012.

Fecal Occult Blood (FOB) is a widely accepted early marker for screening of colorectal cancer. Screening methods for colorectal cancer include the conventional guaiac-based fecal occult blood tests (FOBTs), immunochemical fecal occult blood tests (iFOBTs), barium enema, sigmoidoscopy and colonoscopy.

Conventional FOBTs use the chemical Guaiac, which detects hemoglobin by virtue of its sensitivity to hemoglobin peroxidase activity. Since the late 1970s, these guaiac-based FOBTs have been the primary screening method for colorectal cancer. These tests have a number of limitations such as diet restrictions because of interference from dietary plant peroxidase(s), low sensitivity to clinically significant colorectal neoplasis, non-specificity for human hemoglobin, sample handling and others.

An alternative to conventional guaiac-based FOBTs is immunochemical testing (iFOBTs), which detects only the specific portion of human hemoglobin rather than detecting hemoglobin peroxidase activity, which is prone to interference from dietary plant peroxidase(s). iFOBTs use specific antibodies for capture and detection of FOB hemoglobin in the human fecal samples. iFOBTs thus overcome the critical limitations associated with the conventional guaiac-based FOBTs.

Large randomized controlled clinical trials have shown that iFOB screening can result in decreased colorectal cancer mortality. Over the years, iFOBTs have been slowly replacing the conventional guaiac-based FOBTs. *i*-CHROMA iFOB uses specific monoclonal antibodies for capture and detection of human hemoglobin.

PRINCIPLE

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human fecal sample is mixed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer bind with hemoglobin in the fecal occult blood (FOB).

When the fecal sample mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, more the hemoglobin in the human fecal sample, more the complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

Intensity of the fluorescence is scanned and converted into an electric signal which is correlates to intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample. The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

Computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (negative/positive) manner.

COMPONENTS OF TEST SYSTEM

For performing *i*-CHROMA iFOB test, following items are needed:

- *i*-CHROMA iFOB Test Cartridge
- *i*-CHROMA iFOB Sample Collection Tube (containing detection buffer)
- *i*-CHROMA iFOB ID Chip
- *i*-CHROMA Reader with attached Key Pad

'*i*-CHROMA iFOB Test Cartridge' contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains the '*i*-CHROMA iFOB ID Chip'.

Each '*i*-CHROMA iFOB Sample Collection Tube' contains 1 mL '*i*-CHROMA iFOB Detection Buffer'. The detection buffer contains fluorochrome-labeled anti-hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

i-CHROMA Reader is a fluorometer instrument which scans the sample-loaded *i*-CHROMA iFOB test cartridge and displays the test result. *i*-CHROMA Reader and *i*-CHROMA iFOB test cartridge are compatible only with each other. *i*-CHROMA Reader is marketed/supplied separately on demand.

'*i*-CHROMA iFOB ID chip' contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

MATERIALS SUPPLIED

Commercial '*i*-CHROMA iFOB' test product comprises:

1) *i*-CHROMA iFOB Test Cartridge Box

Contains:

- 25 Test Cartridges
- 1 ID Chip
- 1 Package Insert
- 1 Quick Reference Instructions Guide

2) *i*-CHROMA iFOB Sample Collection Tube Box

Contains:

- 25 Sample Collection Tubes ; each containing 1 mL Detection Buffer

Sample collection tubes box is supplied separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

3) Patient Packs Box

Contains:

- 25 Patient Packs

Patient pack box is supplied with the test cartridge box.

Each patient pack contains following items:

- 1 Patient Instructions Leaflet (for sampling instructions)
- 1 Sample Collection Paper (for fixing onto the toilet bowl)
- 1 Sample Sac containing an absorbent pad (for enclosing the sample collection tube after sampling)
- 1 Return Envelop (for submitting the sample collection tube to the laboratory/ physician office for testing)

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items are also required for performing *i*-CHROMA iFOB tests. However, these items can be ordered separately from '*i*-CHROMA iFOB' as per requirement.

Contact the manufacturer or authorized supplier for more information.

1) *i*-CHROMA Reader
2) *i*-CHROMA iFOB Controls
3) Capillary Tube Bottle
4) Capillary Tube Grabber
5) Microplate

STORAGE AND STABILITY

***i*-CHROMA iFOB Sample Collection Tube(s)**:

- Must be stored at 2~8º C/35.6~46.4º F in a refrigerator.
- Do not freeze.
- Do not use beyond expiration date.

***i*-CHROMA iFOB Test Cartridge(s):**

- Must be stored in sealed condition at 4~30º C/39.2~86º F.
- Do not freeze.
- Do not use beyond expiration date.

WARNINGS AND PRECAUTIONS

A. General:

- Strictly follow the instructions and test procedure as recommended by the manufacturer; otherwise test results may be misleading or erroneous.
- Place one sample collection tube into the sample sac before handing over the patient pack to the patient so that the patient can collect fecal sample and do the sampling himself/herself.
- Occasionally, laboratory may receive fecal sample which has been collected and submitted in a specimen cup or similar container by the patient.

B. Technical:

- Test should be performed using test cartridge, sample collection tube and ID chip; all having exactly matching lot number. Never interchange test products from different lots.
- Do not use the test cartridge or sample collection tube if it has been already used, damaged or stored under improper conditions.
- Misleading or erroneous test results may be obtained with test components which are past the expiration date or stored improperly or not matching with each other.
- Use *i*-CHROMA iFOB test cartridge and *i*-CHROMA Reader only with each other.
- Fecal sample submitted by the patient in *i*-CHROMA iFOB sample collection tube may be stored at ambient temperature (not exceeding 37º C/98.6º F) for up to 72 hours or at 2~8º C/35.6~46.4º F for up to 96 hours after sampling but must be tested within these time limits.
- Fecal sample submitted by the patient in specimen cup may be stored at ambient temperature (not exceeding 37º C/98.6º F) but must be tested within 48 hours after collection.
- However, it is strongly recommended that laboratory should test the fecal sample immediately or as early as possible within the recommended time limits after it is received from the patient.
- Test cartridge and sample collection tube (containing fecal sample or control) must be allowed to attain ambient temperature (15~37 ºC/59~98.6 ºF) before testing.
- A sample collection tube and test cartridge should be used for testing a sample or control only once and should never be reused.

C. Clinical:

- *i*-CHROMA iFOB is meant for *in vitro* diagnostic use only.
- The test should always be performed upon recommendation of attending physician.
- Test result should not be considered conclusive evidence of presence or absence of gastrointestinal bleeding or disorder.
- The test may yield false negative or false positive results owing to certain technical and clinical factors.

D. Patient Instructions:

- Provide appropriate instructions and guidance to the patient regarding sample collection/sampling procedure, entering required information on the label of sample collection tube and returning the sample collection tube to the laboratory for testing within recommended time limits.
- Patient must be instructed to observe following precautions:
  - Dietary restrictions if any; as advised by attending physician, must be followed by the patient before collecting and submitting fecal sample for testing.

- Fecal sample should not be collected during or within three days after menstrual period, or if the patient suffers from bleeding hemorrhoids or urinary bleeding.
- Fecal sample should not come in contact with toilet water and/or urine until collected.

E. Handling and Disposal:

Fecal sample, used test cartridge and used sample collection tube should be considered as potentially infectious and hence must be disposed of in accordance with appropriate local, state or federal requirements.

SYSTEM CHECK MECHANISMS OF *i*-CHROMA READER

A. Preprogrammed 'System Self-check' of *i*-CHROMA Reader:

What it is

- It is a mechanism which routinely checks whether key electronic components representing major functions of the *i*-CHROMA Reader are working in order.

How it is executed

- It is executed automatically whenever the power switch of *i*-CHROMA Reader is turned 'ON'.

What it normally indicates

- Up on turning the power switch on, *i*-CHROMA Reader displays 'Self-test Mode' and then momentarily displays 'OK' and comes in 'MENU' mode.
- This indicates that key electronic components representing major functions of the *i*-CHROMA Reader are working in order.
- You can proceed to perform the tests.

What if it malfunctions?

- If one or more of the key electronic components malfunction, *i*-CHROMA Reader displays any of the error message alerts 'Error 21 Turn Off the Power'-'Error 24 Turn Off the Power' thereby disabling it from further use.
- Contact the manufacturer for technical assistance.

B. Performing 'System Check' on *i*-CHROMA Reader:

Importance

- System Check of *i*-CHROMA Reader must be performed regularly.

Purpose

- To ascertain overall normal functioning of the *i*-CHROMA Reader
- To ascertain whether it would carry out the designated task as intended.

Items specially required

- A set of '*i*-CHROMA System Check Cartridge and System Check ID Chip' is provided with the *i*-CHROMA Reader.

For details

- Refer to the 'Operation Manual of *i*-CHROMA Reader'.

Procedure

- As described under '**D. Performing System Check on *i*-CHROMA Reader**' in the 'Test Procedure' section of this package insert.

When to Perform

- In case of installing the *i*-CHROMA Reader for the first time.
- In case of any concern regarding physical/functional integrity of the Reader
- In case of any question concerning validity or accuracy of test results.
- Before performing the test using *i*-CHROMA Reader after extended period of non-use, changing its operational settings or up-gradation of software.

What the result indicates

- If the result is 'System Check System OK', then:
  - It confirms overall normal functioning of the *i*-CHROMA Reader.
  - *i*-CHROMA iFOB Test results are most likely to be accurate and valid.
  - Proceed for testing the controls or fecal samples.
- If the result is 'System Check Error S1' or 'System Check Error S2', then:
  - Discontinue using the *i*-CHROMA Reader or do not report any test result.
  - Contact the manufacturer for technical assistance.

QUALITY CONTROL

A. External Controls

Importance:

- Controls must be tested regularly if you are using *i*-CHROMA iFOB test under CLIA-waived status.

Purpose:

- To verify whether *i*-CHROMA iFOB test offers expected test results with *i*-CHROMA iFOB controls**.**
- To assure and confirm acceptable performance of *i*-CHROMA iFOB test system.

Items specially required:

- *i*-CHROMA iFOB controls are to be procured separately from the 'Test Cartridge Box' & 'Sample Collection Tube Box'.
- Capillary tubes (10 µL), grabber and microplate are also supplied by the manufacturer on demand.

For details:

- Refer to the package insert of *i*-CHROMA iFOB controls.

Procedure:

- As described under '**E. Testing *i*-CHROMA iFOB Controls**' in test procedure section of this insert.

When to Perform:

- At least once daily before testing fecal samples

- In case of any concern regarding functional integrity of the test cartridge(s) and/or detection buffer in sample collection tube(s)
- In case of any question concerning validity or accuracy of test results
- Before performing the test using any new lot of test components or any new shipment even if it belonged to a previously received lot
- Once every month for routinely checking stability of stored test components.
- If the test is being performed by a new operator
- If the operator has not performed the test within last 7 days.

What the results indicate:

- Control test results should be considered valid/acceptable if '*i*-CHROMA iFOB Negative Control' tests 'iFOB Test Negative' and '*i*-CHROMA iFOB Positive Control' tests 'iFOB Test Positive'.
- **If valid/acceptable results are obtained with both controls, then:**
  - It assures acceptable performance of *i*-CHROMA iFOB test system.
  - Test results with fecal samples are most likely to be accurate and valid.
  - You can proceed to test the fecal samples.
- **If results obtained with any/both controls are invalid/unacceptable, then:**
  - It may be due to one of the following reasons:
    - Proper technique or correct procedure was not followed while testing the controls.
    - Quality/Functional integrity of the controls and /or other components of the test system might have been adversely affected due to improper storage and/or handling.
    - The test system being used may not be performing effectively and hence tests performed on clinical human fecal samples using this test system may yield results of questionable validity and/or accuracy.
  - Test the controls again after correcting any error that might have occurred.
  - If test results with the controls continue to be invalid/unacceptable; then:
    - Do not perform further tests on the fecal samples or do not report any result.
    - Contact the manufacturer for technical assistance.

B. Internal Control

What it is:

- 'Control line' of test cartridge functions as the quality control mechanism which fairly satisfies routine quality control requirement of *i*-CHROMA iFOB test.

How it is executed:

- It is executed automatically whenever a control or fecal sample is tested by *i*-CHROMA iFOB test.

What its normal functioning indicates:

- Internal control mechanism functioned optimally.
- Sufficient quantity of processed test sample was loaded into the sample well.

- The test sample migrated to the control line and test line as required.

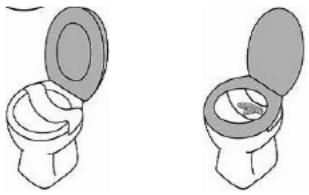
What if it malfunctions?

- In case of malfunction of the internal control due to any reason, *i*-CHROMA Reader displays any of the error message alerts viz. 'Caution! Error', 'iFOB Test Error 26' or 'iFOB Test Error 28' thereby terminating the test.
- Repeat the test using a new test cartridge following correct test procedure.
- If same error message alert(s) is displayed again, contact the manufacturer for technical assistance.

TEST PROCEDURE

A. Sample collection by patient:

1) Lift toilet cover and toilet seat.
2) Position and fix sample collection paper to the sides of rim in rear half of toilet bowl, allowing the paper to sag.
3) Make bowel movement on to the collection paper.
4) Do not remove the collection paper from toilet bowl until fecal sample has been transferred into the '*i*-CHROMA iFOB Sample Collection Tube' or a specimen cup.



B. Sampling by patient or test operator:

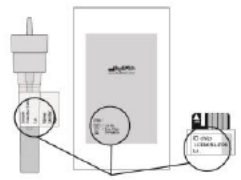
1) Enter required 'Patient Information' on the label of '*i*-CHROMA iFOB Sample Collection Tube'.
2) Unscrew the cap of sample collection tube and remove the sampler.
3) Insert sampling stick of sampler into the stool at 5-6 different sites.
4) Re-apply sampler back into sample collection tube and tighten its cap.

C. Arranging test setup:

1) Arrange following test components:

- *i*-CHROMA iFOB Test Cartridge & ID Chip
- *i*-CHROMA iFOB Sample Collection Tube (containing the fecal sample)
- *i*-CHROMA Reader (attached with key pad and serial printer)

2) All these test components must have been stored properly under recommended storage conditions.
3) Check whether lot number of the ID chip is exactly same as lot numbers of the test cartridge and the sample collection tube.
4) Ensure that test cartridge and sample collection tube has not passed respective expiration dates.
5) Allow the test components to attain ambient temperature (15~37º C/59~98.6º F) for about 30 min.



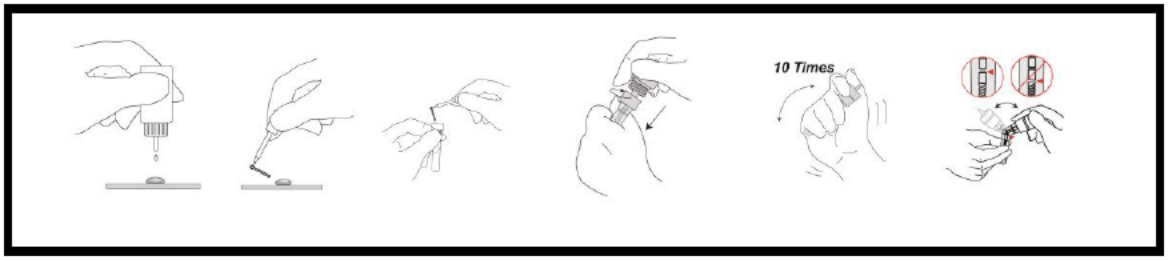
D. Performing 'System Check' on *i*-CHROMA Reader:

1) Arrange '*i*-CHROMA System Check ID Chip & System Check Cartridge'.
2) Turn power switch of *i*-CHROMA Reader 'On'. It will automatically display the default 'MENU'.
3) Select 'Test Mode' and insert 'System Check ID Chip' in the ID chip port.
4) *i*-CHROMA Reader ejects cartridge holder and displays the message alert 'Input Patient ID'.
5) Press 'Select' to skip inputting 'Patient ID'. Message alert 'Insert System Check Cartridge' is displayed.
6) Insert System Check Cartridge in the cartridge holder and press 'Select'.
7) *i*-CHROMA Reader should display 'System Check System OK' indicating overall normal functioning.

E. Testing *i*-CHROMA iFOB Controls:

1) Arrange the test set up but the sample collection tube should not contain fecal sample.
2) Arrange vials of *i*-CHROMA iFOB 'Negative' and 'Positive' controls as well as capillary tubes, grabber and microplate.
3) Allow the vials to attain ambient temperature (15~37ºC/59~98.6ºF) for about 30 minutes.
4) Unscrew cap of the sample collection tube and remove sampler.

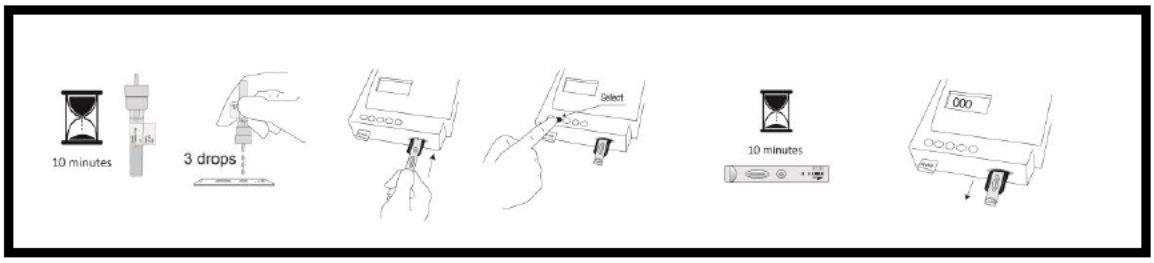
5) Squeeze out 2 drops from the vial of 'Negative' control into a well on the microplate.
6) Hold a capillary tube with the grabber at one end and immerse another end of the tube into the control reagent present in the well of microplate.
7) Ensure that the capillary tube has been completely filled with the control reagent.
8) Carefully drop the filled capillary tube into the sample collection tube such that it falls into the detection buffer reservoir.
9) Re-apply the sampler back into sample collection tube and tighten its cap.
10) Shake the sample collection tube 10 times.
11) Perform further procedure in the manner as described in '**Steps 2-15 under F. Testing human fecal sample**' except that you should skip inputting the patient ID by pressing 'Select' button.
12) Perform the test with 'Positive' control also using new sample collection tube and test cartridge.



F. Testing human fecal sample:

1) Shake the sample collection tube (containing fecal sample) about 10 times.
2) Hold it in vertical position and cut the sampling stick by bending the tube 2-3 times just below the cap.
3) Allow the sample collection tube to stand for 10 minutes in vertical position.
4) Turn power switch of *i*-CHROMA Reader 'On'. It automatically displays the default 'MENU'.
5) Select 'Test Mode' and insert '*i*-CHROMA iFOB ID Chip' in the ID chip port.
6) *i*-CHROMA Reader ejects cartridge holder and displays message alert 'Input Patient ID'.
7) Input an 11-digit patient ID correctly based on the patient information and laboratory record system in the following manner:
   - First six digits for patient's date of birth e.g. enter March 9, 2014 as 030914
   - Next two digits for patient's gender e.g. 01 for male and 02 for female
   - Last three digits for serial number of the test as entered/to be entered in record/ information management system of the laboratory e.g. enter 'Serial No. 1' as '001'
8) After inputting the patient ID, press 'Select'. Message alert 'Insert iFOB Test Cartridge' is displayed.
9) Remove the '*i*-CHROMA iFOB Test Cartridge' from its original pouch and place it on a flat surface.

10) Invert the sample collection tube and squeeze out precisely three drops of fecal sample mixture into 'Sample Well' of the test cartridge.
11) Immediately insert the sample-loaded test cartridge in the cartridge holder in the direction denoted by the 'arrow mark' on face of the cartridge and press 'Select'. Push the test cartridge gently all the way inside the test cartridge holder.
12) *i*-CHROMA Reader will automatically scan the inserted test cartridge after 10 minutes and display test result.
13) If *i*- CHROMA Reader has been set to 'Multi Mode', allow the sample-loaded test cartridge to stand for exactly 10 minutes outside the *i*-CHROMA Reader.
14) After 10 minutes, insert the sample-loaded test cartridge in the cartridge holder and press 'Select'.
15) *i*-CHROMA Reader immediately scans the inserted test cartridge and displays test result.



CATEGORIZATION AND INTERPRETATION OF TEST RESULTS

- Cut-off of *i*-CHROMA iFOB is 100 ng/mL (hemoglobin in fecal sample)
- *i*-CHROMA Reader displays the test result as 'iFOB Test Negative' or 'iFOB Test Positive'
- **Valid Results:**
  - Fecal sample test results should be considered valid if quality control results with both *i*-CHROMA iFOB controls on that day are also valid/acceptable.
  - Report valid test results to the attending physician for correct interpretation and appropriate medical intervention.
- **Invalid Results:**
  - Fecal sample test results should be considered invalid if quality control results with any or both *i*-CHROMA iFOB controls on that day are invalid/unacceptable.
  - Do not report invalid test results.
  - Repeat quality control tests after correcting any error that might have occurred as described in the section 'External Controls' in this package insert.
  - If test results with the controls continue to be invalid/unacceptable; then:
    - Do not perform further tests on the fecal samples or do not report any result.
    - Contact the manufacturer for technical assistance.

- **Indeterminate Results:**
  - Fecal sample test result should be considered indeterminate if it is displayed as one of the following 'Error Message Alerts' but the test results of both *i*-CHROMA iFOB controls on that day are valid/acceptable.
    - 'Caution! Barcode Error'
    - 'Caution! Error'
    - 'iFOB Test Error 26'
    - 'iFOB Test Error 27'
    - 'iFOB Test Error 28'
    - 'iFOB Test Error 29'
  - Repeat the test using a new *i*-CHROMA iFOB test cartridge and/or correcting any operator error that might have occurred.
  - If same error message alert continues to be displayed, contact the manufacturer for technical assistance.

PERFORMANCE CHARACTERISTICS

1. **Cut-off:** Cut-off of *i*-CHROMA iFOB is 100.0 ng/mL (hemoglobin in human fecal sample).
2. **Prozone effect:** *i*-CHROMA iFOB showed no prozone effect upto 2000 ng/mL.
3. **Sensitivity to human hemoglobin variant:** *i*-CHROM iFOB has been found to be equally sensitive to 'Hemoglobin S' as the human hemoglobin variant associated with sickle cell anemia.
4. **Cross-reactivity:** *i*-CHROMA iFOB showed no significant cross-reactivity with animal hemoglobin (bovine, chicken, fish, equine, goat, swine, rabbit, and sheep origin).
5. **Interference:** *i*-CHROMA iFOB showed no significant interference from endogenous substances (Ascorbic Acid, Bilirubin, Albumin and Myoglobin).
6. **Precision:** *i*-CHROMA iFOB test results showed high degree of repeatability as well as reproducibility under different variability conditions.
7. **Comparability:** Test results of method comparison studied performed on several spiked as well as clinical human fecal samples showed acceptable level of agreement between *i*-CHROMA iFOB and the predicate method OC Auto Micro FOB Test (Polymedco Inc., USA).

LIMITATIONS OF THE TEST SYSTEM

i-CHROMA iFOB provides accurate and reliable test results subject to the following constraints:

- Accuracy and reliability of test results is highly dependent on proper handling/storage of test components and test samples as well as strict adherence to the correct testing and quality control procedures described in this insert.
- The test may yield false positive results due to cross-reactions of some components of the fecal sample or the fecal occult blood with the capture/detector antibodies and/or non-specific adhesion of certain components (having similar epitopes) with these antibodies.
- The test may also yield false negative results; the most common factor being non-responsiveness of the antigen to the capture/detector antibodies due to its epitopes being masked by some unknown components such that the antigen cannot be detected or captured by the antibodies. False negative results may also be obtained due to instability or degradation of the hemoglobin antigen with time and/or temperature making it unrecognizable by the antibodies.
- Other factors causing erroneous/misleading results include technical/procedural errors, degradation of the test components/reagents as well as presence of interfering substances in the test samples.
- The user should neither arrive at any conclusion nor take any decision of medical/therapeutic importance after knowing the test result without first consulting the attending physician.
- Any clinical diagnosis and consequent decision of medical/therapeutic importance based on the test result(s) must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

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5. Hardcastle JD, Chamberlain J, Robinson MH, Moss SM, Amar SS, Balfour TW, et al. Randomised controlled trial of fecal occult blood screening for colorectal cancer. Lancet 1996; 348: 1472-1477.
6. Rozen P, Waked A, Vilkin A, et al. Evaluation of a desk top instrument for the automated development and immunochemical quantification of fecal occult blood. Med Sci Moint 2006; 12(6):MT27-32.
7. Oh SW, Moon JD, Park SY, et al. Evaluation of fluorescence hsCRP immunoassay for point of care testing. Clin Chim Acta 2005; 356:172-177.

Note: Please refer to the table below to identify various symbols on the product labels

	Read instructions for use
	Use by
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
IVD	*In vitro* diagnostic medical device
	Temperature limitation
	Do not Reuse

For technical assistance please contact:
Boditech Med Inc.'s Technical Services
Phone: + 82 33 243 1400
E-mail: support@boditech.co.kr

Boditech Med Incorporated
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
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E-mail: support@boditech.co.kr

Website: www.boditech.co.kr

Quick Reference Instructions

i-CHROMA iFOB

CLIA Complexity Waived

- ***i*-CHROMA iFOB** is CLIA-waived for human fecal samples only.
- Laboratories performing this test must hold a 'Certificate of CLIA Waiver'.
- Laboratories with a 'Certificate of CLIA Complexity Waiver' must follow manufacturer's instructions for performing this test.
- If laboratory modifies the test or the manufacturer's instructions, the test will no longer be 'CLIA-waived' and will be classified as 'High Complexity'.
- For complete information, refer to the following instructional material.
  - Package Insert of *i*-CHROMA iFOB
  - Package Insert of *i*-CHROMA iFOB Controls
  - Operation Manual of *i*-CHROMA Reader

Which items you need for the test

- *i*-CHROMA iFOB Test Cartridge
- *i*-CHROMA iFOB Sample Collection Tube
- *i*-CHROMA Reader with attached Key Pad

  Following items are additionally required for quality control tests
- *i*-CHROMA iFOB Negative & Positive Controls
- Capillary Tubes (10 µL)
- Grabber
- Microplate

How you may receive and store the test sample(s)

Fecal sample submitted in *i*-CHROMA iFOB Sample Collection Tube:

- May be stored at ambient temperature (≤ 37º C/98.6º F) for up to 72 hours or at 2~8º C/35.6~46.4º F in a refrigerator for up to 96 hours after sampling by patient.
- Do not freeze.

Fecal sample submitted in a specimen cup:

- May be stored at ambient temperature (≤ 37º C/98.6º F) for up to 48 hours after collection by patient.
- Do not freeze.

How you should store the test products

***i*-CHROMA iFOB Sample Collection Tubes**:

- Must have been stored at 2~8º C/35.6~46.4º F in a refrigerator. Do not freeze.
- Do not use beyond expiration date.

- Use for mixing a fecal sample or a control only once. Never reuse.

***i*-CHROMA iFOB Test Cartridges:**

- Must have been stored in sealed condition at 4~30º C/39.2~86º F. Do not freeze.
- Do not use beyond expiration date.
- Use for testing a fecal sample or a control only once. Never reuse.

***i*-CHROMA iFOB Controls**:

- Vials of Negative and Positive controls must have been stored at 2~8ºC/ 35.6~46.4ºF in a refrigerator. Do not freeze.
- Do not use beyond one month after the vials are opened for the first time.
- Do not use beyond expiration date.

***i*-CHROMA iFOB ID Chip and *i*-CHROMA Reader**:

- Always store and use at ambient temperature (15~37º C/59~98.6º F).
- Store properly and handle gently to avoid any physical damage.
- Keep away from moisture, heat, direct sunlight, vibrations and magnetic field.

System Check Mechanisms of *i*-Chroma Reader

A. Preprogrammed 'System Self-check' of *i*-CHROMA Reader:

What it is

- It is a mechanism which routinely checks whether key electronic components representing major functions of the *i*-CHROMA Reader are working in order.

How it is executed

- It is executed automatically whenever the power switch of *i*-CHROMA Reader is turned 'ON'.

What it normally indicates

- Up on turning the power switch on, *i*-CHROMA Reader displays 'Self-test Mode' and then momentarily displays 'OK' and comes in 'MENU' mode.
- This indicates that key electronic components representing major functions of the *i*-CHROMA Reader are working in order.
- You can proceed to perform the tests.

What if it malfunctions?

- If one or more of the key electronic components malfunction, *i*-CHROMA Reader displays any of the error message alerts 'Error 21 Turn Off the Power'-'Error 24 Turn Off the Power' thereby disabling it from further use.
- Contact the manufacturer for technical assistance.

B. Performing 'System Check' on *i*-CHROMA Reader:

Importance

- System Check of *i*-CHROMA Reader must be performed regularly.

Purpose

- To ascertain overall normal functioning of the *i*-CHROMA Reader
- To ascertain whether it would carry out the designated task as intended.

Items specially required

- A set of '*i*-CHROMA System Check Cartridge and System Check ID Chip' is provided with the *i*-CHROMA Reader.

For details

- Refer to the 'Operation Manual of *i*-CHROMA Reader'.

Procedure

- As described under '**D. Performing System Check on *i*-CHROMA Reader**' in the 'Test Procedure' section of this instruction guide.

When to Perform

- In case of installing the *i*-CHROMA Reader for the first time.
- In case of any concern regarding physical/functional integrity of the Reader
- In case of any question concerning validity or accuracy of test results.
- Before performing the test using *i*-CHROMA Reader after extended period of non-use, changing its operational settings or up-gradation of software.

What the result indicates

- If the result is 'System Check System OK', then:
  - It confirms overall normal functioning of the *i*-CHROMA Reader.
  - *i*-CHROMA iFOB Test results are most likely to be accurate and valid.
  - Proceed for testing the controls or fecal samples.
- If the result is 'System Check Error S1' or 'System Check Error S2', then:
  - Discontinue using the *i*-CHROMA Reader or do not report any test result.
  - Contact the manufacturer for technical assistance.

Quality Control

A. External Controls

Importance:

- Controls must be tested regularly if you are using *i*-CHROMA iFOB test under CLIA-waived status.

Purpose:

- To verify whether *i*-CHROMA iFOB test offers expected test results with *i*-CHROMA iFOB controls**.**
- To assure and confirm acceptable performance of *i*-CHROMA iFOB test system.

Items specially required:

- *i*-CHROMA iFOB controls are to be procured separately from the 'Test Cartridge Box' & 'Sample Collection Tube Box'.

- Capillary tubes (10 µL), grabber and microplate are also supplied by the manufacturer on demand.

For details:

- Refer to the package insert of *i*-CHROMA iFOB controls.

Procedure:

- As described under '**E. Testing *i*-CHROMA iFOB Controls**' in test procedure section of this instruction guide.

When to Perform:

- At least once daily before testing fecal samples
- In case of any concern regarding functional integrity of the test cartridge(s) and/or detection buffer in sample collection tube(s)
- In case of any question concerning validity or accuracy of test results
- Before performing the test using any new lot of test components or any new shipment even if it belonged to a previously received lot
- Once every month for routinely checking stability of stored test components.
- If the test is being performed by a new operator
- If the operator has not performed the test within last 7 days.

What the results indicate:

- Control test results should be considered valid/acceptable if '*i*-CHROMA iFOB Negative Control' tests 'iFOB Test Negative' and '*i*-CHROMA iFOB Positive Control' tests 'iFOB Test Positive'.
- **If valid/acceptable results are obtained with both controls, then:**
  - It assures acceptable performance of *i*-CHROMA iFOB test system.
  - Test results with fecal samples are most likely to be accurate and valid.
  - You can proceed to test the fecal samples.
- **If results obtained with any/both controls are invalid/unacceptable, then:**
  - It may be due to one of the following reasons:
    - Proper technique or correct procedure was not followed while testing the controls.
    - Quality/Functional integrity of the controls and /or other components of the test system might have been adversely affected due to improper storage and/or handling.
    - The test system being used may not be performing effectively and hence tests performed on clinical human fecal samples using this test system may yield results of questionable validity and/or accuracy.
  - Test the controls again after correcting any error that might have occurred.
  - If test results with the controls continue to be invalid/unacceptable; then:

- Do not perform further tests on the fecal samples or do not report any result.
- Contact the manufacturer for technical assistance.

B. Internal Control

What it is:

- 'Control line' of test cartridge functions as the quality control mechanism which fairly satisfies routine quality control requirement of *i*-CHROMA iFOB test.

How it is executed:

- It is executed automatically whenever a control or fecal sample is tested by *i*-CHROMA iFOB test.

What its normal functioning indicates:

- Internal control mechanism functioned optimally.
- Sufficient quantity of processed test sample was loaded into the sample well.
- The test sample migrated to the control line and test line as required.

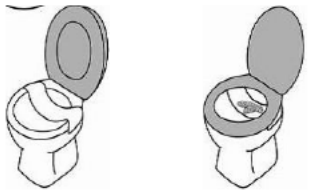
What if it malfunctions?

- In case of malfunction of the internal control due to any reason, *i*-CHROMA Reader displays any of the error message alerts viz. 'Caution! Error', 'iFOB Test Error 26' or 'iFOB Test Error 28' thereby terminating the test.
- Repeat the test using a new test cartridge following correct test procedure.
- If same error message alert(s) is displayed again, contact the manufacturer for technical assistance.

Test Procedure

A. Sample collection by patient:

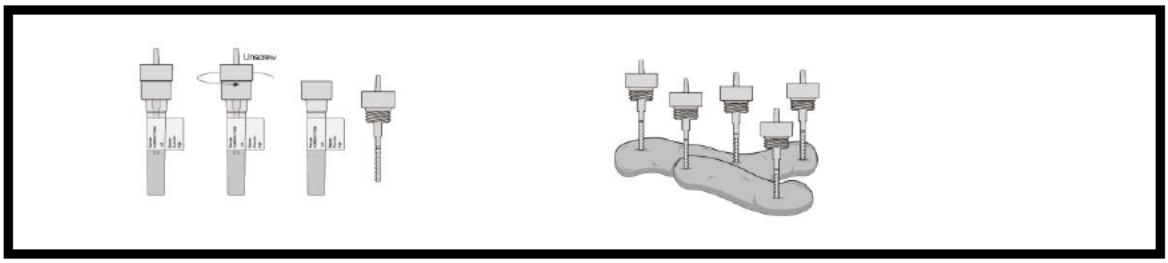
1) Lift toilet cover and toilet seat.
2) Position and fix sample collection paper to the sides of rim in rear half of toilet bowl, allowing the paper to sag.
3) Make bowel movement on to the collection paper.
4) Do not remove the collection paper from toilet bowl until fecal sample has been transferred into the '*i*-CHROMA iFOB Sample Collection Tube' or a specimen cup.



B. Sampling by patient or test operator:

1) Enter required 'Patient Information' on the label of '*i*-CHROMA iFOB Sample Collection Tube'.

2) Unscrew the cap of sample collection tube and remove the sampler.
3) Insert sampling stick of sampler into the stool at 5-6 different sites.
4) Re-apply sampler back into sample collection tube and tighten its cap.



C. Arranging test setup:

1) Arrange following test components:

- *i*-CHROMA iFOB Test Cartridge & ID Chip
- *i*-CHROMA iFOB Sample Collection Tube (containing the fecal sample)
- *i*-CHROMA Reader (attached with key pad and serial printer)

2) All these test components must have been stored properly under recommended storage conditions.
3) Check whether lot number of the ID chip is exactly same as lot numbers of the test cartridge and the sample collection tube.
4) Ensure that test cartridge and sample collection tube has not passed respective expiration dates.
5) Allow the test components to attain ambient temperature (15~37º C/59~98.6º F) for about 30 min.

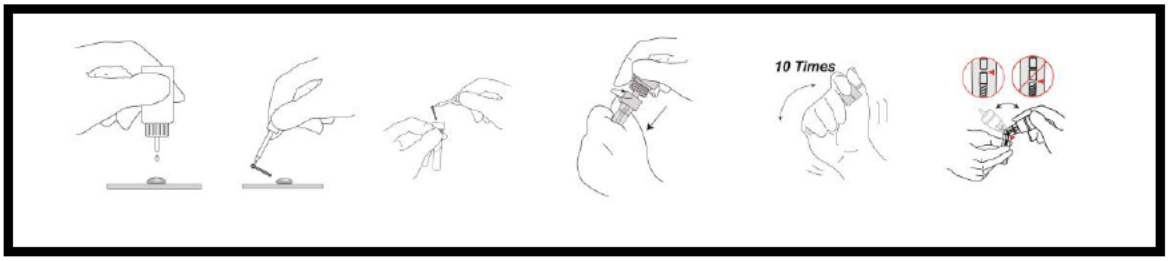
D. Performing 'System Check' on *i*-CHROMA Reader:

1) Arrange '*i*-CHROMA System Check ID Chip & System Check Cartridge'.
2) Turn power switch of *i*-CHROMA Reader 'On'. It will automatically display the default 'MENU'.
3) Select 'Test Mode' and insert 'System Check ID Chip' in the ID chip port.
4) *i*-CHROMA Reader ejects cartridge holder and displays the message alert 'Input Patient ID'.
5) Press 'Select' to skip inputting 'Patient ID'. Message alert 'Insert System Check Cartridge' is displayed.
6) Insert System Check Cartridge in the cartridge holder and press 'Select'.

7) *i*-CHROMA Reader should display 'System Check System OK' indicating overall normal functioning.

E. Testing *i*-CHROMA iFOB Controls:

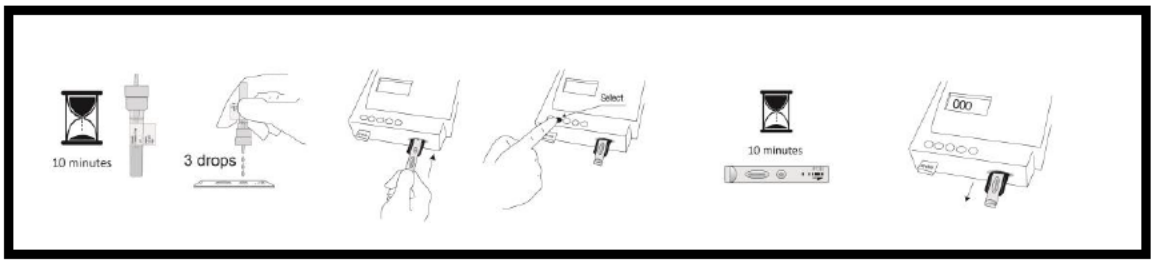
1) Arrange the test set up but the sample collection tube should not contain fecal sample.
2) Arrange vials of *i*-CHROMA iFOB 'Negative' and 'Positive' controls as well as capillary tubes, grabber and microplate.
3) Allow the vials to attain ambient temperature (15~37ºC/59~98.6ºF) for about 30 minutes.
4) Unscrew cap of the sample collection tube and remove sampler.
5) Squeeze out 2 drops from the vial of 'Negative' control into a well of on the microplate.
6) Hold a capillary tube with the grabber at one end and immerse another end of the tube into the control reagent present in the well of microplate.
7) Ensure that the capillary tube has been completely filled with the control reagent.
8) Carefully drop the filled capillary tube into the sample collection tube such that it falls into the detection buffer reservoir.
9) Re-apply the sampler back into sample collection tube and tighten its cap.
10) Shake the sample collection tube 10 times.
11) Perform further procedure in the manner as described in '**Steps 2-15 under F. Testing human fecal sample**' except that you should skip inputting the patient ID by pressing 'Select' button.
12) Perform the test with 'Positive' control also using new sample collection tube and test cartridge.



F. Testing human fecal sample:

1) Shake the sample collection tube (containing fecal sample) about 10 times.
2) Hold it in vertical position and cut the sampling stick by bending the tube 2-3 times just below the cap.
3) Allow the sample collection tube to stand for 10 minutes in vertical position.
4) Turn power switch of *i*-CHROMA Reader 'On'. It automatically displays the default 'MENU'.
5) Select 'Test Mode' and insert '*i*-CHROMA iFOB ID Chip' in the ID chip port.

6) *i*-CHROMA Reader ejects cartridge holder and displays message alert 'Input Patient ID'.
7) Input an 11-digit patient ID correctly based on the patient information and laboratory record system in the following manner:
   - First six digits for patient's date of birth e.g. enter March 9, 2014 as 030914
   - Next two digits for patient's gender e.g. 01 for male and 02 for female
   - Last three digits for serial number of the test as entered/to be entered in record/ information management system of the laboratory e.g. enter 'Serial No. 1' as '001'
8) After inputting the patient ID, press 'Select'. Message alert 'Insert iFOB Test Cartridge' is displayed.
9) Remove the '*i*-CHROMA iFOB Test Cartridge' from its original pouch and place it on a flat surface.
10) Invert the sample collection tube and squeeze out precisely three drops of fecal sample mixture into 'Sample Well' of the test cartridge.
11) Immediately insert the sample-loaded test cartridge in the cartridge holder in the direction denoted by the 'arrow mark' on face of the cartridge and press 'Select'. Push the test cartridge gently all the way inside the test cartridge holder.
12) *i*-CHROMA Reader will automatically scan the inserted test cartridge after 10 minutes and display test result.
13) If *i*- CHROMA Reader has been set to 'Multi Mode', allow the sample-loaded test cartridge to stand for exactly 10 minutes outside the *i*-CHROMA Reader.
14) After 10 minutes, insert the sample-loaded test cartridge in the cartridge holder and press 'Select'.
15) *i*-CHROMA Reader immediately scans the inserted test cartridge and displays test result.



Categorization and Interpretation of Test Results

- Cut-off of *i*-CHROMA iFOB is 100 ng/mL (hemoglobin in fecal sample)
- *i*-CHROMA Reader displays the test result as 'iFOB Test Negative' or 'iFOB Test Positive'
- **Valid Results:**
  - Fecal sample test results should be considered valid if quality control results with both *i*-CHROMA iFOB controls on that day are also valid/acceptable.

- Report valid test results to the attending physician for correct interpretation and appropriate medical intervention.

- **Invalid Results:**
  - Fecal sample test results should be considered invalid if quality control results with any or both *i*-CHROMA iFOB controls on that day are invalid/unacceptable.
  - Do not report invalid test results.
  - Repeat quality control tests after correcting any error that might have occurred as described in the section 'External Controls' in this instruction guide.
  - If test results with the controls continue to be invalid/unacceptable; then:
    - Do not perform further tests on the fecal samples or do not report any result.
    - Contact the manufacturer for technical assistance.

- **Indeterminate Results:**
  - Fecal sample test result should be considered indeterminate if it is displayed as one of the following 'Error Message Alerts' but the test results of both *i*-CHROMA iFOB controls on that day are valid/acceptable.
    - 'Caution! Barcode Error'
    - 'Caution! Error'
    - 'iFOB Test Error 26'
    - 'iFOB Test Error 27'
    - 'iFOB Test Error 28'
    - 'iFOB Test Error 29'
  - Repeat the test using a new *i*-CHROMA iFOB test cartridge and/or correcting any operator error that might have occurred.
  - If same error message alert continues to be displayed, contact the manufacturer for technical assistance.

For technical assistance please contact:

Boditech Med Inc.'s Technical Services

Phone: + 82 33 243 1400

E-mail: support@boditech.co.kr

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Package Insert

i-CHROMA iFOB Controls

INTENDED USE

'*i*-CHROMA iFOB Controls' are external quality control reagents intended for monitoring and ensuring acceptable performance of *i*-CHROMA iFOB test system which is a qualitative *in-vitro* diagnostic test for detection of fecal occult blood having cut-off of 100 ng/mL.

These controls must be tested regularly if '*i*-CHROMA iFOB Test' is being used under CLIA-waived status. *i*-CHROMA iFOB test results of human fecal samples should not be considered valid and reliable unless supported or corroborated with acceptable tests results of *i*-CHROMA iFOB Controls tested by the same *i*-CHROMA iFOB test system.

i-CHROMA iFOB controls represent assayed test materials containing 'Human Hemoglobin A_0' as the analyte.

REAGENTS, ASSIGNED TARGET VALUES AND RANGES

'*i*-CHROMA iFOB Negative Control' and '*i*-CHROMA iFOB Positive Control' are the two control reagents containing different levels of the analyte 'Human Hemoglobin A_0' as follows:

No.	Control Reagent		Assigned Target Value	Acceptable Range
1	Low	*i*-CHROMA iFOB Negative Control	50 ng/mL	45-55 ng/mL
2	High	*i*-CHROMA iFOB Positive Control	150 ng/mL	135-165 ng/mL

Human Hemoglobin A_0 is dissolved in a buffered liquid medium containing preservative.

i-CHROMA iFOB controls have been tested and found safe and non-reactive for Hepatitis B Surface antigen (HBsAg), Hepatitis C (HCV), HIV-1 and HIV-2.

MATERIALS SUPPLIED

'*i*-CHROMA iFOB Control Set' is to be procured separately from other components of the *i*-CHROMA iFOB test.

The control set contains:

i-CHROMA iFOB Negative Control 1 mL/Vial

i-CHROMA iFOB Positive Control 1 mL/Vial

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Capillary Tubes (10 µL) - 200 pieces/Bottle

Capillary Tube Grabber - 1

Microplate - 1

STORAGE AND STABILITY

Vials of *i*-CHROMA iFOB Controls must be stored at 2~8 ºC/35.6~46.4º F in a refrigerator and should not be used beyond the expiration date or beyond one month after opening the vials for the first time; whichever is earlier.

WARNINGS AND PRECAUTIONS

- Strictly follow the instructions and test procedure as described in this package insert; otherwise quality control test results may be misleading or erroneous.
- Refer to the 'Package Insert of *i*-CHROMA iFOB' and 'Operation Manual of *i*-CHROMA Reader' for detail information and operating instructions.
- A control test should be performed using test cartridge, sample collection tube and ID chip; all having exactly matching lot number. Never interchange test products from different lots.
- Do not use the test cartridge or sample collection tube if it has been already used, damaged or stored under improper conditions.
- Misleading or erroneous test result(s) may be obtained with test components which are past the expiration date or stored improperly or not matching with each other.
- Use *i*-CHROMA iFOB test cartridge and *i*-CHROMA Reader only with each other.
- Control vials, test cartridge and sample collection tube must be allowed to attain ambient temperature for about 30 min (15~37ºC/59~98.6ºF) before testing.
- Used test cartridges and used sample collection tubes must be disposed of in accordance with appropriate local, state or federal requirements.

FREQUENCY OF TESTING

i-CHROMA iFOB controls should be tested with *i*-CHROMA iFOB under following circumstances:

- At least once daily before testing fecal samples.
- In case of any concern regarding functional integrity of the test cartridge(s) and/or detection buffer in sample collection tube(s).
- In case of any question concerning validity or accuracy of test results.
- Before performing the test using any new lot of test components.
- Before performing the test using any new shipment of test components even if it belonged to a previously received lot.
- Once every month for routinely checking stability of stored test components.
- If the test is being performed by a new operator.
- If the operator has not performed the test within last 7 days.

CONTROL TEST PROCEDURE

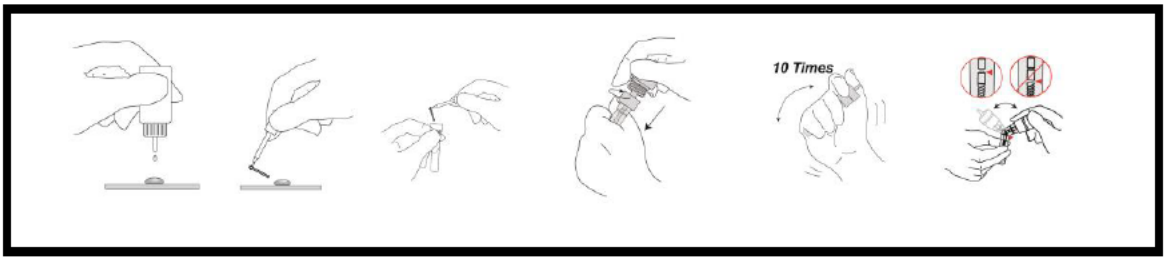
Arranging test setup:

1) Arrange following test components:
   - *i*-CHROMA iFOB 'Negative' and 'Positive' Control Vials
   - *i*-CHROMA iFOB Test Cartridges
   - *i*-CHROMA iFOB ID Chip
   - *i*-CHROMA iFOB Sample Collection Tubes
   - *i*-CHROMA Reader
2) Also arrange following items:
   - Capillary Tubes (10 uL)
   - Capillary Tube Grabber
   - Microplate
3) All the test components must have been stored properly under recommended storage conditions.
4) Check whether lot number of the ID chip is exactly same as lot numbers of the test cartridge and the sample collection tube.
5) Ensure that test cartridges and sample collection tubes or the controls have not passed respective expiration dates.
6) Control vials should not have been opened for the first time more than one month before.
7) Allow the test components to attain ambient temperature (15~37º C/59~98.6º F) for about 30 min.

Testing *i*-CHROMA iFOB Controls:

1) Unscrew cap of the sample collection tube and remove sampler.
2) Squeeze out 2 drops from the vial of 'Negative' control into a well on the microplate.
3) Hold a capillary tube with the grabber at one end and immerse another end of the tube into the control reagent present in the well of microplate.
4) Ensure that the capillary tube has been completely filled with the control reagent.
5) Carefully drop the filled capillary tube into the sample collection tube such that it falls into the detection buffer reservoir.
6) Re-apply the sampler back into sample collection tube and tighten its cap.
7) Shake the sample collection tube 10 times.
8) Hold it in vertical position and cut the sampling stick by bending the tube 2-3 times just below the cap.
9) Allow the sample collection tube to stand for 10 minutes in vertical position.
10) Turn power switch of *i*-CHROMA Reader 'On'. It automatically displays the default 'MENU'.
11) Select 'Test Mode' and insert '*i*-CHROMA iFOB ID Chip' in the ID chip port.

12) *i*-CHROMA Reader ejects cartridge holder and displays message alert 'Input Patient ID'.
13) Press 'Select' to skip inputting 'Patient ID'. Message alert 'Insert iFOB Test Cartridge' is displayed.
14) Remove the '*i*-CHROMA iFOB Test Cartridge' from its original pouch and place it on a flat surface.
15) Invert the sample collection tube and squeeze out precisely three drops of the mixture into 'Sample Well' of the test cartridge.
16) Immediately insert the sample-loaded test cartridge in the cartridge holder and press 'Select'.
17) *i*-CHROMA Reader will automatically scan the inserted test cartridge after 10 minutes and display test result.
18) If *i*- CHROMA Reader has been set to 'Multi Mode', allow the sample-loaded test cartridge to stand for exactly 10 minutes outside the *i*-CHROMA Reader.
19) After 10 minutes, insert the sample-loaded test cartridge in the cartridge holder and press 'Select'.
20) *i*-CHROMA Reader immediately scans the inserted test cartridge and displays test result.



CATEGORIZATION AND INTERPRETATION OF TEST RESULTS

- **Valid Control Results:**
  - Control test results should be considered valid/acceptable if '*i*-CHROMA iFOB Negative Control' tests 'iFOB Test Negative' and '*i*-CHROMA iFOB Positive Control' tests 'iFOB Test Positive'.
  - If valid/acceptable results are obtained with the both controls, then:
    - It assures acceptable performance of *i*-CHROMA iFOB test system.
    - Test results with fecal samples are most likely to be accurate and valid.
    - You can proceed to test the fecal samples.

- **Invalid Control Results:**
  - Control test results should be considered invalid/unacceptable if any or both control test result are not obtained as mentioned above.
  - If invalid/unacceptable results are obtained with any or both controls, then:
    - It may be due to one of the following reasons:
      - Proper technique or correct procedure was not followed while testing the controls.
      - Quality/Functional integrity of the controls and /or other components of the test system might have been adversely affected due to improper storage and/or handling.
      - The test system being used may not be performing effectively and hence tests performed on clinical human fecal samples using this test system may yield results of questionable validity and/or accuracy.
    - Test the controls again after correcting any error that might have occurred.
    - If test results with the controls continue to be invalid/unacceptable; then:
      - Do not perform further tests on the fecal samples or do not report any result.
      - Contact the manufacturer for technical assistance.
- **Indeterminate Results:**
  - Control test result should be considered indeterminate if it is displayed as one of the following 'Error Message Alerts':
    - 'Caution! Barcode Error'
    - 'Caution! Error'
    - 'iFOB Test Error 26'
    - 'iFOB Test Error 27'
    - 'iFOB Test Error 28'
    - 'iFOB Test Error 29'
    - Repeat the test using a new *i*-CHROMA iFOB test cartridge and/or correcting any operator error that might have occurred.
    - If same error message alert continues to be displayed, contact the manufacturer for technical assistance.

LIMITATIONS

- *i*-CHROMA iFOB control testing may have its own limitations. It is remotely possible that test results with fecal samples may be misleading or erroneous even when control test results are valid/acceptable.
- *i*-CHROMA iFOB controls have been tested by recognized methods and found to be safe and negative for communicable disease agents. However, no test method can offer complete assurance that products derived from human source are free from infectious agents.

Note: Please refer to the table below to identify various symbols on the product labels.

	Read instructions for use
	Use by
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
IVD	*In vitro* diagnostic medical device
	Temperature limitation
	Do not Reuse

For technical assistance please contact:
Boditech Med Inc.'s Technical Services
Phone: + 82 33 243 1400
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IMMUNOFLUOROMETER EQUIPMENT

i-CHROMA Reader

Operation Manual

Please read this manual thoroughly before you start testing with

i-CHROMA Reader

This manual provides all the information required for operating the i-CHROMA Reader.
Carefully follow the instructions given in this manual.

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1. Important Information

Intended Use:

i-CHROMA Reader is a portable fluorescence-scanning instrument for qualitative or quantitative detection of designated analyte(s) in human blood, urine and other test samples; duly tested in accordance with various i-CHROMA Immunoassay Tests manufactured by Boditech Med Incorporated.

i-CHROMA Reader is to be used only in conjunction with various ***i***-CHROMA Immunoassay Tests and meant for in vitro diagnostic purpose only.

i-CHROMA Reader can be used for screening, monitoring and/or routine physical examination in centralized laboratories of hospitals and physician offices.

Please note:

- The user of i-CHROMA Reader in conjunction with the i-CHROMA Immunoassay Test should not arrive at any conclusion and/or should not take any decision of medical/therapeutic importance after knowing the test result without first consulting his/her physician.

- Unless otherwise explicitly stated in the package insert; use only fresh blood, urine or other test sample for testing with the *i*-CHROMA Immunoassay Test in conjunction with the *i*-CHROMA Reader.

- i-CHROMA Reader is compatible only with various i-CHROMA Immunoassay Tests manufactured by Boditech Med Incorporated. Use of i-CHROMA Reader in conjunction with immunoassay test devices of other marketed brands may yield misleading results.

- In order to obtain accurate results, the i-CHROMA Immunoassay Tests should be performed and scanned/read on the i-CHROMA Reader in an environment having temperature 15~37℃ (59~98.6 ℉) and maximum relative humidity 75%.

- The test set up should be exposed to the ambient temperature for at least 30 minutes until just prior to performing the test actually.

- Avoid exposure of *i*-CHROMA Reader to dust, water or any other liquid and direct sunlight. Similarly refrain from throwing, shaking, dropping or mishandling the i-CHROMA Reader, which may damage its internal parts.

- Do not operate the i-CHROMA Reader in close proximity of cellular or cordless telephones and electrical or electronic equipment like microwave oven that are sources of electromagnetic radiation, as these may interfere with normal functioning of the i-CHROMA Reader.

- Do not disassemble the i-CHROMA Reader in any case.

Following list explains various symbols, which the user will find in this i-CHROMA Reader operation manual, i-CHROMA product labels & packaging and the i-CHROMA Test package inserts.

IVD	For in vitro diagnostic use
CE	This product fulfills the requirements of Directive 98/79/EC on In Vitro Diagnostic Medical Devices
	Caution! Risk of electric shock
	Attention! Read instructions before use
	LASER Hazard
	Manufacturer
	Direct Current
	Separate collection for electrical and electronic equipment
	Bio Hazard

2. Safety Information

⚠	The user must ensure that i-CHROMA Reader functions safely and it is in proper working condition before being used. Be sure to read thoroughly and follow all instructions, warning and cautions before using i-CHROMA Reader.
	i-CHROMA Reader is based on a high voltage circuit. Never attempt to remove or open any part of the i-CHROMA Reader casing.
	Use of damaged or improperly adjusted i-CHROMA Reader or improper use of **i-CHROMA** Reader could result in personal injury.
	Ensure that the voltage setting of i-CHROMA Reader matches the power supply voltage.
	Use i-CHROMA Reader only for its intended use described in this manual.
	Do not use i-CHROMA Reader with such accessories which are not recommended and/or supplied by Boditech Med Incorporated.
	Do not place anything on top of i-CHROMA Reader even when it is lying idle.
	Unless otherwise instructed specifically, do not insert anything into any opening, socket or holder provided in the i-CHROMA Reader. Similarly do put not anything in any hose or attach anything to any coupling of the i-CHROMA Reader.
	Do not use i-CHROMA Reader in outdoor settings.
	Being electrical equipment, misuse or unwarranted use of i-CHROMA Reader may cause electrocution, burns, fire and other hazards. Use only the power adapter provided with i-CHROMA Reader.
	Never attempt to look into the laser aperture. Never attempt to use mirror or other devices to observe the laser beam or the lens.
	Do not allow i-CHROMA Reader to come in contact with liquid in any manner. If i-CHROMA Reader becomes wet, unplug it before touching it.

3. Principle of Operation

i-CHROMA Reader is a fluorescence scanning instrument to be used in conjunction with various i-CHROMA Immunoassay Tests which are based on antigen-antibody reaction and fluorescence technology.

i-CHROMA Reader uses a semiconductor diode laser as the excitation light source for illuminating the i-CHROMA test cartridge (loaded with the test sample which has been duly mixed with the detection buffer as per the standard test procedure recommended by Boditech Med. Inc.) thereby triggering fluorescence from the fluorochrome-labeled complexes of analyte accumulated on the test line of the test cartridge membrane.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluoresced light. Intensity of the fluorescence is scanned and converted into an electric signal which is in correlation to the intensity of fluorescence produced on the test cartridge membrane.

The on-board microprocessor computes concentration of the analyte in the test sample based on a pre-programmed calibration derived from the ID chip inserted in the ID chip port. The computed and converted result is displayed on the display screen of the i-CHROMA Reader in a qualitative or quantitative manner.

4. Commercial Package Contents

i-CHROMA Reader consists of several items included in the system. For proper operation of the system, the user must know the technical name and use of each item.

The user must ensure that following items are part of the commercial package. If any item is missing, please contact our sales distributor or Boditech Med Inc.'s Technical Services at +82 33 243 1400 in Republic of Korea

1. i-CHROMA Reader
2. Key Pad
3. Plastic Cover for i-CHROMA Reader
4. Box containing Power Cable, Connection Cable and 'Y' Cable
5. i-CHROMA Reader Operation Manual
6. Envelope containing i-CHROMA System Check Cartridge and System Check ID Chip

5. Technical Specifications

Physical Description

- Dimensions 250 mm (L) x 185 mm (W) x 80 mm (H)
- Weight 1.2 Kg
- Power supply 100-240 V AC, 50/60 Hz, 3-5 A
- Data output On-board Display Screen and Printer

Permissible Environmental Conditions

- Temperature 15 °C ~37 °C
- Humidity Maximum Relative Humidity 75 %
- Setting Dry, clean, flat and horizontal surface in an indoor setting away from direct sunlight, mechanical vibration and magnetic field

Optical Description

- Light source Laser Diode, 2.5 mW, 637 nm
- Detector Silicon Photo Diode

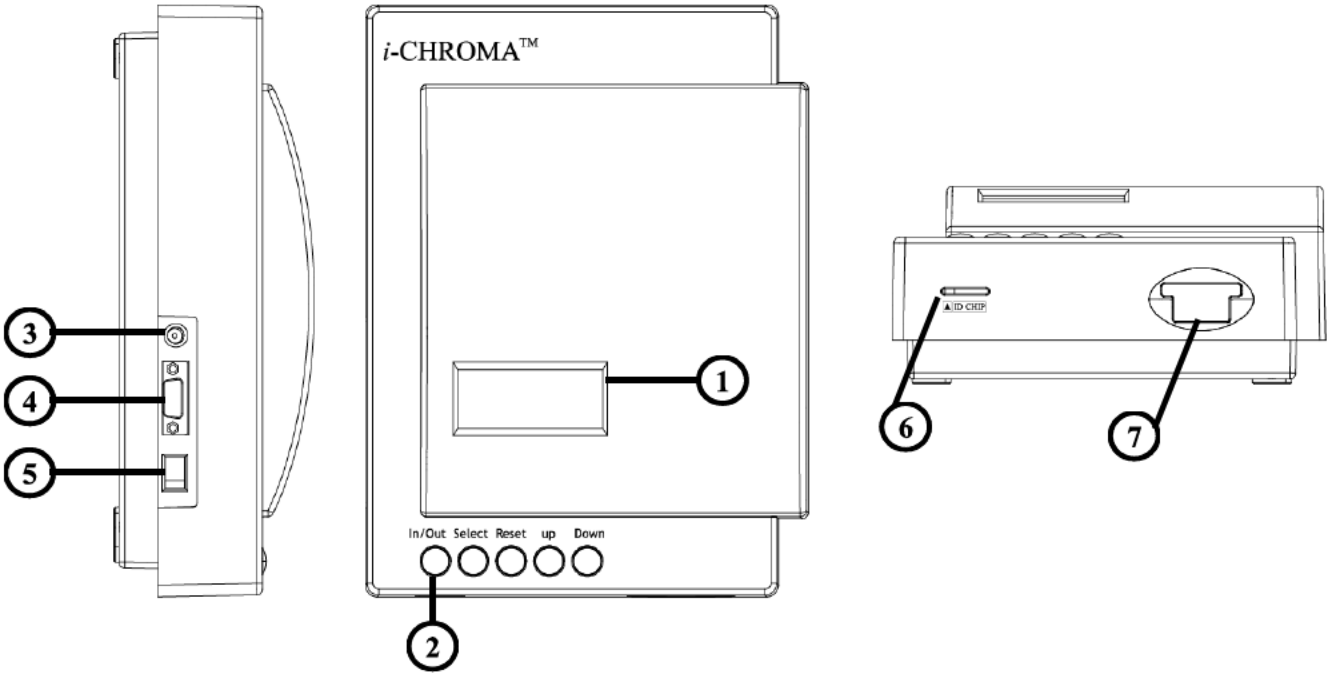
Other

- Driver Motor 12 V
- Interface RS-232 Serial Port (for key pad and printer)
- Printer Thermal (Optional)
- Display LCD (16 x 4 Characters)
- Key Pad 5 Function Keys

i-CHROMA Reader meets the EMC guideline as per EN61326-2-6:2006.

6. Functional and Operational Elements

① LCD Window	Displays 'MENU', time, temperature, patient ID, procedural and error message alerts, test result etc.
② Function Keys	Used to select Menu, Reset , Up and Down functions and In/Out movement of the test cartridge holder
③ Power Jack	Connects the power cord to the i-CHROMA Reader
④ Serial Port	Connects the key pad and/or printer through 'Y' Cable or RS232 Cable or to the i-CHROMA Reader
⑤ Power Switch	Turns the power On/Off
⑥ ID Chip Port	For inserting the ID Chip
⑦ Test Cartridge Port	Accommodates the cartridge holder meant for inserting the sample-loaded i-CHROMA Test Cartridge



7. Initial Installation Procedure

⚠	Before using the i-CHROMA Reader, make sure you have read the warning and cautions described previously in the 'Safety Information' section of this manual.

Power requirements

i-CHROMA Reader will work on household power line i.e. 110-120 V or 220-240 V AC with 50 ~ 60 Hz. If you are uncertain of your power line, consult your utility manager.

Set up

i-CHROMA Reader should be placed on a dry, clean, flat, and horizontal surface in an indoor setting away from direct sunlight, mechanical vibration and any source of electromagnetic radiation (power transformers for example).

To set-up i-CHROMA Reader for the first time, remove the contents from the package. Inspect the contents for any physical damage and/or missing component(s).

Installation

1. Connect the power cord, key pad and printer to the *i*-CHROMA Reader. (**Figure 1**)
2. Plug-in the power cord into an external power outlet.
3. Turn 'ON' the power switch provided on the left side of *i*-CHROMA Reader. (**Figure 2**)
4. *i*-CHROMA Reader will execute a series of self-checking routine; upon successful completion of which; the screen will initially display the following:
   (Actual display may differ in textual content and manner depending on the version of the software programed which is subject to up-gradation).

Figure 1: Connect the Power Cord

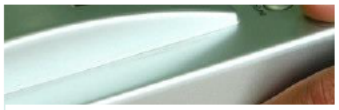


Figure 2: Turn Power Switch 'On'

```
M E N U    XX
      HH:MM:SS
 * Test Mode
  Setting Mode
```

(XX stands for the ambient temperature in degree Celsius and HH:MM:SS stands for time being displayed in Hour : Minute : Second)

5. i-CHROMA Reader is now ready for use.

8. Operation

Operation of i-CHROMA Reader is based on five primary functions; each of which is controlled by one or more keys/buttons provided on the front panel of the i-CHROMA Reader.

However, the numeric key pad needs to be attached to the i-CHROMA Reader for inputting the patient ID while testing clinical samples.

The software programmed in the i-CHROMA Reader has been designed in a concise and user-friendly manner for convenience of the user.

Each of the five primary functions managed by the functional keys/buttons of i-CHROMA Reader is described in the following section.

Function Keys

The term 'cursor' used in the successive description stands for the '*' mark displayed on the screen of i-CHROMA Reader.

Key	Description of the function
In/Out	This key/button function moves the 'Cartridge Holder' in and out of the main body of i-CHROMA Reader. This key is also used to end the test run. At the end of the test run, the cartridge holder stays protruded outside the main body of the i-CHROMA Reader. Pressing this key retracts the cartridge holder back into the main body of the i-CHROMA Reader.
Select	This key/button function selects and executes the command denoted by the position of the cursor.
Reset	This key/button function reverts the system to the immediate previous mode or the 'MENU' mode
Up	This key/button function moves the cursor upwards the line of commands being displayed on the screen at the given time.
Down	This key/button function moves the cursor downwards the line of commands being displayed on the screen at the given time.

9. Procedure for System Check

⚠	The 'System Check' is performed to ascertain whether the i-CHROMA Reader is functioning properly.

Following steps describe the recommended system check procedure for i-CHROMA Reader using the 'System Check Device' which consists of a 'System Check Cartridge' and a 'System Check ID Chip'.

i-CHROMA Reader 'System Check Cartridge' and 'System Check ID Chip'

Applicable Steps and On-Screen Displays

1	When you turn the power switch 'ON', the i-CHROMA Reader will automatically perform a self-check routine (displayed as 'Self-Test Mode') up on completion of which; the system displays the default 'MENU'. (**Ver : U1.X.X.X** stands for the version number of the software programmed in the i-CHROMA Reader at the given time).	**Please Wait** **Self Test Mode** **Ver : U1.X.X.X**
2	In the default 'MENU', the cursor (*) normally denotes 'Test Mode'. Press 'Select' key to proceed. The cursor (*) can be moved with 'Up' or 'Down' key so that it denotes the 'Test Mode' before pressing the 'Select' key to proceed.	**M E N U XX** **HH:MM:SS** *** Test Mode** **Setting Mode**
3	The message 'Insert ID Chip' is displayed on the screen.	**Insert** **ID Chip**
4	Insert the 'System Check ID Chip' in the 'ID Chip Port'.	
5	i-CHROMA Reader automatically ejects the test cartridge holder and displays the message alert 'Input Patient ID'	**Input** **Patient ID** **PID:** **Pre=RST/Next=SEL**
6	Press 'Select' button to skip inputting 'Patient ID'. i-CHROMA Reader displays the message alert 'Insert System Check Cartridge'	**PID** **Insert System** **Check Cartridge** **Select to Start**

7	Insert the 'System Check Cartridge' into the 'Cartridge Holder'. Press the 'Select' button.	
8	The cartridge holder along with the 'System Check Cartridge' will move into the *i*-CHROMA Reader i-CHROMA Reader will scan the 'System Check Cartridge'.	**PID** **System Check** **Reaction** **Progressing**
9	The 'System Check' test result will be displayed on the screen. You can print it also. The cartridge holder along with the 'System Check Cartridge' will be automatically ejected. Press the 'Reset' key twice. Screen will return to the 'MENU' mode. Remove the 'System Check ID Chip' from the 'ID Chip Port'. Now you can proceed to perform the tests on controls or samples.	**PID** **System Check** **System OK**

⚠	If *i*-CHROMA Reader displays the error message alerts '**System Check Error S1**' or '**System Check Error S2**', contact Boditech Med Inc.'s Technical Services.

10. Test Cartridge Handling

The patient sample or control (mixed with detection buffer) should be loaded into the ‘Sample Well’ of the ‘i-CHROMA Test Cartridge’.

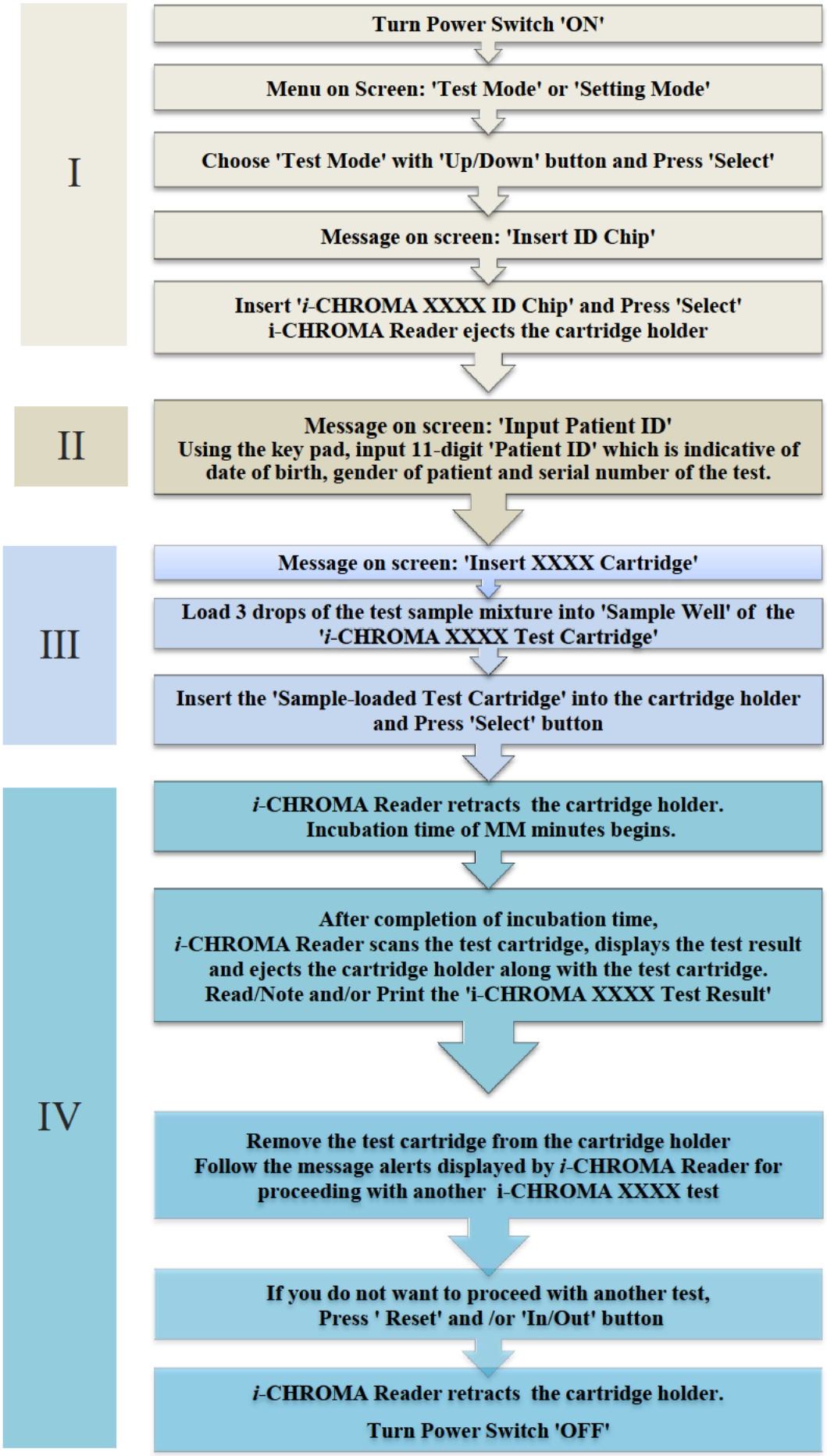
The sample-loaded test cartridge should be inserted into the cartridge holder in the direction pointed by the ‘Arrow’ specially marked on the test cartridge so that the sample well is oriented towards the i-CHROMA Reader.

For inserting the sample-loaded test cartridge, push it gently using your thumb or the index finger, all the way into the cartridge holder until it comes to a stop. Use of excessive force for this purpose may result in mechanical failure of the system.

Used test cartridges and sample collection tubes should be treated as being potentially infectious and be disposed of in accordance with local, state or federal regulations regarding the disposal of bio-hazardous materials.

	For reducing the chances of bio-hazards, high temperature autoclaving of the used i-CHROMA test cartridges followed by their incineration is recommended.

11. Flow Chart for Test Mode *i*-CHROMA Reader



12. Procedure for Test Mode

⚠	Actual display may differ in textual content and manner depending on the version of the software programed which is subject to up gradation. If an error message is displayed on the screen, refer to chapter 14 'Troubleshooting'.)

Following steps describe the operational part of i-CHROMA Reader for performing a test using the specific 'i-CHROMA Test Cartridge'.
Before performing any i-CHROMA Test, please read the respective package insert carefully for other details of the test procedure.

Applicable Steps and On-Screen Displays

1	When you turn the power switch 'ON', the i-CHROMA Reader will automatically perform a self-check routine (displayed as 'Self-Test Mode') up on completion of which; the system displays the default 'MENU'.	**Please Wait** **Self Test Mode** **Ver : U1. X.X.X**
2	In the default 'MENU', the cursor (*) normally denotes 'Test Mode'. Press 'Select' button to proceed. The cursor (*) can be moved with 'Up' or 'Down' button so that it denotes the 'Test Mode' before pressing the 'Select' button to proceed.	**M E N U XX** **HH:MM:SS** *** Test Mode** **Setting Mode**
3	The message 'Insert ID Chip' is displayed on the screen.	**Insert** **ID Chip**
4	Insert the appropriate and matching 'ID Chip' in the 'ID Chip Port'.	
5	i-CHROMA Reader automatically ejects the test cartridge holder and displays the message alert 'Input Patient ID'	**Input** **Patient ID** **PID:** **Pre=RST/Next=SEL**
6	Using the key pad, input an 11-digit patient ID based on the patient information and laboratory record system, in the following manner: - First six digits for patient's date of birth e.g. enter March 9, 2014 as 030914 - Next two digits for patient's gender e.g. 01 for male and 02 for female - Last three digits for serial number of the test as entered/to be entered in record/ information management system of the laboratory e.g. enter 'Serial No. 1' as '001' (Note: *You can skip inputting the 'Patient ID' while testing controls by pressing the 'Select' button.*	**Input** **Patient ID** **PID: 03091401001** **Pre=RST/Next=SEL**

7	After inputting an appropriate 'Patient ID', press 'Select' button. *i*-CHROMA Reader displays the message alert 'Insert XXXX Cartridge'	**PID** **Insert XXXX** **Cartridge** **Select to Start**
8	If the i-CHROMA Reader is in default i.e 'Single' mode of reaction time setting, insert the test cartridge immediately into the cartridge holder (after loading with test sample or control duly mixed with the detection buffer). Press 'Select' button.	
9	The cartridge holder along with the test cartridge will move into the i-CHROMA Reader. i-CHROMA Reader will automatically scan the inserted test cartridge after the specific incubation time is over. (**Note:** *If the i-CHROMA Reader has been set in 'Multi' mode of reaction time setting, allow the sample-loaded test cartridge to complete the specific incubation time and then insert into the cartridge holder.* *Up on pressing 'Select' button, i-CHROMA Reader will scan the sample-loaded test cartridge immediately after inserting it in the cartridge holder.* *For more details, refer to 'Setting Reaction Time' in 'Chapter 13. Procedure for Setting Mode'*	**XXXX Test** **Reaction** **Progressing** **10.00**
10	The test result will be displayed on the screen. You can also print the test result (optional). The cartridge holder along with the test cartridge will be automatically ejected. Remove the test cartridge from the cartridge holder.	**XXXX Test** **Test Result** **PID**
11	If you wish to perform the same type of test again, press 'Reset' button and repeat the procedure mentioned in step no. 6 ~ 9 for testing another sample using a new test cartridge. If you do not wish to perform another test immediately, Press 'Reset' button twice. System will return to the 'MENU' mode. Remove the 'ID Chip. You can perform another test after some time by repeating the procedure mentioned in step no. 2 ~ 9. If you do not wish to perform any more tests later in the day, press the 'In/Out' button. The cartridge holder will move back inside the i-CHROMA Reader. Turn the power switch 'OFF' Disconnect the power cable. Keep the i-CHROMA Reader covered till further use.	**M E N U XX** **HH:MM:SS** *** Test Mode** **Setting Mode**

13. Procedure for Setting Mode

1	When you turn the power switch 'ON', i-CHROMA Reader will automatically perform the pre-programmed system self-check routine (displayed as 'Self-Test Mode') up on completion of which; the system displays the default 'MENU'.	Please Wait Self Test Mode Ver : X.XX
2	In the default 'MENU', the cursor (*) normally denotes 'Test Mode'.	M E N U XX HH:MM:SS * Test Mode Setting Mode
3	Move the cursor with 'Up' or 'Down' button so that it denotes the '**Setting Mode**'. Press 'Select' button to proceed.	M E N U XX°C HH:MM:SS Test Mode * Setting Mode
4	Move the cursor again with 'Up' or 'Down' button so that it denotes any of the four functions/parameters you want to set. Press 'Select' key to proceed.	* Recall Result Time Set Calibration Reaction Time
	A. Procedure for 'Recall Result':	
5	'Recall Result' mode is used to recall or retrieve stored/previous test results. Enter the system into the 'Setting Mode' and then select 'Recall Result' You can recall and retrieve/print up to 50 stored test results. You can search the test result(s) in order of default test no. as stored in the memory of *i*-CHROMA Reader by pressing 'Up' or 'Down' button.	XXX Test 1234 Test Result PID:
6	For printing the test result(s), press 'Select' button. Select 'One' mode (for printing the particular test result after searching it) or 'All' mode (for printing the entire stored data) with 'Up' or 'Down' button and then press 'Select' button to proceed. When you finish noting/printing the test result(s), you can revert to 'Menu' mode step by step by repeatedly pressing the 'Reset' button. For clearing the memory and/or deleting the stored test results, select 'Erase'. However, test result(s); once erased cannot be retrieved.	Print Data * One All Erase
	B. Procedure for 'Time Set':	
7	'Time Set' mode is for setting the date/time when you install the i-CHROMA Reader for the first time or reuse the i-CHROMA Reader after not using it for more than a month. Enter the system into the 'Setting Mode' and then select 'Time Set'. Press 'Select' button for starting with setting date and/or time.	MENU → RESET SET → SELECT Date. Month. Year Hour : Minute

8	Keep on pressing the 'Select' button to move forward from Date → Month → Year → Hour → Minute while setting date and/or time. Press 'Reset' button to move backward. Enter the desired value for date, month, year, hour and minute by repeatedly pressing 'UP' or 'Down' button. When you finish setting the date and time, you can revert to 'Menu' mode step by step by repeatedly pressing the 'Reset' button.	**MENU → RESET** **SET → SELECT** **Date. Month. Year** **Hour : Minute**
	C. Procedure for 'Calibration'	
9	'Calibration' mode is used to adjust the calibration factor (in terms of a percentage factor) for quantitative *i*-CHROMA tests as per requirement of the laboratory. Enter the system into the 'Setting Mode' and then select 'Calibration' You can search the required i-CHROMA test by pressing 'In/Out' button to move serially forward or by pressing 'Select' button to move serially backward.	**Item → IN/SELECT** **Value → Up/Down** **1. PSA** **CAL = 1%**
10	You can enter the desired value of calibration factor for the particular i-CHROMA test by pressing the 'Up' and/or 'Down' buttons. After setting the desired calibration factor, you can revert to 'Menu' mode step by step by repeatedly pressing the 'Reset' button. Calibration setting is not applicable to qualitative *i*-CHROMA tests like the *i*-CHROMA iFOB test.	**Item → IN/SELECT** **Value → Up/Down** **3. hsCRP** **CAL = 5%**
	D. Procedure for 'Reaction Time'	
11	'Reaction Time' mode is used to program/set the manner whether the sample-loaded test cartridge is to be inserted in the cartridge holder immediately or after completing the specific incubation time outside the cartridge holder (after loading the test sample into its sample well). Enter the system into 'Setting Mode' and then select 'Reaction Time' To choose the required mode, move the cursor with 'Up' or 'Down' button and press 'Select'.	**< Choose One>** **Multi** ***Single** **Individual**
12	By default, i-CHROMA Reader has been set in 'Single' mode. In '**Single**' mode, reaction time of each i-CHROMA test has been set differently as fixed by Boditech Med Inc. because reaction time is different for various i-CHROMA tests. Hence, if you have to perform i-CHROMA iFOB test, you must insert the sample-loaded test cartridge immediately into the cartridge holder (after loading the test sample mixed with detection buffer into the 'sample well'). Up on pressing 'Select' button, i-CHROMA Reader will automatically scan the inserted test cartridge after the incubation time i.e. 10 minutes. Advantage of 'Single' mode is that you need not pay attention and/or watch carefully till the incubation time is over because incubation time is completed inside the i-CHROMA Reader. Disadvantage of 'Single' mode is that in case of i-CHROMA tests having long incubation time e.g. i-CHROMA iFOB (10 min), i-CHROMA PSA (15 min) etc., you can perform only 4-5 tests per hour.	

In '**Multi**' mode, reaction time of all i-CHROMA tests has been set to a default value of 0 minute.

Hence, if you want to perform i-CHROMA iFOB test, you must keep the sample-loaded test cartridge for 10 minutes (after loading the test sample mixed with detection buffer into the 'sample well') and then insert it into the cartridge holder .

12 Up on pressing 'Select' button, i-CHROMA Reader will immediately scan the inserted test cartridge.

Advantage of 'Multi' mode is that you can perform many tests per hour even if the incubation time is long e.g. i-CHROMA iFOB (10 min) and i-CHROMA PSA (15 min) etc.

Disadvantage of 'Multi' mode is that you have to carefully watch for the incubation time to complete.

'**Individual**' mode combines the features of 'single' mode and 'Multi' mode. 'Individual' mode is ideal for better time management in relation to the work load.

Item → IN/SELECT
Value → Up/Down
25. iFOB
Reaction 0 min

If you select 'Individual' mode, you can perform some i-CHROMA tests on the basis of 'single' mode and some i-CHROMA tests on the basis of 'Multi' mode.

Suppose your laboratory mostly performs many i-CHROMA CRP and i-CHROMA iFOB tests on daily basis.

If you operate the i-CHROMA Reader in 'Single' mode, you will be able to perform only 5-6 i-CHROMA iFOB tests per hour because the reaction time of i-CHROMA iFOB test is 10 minutes.

If you operate the i-CHROMA Reader in 'Multi' mode, you have to ensure that the test cartridge(s) is inserted in the i-CHROMA iFOB Reader after specific reaction time is over. You will have to be very careful while
13 performing the i-CHROMA CRP test which has the reaction time of just 3 minutes.

Hence 'Individual' mode is recommended in such cases. In 'Individual' mode, set the reaction times of i-CHROMA CRP and -CHROMA iFOB tests to 3 and 0 minutes respectively.'

If you operate the i-CHROMA iFOB Reader in 'Individual' mode, you will not have to note the time while performing the i-CHROMA CRP test because you will perform the i-CHROMA CRP test in a manner similar to 'Single' mode.

Moreover, you will be able to perform more than 5-6 i-CHROMA iFOB tests per hour because you will perform the i-CHROMA iFOB test in a manner similar to 'Multi' mode.

In 'Individual' mode, you can set the reaction time with 'Up' or 'Down' button after changing the test with 'In' or 'Select' key.

For reverting to previous screen, press 'Reset' button.

Important	Reaction time varies depending on the i-CHROMA test being performed. Please read the package insert of the i-CHROMA test under consideration for confirming the reaction time.

14. Troubleshooting

Though the i-CHROMA Reader in conjunction with the i-CHROMA Tests has been designed to be a perfectly working system, it may encounter some operational problems occasionally. The symptoms, probable causes and recommended remedial/corrective measures for these problems have been listed in the table below.

Operational stage	Symptom/Error message alert	Probable cause(s) Symptom or Error message alert	Remedial measure(s)/ Corrective action(s)
Power switch turned 'ON'	No sign of functioning.	Power failure	Check whether external power outlet is live.
		Main power switch is 'Off'.	Turn the main power switch 'On'.
		Poor connection between the power cable and the power adapter	Remove the power cable from the power adaptor and reconnect firmly.
		Faulty power adapter	Contact manufacturer's technical services
	'Screen Display' does not function properly.	Electrostatic discharge circuit of LCD device is faulty.	Contact manufacturer's technical services
		Malfunctioning of the LCD device	
	'Self-test Mode' followed by 'Error 21 Turn Off the Power'	Malfunctioning of photo interrupter and/or motor	Contact manufacturer's technical services
	'Self-test Mode' followed by 'Error 22 Turn Off the Power'	Malfunctioning of barcode signal sensor	Contact manufacturer's technical services
	'Self-test Mode' followed by 'Error 23 Turn Off the Power'	Malfunctioning of LEDs and/or the detector (for hemoglobin measurement)	Contact manufacturer's technical services
	'Self-test Mode' followed by 'Error 24 Turn Off the Power'	Malfunctioning of illuminating light source (laser)	Contact manufacturer's technical services
'System Check'	System Check Error S1	Malfunctioning of main photo sensor and/or the illuminating light source (laser)	Contact manufacturer's technical services
	System Check Error S2	Malfunctioning of LEDs and/or the LED photo sensor	Contact manufacturer's technical services
Test Mode	Insert ID Chip (even after inserting the ID Chip'	Inserted ID Chip could not be sensed by the *i*-CHROMA Reader due to: ➢ Malfunctioning of the 'ID Chip Socket' ➢ Malfunctioning of the inserted ID Chip due to physical damage or faulty circuit	Contact manufacturer's technical services

	Invalid Item	Inserted ID Chip was sensed but the calibration data encoded in the inserted ID chip was found unacceptable	Contact manufacturer's technical services
	Cartridge holder not ejected at all or not ejected as and when prompted	Malfunctioning of software	Turn the power 'Off' and turn it 'On' again.
		Mechanical failure	Contact manufacturer's technical services
	Cartridge holder not ejected smoothly or buzzing noise heard during ejection	Temporary mechanical misalignment of test cartridge holder	Press 'Reset' button.
	Caution! Barcode Error	1) Barcode printed on face of the inserted test cartridge has been partially obscured due to presences of blemishes or misprinting. 2) Test cartridge has not been inserted completely all the way inside the cartridge holder. 3) Test cartridge has been inserted: - in a direction opposite to that denoted by the 'arrow' marked on its face - in an inverted position i.e. without facing its right surface (sample well and scanning window) upwards	Repeat the test by using a new test cartridge or by re-inserting the test cartridge properly in the cartridge holder.
	'Caution! ID Chip Lot Number Mismatch'	Lot number of the ID Chip is not exactly same as the lot number of inserted test cartridge.	Repeat the test using ID Chip and test cartridge having exactly same lot number.
	'Caution! ID Chip Cartridge Mismatch'	ID Chip does not match with the inserted test cartridge.	Repeat the test using matching ID Chip and Test Cartridge.
	Caution! Error	Test cartridge has been inserted but: ➢ Without loading the sample mixture **or** ➢ After loading just 1 drop or 2 drops of the sample mixture.	Repeat the test after correcting the error
	Caution! Error	Malfunctioning of internal/procedural control of the test cartridge	Repeat the test with a new test cartridge.
	Error 26~29	Malfunctioning of the inserted test cartridge such that the signal generated at its test line or control line could not be detected/processed by the Reader.	Repeat the test with a new test cartridge and/or sample collection tube.

15. Care, Handling and Storage

Do not disassemble the i-CHROMA Reader. If you have any questions, please contact our local distributor or authorized representative.

Please use the i-CHROMA Reader gently. Avoid throwing, shaking or dropping it, which may damage its internal components.

Keep the i-CHROMA Reader free of dust. Occasionally clean or wipe the exterior of the i-CHROMA Reader with a soft cloth slightly dampened with water.

Do not use industrial solvents for cleaning the i-CHROMA Reader.

Do not wash the i-CHROMA Reader or pour any liquid over it.

Handle the i-CHROMA Reader with care and avoid exposing it to direct sunlight and/or extreme temperatures.

Do not expose the i-CHROMA Reader to an environment having high humidity such as bathroom, kitchen etc.

Store and transport the i-CHROMA Reader in dry conditions having temperatures 15~35℃ (59~95°F).

It is recommended to use the carrying case whenever required.

Expose the test system to ambient temperature for at least 30 minutes until just prior to performing the test actually.

16. Maintenance, Servicing and Disposal

No maintenance other than proper replacement and periodic cleaning is required for the i-CHROMA Reader normally. Occasional cleansing of the exterior with a soft and dry cloth is sufficient. However, if any service or maintenance were to be required, i-CHROMA Reader should be sent to Boditech Med Inc.

Power Supply

Use only the AC/DC power adapter provided with the i-CHROMA Reader. In case the power adapter needs replacement, you should contact Boditech Med Inc. or its authorized representative. Boditech Med Inc. provides CE certified Class 2 power adapters, rated at +12V 3-5A.

Return Procedure

Should your i-CHROMA Reader malfunction, first call Boditech Med Inc.'s Technical services on +82 33 243 1400 for consultation. If it is decided that the unit be returned to Boditech Med Inc., a return authorization number will be issued. Boditech Med Inc. will then send a replacement for the i-CHROMA Reader. The user is expected to utilize the packaging supplies accompanying the replacement to ship the malfunctioning unit. Verify the return authorization number on the package and send the malfunctioning unit to Boditech Med Inc. upon receiving the replacement for i-CHROMA Reader.

Transportation and Storage

The original shipping container/box should be used to ship or transport i-CHROMA Reader. The same container/box is also recommended for storing i-CHROMA Reader over an extended period of non-use.

⚠	When transporting or storing i-CHROMA Reader, keep it dry in an upright position and protect it from mechanical shocks.

Disposal

If the i-CHROMA Reader is to be disposed of for any reason, the user is advised to observe standing applicable ordinances regarding disposal of electrical equipment.

	Important! At the end of its useful life, the i-CHROMA Reader could be sent back to Boditech Med Inc. for recycling or proper disposal. Alternatively it should be disposed of in accordance with local regulations.

17. Statement of Conformity

Boditech Med Inc. declares that i-CHROMA Reader meets the CE Mark Requirements according to Annex III, IV, VII of the in-vitro diagnostic medical devices Directive 98/79/EC following standards:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
ISO 9002:1994 Quality systems – Model for quality assurance in production, installation and servicing
EN 980:2008 Symbols for use in the labeling of medical devices
ISO 18113-1:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements
ISO 18113-5:2009 In vitro diagnostic medical devices- Part 5 – In vitro diagnostic instruments for self-testing
EN 13532:2002 General requirements for in vitro diagnostic medical devices for self-testing
EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2009 Medical devices - Application of risk management to medical devices
IEC 61010-1:2001 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC 61010-2-101:2001 Safety requirements for electrical equipment for measurement, control and laboratory use: Particular requirements for in vitro diagnostic (IVD) medical equipment.
EN 61326-2-6:2006 Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
IEC 62304:2006 Medical device software- Software life cycle processes

18. Warranty

i-CHROMA Reader has passed strict quality assurance and testing procedures. Boditech Med Inc.'s expressed and implied warranties are conditional upon full observance of Boditech Med Inc.'s published directions with respect to the use of Boditech Med Inc.'s products. Under no circumstances whatsoever shall Boditech Med Inc. be held liable for any indirect or consequential damages.

To avail the warranty service, the consumer must return the defective i-CHROMA Reader or its component along with proof of purchase to the nearest Boditech Med Inc's Technical Services.

Warranty Information

1 During the warranty period (12 months from the date of purchase), defective or spontaneously malfunctioning i-CHROMA Reader or its components will be repaired free of cost or may be compensated for in accordance with consumer protection rules and regulations.

2 The consumer may be charged for repair of i-CHROMA Reader even during the warranty period in following cases:

- 2.1 Improper use or misuse
- 2.2 Consumer's intentional mishandling, abuse or neglect of the product(s)
- 2.3 Unauthorized repair or replacement of any component
- 2.4 Lost product warranty or changes in contents
- 2.5 Damages or defects due to fire, pollution, earthquake or other natural disasters.

For after-sales inquiry, please contact:

Boditech Med Incorporated
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPIUBLIC OF KOREA.

Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr
Website: www.boditech.co.kr

Warranty Card

Thank you for purchasing i-CHROMA Reader.
Please fill the required information and send one copy of this warranty card within 30 days of purchasing the i-CHROMA Reader.

Product Name	
Serial No.	
Date of Manufacture	
Warranty Period	12 months from the date of purchase
Date of Purchase	Year _____ Month ____ Day
Manufacturer	Boditech Med Inc.

19. Contact Information

For technical assistance, please contact:
Boditech Med Inc.'s Technical Services
Tel: + 82 33 243 1400
E-mail: support@boditech.co.kr

Boditech Med Incorporated
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.

Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr

Website: www.boditech.co.kr

Appendix VI:

System Information and Clinical Testing for CLIA Waiver Application of *i*-CHROMA iFOB

Based on the USFDA guidance document "Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices (issued on: January 30, 2008), following integrated approach has been adopted to establish suitability of *i*-CHROMA iFOB for CLIA Waiver application:

VI.1) Demonstrating 'simplicity' of *i*-CHROMA iFOB for use/operation

VI.2) Demonstrating 'insignificant risk of erroneous result(s)' through:

- **a)** Performing 'risk analysis' including identification of potential sources of error for *i*-CHROMA iFOB
- **b)** Conducting 'flex studies' and evaluating the results to establish 'robust design' of *i*-CHROMA iFOB test system making it 'insensitive to environmental and usage variation under conditions of stress'
- **c)** Using 'risk management' for evaluation and effective control of risk of all known potential errors associated with *i*-CHROMA iFOB by:
  - **i)** Specifying/describing appropriate 'risk control measures'; particularly the 'fail-safe' and 'failure alert' mechanisms incorporated in the test system to mitigate the risk of errors **&**
  - **ii)** Performing validation and/or verification studies to demonstrate the ability/ effectiveness of these fail-safe & failure alert mechanisms and other risk control measures in mitigating the risk of errors

VI.3) Performing clinical testing with appropriate study design and evaluating the results to demonstrate 'accuracy' of *i*-CHROMA iFOB at the hands of intended operator(s)

VI.4) Providing proposed 'labeling/instructional material' i.e. 'Package Insert' and 'Quick Reference Instructions' which are consistent with the 'simple' feature of *i*-CHROMA iFOB

VI.1 Demonstrating 'simplicity' of *i*-CHROMA iFOB for use:

Following features of *i*-CHROMA iFOB establish the fact that *i*-CHROMA iFOB in conjunction with *i*-CHROMA Reader is 'simple' to use and operate:

1) Self-contained semi-automated nature:

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

The antigen-antibody complexes formed after mixing the human fecal sample with the detection buffer are captured onto the capture antibodies immobilized at the test line and the control line of the test cartridge upon loading the sample mixture into the its sample well.

The sample-loaded test cartridge is further scanned by the *i*-CHROMA Reader which computes, converts, and displays the test result in a qualitative (positive or negative) manner.

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip', a 'Sample Collection Tube' containing the 'Detection Buffer' and '*i*-CHROMA Reader'

Thus *i*-CHROMA iFOB is a self-contained semi-automated test because the user does not require any reagent(s) and/or instrument other than those provided by the manufacturer.

2) Use of human fecal samples/specimens without any processing:

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

i-CHROMA iFOB is based on antigen-antibody reaction and fluorescence technology wherein the antigen-antibody complexes formed after mixing the test sample with the detection buffer are captured while migrating through the test cartridge which is scanned by the *i*-CHROMA Reader to compute, convert and display the test result in a qualitative (positive or negative) manner.

Sample preparation for *i*-CHROMA iFOB comprises two simple steps as follows:

i) Sampling/Transferring the fecal sample into the detection buffer tube by patient or operator **&**

ii) Mixing the fecal sample with the detection buffer by simply shaking the sample collection tube before performing the test

Thus *i*-CHROMA iFOB is a simple test which does not involve any specialized processing of the test sample other than simply transferring and mixing the fecal sample with the detection buffer in the sample collection tube.

3) Basic, non-technique-dependent specimen manipulation, including any decontamination:

It is recommended that the laboratory/physician office should put one '*i*-CHROMA iFOB Sample Collection Tube' into the 'Sample Sac' contained in the 'Patient Pack' before handing over the 'Patient Pack' to the patient.

The patient is supposed to transfer fecal sample into the *i*-CHROMA iFOB sample collection tube at home and returns it to the laboratory for testing.

Sample collection/Sampling procedure and other relevant instructions have been illustrated with help of suitable diagrams in the 'Patient Information Leaflet' provided in the patient pack.

The patient returns the sample collection tube to the physician office/laboratory where this fecal sample mixture (in the sample collection tube) is used for the test without any processing.

Thus *i*-CHROMA iFOB involves only basic, non-technique-dependent specimen manipulation without any need for decontamination of the test sample.

4) Basic, non-technique-dependent reagent manipulation:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer'.

None of these test components needs any modification or processing. The sample collection tube needs to be simply shaken to mix the fecal sample with the detection buffer.

Thus *i*-CHROMA iFOB involves only basic, non-technique-dependent reagent manipulation.

5) No need of operator intervention during the analysis steps:

Upon inserting the sample-loaded test cartridge in the cartridge holder, the *i*-CHROMA Reader scans the inserted test cartridge to automatically compute and convert the test result based on a pre-programed calibration.

i-CHROMA Reader then displays the test result in a qualitative (positive or negative) manner.

The test result is to be reported to the attending physician for valid interpretation and appropriate medical intervention.

Thus *i*-CHROMA iFOB test does not require any operator intervention during the analysis steps.

6) No need of technical or specialized training with respect to troubleshooting or interpretation of multiple or complex error codes:

i-CHROMA Reader is meant for scanning the sample-loaded test cartridge for automatic computation, conversion and display of test result.

i-CHROMA Reader has been designed to perform these tasks in a preprogrammed manner.

Error message alerts/codes if any; are also displayed by the *i*-CHROMA Reader.

'*i*-CHROMA Reader Operation Manual' contains all the information on interpretation and preventive or corrective actions required for troubleshooting in case any error code is displayed by the *i*-CHROMA Reader.

This information has been provided in a simple and easily understandable manner.

Most of the error codes have been incorporated into test system as the ‘fail-safe mechanisms’ whereby the test is terminated without any test result and the operator has to repeat the test using another test cartridge.

'*i*-CHROMA iFOB Quick Reference Instructions' and '*i*-CHROMA iFOB Package Insert' also contain the relevant information.

Thus the system operator does not require any technical knowledge or specialized training for the purpose of the test with respect to troubleshooting or interpretation of multiple or complex error codes.

7) No need of electronic or mechanical maintenance beyond simple tasks:

The laboratory or physician office does not need to carry out any electronic or mechanical maintenance of any *i*-CHROMA iFOB test component including the *i*-CHROMA Reader.

The ‘Test Cartridge’, ‘ID Chip’ and ‘Sample Collection Tube’ just need to be stored in appropriate conditions as mentioned in the instructional material.

The operator has to simply arrange the power connection for the *i*-CHROMA Reader. Only periodic cleaning of the exterior of *i*-CHROMA Reader is required normally.

The manufacturer strongly discourages any electronic or mechanical maintenance and/or repair of the system at the user level. If warranted, the manufacture offers authorized repair or replacement services. Instructions to this effect have been included in the instructional material.

8) Direct read-out of test results i.e. no need of calibration, interpretation, or calculation by the operator:

‘ID Chip’ is an essential component of *i*-CHROMA iFOB. A matching ID Chip needs to be inserted in the ‘ID Chip Port’ of the *i*-CHROMA Reader before inserting the sample-loaded test cartridge in the cartridge holder. The ID chip contains a memory device encoding the calibration data/information.

i-CHROMA Reader scans the inserted test cartridge to automatically compute, convert and display the test result in a qualitative i.e. ‘Negative’ or ‘Positive’ manner based on a pre-programed calibration presented by the already inserted ID chip.

The test result is to be reported to the attending physician for valid interpretation and appropriate medical intervention.

Thus as *i*-CHROMA iFOB provides direct read-out of test results, the operator has no role in calibration, calculation and interpretation with respect to the test result.

9) Easy-to-determine test results:

Though the underlying measurement is quantitative, *i*-CHROMA iFOB test system would display the test results in a qualitative i.e. ‘Negative’ or ‘Positive’ manner only; thus offering easy-to-determine test results.

10) Instructions in the package insert for confirmation testing if advisable:

It has been clearly instructed in the '*i*-CHROMA iFOB Package Insert' that the test result(s) must be reported to the attending physician for valid interpretation and appropriate medical intervention which may include obtaining or shipping the fecal sample(s) for confirmation testing if advised by the physician.

11) Test performance comparable to a traceable reference method:

Clinical performance testing of *i*-CHROMA iFOB in comparison to a traceable reference method ‘OC Auto Micro FOB with OC Auto Micro 80 Analyzer’ (Polymedco Inc., USA) was carried out by prospective testing human fecal samples in intended use sites.
The study demonstrated that performance of *i*-CHROMA iFOB was comparable to the reference method.

12) Quick Reference Instructions (QRI) sheet written at no higher than a 7th grade reading level:

‘*i*-CHROMA iFOB Quick Rererence Instructions (QRI)' guide has been written at no higher than a 7th grade reading level.

In the clinical study, *i*-CHROMA iFOB testing was performed by operators who had minimum or no qualifications and/or previous training/experience relevant to laboratory clinical testing.

Written feedback obtained from the each operator participated in the clinical studies of *i*-CHROMA iFOB revealed that *i*-CHROMA iFOB Quick Rererence Instructions (QRI) guide had been written at no higher than a 7th grade reading level.

A ‘Patient Instruction Leaflet’ has also been included in the ‘Patient Pack’ for assisting the patient with sampling/transferring the fecal sample to the sample collection tube.

Other instructional material such as '*i*-CHROMA iFOB Package Insert', '*i*-CHROMA iFOB Control Insert' and '*i*-CHROMA Reader Operation Manual' also explain all the information required for performing the test in the simplest possible manner easily understandable by the intended operator.

VI.2 Demonstrating 'insignificant risk of erroneous test results with *i*-CHROMA iFOB:

The studies conducted for demonstrating insignificant risk of erroneous result(s) with *i*-CHROMA iFOB involved following steps:

a) Performing 'risk analysis' including identification of potential sources of error for *i*-CHROMA iFOB

b) Conducting 'flex studies' and evaluating the results to establish 'robust design' of *i*-CHROMA iFOB test system rendering it 'insensitive to environmental and usage variation under conditions of stress'

c) Using 'risk management' for evaluation and effective control of risk of all known potential errors associated with *i*-CHROMA iFOB by:

- **i)** Specifying/describing appropriate 'risk control measures'; particularly the 'fail-safe' and 'failure alert' mechanisms incorporated in the test system to mitigate the risk of errors **&**
- **ii)** Performing validation and/or verification studies to demonstrate the ability/ effectiveness of these fail-safe & failure alert mechanisms and other risk control measures in mitigating the risk of errors

A two-tiered approach, as outlined below, was adopted to demonstrate the robustness of *i*-CHROMA iFOB test system and provision of appropriate and effective risk control measures to ensure insignificant risk of an erroneous result with *i*-CHROMA iFOB.

Tier 1: Risk Analysis and Flex Studies

Tier 2: Fail-Safe and Failure Alert Mechanisms

VI.2.1 Risk Analysis:

As a part of the overall risk management process for *i*-CHROMA iFOB test system, a systematic and comprehensive risk analysis was conducted by identifying all potential sources of error including test system failures & operator errors, identifying the associated hazards and estimating the corresponding risks.

Implementation of the planned risk analysis activities and results of the risk analysis have been recorded in the **'Risk Analysis of *i*-CHROMA iFOB' (Appendix VII)**.

VI.2.2 Flex Studies:

Flex studies were conducted based on results of the risk analysis and potential problems regarding sensitivity of *i*-CHROMA iFOB test system to environmental and usage variation.

Flex studies were designed to challenge *i*-CHROMA iFOB test system under conditions of stress for identifying potential deficiencies (including failures) as well as determining robustness of the test system.

In addition to the stability studies described Section 18, some flex studies were performed through following approaches:

A) Flex studies on human fecal samples without mixing with detection buffer:

- Hemoglobin-negative fresh fecal samples spiked with human blood (with known hemoglobin level to obtain test samples containing 75 ng/mL & 125 ng/mL levels of hemoglobin)
- Sample collection tubes containing detection buffer stored at 2~8° C
- Sealed test cartridges stored at 4° **C** ~ 30 ° **C**
- Spiked fecal samples (without mixing with detection buffer) stored and tested as per following conditions:

Sr. No.	**Spiked samples stored at room temperature (15~37°C) for less than 12 hours**		**Spiked samples stored in freezing condition for 48 hours and thawed before mixing with detection buffer and testing**		**Spiked samples stored at 45° C for 72 hours**	
	75 ng/mL	**125 ng/mL**	**75 ng/mL**	**125 ng/mL**	**75 ng/mL**	**125 ng/mL**
1	Negative	Positive	Negative	Positive	Negative	Negative
2	Negative	Positive	Negative	Positive	Negative	Positive
3	Negative	Positive	Negative	Positive	Negative	Negative
4	Negative	Positive	Negative	Positive	Negative	Negative
5	Negative	Positive	Negative	Positive	Negative	Negative

B) Flex studies on human fecal samples mixed with detection buffer:

- Hemoglobin-negative fresh fecal samples spiked with human blood (with known hemoglobin level to obtain test samples containing 75 ng/mL & 125 ng/mL levels of hemoglobin)
- Sealed test cartridges stored at 4° **C** ~ 30° **C**
- Spiked fecal samples mixed with the detection buffer in sample collection tubes and stored and tested as per following conditions:

Sr. No.	**Spiked fecal samples tested immediately after mixing with detection buffer**		**Spiked fecal samples (mixed with detection buffer) stored in freezing condition for 96 hours & thawed before testing**		**Spiked fecal samples (mixed with detection buffer) stored at 45°C for 96 hours**		**Spiked fecal samples (mixed with detection buffer) stored at 2~8°C for 120 hours**	
	75 ng/mL	**125 ng/mL**	**75 ng/mL**	**125 ng/mL**	**75 ng/mL**	**125 ng/mL**	**75 ng/mL**	**125 ng/mL**
1	Negative	Positive	Negative	Positive	Negative	Negative	Negative	Positive
2	Negative	Positive	Negative	Positive	Negative	Positive	Negative	Negative
3	Negative	Positive	Negative	Positive	Negative	Negative	Negative	Negative
4	Negative	Positive	Negative	Positive	Negative	Negative	Negative	Positive
5	Negative	Positive	Negative	Positive	Negative	Negative	Negative	Negative

C) Flex studies on sample collection tubes containing detection buffer:

- Hemoglobin-negative fresh fecal samples spiked with human blood (with known hemoglobin level to obtain test samples containing 75 ng/mL & 125 ng/mL levels of hemoglobin)
- Sealed test cartridges stored at 4° **C** ~ 30° **C**
- Spiked fecal samples tested using sample collection tubes (containing detection buffer) stored as per following conditions:

Sr. No.	**Fresh spiked samples tested using detection buffer stored at 2~8° C**		**Fresh spiked samples tested using detection buffer stored in freezing condition for 3 months & thawed before using for the test**		**Fresh spiked samples tested using detection buffer stored at 37°C for 3 months**		**Fresh spiked samples tested using post-expiry detection buffer stored at 2~8°C**	
	75 ng/mL	**125 ng/mL**	**75 ng/mL**	**125 ng/mL**	**75 ng/mL**	**125 ng/mL**	**75 ng/mL**	**125 ng/mL**
1	Negative	Positive	Negative	Positive	Negative	Positive	Negative	Positive
2	Negative	Positive	Negative	Positive	Negative	Negative	Negative	Positive
3	Negative	Positive	Negative	Positive	Negative	Positive	Negative	Negative
4	Negative	Positive	Negative	Positive	Negative	Negative	Negative	Positive
5	Negative	Positive	Negative	Positive	Negative	Negative	Negative	Negative

D) Flex studies on test cartridges:

- Hemoglobin-negative fresh fecal samples spiked with human blood (with known hemoglobin level to obtain test samples containing 75 ng/mL & 125 ng/mL levels of hemoglobin)
- Spiked fecal samples mixed with the detection buffer in sample collection tubes stored at 2~8° C
- Spiked fecal samples tested using sealed test cartridges stored as per following conditions:

Sr. No.	**Spiked samples tested using test cartridges stored at** 4° **C** ~ 30° **C**		**Spiked samples tested using test cartridges stored in freezing condition for 3 months & thawed before using for the test**		**Spiked fecal sample tested using test cartridges stored at 45° C for 3 months**		**Spiked fecal samples tested using two months post-expiry test cartridges stored at** 4° **C** ~ 30° **C**	
	75 ng/mL	**125 ng/mL**	**75 ng/mL**	**125 ng/mL**	**75 ng/mL**	**125 ng/mL**	**75 ng/mL**	**125 ng/mL**
1	Negative	Positive	Negative	Positive	Negative	Positive	Negative	Positive
2	Negative	Positive	Negative	Positive	Negative	Negative	Negative	Positive
3	Negative	Positive	Negative	Positive	Negative	Negative	Negative	Positive
4	Negative	Positive	Negative	Positive	Negative	Negative	Negative	Positive
5	Negative	Positive	Negative	Positive	Negative	Negative	Negative	Positive

E) Flex studies using less than and more than the recommended quantity of test sample:

- Hemoglobin-negative fresh fecal samples spiked with human blood (with known hemoglobin level to obtain test samples containing 75 ng/mL & 150 ng/mL levels of hemoglobin)
- Spiked fecal samples mixed with the detection buffer in sample collection tubes stored at 2~8° C
- Sealed test cartridges stored at 4° **C ~** 30° **C**

Sr. No.	**No. of drops of fecal sample mixture loaded into the sample well of the test cartridge**											
	Spiked fecal sample (75 ng/mL) mixed with detection buffer						**Spiked fecal sample (125 ng/mL) mixed with detection buffer**					
	1 Drop	**2 Drops**	**3 Drops**	**4 Drops**	**5 Drops**	**6 Drops**	**1 Drop**	**2 Drops**	**3 Drops**	**4 Drops**	**5 Drops**	**6 Drops**
1	Caution Error	Caution Error	Negative	Negative	Negative	Negative	Caution Error	Caution Error	Positive	Positive	Positive	Positive
2	Caution Error	Caution Error	Negative	Negative	Negative	Negative	Caution Error	Caution Error	Positive	Positive	Positive	Positive
3	Caution Error	Caution Error	Negative	Negative	Negative	Negative	Caution Error	Caution Error	Positive	Positive	Positive	Positive
4	Caution Error	Caution Error	Negative	Negative	Negative	Negative	Caution Error	Caution Error	Positive	Positive	Positive	Positive
5	Caution Error	Caution Error	Negative	Negative	Negative	Negative	Caution Error	Caution Error	Positive	Positive	Positive	Positive

F) Flex studies by arranging the test setup and operating the *i*-CHROMA Reader outside the recommended operational environment of 15° C~ 37° C.

- Hemoglobin-negative fresh fecal samples spiked with human blood (with known hemoglobin level to obtain test samples containing 75 ng/mL & 125 ng/mL levels of hemoglobin)
- Spiked fecal samples mixed with the detection buffer in sample collection tubes stored at 2~8° C and Sealed test cartridges stored at 4° **C ~** 30° **C**

Sr. No.	**Test performed by arranging the test setup and operating *i*-CHROMA Reader at**					
	8° C~14° C		**15° C~37° C**		**38° C~45° C**	
	Spiked Fecal Sample (75 ng/mL)	**Spiked Fecal Sample** (125 ng/mL)	**Spiked Fecal Sample** (75 ng/mL)	**Spiked Fecal Sample** (125 ng/mL)	**Spiked Fecal Sample** (75 ng/mL)	**Spiked Fecal Sample** (125 ng/mL)
1	Negative	Positive	Negative	Positive	Negative	Positive
2	Negative	Positive	Negative	Positive	Negative	Positive
3	Negative	Positive	Negative	Positive	Negative	Positive
4	Negative	Positive	Negative	Positive	Negative	Positive
5	Negative	Positive	Negative	Positive	Negative	Positive

(*The term 'human fecal sample mixture' represents 'human fecal sample mixed with detection buffer in the i-CHROMA iFOB sample collection tube' as per i-CHROMA iFOB test procedure*.)

A) Storage of human fecal sample(s) (without mixing with detection buffer) under stress conditions:

1) Stored in freezing condition for 48 hours and thawed before mixing with detection buffer

2) Stored at 45 ºC for 72 hours before mixing with detection buffer

Summary of Results:

No erroneous test results were obtained with human fecal sample(s) stored in freezing condition for 48 hours and thawed before mixing with the detection buffer in the *i*-CHROMA iFOB sample collection tubes.

However, erroneous test results were obtained with human fecal sample(s) stored at 45 ºC for 72 hours before mixing with the detection buffer in the *i*-CHROMA iFOB sample collection tubes'.

B) Storage of human fecal sample(s) (mixed with detection buffer) under stress conditions:

1) Stored in freezing condition for 96 hours after mixing and thawed before testing

2) Stored at 45 ºC for 96 hours after mixing

3) Stored at 2~8 ºC for 120 hours after mixing

Summary of Results:

No erroneous test results were obtained with human fecal sample(s) mixed with detection buffer in the *i*-CHROMA iFOB sample collection tubes and stored in freezing condition for 96 hours after mixing and thawed before testing.

However, erroneous test results were obtained with human fecal sample(s) mixed with detection buffer in the *i*-CHROMA iFOB sample collection tubes and stored at 45º C for 96 hours after mixing.

Similarly, erroneous test results were also obtained with human fecal sample(s) mixed with detection buffer in the *i*-CHROMA iFOB sample collection tubes and stored at 2~8º C for 120 hours after mixing.

C) Storage of *i*-CHROMA iFOB sample collection tubes containing detection buffer under stress conditions

1) Stored in freezing condition for 3 months and thawed before using for the test

2) Stored at 37 ºC for up to 3 months.

3) Stored at 2~8 ºC but used beyond the expiration date.

Summary of Results:

No erroneous test results were obtained with *i*-CHROMA iFOB sample collection tubes containing detection buffer stored in freezing condition for 3 months and thawed before using for the test.

However, erroneous test results were obtained with *i*-CHROMA iFOB sample collection tubes containing detection buffer stored at 37 ºC for 3 months.

Similarly, erroneous test results were also obtained with *i*-CHROMA iFOB sample collection tubes containing detection buffer stored at 2~8 ºC but used beyond the expiration date.

D) Storage of sealed *i*-CHROMA iFOB test cartridges under stress conditions

1) Stored in freezing condition for 3 months and thawed before using for the test

2) Stored at 45 ºC for up to 3 months

3) Stored at 4~30 ºC but used two months beyond the expiration date

Summary of Results:

No erroneous test results were obtained with *i*-CHROMA iFOB test cartridges stored in freezing condition for 3 months and thawed before using for the test.

However, erroneous test results were obtained with *i*-CHROMA iFOB test cartridges stored at 45 ºC for 3 months.

No erroneous test results were obtained with *i*-CHROMA iFOB test cartridges stored at 4~30 ºC but used two months beyond the expiration date.

E) Use of less than or more than the recommended quantity (3 drops) of 'human fecal sample processed with detection buffer in the sample collection tube' while performing the test:

1) Loading less than 3 drops (i.e. 1 and 2 drops) of human fecal sample(s) mixed with detection buffer

2) Loading more than 3 drops (i.e. 4, 5 and 6 drops) of human fecal sample(s) mixed with detection buffer

Summary of Results:

When the tests were performed by loading 1 drop and 2 drops of the human fecal sample mixture into the 'sample well' of the test cartridges, *i*-CHROMA Reader displayed the error message alert 'Caution! Error', thereby terminating the tests.

However, no erroneous test results were observed when the tests were performed by loading 4, 5 and 6 drops of the human fecal sample mixture into the 'sample well' of the test cartridges.

F) Performing '*i*-CHROMA iFOB tests' under stress conditions outside the recommended operational environment (15-37 ºC).

1) Arranging the test setup and operating the *i*-CHROMA Reader in an environment having temperature of 8~14 ºC.

2) Arranging the test setup and operating the *i*-CHROMA Reader in an environment having temperature of 38~45 ºC.

Summary of Results:

Compared with the test results obtained when *i*-CHROMA iFOB tests were performed in the recommended operational environment (15-37 ºC), no erroneous test results were observed when the tests were performed by arranging the test setup and operating the *i*-CHROMA Reader in an environment having temperature of 8~14 ºC or 38~45 ºC.

(b)(4)Trade Secret Process - Validation & Verification Report

(b)(4)Trade Secret Process - Validation & Verification Report

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(b)(4)Trade Secret Process - Validation & Verification Report

(b)(4)Trade Secret Process - Validation & Verification Report

(b)(4)Trade Secret Process - Validation & Verification Report

(b)(4)Trade Secret Process - Product Specs

[redacted]

Clinical testing sites:

- Clinical testing of *i*-CHROMA iFOB was conducted at following three sites at different demographic locations:
  - (b)(4)Trade Secret Process - Product Specs [redacted] of Korea
  - (b)(4)Trade Secret Process - Product Specs [redacted]n, Republic of Korea
  - (b)(4)Trade Secret Process - [redacted] USA
- These sites were selected to closely replicate the clinical setting actually intended for proposed clinical use of *i*-CHROMA iFOB.
- Details of these clinical testing sites are as follows:

Study site 1:

(b)(4)Trade Secret [redacted]
Process - Product [redacted]

(b)(4)Trade Secret Process - Product Specs [redacted] Republic of Korea

(b)(4)Trade Secret Process - Product Specs [redacted]

Study site 2:

(b)(4)Trade Secret Process - Product Specs [redacted] Republic of Korea

(b)(4)Trade Secret Process - Product Specs [redacted]

Study site 3:

(b)(4)Trade Secret Process - Product Specs [redacted], USA

(b)(4)Trade Secret Process - Product Specs [redacted]

Clinical investigators:

- Clinical investigators were not involved in the clinical testing of *i*-CHROMA iFOB conducted at the three testing sites.

Operators:

- It was aimed to enroll 3 operators at each testing site so as to have the participation of a minimum of 9 operators in total over the three clinical testing sites.
- At the two Korean sites (Study Site No. CSS-1 & CSS-2), special arrangements were made to ensure that *i*-CHROMA iFOB testing was performed by operators other than the regular laboratory technical staff performing routine clinical laboratory tests at these sites.
- These new operators were either biomedical laboratory science or clinical pathology undergraduate students doing internship at these hospitals or the staff serving in other support functions like administration, office assistance, nursing/patient counselling etc. at these hospitals.
- At (b)(4)Trade Secret Process - Product Specs Study Site No. CSS-1), eight laboratory technicians were available which included two biomedical laboratory science interns. These two intern students and one person from amongst the support staff were enrolled as *i*-CHROMA iFOB operators.
- At (b)(4)Trade Secret Process - Product Specs (Study Site No. CSS-2), four laboratory technicians were available which included one clinical pathology intern student. The

intern student and two persons from amongst the support staff were enrolled as *i*-CHROMA iFOB operator.

- Thus, these new operators had minimum or no qualifications and/or previous training/experience relevant to laboratory clinical testing.
- At the US study site (Site No. CSS-3), operators with least level of academic qualifications and professional training/experience from amongst the operators available at the site, were enrolled to participate in the study.
- However, OC Auto Micro FOB testing was performed by the technician/professional-in-charge of the analyzer at the respective sites.
- **Table VI.3.A** shows the number of operators available and number of operators enrolled to participate in clinical testing of *i*-CHROMA iFOB at the designated testing.

Table VI.3.A: Site-wise availability, enrolment and participation of operators for the clinical testing study of *i*-CHROMA iFOB

Site No.	Clinical testing site	Number of operators at the testing site	
		Available	Chosen to enroll & participate in the clinical testing
CSS-1	(b)(4)Trade Secret Process - Product Specs Republic of Korea	06 + 2*	**2*** (CSS1-O1 & CSS1-O2) **+ 1Δ** (CSS1-O3)
CSS-2	(b)(4)Trade Secret Process - Product Specs Republic of Korea	03 + 1*	**1*** (CSS2-O1) **+ 2Δ** (CSS2-O2 & CSS2-O3)
CSS-3	(b)(4)Trade Secret Process - Product Specs USA	04	**03** (CSS3-O1, CSS3-O2 & CSS3-O3)
	Total	**16**	**09**

* *These operators were either biomedical laboratory science or clinical pathology undergraduate students doing internship at these hospitals.*

Δ *These operators were the staff serving in other support functions like nursing, administration, office assistance, patient counselling etc. at these hospitals.*

- Details of education, occupation, training/experience etc. of the enrolled operators have been provided in **Table VI.3.B**
- Details of education, occupation, training/experience etc. of the operators that were available at the testing sites but not enrolled for the study, have been provided in **Table VI.3.C**

Table VI.3.B: Details of education, occupation, training/experience etc. of the operators enrolled for the clinical testing of *i*-CHROMA iFOB				
Study site	**Information**	**Operators enrolled for & participated in the clinical study**		
		Operator CSS1-O1	**Operator CSS1-O2**	**Operator CSS1-O3**
CSS-1: (b)(4)Trade Secret Process - Product Specs, Republic of Korea	**Education**	Biomedical Laboratory Science Undergraduate student	Biomedical Laboratory Science Undergraduate student	Bachelor in Physics
	Occupation	Medical Laboratory Intern	Medical Laboratory Intern	Hospital General Support Staff
	Training and/ or Experience	Very little professional experience of clinical laboratory testing	Very little professional experience of clinical laboratory testing	No professional experience of clinical laboratory testing
CSS-2: (b)(4)Trade Secret Process - Product Specs Republic of Korea	**Education**	Clinical Pathology Undergraduate student	Diploma in Nursing	Bachelor of Hospital Administration
	Occupation	Medical Laboratory Intern	Hospital Nurse	Hospital Assistant
	Training and/ or Experience	Very little professional experience of clinical laboratory testing	No professional experience of clinical laboratory testing	No professional experience of clinical laboratory testing
CSS-3: (b)(4)Trade Secret Process - Product Specs USA	**Education**	Bachelor in Bioscience	Two year college education	Bachelor in Bioscience
	Occupation	Medical Technician	Medical Technician	Medical Technician
	Training and/or Experience	ASCP certification with three years professional experience	ASCP certification with one year professional experience	ASCP certification

Table VI.3.C: Details of education, occupation, training/experience etc. of the operators that were available at the testing sites but not enrolled for the clinical testing				
Study site	**Information**	**Operators enrolled for & participated in the clinical study**		
		Operator CSS1-O4	**Operator CSS1-O5**	**Operator CSS1-O6**
CSS-1: (b)(4)Trade Secret Process - Product Specs, Republic of Korea	**Education**	Bachelor in Biomedical Laboratory Science	Bachelor in Clinical Pathology	Bachelor in Clinical Pathology
	Occupation	Senior Medical Laboratory Technician	Senior Medical Laboratory Technician	Medical Laboratory Technician
	Training and/ or Experience	12 years professional experience	7 years professional experience	5 years professional
CSS-1: (b)(4)Trade Secret Process - Product Specs, Republic of Korea		**Operator CSS1-O7**	**Operator CSS1-O8**	**Operator CSS1-O9**
	Education	Bachelor in Clinical Pathology	Bachelor in Clinical Pathology	Bachelor in Biomedical Laboratory Science
	Occupation	Medical Laboratory Technician	Medical Laboratory Technician	Medical Laboratory Technician
	Training and/ or Experience	5 years professional experience	2 years professional experience	4 years professional experience
CSS-2: (b)(4)Trade Secret Process - Product Specs, Republic of Korea		**Operator CSS2-O4**	**Operator SS2-O5**	**Operator CSS2-O6**
	Education	Bachelor in Clinical Pathology	Bachelor in Clinical Pathology	Bachelor in Biomedical Laboratory Science
	Occupation	Medical Laboratory Technician	Medical Laboratory Technician	Medical Laboratory Technician
	Training and/ or Experience	6 years professional experience	2 years professional experience	5 years professional experience
CSS-3: (b)(4)Trade Secret Process - Product Specs, USA		**Operator CSS3-O4**	--	--
	Education	Bachelor Degree	--	--
	Occupation	Medical Technician	--	--
	Training and/or Experience	ASCP certification with five years professional experience	--	--

(b)(4)Trade Secret Process - Testing Report

Clinical testing methodology:

(b)(4)Trade Secret Process - Testing Report

[redacted]

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

Table VI.3.D: Results of clinical method comparison study of *i*-CHROMA iFOB

Study Site CSS-1: (b)(4)Trade Secret Process - Testing Report [redacted]

Study Period: January 6, 2014 – February 14, 2014 ***i*-CHROMA iFOB Lot No.:** FOYKA10

Manufacturing Date: November 7, 2013 **Expiry Date:** July 7, 2015

***i*-CHROMA iFOB Lot No.:** PFR13K293714 **Operator CSS1-O1:** (b)(4)Trade [redacted] i

Operator CSS1-O2: (b)(4)Trade [redacted] **Operator CSS1-O3:** (b)(4)Trade Secret

OC Auto Micro FOB Lot No.: 38838 **Expiry Date:** February 2015

Serial Number of Testing	*i*-CHROMA iFOB Test Operator	Clinical Sample Code Number	Colonoscopic /Clinical Status of the Test Sample	*i*-CHROMA iFOB Test Result	OC Auto Micro FOB Test Result	
					Qualitative Test Result	Quantitative Test Result (ng/mL)
01	**Operator CSS1-O1**	**CSS1-001**	Positive	Positive	Positive	951
02		**CSS1-002**	Positive	Positive	Positive	253
03		**CSS1-003**	Negative	Negative	Negative	18
04		**CSS1-004**	Negative	Negative	Negative	91
05		**CSS1-005**	Positive	Positive	Positive	174
06		**CSS1-006**	Positive	Positive	Positive	491
07		**CSS1-007**	Negative	Negative	Negative	84
08		**CSS1-008**	Negative	Negative	Negative	45
09		**CSS1-009**	Positive	Positive	Positive	136
10		**CSS1-010**	Negative	Negative	Negative	65
11		**CSS1-011**	Positive	Positive	Positive	651
12		**CSS1-012**	Positive	Positive	Positive	332
13		**CSS1-013**	Negative	Negative	Negative	40
14		**CSS1-014**	Negative	Negative	Negative	75
15		**CSS1-015**	Positive	Positive	Positive	285
16		**CSS1-016**	Negative	Negative	Negative	19
17		**CSS1-017**	Positive	Positive	Positive	102
18		**CSS1-018**	Negative	Negative	Negative	79
19		**CSS1-019**	Negative	Positive	Negative	94
20		**CSS1-020**	Negative	Negative	Negative	38
21		**CSS1-021**	Negative	Negative	Negative	58
22		**CSS1-022**	Positive	Positive	Positive	711
23		**CSS1-023**	Negative	Negative	Negative	65
24		**CSS1-024**	Positive	Positive	Positive	140
25		**CSS1-025**	Negative	Negative	Negative	37
26		**CSS1-026**	Positive	Positive	Positive	251
27		**CSS1-027**	Negative	Negative	Negative	77
28		**CSS1-028**	Positive	Positive	Positive	373
29		**CSS1-029**	Negative	Negative	Negative	65
30		**CSS1-030**	Negative	Negative	Negative	71
31		**CSS1-031**	Negative	Negative	Negative	41
32		**CSS1-032**	Positive	Positive	Positive	185

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***Continued* Table VI.3.D:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-1: (b)(4)Trade Secret Process - Testing Report [redacted] South Korea						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
33	**Operator CSS1-O1**	**CSS1-033**	Negative	Negative	Negative	43
34		**CSS1-034**	Negative	Negative	Negative	94
35		**CSS1-035**	Negative	Negative	Negative	54
36		**CSS1-036**	Positive	Positive	Positive	877
37		**CSS1-037**	Positive	Positive	Positive	384
38		**CSS1-038**	Negative	Negative	Negative	38
39		**CSS1-039**	Negative	Negative	Negative	11
40	**Operator CSS1-O2**	**CSS1-040**	Positive	Positive	Positive	1002
41		**CSS1-041**	Positive	Positive	Positive	123
42		**CSS1-042**	Negative	Negative	Negative	60
43		**CSS1-043**	Positive	Positive	Positive	863
44		**CSS1-044**	Negative	Negative	Negative	75
45		**CSS1-045**	Negative	Negative	Negative	32
46		**CSS1-046**	Positive	Positive	Positive	252
47		**CSS1-047**	Negative	Negative	Negative	67
48		**CSS1-048**	Positive	Positive	Positive	561
49		**CSS1-049**	Negative	Negative	Negative	76
50		**CSS1-050**	Positive	Positive	Positive	433
51		**CSS1-051**	Negative	Negative	Negative	64
52		**CSS1-052**	Positive	Positive	Positive	843
53		**CSS1-053**	Positive	Positive	Positive	473
54		**CSS1-054**	Negative	Negative	Negative	49
55		**CSS1-055**	Negative	Negative	Negative	34
56		**CSS1-056**	Positive	Positive	Positive	585
57		**CSS1-057**	Positive	Positive	Positive	217
58		**CSS1-058**	Negative	Negative	Negative	85
59		**CSS1-059**	Negative	Negative	Negative	54
60		**CSS1-060**	Positive	Positive	Positive	130
61		**CSS1-061**	Negative	Negative	Negative	41
62		**CSS1-062**	Positive	Positive	Positive	114
63		**CSS1-063**	Negative	Negative	Negative	81
64		**CSS1-064**	Positive	Positive	Positive	158
65		**CSS1-065**	Negative	Negative	Negative	20
66		**CSS1-066**	Negative	Negative	Negative	43
67		**CSS1-067**	Positive	Positive	Positive	914
68		**CSS1-068**	Negative	Negative	Negative	50

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***Continued* Table VI.3.D:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-1: (b)(4)Trade Secret Process - Testing Report [redacted], South Korea						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
69	**Operator CSS1-O2**	**CSS1-069**	Negative	Negative	Negative	74
70		**CSS1-070**	Negative	Negative	Negative	39
71		**CSS1-071**	Positive	Positive	Positive	127
72		**CSS1-072**	Negative	Negative	Negative	83
73		**CSS1-073**	Negative	Negative	Negative	79
74		**CSS1-074**	Negative	Negative	Negative	94
75		**CSS1-075**	Positive	Positive	Positive	484
76		**CSS1-076**	Positive	Positive	Positive	149
77		**CSS1-077**	Negative	Negative	Negative	31
78		**CSS1-078**	Positive	Positive	Positive	676
79		**CSS1-079**	Positive	Positive	Positive	199
80		**CSS1-080**	Positive	Positive	Positive	702
81		**CSS1-081**	Negative	Negative	Negative	33
82		**CSS1-082**	Positive	Positive	Positive	253
83		**CSS1-083**	Negative	Negative	Negative	63
84	**Operator CSS1-O3**	**CSS1-084**	Positive	Positive	Positive	258
85		**CSS1-085**	Positive	Positive	Positive	396
86		**CSS1-086**	Negative	Negative	Negative	27
87		**CSS1-087**	Negative	Negative	Negative	35
88		**CSS1-088**	Positive	Positive	Positive	907
89		**CSS1-089**	Negative	Negative	Negative	23
90		**CSS1-090**	Negative	Negative	Negative	20
91		**CSS1-091**	Positive	Positive	Positive	478
92		**CSS1-092**	Positive	Positive	Positive	518
93		**CSS1-093**	Positive	Positive	Positive	439
94		**CSS1-094**	Negative	Negative	Negative	40
95		**CSS1-095**	Positive	Positive	Positive	419
96		**CSS1-096**	Negative	Negative	Negative	41
97		**CSS1-097**	Positive	Positive	Positive	233
98		**CSS1-098**	Negative	Negative	Negative	26
99		**CSS1-099**	Negative	Negative	Negative	22
100		**CSS1-100**	Negative	Negative	Negative	27
101		**CSS1-101**	Positive	Positive	Positive	117
102		**CSS1-102**	Positive	Positive	Positive	103
103		**CSS1-103**	Negative	Negative	Negative	72
104		**CSS1-104**	Positive	Positive	Positive	818

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***Continued* Table VI.3.D:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-1: (b)(4)Trade Secret Process - Testing Report [redacted] South Korea						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
105	**Operator CSS1-O3**	**CSS1-105**	Negative	Negative	Negative	64
106		**CSS1-106**	Negative	Negative	Negative	38
107		**CSS1-107**	Positive	Positive	Positive	218
108		**CSS1-108**	Positive	Positive	Positive	118
109		**CSS1-109**	Negative	Negative	Negative	49
110		**CSS1-110**	Negative	Negative	Negative	40
111		**CSS1-111**	Positive	Positive	Positive	428
112		**CSS1-112**	Negative	Negative	Positive	108
113		**CSS1-113**	Positive	Positive	Positive	742
114		**CSS1-114**	Positive	Positive	Positive	512
115		**CSS1-115**	Positive	Positive	Positive	846
116		**CSS1-116**	Negative	Negative	Negative	63
117		**CSS1-117**	Negative	Negative	Negative	14

Table VI.3.E: Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-2: (b)(4)Trade Secret Process - Testing Report [redacted], South Korea						
Study Period: January 8 2014 – February 20, 2014 ***i*-CHROMA iFOB Lot No.:** FOYKA10 **Manufacturing Date:** November 7, 2013 **Expiry Date:** July 7, 2015 ***i*-CHROMA iFOB Lot No** PFR13K293712 **Operator CSS2-O1:** (b)(4)Trade [redacted] **Operator CSS2-O2:** (b)(4)Trade Secret [redacted] **Operator CSS2-O3:** (b)(4)Trade Secret [redacted] **OC Auto Micro FOB Lot No.:** 38838 **Expiry Date:** February 2015						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
01	**Operator CSS2-O1**	**CSS2-001**	Negative	Negative	Negative	24
02		**CSS2-002**	Positive	Positive	Positive	845
03		**CSS2-003**	Negative	Negative	Negative	67
04		**CSS2-004**	Positive	Positive	Positive	296
05		**CSS2-005**	Positive	Positive	Positive	466
06		**CSS2-006**	Negative	Negative	Negative	74
07		**CSS2-007**	Positive	Positive	Positive	913
08		**CSS2-008**	Negative	Negative	Negative	54
09		**CSS2-009**	Positive	Positive	Positive	132

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***Continued* Table VI.3.E:** Results of clinical method comparison study of *i*-CHROMA iFOB

Study Site CSS-2: (b)(4)Trade Secret Process - Testing Report [redacted], South Korea

Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
10	**Operator CSS2-O1**	**CSS2-010**	Negative	Negative	Negative	45
11		**CSS2-011**	Negative	Positive	Negative	97
12		**CSS2-012**	Positive	Positive	Positive	185
13		**CSS2-013**	Positive	Positive	Positive	644
14		**CSS2-014**	Negative	Negative	Negative	87
15		**CSS2-015**	Positive	Positive	Positive	795
16		**CSS3-016**	Negative	Negative	Negative	43
17		**CSS2-017**	Negative	Negative	Negative	54
18		**CSS2-018**	Negative	Negative	Negative	65
19		**CSS2-019**	Positive	Positive	Positive	885
20		**CSS2-020**	Negative	Negative	Negative	56
21		**CSS2-021**	Negative	Negative	Negative	21
22		**CSS2-022**	Positive	Positive	Positive	295
23		**CSS2-023**	Positive	Positive	Positive	174
24		**CSS2-024**	Negative	Negative	Negative	84
25		**CSS2-025**	Negative	Negative	Negative	46
26		**CSS2-026**	Positive	Positive	Positive	159
27		**CSS2-027**	Negative	Negative	Negative	54
28		**CSS2-028**	Positive	Positive	Positive	216
29		**CSS2-029**	Negative	Negative	Negative	68
30		**CSS2-030**	Negative	Negative	Negative	63
31		**CSS2-031**	Positive	Positive	Positive	107
32		**CSS2-032**	Positive	Positive	Positive	165
33		**CSS2-033**	Negative	Negative	Negative	85
34		**CSS2-034**	Negative	Negative	Negative	99
35		**CSS2-035**	Positive	Positive	Positive	654
36		**CSS2-036**	Negative	Negative	Negative	46
37		**CSS2-037**	Positive	Positive	Positive	158
38		**CSS2-038**	Positive	Positive	Positive	387
39		**CSS2-039**	Negative	Negative	Negative	42
40		**CSS2-040**	Positive	Positive	Positive	495
41		**CSS2-041**	Negative	Negative	Negative	18
42		**CSS2-042**	Positive	Positive	Positive	167
43	**Operator CSS2-O2**	**CSS2-043**	Negative	Negative	Negative	38
44		**CSS2-044**	Positive	Positive	Positive	879
45		**CSS2-045**	Positive	Positive	Positive	694

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***Continued* Table VI.3.E:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-2: (b)(4)Trade Secret Process - Testing Report [redacted], South Korea						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
46	**Operator CSS2-O2**	**CSS2-046**	Negative	Negative	Negative	57
47		**CSS2-047**	Positive	Positive	Positive	916
48		**CSS2-048**	Negative	Negative	Negative	97
49		**CSS2-049**	Negative	Negative	Negative	39
50		**CSS2-050**	Positive	Positive	Positive	1077
51		**CSS2-051**	Negative	Negative	Negative	87
52		**CSS2-052**	Positive	Positive	Positive	954
53		**CSS2-053**	Negative	Negative	Negative	45
54		**CSS2-054**	Positive	Positive	Positive	145
55		**CSS2-055**	Positive	Positive	Positive	684
56		**CSS2-056**	Positive	Positive	Positive	439
57		**CSS2-057**	Negative	Negative	Negative	82
58		**CSS2-058**	Positive	Positive	Positive	124
59		**CSS2-059**	Negative	Positive	Negative	96
60		**CSS2-060**	Positive	Positive	Positive	111
61		**CSS2-061**	Positive	Positive	Positive	247
62		**CSS2-062**	Negative	Negative	Negative	68
63		**CSS2-063**	Negative	Negative	Negative	43
64		**CSS2-064**	Negative	Negative	Negative	38
65		**CSS2-065**	Positive	Positive	Positive	846
66		**CSS2-066**	Positive	Positive	Positive	315
67		**CSS2-067**	Positive	Negative	Positive	108
68		**CSS2-068**	Negative	Negative	Negative	28
69		**CSS2-069**	Positive	Positive	Positive	943
70		**CSS2-070**	Negative	Negative	Negative	16
71		**CSS2-071**	Positive	Positive	Positive	154
72		**CSS2-072**	Negative	Negative	Negative	75
73		**CSS2-073**	Negative	Negative	Negative	83
74		**CSS2-074**	Positive	Positive	Positive	862
75		**CSS2-075**	Negative	Negative	Negative	72
76		**CSS2-076**	Positive	Positive	Positive	533
77		**CSS2-077**	Negative	Negative	Negative	66
78		**CSS2-078**	Negative	Negative	Negative	46
79		**CSS2-079**	Positive	Positive	Positive	617
80	**Operator CSS2-O3**	**CSS2-080**	Negative	Negative	Negative	91
81		**CSS2-081**	Negative	Negative	Negative	36

Continued from previous page ……

***Continued* Table VI.3.E:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-2: (b)(4)Trade Secret Process - Testing Report [redacted], South Korea						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
82	**Operator CSS2-O3**	**CSS2-082**	Positive	Positive	Positive	249
83		**CSS2-083**	Negative	Negative	Negative	78
84		**CSS2-084**	Positive	Positive	Positive	173
85		**CSS2-085**	Negative	Negative	Negative	64
86		**CSS2-086**	Negative	Negative	Negative	17
87		**CSS2-087**	Positive	Positive	Positive	244
88		**CSS2-088**	Negative	Negative	Negative	94
89		**CSS2-089**	Positive	Positive	Positive	394
90		**CSS2-090**	Negative	Negative	Negative	58
91		**CSS2-091**	Negative	Negative	Negative	61
92		**CSS2-092**	Positive	Positive	Positive	421
93		**CSS2-093**	Positive	Positive	Positive	264
94		**CSS2-094**	Negative	Negative	Negative	72
95		**CSS2-095**	Negative	Negative	Negative	91
96		**CSS2-096**	Negative	Negative	Negative	34
97		**CSS2-097**	Positive	Positive	Positive	139
98		**CSS2-098**	Positive	Positive	Positive	711
99		**CSS2-099**	Negative	Negative	Negative	16
100		**CSS2-100**	Positive	Positive	Positive	976
101		**CSS2-101**	Negative	Negative	Negative	82
102		**CSS2-102**	Negative	Negative	Negative	42
103		**CSS2-103**	Positive	Positive	Positive	841
104		**CSS2-104**	Positive	Positive	Positive	146
105		**CSS2-105**	Negative	Negative	Negative	91
106		**CSS2-106**	Positive	Positive	Positive	290
107		**CSS2-107**	Negative	Negative	Negative	67
108		**CSS2-108**	Negative	Negative	Negative	84
109		**CSS2-109**	Negative	Negative	Negative	77
110		**CSS2-110**	Positive	Positive	Positive	167
111		**CSS2-111**	Negative	Negative	Negative	28
112		**CSS2-112**	Negative	Negative	Negative	94
113		**CSS2-113**	Positive	Positive	Positive	529
114		**CSS2-114**	Negative	Negative	Negative	56
115		**CSS2-115**	Positive	Positive	Positive	876
116		**CSS2-116**	Positive	Positive	Positive	599
117		**CSS2-117**	Positive	Positive	Positive	758

Continued from previous page ……

***Continued* Table VI.3.E:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-2: (b)(4)Trade Secret Process - Testing Report [redacted], South Korea						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
118	**Operator CSS2-O3**	**CSS2-118**	Negative	Negative	Negative	43
119		**CSS2-119**	Negative	Negative	Negative	56
120		**CSS2-120**	Positive	Positive	Positive	852
121		**CSS2-121**	Positive	Positive	Positive	285
122		**CSS2-122**	Negative	Negative	Negative	40
123		**CSS2-123**	Negative	Negative	Negative	64

Table VI.3.F: Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-3: (b)(4)Trade Secret Process - Testing USA						
Study Period: January 13, 2014 – January 31, 2014 ***i*-CHROMA iFOB Lot No.:** FOYKA10 **Manufacturing Date:** November 19, 2013 **Expiry Date:** July 19, 2015 ***i*-CHROMA iFOB Lot No.:** PFR13J183123 **Operator CSS3-O1:** (b)[redacted] **Operator CSS3-O2:** (b)(4)Trade [redacted] **Operator CSS3-O3:** (b)(4)Trade [redacted] **OC Auto Micro FOB Lot No.:** 29209 **Expiry Date:** March 2014						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
01	**Operator CSS3-O1**	**1**	Positive	Positive	Positive	136
02		**2**	Positive	Positive	Positive	191
03		**3**	Negative	Negative	Negative	33
04		**4**	Negative	Negative	Negative	54
05		**5**	Positive	Positive	Positive	879
06		**6**	Negative	Negative	Negative	43
07		**7**	Negative	Negative	Negative	28
08		**8**	Negative	Negative	Negative	22
09		**9**	Negative	Negative	Negative	30
10		**10**	Positive	Positive	Positive	108
11		**11**	Negative	Negative	Negative	68
12		**12**	Negative	Negative	Negative	78
13		**13**	Positive	Positive	Positive	875
14		**14**	Positive	Positive	Positive	646
15		**15**	Negative	Negative	Negative	82
16		**16**	Negative	Negative	Negative	29

Continued from previous page ……

***Continued* Table VI.3.F:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-3: (b)(4)Trade Secret Process - [redacted], USA						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
17	**Operator CSS3-O1**	**17**	Positive	Positive	Positive	282
18		**18**	Positive	Positive	Positive	845
19		**19**	Negative	Negative	Negative	94
20		**20**	Negative	Negative	Negative	68
21		**21**	Positive	Positive	Positive	564
22		**22**	Negative	Negative	Negative	75
23		**23**	Positive	Positive	Positive	242
24		**24**	Negative	Negative	Negative	48
25		**25**	Negative	Negative	Negative	43
26		**26**	Positive	Positive	Positive	118
27		**27**	Negative	Negative	Negative	56
28	**Operator CSS3-O2**	**28**	Positive	Positive	Positive	554
29		**29**	Negative	Negative	Negative	44
30		**30**	Negative	Negative	Negative	39
31		**31**	Negative	Negative	Negative	22
32		**32**	Negative	Negative	Negative	98
33		**33**	Negative	Negative	Negative	74
34		**34**	Negative	Negative	Negative	46
35		**35**	Positive	Positive	Positive	414
36		**36**	Negative	Negative	Negative	16
37		**37**	Negative	Negative	Negative	49
38		**38**	Positive	Positive	Positive	119
39		**39**	Negative	Negative	Negative	87
40		**40**	Negative	Negative	Negative	16
41		**41**	Positive	Positive	Positive	168
42		**42**	Negative	Negative	Negative	79
43		**43**	Positive	Positive	Positive	246
44		**44**	Negative	Negative	Negative	49
45		**45**	Positive	Positive	Positive	546
46		**46**	Positive	Positive	Positive	654
47		**47**	Negative	Negative	Negative	58
48		**48**	Negative	Negative	Negative	92
49		**49**	Negative	Negative	Negative	11
50		**50**	Positive	Positive	Positive	886
51		**51**	Negative	Negative	Negative	38
52		**52**	Negative	Negative	Negative	85

Continued from previous page ……

***Continued* Table VI.3.F:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-3: (b)(4)Trade Secret Process - Testing USA						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
53	**Operator CSS3-O2**	**53**	Positive	Positive	Positive	562
54		**54**	Negative	Negative	Negative	95
55		**55**	Negative	Positive	Negative	98
56		**56**	Positive	Positive	Positive	1026
57		**57**	Negative	Negative	Negative	78
58		**58**	Negative	Negative	Negative	53
59		**59**	Positive	Positive	Positive	213
60		**60**	Negative	Negative	Negative	24
61		**61**	Negative	Negative	Negative	96
62		**62**	Positive	Positive	Positive	298
63		**63**	Positive	Positive	Positive	946
64	**Operator CSS3-O3**	**64**	Negative	Negative	Negative	72
65		**65**	Positive	Positive	Positive	735
66		**66**	Positive	Positive	Positive	111
67		**67**	Positive	Positive	Positive	213
68		**68**	Negative	Negative	Negative	66
69		**69**	Positive	Positive	Positive	857
70		**70**	Negative	Negative	Negative	49
71		**71**	Negative	Negative	Negative	67
72		**72**	Negative	Negative	Negative	53
73		**73**	Positive	Positive	Positive	165
74		**74**	Positive	Positive	Positive	415
75		**75**	Negative	Negative	Negative	81
76		**76**	Negative	Negative	Negative	52
77		**77**	Positive	Positive	Positive	120
78		**78**	Negative	Negative	Negative	35
79		**79**	Negative	Negative	Negative	49
80		**80**	Negative	Negative	Negative	58
81		**81**	Positive	Positive	Positive	258
82		**82**	Positive	Positive	Positive	835
83		**83**	Negative	Negative	Negative	25

Table VI.3.G: Site-wise and operator-wise number of clinical fecal samples tested during clinical method comparison study of *i*-CHROMA iFOB

Study Site	Operator-wise number of clinical fecal samples tested											
	Operator 1			Operator 2			Operator 3			Operator 1+2+3		
	Positive	Negative	Total	Positive	Negative	Total	Positive	Negative	Total	Positive	Negative	Total
CSS-1: (b)(4)Trade Secret Process - [redacted] Testing Report Republic of Korea	16	23	**39**	21	23	**44**	18	16	**34**	55	62	**117**
CSS-2: (b)(4)Trade Secret Process - [redacted] Testing Report Republic of Korea	20	22	**42**	19	18	**37**	19	25	**44**	58	65	**123**
CSS-3: (b)(4)Trade Secret Process - [redacted] USA	11	16	**27**	13	23	**36**	09	11	**20**	33	50	**83**
									Total	**146**	**177**	**323**

Table VI.3.H: Statistical analysis of clinical method comparison study of *i*-CHROMA iFOB

Study site	Waiver Method (WM)	Comparative Method (CM)			Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
		OC Auto Micro FOB					
	i-CHROMA iFOB	Positive Results	Negative Results	Total Results			
CSS-1	**Positive Results**	**54**	01	55	**98.29%**	**98.18%** (90.40% - 99.68%)	**98.39%** (91.41% - 99.72%)
	Negative Results	01	**61**	62			
	Total Results	**55**	**62**	**117**			
CSS-2	**Positive Results**	**57**	02	59	**97.56%**	**98.3%** (90.86% - 99.70%)	**96.9%** (89.46% - 99.15%)
	Negative Results	01	**63**	64			
	Total Results	**58**	**65**	**123**			
CSS-3	**Positive Results**	**32**	01	33	**98.80%**	**100%** (89.28% - 100%)	**98.04%** (89.70% - 99.65%)
	Negative Results	00	**50**	50			
	Total Results	**32**	**51**	**83**			
CSS-1+CSS-2 +CSS-3	**Positive Results**	**143**	04	147	**98.14%**	**98.6%** (95.18% - 99.63%)	**97.8%** (94.43% - 99.13%)
	Negative Results	02	**174**	176			
	Total Results	**145**	**178**	**323**			

Results of VI.3.2 Determination of performance of *i*-CHROMA iFOB at analyte concentrations near the cutoff:

- Site-wise as well as combined information regarding the percent of the positive and negative results obtained with 60 aliquots of the weak positive sample and 60 aliquots of the weak negative sample tested by *i*-CHROMA iFOB have been shown in **Table VI.3.I**
- No invalid or indeterminate result was obtained in this part of the study.

Table VI.3.I: *i*-CHROMA iFOB Test Results of 60 aliquots of the Weak Positive Sample and 60 aliqouts of the Weak Negative Sample tested at each study site of clinical method comparison study of *i*-CHROMA iFOB

Number and Name of Testing Site	Operator	Number of Aliquots Tested		*i*-CHROMA iFOB (WM) Test Results			
				Aliquots of the Weak Positive Sample		Aliquots of the Weak Negative Samples	
		Aliquots of Weak Positive Sample	Aliquots of Weak Negative Sample	True Positive Results	False Negative Results	True Negative Results	False Positive Results
CSS-1 (b)(4)Trade Secret Process - Testing Report Republic of Korea	Operator CSS1-O1	20	20	20	00	20	00
	Operator CSS1-O2	20	20	19	01	20	00
	Operator CSS1-O3	20	20	19	01	19	01
	Total	**60**	**60**	**58 (96.66%)**	**02 (3.33%)**	**59 (98.33%)**	**01 (1.66%)**
CSS-2 (b)(4)Trade Secret Process - Testing Report Republic of Korea	Operator CSS2-O1	20	20	19	01	18	02
	Operator CSS2-O2	20	20	18	02	20	00
	Operator CSS2-O3	20	20	20	00	20	00
	Total	**60**	**60**	**57 (95%)**	**03 (5%)**	**58 (96.66%)**	**02 (3.33%)**
CSS-3 (b)(4)Trade Secret USA	Operator CSS3-O1	20	20	20	00	19	01
	Operator CSS3-O2	20	20	20	00	20	00
	Operator CSS3-O3	20	20	19	01	18	02
	Total	**60**	**60**	**59 (98.33%)**	**01 (1.66%)**	**57 (95%)**	**03 (5%)**
Testing Sites CSS-1 + CSS-2 + CSS-3	**Grand Total**	**180**	**180**	**174 (96.66%)**	**06 (3.33%)**	**174 (96.66%)**	**06 (3.33%)**

- Site-wise as well as combined estimates of percent of positive results (obtained with aliquots of the weak positive sample) and percent of negative results (obtained with aliquots of the weak negative sample) along with respective two-sided 95% confidence intervals have been shown in **Table VI.3.J**.

Table VI.3.J: Site-wise as well as combined estimates of percent of positive results (obtained with aliquots of the weak positive sample) and percent of negative results (obtained with aliquots of the weak negative sample) along with respective two-sided 95% confidence intervals tested with *i*-CHROMA iFOB				
Type of Weak Sample Tested by *i*-CHROMA iFOB	**Percent of positive and negative Results (along with 95% confidence intervals) obtained with *i*-CHROMA iFOB**			
	Site CSS-1 (b)(4)Trade Secret Process - Testing Report Republic of Korea	**Site CSS-2** (b)(4)Trade Secret Process - Testing Report Republic of Korea	**Site CSS-3** (b)(4)Trade Secret Process - Testing Report USA	**Site CSS-1 + Site CSS-2 + Site CSS-3**
60 Aliquots of Weak Positive Sample	**96.67%** (88.64%-99.08%)	**95%** (86.30%-98.29%)	**98.33%** (91.15%-99.71%)	**96.67%** (92.92%-98.46%)
60 Aliquots of Weak Negative Sample	**98.33%** (91.15%-99.71%)	**96.67%** (88.64%-99.08%)	**95%** (86.30%-98.29%)	**96.67%** (92.92%-98.46%)

- The differences in percent of positive results (for the weak positive sample) among the three sites and also the differences in percent of negative results (for the weak negative sample) among the three testing sites were not found to be statistically significant at alpha = 0.05.

Operators' Feedback:

- In order to evaluate the simplicity of *i*-CHROMA iFOB test as a whole and ease of operation of *i*-CHROMA Reader in particular and also to evaluate the ease of understanding the proposed instructional material of *i*-CHROMA iFOB, a questionnaire containing multiple choice questions related to above aspects of the test, was given to each operator participated in the clinical method comparison study of *i*-CHROMA iFOB.
- Feedback was obtained from each operator after completion of his/her role in the study.
- Test operators who participated in the clinical study conducted at the two Korean sites (Study Site No.CSS-1 & CSS-2) were provided with Korean language version of the questionnaire while operators at the USA site (Study Site No. CSS-3) were provided with proper English draft of the same.
- Content of the operator questionnaire as well as site-wise/operator-wise and combined feedback have been shown in **Table VI.3.K**.

Table VI.3.K: Content of the operator questionnaire as well as site-wise/operator-wise and combined feedback obtained from test operators participated in the clinical method comparison study of *i*-CHROMA iFOB

Que. No.	Question with Options	Clinical Study Sites			Combined Responses
		Site CSS-1	Site CSS-2	Site CSS-3	
		3 Operators	3 Operators	3 Operators	9 Operators
1	**How it was to understand the test instructions.**				
a	Very easy	02	03	03	**08**
b	Easy	01	00	00	**01**
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
2	**How it was to follow the test instructions.**				
a	Very easy	02	03	03	**08**
b	Easy	01	00	00	**01**
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
3	**How it was to apply the fecal sample mixture into 'sample well' of the test cartridge correctly.**				
a	Very easy	03	03	03	**09**
b	Easy	--	--	--	--
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
4	**How it was to test the i-CHROMA iFOB external controls.**				
a	Very easy	01	02	02	**05**
b	Easy	02	01	01	**04**
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
5	**How it was to operate the *i*-CHROMA Reader.**				
a	Very easy	02	02	03	**07**
b	Easy	01	01	00	**02**
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--

Continued from previous page:

Continued **Table VI.3.K:** Content of the operator questionnaire as well as site-wise/ operator-wise and combined feedback obtained from test operators participated in the clinical method comparison study of *i*-CHROMA iFOB

Que. No.	Question with Options	Clinical Study Sites			Combined Responses
		Site CSS-1	Site CSS-2	Site CSS-3	
		3 Operators	3 Operators	3 Operators	9 Operators
6	**How it was to read/understand the normal procedural message alerts displayed by *i*-CHROMA Reader.**				
a	Very easy	03	03	03	**09**
b	Easy	--	--	--	--
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
7	**How it was to read and understand the test results displayed by *i*-CHROMA Reader.**				
a	Very easy	03	03	03	**09**
b	Easy	--	--	--	--
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
8	**How it was to read and understand the error message alerts; if any displayed by *i*-CHROMA Reader.**				
a	Very easy	--	--	--	--
b	Easy	--	--	--	--
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
f	I did not encounter any error message alert	03	03	03	**09**
9	**How it was to perform the overall testing process.**				
a	Very simple	01	02	02	**05**
b	Simple	02	01	01	**04**
c	Somewhat complex	--	--	--	--
d	Complex	--	--	--	--
e	Highly complex	--	--	--	--
10	**How the instructional material explains what to do if a test result is invalid?**				
a	Very clearly	02	02	03	**07**
b	Clearly	01	01	00	**02**
c	Ambiguously	--	--	--	--
d	Vaguely	--	--	--	--
e	Not at all	--	--	--	--

Continued from previous page:

Table VI.3.K: Content of the operator questionnaire as well as site-wise/operator-wise and combined feedback obtained from test operators participated in the clinical method comparison study of *i*-CHROMA iFOB

Que. No.	Question with Options	Clinical Study Sites			Combined Responses
		Site CSS-1	Site CSS-2	Site CSS-3	
		3 Operators	3 Operators	3 Operators	9 Operators
11	**How the instructional material explains what to do if any error message alert is displayed by the *i*-CHROMA Reader?**				
a	Very clearly	02	02	03	**07**
b	Clearly	01	01	00	**02**
c	Ambiguously	--	--	--	--
d	Vaguely	--	--	--	--
e	Not at all	--	--	--	--
12	**You could perform the test properly the first time after …..**				
a	Merely reading the instructional material	02	03	03	**08**
b	Reading the instructional material as well as contacting the technical assistance services of the manufacturer	01	00	00	**01**
c	Discussing the test with other test operator(s)	--	--	--	--
d	Taking help from other test operator(s)	--	--	--	--

Conclusion:

- Considering the acceptance/performance criteria, results of the clinical testing study establish the accuracy of *i*-CHROMA iFOB as a qualitative in-vitro diagnostic fecal occult blood test for its proposed use in clinical settings.

VI.4 Labeling/Instructional material consistent with simple feature of *i*-CHROMA iFOB:

Labels of various components of *i*-CHROMA iFOB test system have been outlined in 'Section 13: Proposed Labelling'.

Appropriate instructional materials consistent with the proposed 'CLIA Waiver' application of *i*-CHROMA iFOB test system, have been included in Appendix II – V as per following details:

Appendix II: *i*-CHROMA iFOB Test Package Insert

Appendix III: *i*-CHROMA iFOB Test Quick Reference Instructions (QRI)

Appendix IV: *i*-CHROMA iFOB Control Package Insert

Appendix V: *i*-CHROMA Reader Operational Manual

(b)(4)Trade Secret Process - Risk Analysis

(b)(4)Trade Secret Process - Risk Analysis

(b)(4)Trade Secret Process - Risk Analysis

(b)(4)Trade Secret Process - Risk Analysis

(b)(4)Trade Secret Process - Risk Analysis

(b)(4)Trade Secret Process - Risk Analysis

(b)(4)Trade Secret Process - Risk Analysis

Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2015. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Boditech Med Inc.

2. Date of the Application/Submission Which This Certification Accompanies
02/28/2014

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
43, Gedudanji 1-gil

Address 2 *(Apartment, suite, unit, building, floor, etc.)*
Dongnae-myeon,

City: Chunchcon-si
State/Province/Region: Gangwon-do
Country: Republic of Korea (South Korea)
ZIP or Postal Code: 200883

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*
(Tel): +82 33 243 1400
(Fax): +82 33 243 9373

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Common Name: i-CHROMA iFOB
Classification Name: Automated Occult Blood analyzer
Trade Name: i-CHROMA iFOB with i-CHROMA Reader
Class: II
Panel: Hematology
Product Code: OOX

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*
132167

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Sang Yeol Park	Senior Director (Quality Assurance & Regulatory Affairs)

12. Address

Address 1 *(Street address, P.O. box, company name c/o)* Boditech Med Inc.	
Address 2 *(Apartment, suite, unit, building, floor, etc.)* 43, Geodudanji 1-gil, Dongnae-myeon,	
City Chuncheon-si	State/Province/Region Gangwon-do
Country Republic of Korea (South Korea)	ZIP or Postal Code 200883

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): +82 33 243 1400

(Fax): +82 33 243 9373

14. Date of Certification

02/28/2014

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1-CD

K132167/S002

April 23, 2014

FDA CDRH DMC

APR 25 2014

Received

To,

Food and Drug Administration,
Center for Devices and Radiological Health,
Document Control Center – WO66-G609,
10903 New Hampshire Avenue,
Silver Spring, MD 20993-0002,
USA.

Subject: Submission of "**Additional Information**" in response to "**K132167 S001 Review Memo'** dated **April 2, 2014** and **'Subsequent K132167 Hold Letter**" dated **April 7, 2014** issued by FDA in connection with *i*-CHROMA iFOB 510(k) submission

Dear Sir/Madam,

Please find enclosed herewith a '**Paper Copy**' and an '**eCopy**' of the '**Additional Information to K132167 S001 Review**' which we intend to submit in response to '**K132167 Hold Letter'** dated **April 7, 2014** issued by FDA in connection with the *i*-CHROMA iFOB 510(k) Pre-market Notification submitted by Boditech Med Inc., Republic of Korea.

The 'eCopy' comprises 15 *.pdf* files burned on to a CD.

The eCopy is an exact duplicate of the paper copy.

To the best of our understanding, the additional information being submitted by us comprises a complete response to the deficiencies identified by FDA in the "K132167 S001 Review Memo" dated April 2, 2014 and "Subsequent K132167 Hold Letter" dated April 7, 2014

However, we look forward to provide further information if any; sought by FDA.

Thanks for your time and consideration.

Encl:

1) A Paper Copy of "Additional Information to K132167 S001 Review"
2) A CD containing the eCopy (comprising 15 *.pdf* files) of "Additional Information to K132167 S001 Review"

Sincerely yours,

Sang Yeol Park Ph.D.
Director
Quality Assurance &
Regulatory Affairs
psy@boditech.co.kr

Sang Yeol Park

Boditech Med Inc. www.boditech.co.kr
43, Geoduda ji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 200-883, Korea
바디텍메드(주) 강원도 춘천시 동내면 거두단지 1길 43 Tel +82-33-243-1400 Fax +82-33-243-9373

ichroma
Respect for life
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SO

ichroma

Respect for life

boditech BIO TECHNOLOGY

April 23, 2014

To,

Food and Drug Administration,
Center for Devices and Radiological Health,
Document Control Center – WO66-G609,
10903 New Hampshire Avenue,
Silver Spring, MD 20993-0002,
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Subject: Submission of "**Additional Information**" in response to "**K132167 S001 Review Memo'** dated **April 2, 2014** and **'Subsequent K132167 Hold Letter**" dated **April 7, 2014** issued by FDA in connection with *i*-CHROMA iFOB 510(k) submission

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However, we look forward to provide further information if any; sought by FDA.

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1) A Paper Copy of "Additional Information to K132167 S001 Review"
2) A CD containing the eCopy (comprising 15 *.pdf* files) of "Additional Information to K132167 S001 Review"

Sincerely yours,

Sang Yeol Park Ph.D.
Director
Quality Assurance &
Regulatory Affairs
psy@boditech.co.kr

Minutes of Teleconference between FDA and K132167 *i*-CHROMA iFOB Sponsor

As proposed by FDA and agreed up on mutually, a teleconference between FDA review committee and Boditech Med Inc.'s staff was set up on April 10, 2014, 9–10 am EST (April 10, 2014, 10-11 pm KST).

The teleconference was primarily intended for addressing the additional concerns as reflected in 'K132167/S001 Review Memo' dated April 2, 2014 and the subsequent 'K132167 Hold Letter' dated April 7, 2014.

The participants were as follows:

FDA review staff:

1) **Dr. Yvonne Doswell**, K132167 Lead Reviewer, CDRH/OIR/DIHD

2) **Dr. Maria Chan,** Director, Division of Immunology/Hematology Devices, OIVD, CDRH

Boditech Med Inc. staff:

1) **Dr. Keith Nahm,** Chief Technical Officer

2) **Dr. Sang Yeol Park,** Senior Director (Regulatory Affairs & Quality Assurance)

3) **Hyung Ju Oh,** Manager (Regulatory Affairs)

4) **Dr. Parag Bhurchandi,** Senior Research Scientist (Regulatory Affairs)

Proper telephonic contact was established at around 9.15 am EST.

Participants from either side introduced themselves and greeted each other.

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Index of Revision/Corrections in Various Sections and Appendices of Additional Information to K132167 *i*-CHROMA iFOB 510(k) Submission Made in Response to K132167 S001 Review Memo dated April 2, 2014

No.	Corrected Section/Appendix	Page Numbers on which Revision/ Corrections Have Been Made
1	**Section 3:** 510(k) Cover Letter	Page 3.2
2	**Section 5:** 510(k) Summary	Pages 5.3 and 5.5
3	**Section 10:** Executive Summary	Pages 10.4 and 10.7-10.9
4	**Section 11:** Device Description	Pages 11.5 and 11.7- 11.9
5	**Section 12:** Substantial Equivalence Discussion	Pages 12.4 and 12.5
6	**Section 13:** Proposed Labeling	Pages 13.7 and 13.8
7	**Section 14:** Sterilization and Shelf-life	Pages 14.1 and 14.2
8	**Section 18:** Analytical Performance Testing (Bench)	Pages 18.1-18.4, 18.8, 18.36-18.43, 18.48-18.56 and 18.64
9	**Appendix I:** *i*-CHROMA iFOB System Information	Pages I.12-I.18, I.26 and I.27
10	**Appendix II:** *i*-CHROMA iFOB Package Insert	Pages II.2, II.5, II.12 and II.13
11	**Appendix III:** *i*-CHROMA iFOB Quick Reference Instructions	Pages III.1 and III.8
12	**Appendix VI:** System Information and Clinical Testing for CLIA Waiver Application of *i*-CHROMA iFOB	Pages VI.21-VI.22, VI.38-VI.40 and VI.55

April 23, 2014

To
Food and Drug Administration,
Center for Devices and Radiological Health,
Document Mail Center - WO66-G609,
10903 New Hampshire Avenue,
Silver Spring, Maryland 20993-0002,
USA.

510(k) Notification

21 CFR 807.90(e)

To whom it may concern

Dear Sir/Madam,

This is to notify you of the intention of Boditech Med Inc. to manufacture and market the following device:

Device Type/Common Name: Fecal Occult Blood Test

Trade/Proprietary Name **:** *i*-CHROMA iFOB with *i*-CHROMA Reader

Type of Submission **:** Traditional 510(k) Submission

Basis for Submission **:** Additional Information to 510(k) Hold Letter for a New Device

Submitter **: Boditech Med Inc.**
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: psy@boditech.co.kr
Website: www.boditech.co.kr

Contact Person **: Sang Yeol Park**/ Senior Director/ Ph.D.

Establishment Registration Number **:** Establishment will be registered following FDA clearance

Name(s) and Address(es) of Manufacturing Facility **: Boditech Med Inc.**
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.

Classification Regulation : 21 CFR § 864.6550

Class : II

Panel : Hematology

Product Code : OOX; Automated Occult Blood Analyzer

Prior FDA Document Numbers:

(1) **USFDA 510(k) No. k062981** accorded to the clearance of *i*-Chroma CRP Test of which *i*-CHROMA Reader is an associated device

(2) **FDA's Memo** dated **October 27, 2011** regarding **Pre-IDE Submission No. I110619** for *i*-Chroma iFOB

(3) **K132167 Hold Letter** dated **September 9, 2013** regarding *i*-CHROMA iFOB 510k Submission

(4) **Q131368 Final Review Memo** dated **December 11, 2013** and **E-mail Response** dated **December 24, 2013**

(5) **K132167 S001 Review Memo** dated April 3, 2014 and subsequent **K132167 Hold Letter** dated April 7, 2014

Predicate Device : OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer

Predicate Device 'K' Number : K041408

Predicate Device Product Code : KHE-Reagent, Occult Blood

Compliance with any special control : Not Applicable

Preference for continued confidentiality (21 CFR 807.95) : Not Applicable

Table 3.1: Design and Use of the Device

No.	Question	Yes/No
1	Is the device intended for prescription use (21 CFR 801 Subpart D)?	**Yes**
2	Is the device intended for over-the-counter use (21 CFR 807 Subpart C)	**No**
3	Does the device contain components derived from a tissue or other	**Yes**

	biologic source?	
4	Is the device provided sterile?	**No**
5	Is the device intended for single use?	**Yes***
6	Is the device a reprocessed single use device?	**No**
7	If yes, does this device type require reprocessed validation data?	**Not Applicable**
8	Does the device contain a drug?	**No**
9	Does the device contain a biologic?	**Yes**
10	Does the device use software?	**Yes**[Δ]
11	Does the submission include clinical information?	**No**
12	Is the device implanted?	**No**

***** *i*-CHROMA iFOB is intended for single use while *i*-CHROMA Reader is intended for scanning the sample-loaded *i*-CHROMA iFOB Test Cartridges as well as for being used in conjunction with other *in vitro* diagnostic tests manufactured by Boditech Med Inc.

[Δ] Functioning of *i*-CHROMA Reader is based on the use of software.

Standard procedure prescribed by the USFDA has been followed and required documentation has been enclosed.

Thank you in advance for your consideration of our application.

Please feel free to contact us in case of any question or comment about this submission.

Sincerely yours,

Sang Yeol Park
Director of Quality Assurance
& Regulatory Affairs

Section 5: 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR, Section 807.92 (c).

Submitter Information: Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: psy@boditech.co.kr
Website: www.boditech.co.kr

Contact Person: **Sang Yeol Park**/ Senior Director/ Ph.D.

Date: **March 03, 2014**

Device Information:

Trade Name: *i*-CHROMA iFOB with *i*-CHROMA Reader
Common Name: *i*-CHROMA iFOB
Classification Name: Automated Occult Blood Analyzer
Class: II
Panel: Hematology
Product Code: OOX
Regulation: 21 CFR § 864.6550

Predicate Device: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer
Predicate K Number: K041408

Device Description:

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

Intended Use(s):

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples. *i*-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Indications for Use(s):

i-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Components of *i*-CHROMA iFOB:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer' and *i*-CHROMA Reader

- The test cartridge contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.

- The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each sample collection tube contains 1 mL detection buffer. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

- Additionally, 'Patient Packs' are provided along with the test cartridge box and also separately on demand.

  Each 'Patient Pack' contains following items:
  - 1 Patient Instructions Leaflet (for sampling instructions)
  - 1 Sample Collection Paper (for fixing onto the toilet bowl)
  - 1 Sample Sac (for enclosing the sample collection tube after sampling)
  - 1 Return Envelop (for submitting the sample collection tube to the laboratory/physician office for testing)

- *i*-CHROMA Reader is a fluorometer instrument which scans the sample-loaded *i*-CHROMA iFOB test cartridge and displays the test result. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other. *i*-CHROMA Reader is marketed/supplied separately on demand.

- The ID chip contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

***i*-CHROMA iFOB Test Cartridge:**

i-CHROMA iFOB Test Cartridge is composed of a test strip enclosed in a disposable plastic housing.

The components of the test strip are:

- An antibody-immobilized nitrocellulose membrane
- A sample pad
- An absorption pad (also called absorbing pad or absorbent pad)
- A plastic backing

***i*-CHROMA iFOB Sample Collection Tube:**

'Sample Collection Tube' is an essential component of *i*-CHROMA iFOB. A box containing 25 pre-filled sample collection tubes, is delivered separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

The sample collection tube is a specially designed plastic container. Each sample collection tube contains 1mL Detection Buffer. Apart from being the container for the detection buffer, the sample collection tube serves the following purposes:

i) Proper sampling of the fecal sample

ii) Thorough mixing of the fecal sample with the detection buffer for ensuring complete extraction of the fecal sample

iii) Application of precise quantity of the sample mixture into the 'Sample well' of the *i*-CHROMA iFOB test cartridge

'*i*-CHROMA iFOB Sample Collection Tube' contains 1 mL 'Detection Buffer'. Approximately 13 mg (±1.82 mg) of human fecal sample is actually delivered into the detection buffer in the '*i*-CHROMA iFOB Sample Collection Tube' following the sampling procedure described in the package insert of *i*-CHROMA iFOB test.

***i*-CHROMA Reader:**

i-CHROMA Reader is a custom-configured, portable, desktop, fluorescence-scanning instrument for qualitative detection of fecal occult blood (FOB) in human fecal samples; duly mixed with the detection buffer and tested by *i*-CHROMA iFOB. Up on upgrading the software, *i*-CHROMA Reader can also be used for quantitative determination of various other analytes/disease markers when used in conjunction with other *in vitro* diagnostic immunoassay tests manufactured by Boditech Med Inc. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other.

i-CHROMA Reader is intended to be used only in conjunction with *i*-CHROMA iFOB for *in vitro* diagnostic purpose by laboratories and physician offices. *i*-CHROMA Reader measures 250 mm (L) x 185 mm (W) x 80 mm (H) in size and weighs 1.2 Kg.

The *i*-CHROMA iFOB test cartridge is loaded with the human fecal sample which has been duly mixed with the detection buffer in *i*-CHROMA iFOB Sample Collection Tube as per the standard test procedure recommended by Boditech Med Inc. This sample-loaded test cartridge is inserted in to the cartridge holder of the *i*-CHROMA Reader for the purpose of being scanned.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes accumulated at the test line as well at the control line.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration. The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

Test Principle:

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human fecal sample is mixed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer binds with hemoglobin in the fecal occult blood (FOB).

When the fecal sample mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, the fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, more the hemoglobin in the human fecal sample, more the complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the

fluorescence is scanned and converted into an electric signal which is correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner based on an analytical cut-off of 100 ng/mL (hemoglobin in fecal sample mixed with detection buffer) which is equivalent to 8µg i.e. 0.008 mg hemoglobin per gram of stool.

i-CHROMA iFOB and *i*-CHROMA Reader are compatible only with each other.

Substantial Equivalence Information:

Predicate Device: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer

Predicate K Number: K041408

Comparison with the Predicate Device:

Following table summarizes similarities and difference between the test device *i*-CHROMA iFOB and the predicate device OC Auto Micro FOB Test.

SIMILARITIES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Principle	Immunological test system using antigen-antibody reaction for detection of human hemoglobin in human fecal samples.	Immunological test system intended for qualitative detection of fecal occult blood in feces
2	Intended Use	Qualitative detection of fecal occult blood (FOB) in human fecal samples by laboratories and physician offices	Qualitative detection of fecal occult blood in feces by professional laboratories
3	Test Sample	Human fecal sample mixed with detection buffer in the sample collection tube	Feces in an extraction buffer
4	Test Cut-off	100 ng/mL (Human hemoglobin in human fecal sample mixed with detection buffer)	100 ng/mL (Human hemoglobin in feces processed in extraction buffer)
DIFFERENCES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**

1	Test Platform	Fluorescence immunoassay using lateral flow technology	Automated immunoassay using latex fixation
2	Test Time	10 minutes	5~10 minutes
3	Detection Mechanism	Involves scanning/measurement of intensity of fluorescence on the test cartridge membrane	Involves optical measurement of agglutination of latex particles

Standard/Guidance Document Referenced:

USFDA guidance document for industry and FDA staff:
'Review Criteria for Assessment of Qualitative Fecal Occult Blood In Vitro Diagnostic Devices' (Issue date: August 8, 2007**)**

Summary of Performance Testing (Bench):

- *i*-CHROMA iFOB showed **no prozone/hook effect up to** analyte concentration **2000 ng/mL**.
- *i*-CHROMA iFOB was found to be **equally sensitive to** 'Hemoglobin S' as the **abnormal hemoglobin** associated with sickle cell anemia.
- *i*-CHROMA iFOB showed **no significant cross-reactivity with** any of the eight **animal hemoglobin** (i.e. bovine, chicken, fish, horse/equine, goat, pig/swine, rabbit, and sheep origin) **and no significant interference from** any of the four **endogenous substances** (Ascorbic acid, Bilirubin, Albumin and Myoglobin).
- *i*-CHROMA iFOB **showed high degree of repeatability as well as** between-run, lot-to-lot, instrument-to-instrument and site-site **reproducibility.**
- **Analytical method comparison** study at three US sites performed on spiked human fecal samples **showed high degree of overall percent agreement** as well as **positive** percent agreement **and negative percent agreement between** test results obtained with ***i*-CHROMA iFOB** and the predicate method **OC Auto Micro FOB**.
- **Clinical testing study** at two Korean and one US site involving prospective testing of clinical human fecal samples showed:
  - **More than 96% positive and negative percent agreements** in test results when compared **with** the predicate method **OC Auto Micro FOB.**
  - **95-99.66% accuracy** in test results **with weak positive and weak negative samples.**

Section 10: Executive Summary

Submitter's Information:

Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: psy@boditech.co.kr
Website: www.boditech.co.kr

Device Information:

Trade Name: *i*-CHROMA iFOB with *i*-CHROMA Reader
Common Name: *i*-CHROMA iFOB
Classification Name: Automated Occult Blood Analyzer
Class: II
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Predicate Device: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer
Predicate K Number: K041408

Intended Use(s):

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Indications for Use(s):

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i) Proper sampling of the fecal sample
ii) Thorough mixing of the fecal sample with the detection buffer for ensuring complete extraction of the fecal sample
iii) Application of precise quantity of the sample mixture into the 'Sample well' of the *i*-CHROMA iFOB test cartridge

_i_-CHROMA Reader:

i-CHROMA Reader is a custom-configured, portable, desktop, fluorescence-scanning instrument for qualitative detection of fecal occult blood (FOB) in human fecal samples; duly mixed with the detection buffer and tested by *i*-CHROMA iFOB. Up on upgrading the software, *i*-CHROMA Reader can also be used for quantitative determination of various other analytes/disease markers when used in conjunction with other *in vitro* diagnostic immunoassay tests manufactured by Boditech Med Inc. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other.

i-CHROMA Reader is intended to be used only in conjunction with *i*-CHROMA iFOB for *in vitro* diagnostic purpose by laboratories and physician offices. *i*-CHROMA Reader measures 250 mm (L) x 185 mm (W) x 80 mm (H) in size and weighs 1.2 Kg.

The *i*-CHROMA iFOB test cartridge is loaded with the human fecal sample which has been duly mixed with the detection buffer in *i*-CHROMA iFOB Sample Collection Tube as per the standard test procedure recommended by Boditech Med Inc. This sample-loaded test cartridge is inserted in to the cartridge holder of the *i*-CHROMA Reader for the purpose of being scanned.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the

fluorochrome-labeled complexes of hemoglobin (accumulated at the test line). The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration. The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner.

Test Principle:

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human fecal sample is mixed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer binds with hemoglobin in the fecal occult blood (FOB).

When the fecal sample mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, the fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, more the hemoglobin in the human fecal sample, more the complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROM Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner based on an analytical cut-off of 100 ng/mL (hemoglobin in fecal sample mixed with detection buffer) which is equivalent to 8µg i.e. 0.008 mg hemoglobin per gram of stool.

i-CHROMA iFOB and *i*-CHROMA Reader are compatible only with each other.

Comparison with the Predicate Device:

Following table summarizes similarities and difference between the test device *i*-CHROMA iFOB and the predicate device OC Auto Micro FOB Test.

SIMILARITIES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Nature of the Test	Rapid, convenient, sensitive and reliable *in vitro* diagnostic test	Rapid, convenient, sensitive and reliable *in vitro* diagnostic test
2	Intended Use	Qualitative detection of fecal occult blood (FOB) in human fecal samples by laboratories and physician offices	Qualitative detection of fecal occult blood in feces by professional laboratories
3	Indications for Use(s)	Routine physical examination when gastrointestinal bleeding may be suspected	(1) Routine physical examinations (2) Monitoring for bleeding in patients and (3) Screening for colorectal cancer or gastrointestinal bleeding.
4	User(s)	Laboratories and physician offices	Professional laboratories
5	Test Sample	Human fecal sample mixed with detection buffer in the sample collection tube	Feces in an extraction buffer
6	Test Principle	Immunological test system based on fluorescence technology for qualitative detection of human hemoglobin in human fecal samples.	Immunological test system intended for qualitative detection of fecal occult blood in feces
7	Special Instrument Requirement	'*i*-CHROMA Reader' for scanning the *i*-CHROMA iFOB test cartridge which has been loaded with the fecal sample mixed with the detection buffer	'Polymedco OC Auto Micro 80 Analyzer' on which the 'OC Auto Sampling Bottle(s)' containing the fecal sample(s) are placed for performing the automated test
8	Work Flow	Normally, patient receives 'Patient Pack' and the sample collection tube from the laboratory/ physician office. Patient collects/transfers fecal sample in to the sample collection tube and submits it to the laboratory/physician office for testing. Occasionally, the physician office / laboratory may receive fecal sample which has been submitted by the patient in a specimen cup or other suitable container.	Fecal sample is collected/transferred by the patient in to the sampling bottle which is sent to the professional laboratory for testing.

9	Sampling / Mixing the sample with detection buffer	Sampling is done with the help of the 'Sampling Stick' / 'Sampler' which is a part of the sample collection tube. The fecal sample is thus delivered into the sample collection tube containing the detection buffer which extracts it.	Sampling is done with the help of the 'Sampling Probe' which is a part of the 'OC-Auto Sampling Bottle'. The fecal sample is thus delivered into the sampling bottle containing the buffer which extracts it.
10	Test Cut-off	100 ng/mL (human hemoglobin in the human fecal sample mixed with detection buffer)	100 ng/mL (human hemoglobin in processed feces)
11	Presentation of Test Results	Qualitative (Positive if ≥ 100 ng/mL and Negative if <100 ng/mL)	Qualitative (Positive if ≥ 100 ng/mL and Negative if <100 ng/mL)
12	Biohazard and Compatibility with Environment	➢ Used test cartridges and sample collection tubes should be considered as a biohazard. ➢ Test components should be handled strictly as per the instructions given in the package insert and the operation manual. ➢ Used test cartridges and sample collection tubes should be disposed of in accordance with relevant local, state or federal regulations. ➢ If needed, the *i*-CHROMA Reader should be disposed of in accordance with applicable regulations.	➢ Similar handling precautions and disposal directives are prescribed by the manufacturer.
13	Compatibility with other Devices	➢ '*i*-CHROMA iFOB' and the '*i*-CHROMA Reader' are compatible only with each other for the purpose of this test. ➢ Up on upgrading the software, *i*-CHROMA Reader can also be used for measurement of various analytes/ disease markers when used in conjunction with other *in vitro* diagnostic tests manufactured by Boditech Med Inc.	➢ 'OC Auto Micro FOB Test' and 'Polymedco OC Auto Micro 80 Analyzer' are designed to be used together for the purpose of this test system.
14	Chemical Safety	If used in accordance with the warnings, precautions, instructions and procedure prescribed in the package insert, '*i*-CHROMA iFOB' has assured chemical safety profile.	'OC Auto Micro FOB Test' is reportedly safe on this count

Discussion of Similarities:

As evident from the table above *i*-CHROMA iFOB (along with *i*-CHROMA Reader) shares a very close similarity with the predicate device OC Auto Micro FOB Test (along with OC Auto Micro 80 Analyzer) when compared on different parameters related to scientific rationale, test principle, intended use(s), indications for use(s), user(s) profile, work flow, performance characteristics, effectiveness, energy used, bio-hazard and environmental compatibility, safety profile etc. This explicit similarity forms a robust foundation for substantial equivalence of *i*-CHROMA iFOB (along with *i*-CHROMA Reader) to the predicate device.

DIFFERENCES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Platform/ Format	Lateral flow chromatographic fluorescence immunoassay	Automated immunoassay using latex fixation
2	Test Components	➢ *i*-CHROMA iFOB Test Cartridge ➢ *i*-CHROMA iFOB Sample Collection Tube containing the Detection Buffer ➢ *i*-CHROMA iFOB ID Chip which contains encoded calibration data **&** ➢ *i*-CHROMA Reader	➢ Closed tube-type Sampling Bottle containing the Extraction Buffer ➢ Test Reagents (Latex reagent, Buffer, Negative & Positive Controls, Wash Concentrate, and Calibrator) **&** ➢ OC Auto Micro 80 Analyzer
3	Test Device	Test Cartridge (Test strip enclosed in a plastic housing)	Sampling Bottle containing an extraction buffer
4	Detection Mechanism	Involves scanning/measurement of intensity of fluorescence on the processed sample-loaded test cartridge membrane	Involves optical measurement of agglutination of latex particles
5	Quantity of fecal sample delivered into the sample collection device after sampling	Approx. 13 mg (±1.82 mg) of human fecal sample is actually delivered into 1mL detection buffer in the '*i*-CHROMA iFOB Sample Collection Tube'	Approx. 10 mg of human fecal sample is actually delivered into 2 mL extraction buffer in the 'OC Sample Bottle'
6	Correlation between ng Hb/mL fecal sample + detection buffer mixture and µg or mg Hb/g stool	1 ng Hb/mL fecal sample + detection buffer mixture is equivalent to 0.08 µg or 0.00008 mg Hb/g stool	1 ng Hb/mL fecal sample + extraction buffer mixture is equivalent to 0.2 µg or 0.0002 mg Hb/g stool

7	Cut-off in terms of µg or mg hemoglobin per gm of stool	100 ng Hb/mL fecal sample + detection buffer mixture is equivalent to 8 µg or 0.008 mg Hb/g stool	100 ng Hb/mL fecal sample + extraction buffer mixture is equivalent to 20 µg or 0.02 mg Hb/g stool

Discussion of Differences:

i-CHROMA iFOB (along with *i*-CHROMA Reader) differs from the predicate device OC Auto Micro FOB Test (along with OC Auto Micro 80 Analyzer) with respect to the test platform/format, test device & components and detection mechanism.

However, these differences are in accordance with the respective technology platforms on which the test device and the predicate device are based.

i-CHROMA iFOB is a fluorescence immuno-chromatographic assay based on lateral flow format while OC Auto Micro FOB Test is an automated immunoassay using latex fixation. The lateral flow technology is a quite well-established and proven platform for development of modern rapid, sensitive, reliable and user-friendly *in vitro* diagnostic tests.

i-CHROMA iFOB differs from the predicate device in terms of test components. In *i*-CHROMA iFOB, the test components are viz. a 'Test Cartridge', a 'Sample Collection Tube containing Detection Buffer', an 'ID Chip' and the '*i*-CHROMA Reader' while in OC Auto Micro FOB test, the test components are: a closed tube-type 'OC-Auto Sampling Bottle containing Extraction Buffer', 'Test Reagents' (Latex Reagent, Buffer, Negative & Positive Controls, Wash Concentrate, and Calibrator) and the 'OC Auto Micro 80 Analyzer'.

i-CHROMA iFOB test cartridge and the sample collection tube (containing the detection buffer) collectively carry out the function which is analogous to the role of OC-auto sampling bottle (containing the extraction buffer) and the latex & buffer reagent provided as a part of the predicate test.

In case of *i*-CHROMA iFOB, the ID chip contains encoded calibration data. An ID chip having a lot number matching with that of the test cartridge and the sample collection tube; is inserted into the designated port of the *i*-CHROMA Reader which utilizes the calibration data for computing and converting the test result. In case of OC Auto Micro FOB test, calibration curve needs to be plotted for each measurement by serially diluting the primary calibrator and plotting the known concentrations of human hemoglobin in the control dilutions against the corresponding absorbance values.

i-CHROMA iFOB Control reagents are supplied on demand separately from the test components while negative & positive controls are supplied as components of the OC Auto Micro FOB test.

i-CHROMA iFOB test cartridge (loaded with a test sample mixed with the detection buffer) is to be inserted in the *i*-CHROMA Reader which scans it and automatically displays the test result. In case of the predicate device, similar role is played by the OC Auto Micro 80 Analyzer. OC-auto sampling bottle(s) containing the extracted fecal sample(s) is placed on the rack(s) of the OC Auto Micro 80 Analyzer which performs the automated immunoassay and displays the test result.

There is difference between the quantities of fecal sample delivered per sampling into the '*i*-CHROMA iFOB Sample Collection Tube' (13 mg/1mL detection buffer) and the 'OC FIT-Chek Sample Bottle' (10 mg/2mL extraction buffer).

However, this difference does not necessarily affect the equivalence between the two tests adversely.

Both are immunochemical tests having same cut-off but they are based on different test formats/platforms and measurement technologies.

i-CHROMA iFOB is a lateral flow chromatographic fluorescence immunoassay while OC Auto Micro FOB is an automated immunoassay using latex fixation. Moreover, the two tests follow different calibration procedures.

Further, stearic properties and epitope configuration of antibodies used in the test reagent/devices of the two tests may be different leading to difference in their detection abilities and conjugation properties.

Hence substantial equivalence of *i*-CHROMA iFOB with OC Auto Micro FOB can only be determined by analytical method comparison and other performance studies using spiked or clinical fecal samples.

Thus it is undoubtedly established that above differences neither deviate *i*-CHROMA iFOB from being substantially equivalent to the predicate device nor adversely affect the performance, effectiveness and safety of *i*-CHROMA iFOB in any manner.

Summary of Performance Testing (Bench):

1) Cut-off:

- Analytical characterization of cut-off of *i*-CHROMA iFOB involved testing of 219 human fecal samples comprising 125 normal/negative samples and 94 positive samples as confirmed with the predicate test OC Auto Micro FOB.
- Test results were statistically analyzed by ROC Analysis and analyte concentration corresponding to maximum sensitivity as well as maximum specificity of *i*-CHROMA iFOB was taken as the cut-off.
- Cut-off of *i*-CHROMA iFOB was determined to be 100 ng/mL (hemoglobin in fecal sample mixed with detection buffer) which is equivalent to 8µg i.e. 0.008 mg hemoglobin per gram of stool.

2) Prozone (hook) effect:

- Susceptibility of *i*-CHROMA iFOB to prozone effect was evaluated by testing 20 replicates of fecal samples spiked with human blood so as to obtain test samples containing human hemoglobin levels up to 2000 ng/mL.

- *i*-CHROMA iFOB was not found susceptible to prozone/hook effect as it would display positive test results with fecal samples containing hemoglobin concentration up to 2000 ng/mL.

3) Analytical specificity:

A) Sensitivity to human hemoglobin variant:

- Sensitivity of *i*-CHROMA iFOB to 'Hemoglobin S' as the human hemoglobin variant associated with sickle cell anemia was evaluated by testing 20 replicates of fecal samples spiked with blood of a sickle cell anemia patient so as to obtain test samples with five different concentrations of 'Hemoglobin S' (50 ng/mL, 85 ng/mL, 100 ng/mL, 115 ng/mL & 150 ng/mL).
- *i*-CHROMA iFOB was found to be equally sensitive to 'Hemoglobin S' as the human hemoglobin variant associated with sickle cell anemia.

B) Interference from animal hemoglobin:

- Cross-reactivity of *i*-CHROMA iFOB with animal hemoglobin was evaluated by testing 20 replicates of fecal samples spiked with human blood so as to obtain samples with 0 ng/mL, 50 ng/mL, 85 ng/mL, 100 ng/mL, 115 ng/mL & 150 ng/mL concentrations of human hemoglobin and further spiking them with blood of eight different animal species.
- Separate samples were prepared to obtain test samples containing intended level of respective animal hemoglobin such as bovine (2000 µg/mL), chicken (500 µg/mL), fish (100 µg/mL), horse/equine (500 µg/mL), goat (500 µg/mL), pig/swine (500 µg/mL), rabbit , (500 µg/mL) and sheep (500 µg/mL).
- *i*-CHROMA iFOB did not show significant cross-reactivity with any of the animal hemoglobin tested.

C) Interference from endogenous substances:

- Susceptibility of *i*-CHROMA iFOB to interference from endogenous substances was evaluated by testing 20 replicates of fecal samples spiked with human blood so as to obtain samples with 0 ng/mL, 50 ng/mL, 85 ng/mL, 100 ng/mL, 115 ng/mL & 150 ng/mL concentrations of human hemoglobin and further spiking them with solutions containing intended concentrations of four endogenous substances Ascorbic acid, Bilirubin, Albumin and Myoglobin.
- Separate samples were prepared to obtain test samples containing intended concentrations of the respective endogenous substance i.e. Ascorbic acid (30 µg/mL), Bilirubin (200 µg/mL), Albumin (60 mg/mL) and Myoglobin (2000 µg/mL).
- *i*-CHROMA iFOB did not show significant interference from any of the four endogenous substances which were tested.

4. Precision (Repeatability/Reproducibility):

- Imprecision (repeatability and reproducibility) of *i*-CHROMA iFOB was evaluated by testing 20 replicates of fecal samples spiked with human blood so as to obtain test

samples containing seven different concentrations of human hemoglobin such as 50 ng/mL, 85 ng/mL, 90 ng/mL, 100 ng/mL, 110 ng/mL, 115 ng/mL and 1000 ng/mL under specific variability conditions with respect to device lots, instruments, operators, testing sites etc.

- Repeatability (within-run variability), between-run reproducibility, instrument-to-instrument reproducibility and lot-to-lot reproducibility studies were conducted at a hospital site in Republic of Korea. These studies involved three *i*-CHROMA iFOB lots, three *i*-CHROMA Readers, three operators etc. as appropriate.
- Site-to-site reproducibility study was conducted at three intended use sites in USA using three different lots of *i*-CHROMA iFOB i.e. different lot for each site using same/common test samples.
- *i*-CHROMA iFOB showed high degree of repeatability as well as between-run reproducibility, instrument-to-instrument reproducibility, lot-to-lot reproducibility and site-to-site reproducibility.

5. Analytical method comparison:

- Analytical method comparison study of *i*-CHROMA iFOB was conducted at three intended use sites in USA. However, it was independent from the site-to-site reproducibility study conducted at the same sites on different dates.
- 20 replicates of fecal samples spiked with human blood so as to obtain test samples containing seven different concentrations of human hemoglobin (such as 50 ng/mL, 85 ng/mL, 90 ng/mL, 100 ng/mL, 110 ng/mL, 115 ng/mL and 1000 ng/mL) were prepared separately for each site but were tested using same lot of *i*-CHROMA iFOB across the three sites.
- After testing with *i*-CHROMA iFOB, test samples from each site were tested with the predicate test OC Auto Micro FOB installed at one of the three sites.
- Site-wise as well as combined analysis of the study results showed that *i*-CHROMA iFOB test results had high degree of overall percent agreement as well as positive percent agreement and negative percent agreement with OC Auto Micro FOB test results.

6. Clinical testing for CLIA-waiver application:

- The study was conducted at two hospitals in Korea and one laboratory in USA through prospective testing of clinical human fecal samples obtained from asymptomatic as well as high-risk individuals who had already been screened with colonoscopy in the past.
- Clinical method comparison study was performed on total 323 clinical fecal samples comprising 146 positive samples and 177 negative samples (as tested by the comparative method OC Auto Micro FOB).
- Performance of *i*-CHROMA iFOB at analyte concentrations near the cutoff was evaluated by testing 60 aliquots each of a weak positive and a weak negative clinical sample at each of the three sites.

- Site-wise as well as combined analysis of results of clinical testing study showed:
  - High degree (more than 96% in each case) of overall percent agreement as well as positive percent agreement and negative percent agreements between test results obtained with *i*-CHROMA iFOB and OC Auto Micro FOB.
  - 95-99.66% positive and negative results with 60 aliquots each of the weak positive sample and the weak negative sample respectively at each of the three sites.

Conclusions:

In view of the matter mentioned above, it can be positively concluded that *i*-CHROMA iFOB is substantially equivalent to the predicate device OC Auto Micro FOB Test.

Section 11: Device Description

Device Information:

Trade Name: *i*-CHROMA iFOB with *i*-CHROMA Reader
Common Name: *i*-CHROMA iFOB
Classification Name: Automated Occult Blood Analyzer
Class: II
Panel: Hematology
Product Code: OOX
Regulation: 21 CFR § 864.6550

Intended Use(s):

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples. *i*-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Indications for Use(s):

i-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

Introduction

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology wherein the antigen-antibody complexes formed after mixing the test sample with the detection buffer, are captured while migrating through the test cartridge which is scanned by the *i*-CHROMA Reader to compute, convert and display the test result in a qualitative (positive or negative) manner.

i-CHROMA iFOB:

Components of *i*-CHROMA iFOB:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer' and *i*-CHROMA Reader

- The test cartridge contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.

- The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each sample collection tube contains 1 mL detection buffer. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

- Additionally, 'Patient Packs' are provided along with the test cartridge box and also separately on demand.

  Each 'Patient Pack' contains following items:

  - 1 Patient Instructions Leaflet (for sampling instructions)
  - 1 Sample Collection Paper (for fixing onto the toilet bowl)
  - 1 Sample Sac containing an absorption pad (for enclosing the sample collection tube after sampling)
  - 1 Return Envelop (for submitting the sample collection tube to the laboratory/physician office for testing)

- *i*-CHROMA Reader is a fluorometer instrument which scans the sample-loaded *i*-CHROMA iFOB test cartridge and displays the test result. *i*-CHROMA Reader and *i*-CHROMA iFOB test cartridge are compatible only with each other. *i*-CHROMA Reader is marketed/supplied separately on demand.

- The ID chip contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

i-CHROMA iFOB Test Cartridge Format and Structure:

i-CHROMA iFOB test cartridge is composed of a test strip enclosed in a disposable plastic housing as shown in **Figure 11.1**.

The components of the test strip are:

- An antibody-immobilized nitrocellulose membrane
- A sample pad
- An absorption pad (also called absorbing pad or absorbent pad)
- A plastic backing

(b)(4)Trade Secret Process

[redacted]

Figure 11.1: Structure and Format of *i*-CHROMA iFOB Test Cartrige

i-CHROMA iFOB Sample Collection Tube:

Sample Collection Tube is an essential component of *i*-CHROMA iFOB. A box containing 25 pre-filled sample collection tubes is delivered separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

The sample collection tube is a specially designed plastic container. Each sample collection tube contains 1mL Detection Buffer. Apart from being the container for the detection buffer, the sample collection tube serves the following purposes:

i) Proper sampling of the fecal sample

ii) Thorough mixing of the fecal sample with the detection buffer for ensuring complete extraction of the fecal sample

iii) Application of precise quantity of the fecal sample mixture into the 'Sample well' of the *i*-CHROMA iFOB test cartridge

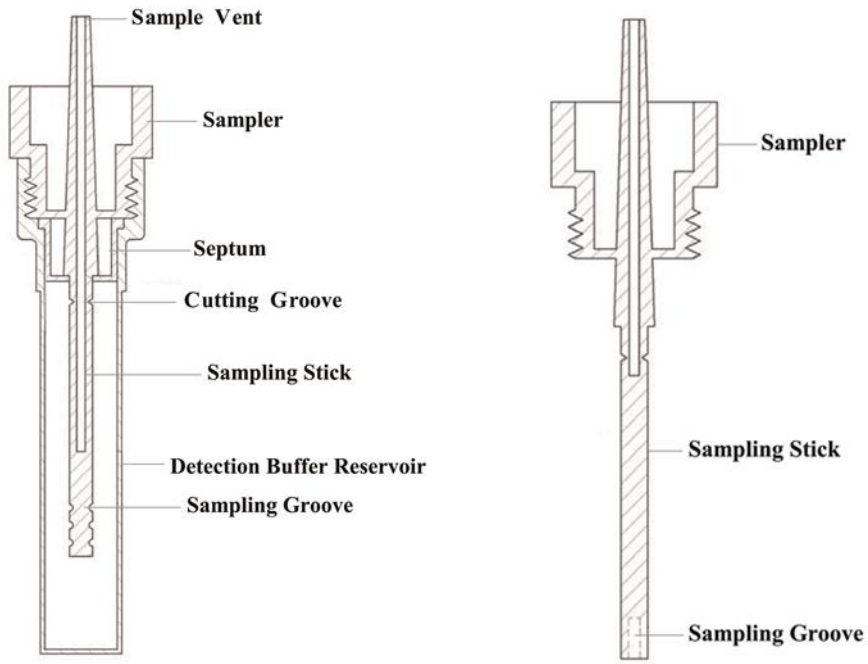


Figure 11.2: Diagram of *i*-CHROMA iFOB Sample Collection Tube

The sample collection tube is made up of two distinct and detachable components viz. the '**Detection Buffer Reservoir**' and the '**Sampler**'.

The **Detection Buffer Reservoir** is a cylindrical, near-transparent, plastic container similar in shape to a test tube which acts as the vessel for the detection buffer as well as its mixture with the fecal sample.

The open end of the detection buffer reservoir is enlarged and threaded on the inner surface so as to screw-in the sampler.

Just below the enlarged, and threaded open-end of the detection buffer reservoir, a '**Septum**' in the form of a small, cylindrical disc-like, plastic structure with a minute aperture at its center; has been fitted inside the detection buffer reservoir. This septum wipes the excess fecal material from the sampling stick when it passes through the aperture of the septum after sampling. Secondly, as the sampling stick exactly fits into this aperture of the septum, it prevents the mixture of the fecal sample and the detection buffer from splashing out of sample collection tube during shaking/mixing.

The **Sampler** is somewhat an inverted umbrella-like plastic structure. The sampler is in the form of a long stalk called as the '**Sampling Stick**', the upper end of which passes through a '**Cap**' The lower portion of the cap is threaded. It is this threaded portion which screws-in the sampler into the detection buffer reservoir.

The upper $^{2}/_{3}^{rd}$ portion of the sampling stick has been actually made into a hollow tube while the basal $^{1}/_{3}^{rd}$ portion is non-hollow. The surface of the sampling stick in lowermost part of this basal portion is grooved which is called as '**Sampling Grooves**'.

For sampling, the cap is unscrewed and the sampler/sampling stick is removed from the sample collection tube. While removing the sampling stick, the septum remains fitted inside the detection buffer reservoir otherwise there is possibility of the detection buffer spilling out of the reservoir.

The grooved end of the sampling stick is inserted into the fecal sample at 5~6 different sites so as to ensure a representative sampling. Sampling grooves on the sampling stick should be covered with sufficient fecal sample while ensuring that the quantity is not too much.

The sample-ridden sampling stick is then inserted back into the sample collection tube and the cap of the sampler is screwed-in tightly. The excess fecal material is wiped off from the sampling stick when it passes though the septum of the detection buffer reservoir. At this stage, the sampling system of *i*-CHROMA iFOB delivers the fecal material into detection buffer already present in the sample collection tube.

'*i*-CHROMA iFOB Sample Collection Tube' contains 1 mL 'Detection Buffer'. Approximately 13 mg (±1.82 mg) of human fecal sample is actually delivered into the detection buffer in the '*i*-CHROMA iFOB Sample Collection Tube' following the sampling procedure described as above.

Fecal sample submitted by the patient in *i*-CHROMA iFOB sample collection tube should be tested before 72 hours after sampling if stored at 4º C (2~8º C/35.6~46.4º F) and before 48 hours after sampling if stored at ambient temperature not exceeding 37º C/98.6º F.

Laboratory should test the fecal sample as early as possible within the above time limits after it is received from the patient. However, it is strongly recommended to test the fecal sample immediately after sampling and/or receipt at laboratory if it has been exposed to ambient temperature exceeding 37º C/98.6º F.

Contents of the sample collection tube are shaken well and mixed thoroughly to yield a homogenous suspension for complete extraction of the fecal sample. Fecal sample mixture thus obtained; should be kept standing at least for 10 minutes.

Before loading the fecal sample mixture into the sample well of the *i*-CHROMA iFOB test cartridge, the sample collection tube is held in vertical position and the sampling stick is cut by bending it the 2-3 times just below the cap i.e. at the '**Cutting Groove**' which is the first designated point below the cap as shown in the figure above. The sample collection tube must be held in an upright position during this stick-cutting process.

After the stick-cutting process, the basal non-hollow portion of the sampling stick will remain suspended in the fecal sample mixture while its upper hollow tube-like portion will now open into the detection buffer reservoir.

The fecal sample mixture can now be squeezed out by inverting the sample collection tube. In this position, the fecal sample mixture will squeeze out from the '**Sample Vent**' of the sampler.

Three drops of the fecal sample mixture are loaded into the sample well of the *i*-CHROMA iFOB test cartridge. The sample-loaded test cartridge is then immediately inserted in the cartridge holder of the *i*-CHROMA Reader which scans it after 10 minutes (as per the default reaction time setting i.e. Single Mode) to compute and display the test result.

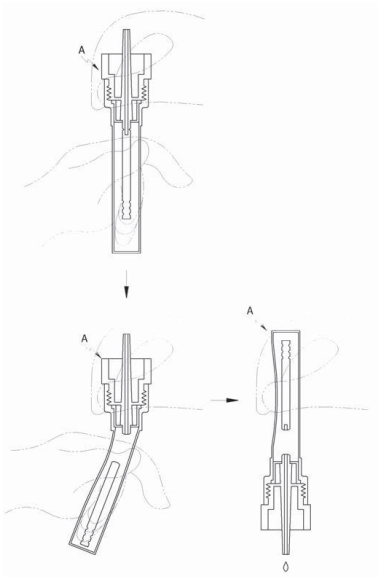


Figure 11.3: Using the *i*-CHROMA iFOB Sample Collection Tube

i-CHROMA iFOB Test Principle:

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology as depicted in **Figure 11.4**.

When a human fecal sample is mixed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer bind with hemoglobin in the fecal occult blood (FOB).

When the fecal sample mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, the fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, the more hemoglobin in the human fecal sample, the more complexes get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner based on an analytical cut-off of 100 ng/mL (hemoglobin in fecal sample mixed with detection buffer) which is equivalent to 8µg i.e. 0.008 mg hemoglobin per gram of stool.

i-CHROMA iFOB and *i*-CHROMA Reader are compatible only with each other.

(b)(4)Trade Secret Process

[redacted]

Figure 11.4: Principle of *i*-CHROMA iFOB

i-CHROMA Reader:

Introduction:

i-CHROMA Reader is a custom-configured, portable, desktop, fluorescence-scanning instrument for qualitative detection of fecal occult blood (FOB) in human fecal samples; duly processed and tested by *i*-CHROMA iFOB. Upon upgrading the software, *i*-CHROMA Reader can also be used for quantitative determination of various other analytes/disease markers when used in conjunction with other *in vitro* diagnostic immunoassay tests manufactured by Boditech Med Inc. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other.

i-CHROMA Reader is intended to be used only in conjunction with *i*-CHROMA iFOB for *in vitro* diagnostic purpose by laboratories and physician offices. *i*-CHROMA Reader measures 250 mm (L) x 185 mm (W) x 80 mm (H) in size and weighs 1.2 Kg.

i-CHROMA iFOB test cartridge is loaded with human fecal sample which has been duly mixed with the detection buffer in the '*i*-CHROMA iFOB sample collection tube' as per the standard test procedure recommended by Boditech Med Inc. This sample-loaded test cartridge is inserted in to the cartridge holder of *i*-CHROMA Reader for the purpose of being scanned.

i-CHROMA Reader is designed to extract designated information off the sample-loaded *i*-CHROMA iFOB test cartridge (manufactured by Boditech Med Inc.). *i*-CHROMA Reader includes specific components required to perform this task in a preprogrammed manner.

The *i*-CHROMA iFOB test cartridge contains a test line and a control line both of which have been tagged with capture antibodies. Test line of the test strip has been tagged with 'anti-human hemoglobin antibodies' while the control line has been tagged with 'rabbit immunoglobulin-G'.

The detection buffer (dispensed in the *i*-CHROMA iFOB Sample Collection Tubes) contains the detector antibodies i.e. 'fluorochrome-labeled anti-human hemoglobin antibodies' and 'fluorochrome-labeled anti-rabbit immunoglobulin-G'.

When the fecal sample-detection buffer mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

Complexes of the detector antibody (fluorochrome-labeled anti-human hemoglobin antibody)-analyte (FOB hemoglobin)-capture antibody (anti-human hemoglobin antibody) accumulate at the test line of the test strip.

Similarly, complexes of the detector antibody (fluorochrome-labeled anti-rabbit immunoglobulin-G)-capture antibody (rabbit immunoglobulin-G) accumulate at the control line of the test strip.

One would need an external light source to excite these fluorochrome-labeled complexes accumulated at the test line and the control line so that they would emit characteristic radiation i.e. fluorescence. *i*-CHROMA Reader uses a semiconductor diode laser as the excitation light source.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin accumulated at the test line as well at the control line.

i-CHROMA Reader scans the test cartridge across the test and the control lines while illuminating the cartridge with the laser radiation to measure the intensities of fluorescence generated at the test line and the control line and converts them into electrical signals.

Thus, fluorescence generated at the 'test line' and 'control line' are collected by the optical assembly onto a photosensor to convert them into the corresponding electric signals, which are translated by *i*-CHROMA Reader into corresponding curves.

Intensity of the fluorescence generated at the test line is proportional to the concentration of FOB hemoglobin present in the test sample.

This correlation is observed till FOB hemoglobin concentration of 1500 ng/mL beyond which hook/prozone effect comes into play.

However, as *i*-CHROMA reader has been programed to display test results qualitatively only in terms of 'iFOB Test Positive' or 'iFOB Test Positive', test samples with FOB hemoglobin concentrations up to 2000 ng/mL have been found to test positive with '*i*-CHROMA iFOB'.

Thus, summation of whole fluorescence emission at the test line is closely correlated with the concentration of FOB hemoglobin present in the test sample (upto hemoglobin concentration of 1500 ng/mL).

Control line of *i*-CHROMA iFOB test cartridge functions as the built-in procedural control which fairly satisfies the routine quality control requirement of *i*-CHROMA iFOB test(s).

While computing the test result, *i*-CHROMA Reader takes into account the ratio of fluorescence generated at the test line to that at the control line. This ratio further determines quality of the test run.

i-CHROMA Reader automatically calculates ratio of 'Area under Curve'/AUC (above base line) at the 'Test Line' (A_T) to the AUC at the 'Control Line' (A_C).

The on-board microprocessor computes the FOB hemoglobin concentration (in terms of ng/mL) based on a pre-programmed calibration formula encoded in the '*i*-CHROMA iFOB ID Chip inserted in the ID chip port of *i*-CHROMA Reader.

However, *i*-CHROMA Reader would display the test result qualitatively as 'iFOB Test Negative' or 'iFOB Test Positive' based on the cut-off of 100 ng/mL.

The 'ID Chip' provided with *i*-CHROMA test cartridge(s) contains a memory device which contains encoded calibration data. An ID chip having a lot number matching with that of the test cartridge and the sample collection tube is inserted into the designated port of the *i*-CHROMA Reader which utilizes the calibration data for computing the test result(s). Hence the user is not required to perform routine calibration before performing the test.

Regarding prior FDA clearance of *i*-CHROMA Reader:

i-CHROMA Reader has received prior clearance from FDA as the associated instrument of the ***i*-CHROMA CRP Test which has been cleared by FDA** vide **the 510(k) number k062981**

Risk Control Measures Incorporated in *i*-CHROMA iFOB Test System

Risk management has been used for proper identification and effective control of error sources which may be associated with the intended use of *i*-CHROMA iFOB.

Appropriate risk control measures in the form of fail-safe and/or failure alert mechanisms have been incorporated in *i*-CHROMA iFOB test system.

These fail-safe and failure alert mechanisms help assure that *i*-CHROMA iFOB test has an insignificant risk of an erroneous result.

Various fail-safe and/or failure alert mechanisms incorporated in *i*-CHROMA iFOB test system can be broadly classified as follows:

- Appropriate design and physical features to prevent operator errors
- Electronic controls in *i*-CHROMA Reader
- Mechanism for identification and validation of *i*-CHROMA iFOB ID chip
- Unique barcode and mechanism for identification/validation of *i*-CHROMA iFOB test cartridge
- Procedural/Internal control of *i*-CHROMA iFOB
- *i*-CHROMA iFOB external controls

Various fail-safe & failure alert mechanisms and other risk control measures incorporated in the *i*-CHROMA iFOB test system have been described in detail in following appendices:

Appendix VI: System Information and Clinical Testing for CLIA Waiver Application of *i*-CHROMA iFOB

Appendix VII: Risk Analysis of *i*-CHROMA iFOB Test System

Section 12: Substantial Equivalence Discussion

Device Information:

Trade Name: *i*-CHROMA iFOB with *i*-CHROMA Reader
Common Name: *i*-CHROMA iFOB
Manufacturer: **Boditech Med Inc.**
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: psy@boditech.co.kr
Website: www.boditech.co.kr

Predicate Information:

Trade Name: OC Auto Micro FOB Test and Polymedco OC Auto Micro 80 Analyzer
510(k) Number: **K041408**
510(k) Holder: **Polymedco Inc.**
510 Furnace Dock Rd,
Cortlandt Manor, NY 10567,
USA.
Phone: 1-800-431-2123 or 914-739-5400
Fax: 914-739-5890

Comparison with the Predicate Device:

Following table summarizes similarities and difference between the test device *i*-CHROMA iFOB and the predicate device OC Auto Micro FOB Test.

SIMILARITIES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Nature of the Test	Rapid, convenient, sensitive and reliable *in vitro* diagnostic test	Rapid, convenient, sensitive and reliable *in vitro* diagnostic test
2	Intended Use	Qualitative detection of fecal occult blood (FOB) in human fecal samples by laboratories and physician offices	Qualitative detection of fecal occult blood in feces by professional laboratories
3	Indications for Use(s)	Routine physical examination when gastrointestinal bleeding may be suspected	(1) Routine physical examinations, (2) Monitoring for bleeding in patients, and (3) Screening for colorectal cancer or gastrointestinal bleeding.

4	User(s)	Laboratories and physician offices	Professional laboratories
5	Test Sample	Human fecal sample mixed with detection buffer in the sample collection tube	Feces in an extraction buffer
6	Test Principle	Immunological test system based on fluorescence technology for qualitative detection of human hemoglobin in human fecal samples.	Immunological test system intended for qualitative detection of fecal occult blood in feces
7	Special Instrument Requirement	'*i*-CHROMA Reader' for scanning the *i*-CHROMA iFOB test cartridge which has been loaded with the fecal sample mixed with the detection buffer	'Polymedco OC Auto Micro 80 Analyzer' on which the 'OC Auto Sampling Bottle(s)' containing the fecal sample(s) are placed for performing the automated test
8	Work Flow	Normally, patient receives 'Patient Pack' and the sample collection tube from the laboratory/ physician office. Patient collects/transfers fecal sample in to the sample collection tube and submits it to the laboratory/physician office for testing. Occasionally, the physician office / laboratory may receive fecal sample which has been submitted by the patient in a specimen cup or other suitable container.	Fecal sample is collected/transferred by the patient in to the sampling bottle which is sent to the professional laboratory for testing.
9	Sampling / Mixing the sample with detection buffer	Sampling is done with the help of the 'Sampling Stick' / 'Sampler' which is a part of the sample collection tube. The fecal sample is thus delivered into the sample collection tube containing the detection buffer which extracts it.	Sampling is done with the help of the 'Sampling Probe' which is a part of the 'OC-Auto Sampling Bottle'. The fecal sample is thus delivered into the sampling bottle containing the buffer which extracts it.
10	Test Cut-off	100 ng/mL (human hemoglobin in the human fecal sample mixed with detection buffer)	100 ng/mL (human hemoglobin in processed feces)
11	Presentation of Test Results	Qualitative (Positive if ≥ 100 ng/mL and Negative if < 100 ng/mL)	Qualitative (Positive if ≥ 100 ng/mL and Negative if <100 ng/mL)
12	Biohazard and Compatibility with Environment	➢ Used test cartridges and sample collection tubes should be considered as a biohazard. ➢ Test components should be handled strictly as per the instructions given in the package insert and the operation manual. ➢ Used test cartridges and sample collection tubes should be disposed of	➢ Similar handling precautions and disposal directives are prescribed

		in accordance with relevant local, state or federal regulations. ➢ If needed, the *i*-CHROMA Reader should be disposed of in accordance with applicable regulations.	by the manufacturer.
13	Compatibility with other Devices	➢ '*i*-CHROMA iFOB' and the '*i*-CHROMA Reader' are compatible only with each other for the purpose of this test system. ➢ Up on upgrading the software, *i*-CHROMA Reader can also be used for measurement of various analytes/disease markers when used in conjunction with other *in vitro* diagnostic tests manufactured by Boditech Med Inc.	➢ 'OC Auto Micro FOB Test' and 'Polymedco OC Auto Micro 80 Analyzer' are designed to be used together for the purpose of this test system.
14	Chemical Safety	If used in accordance with the warnings, precautions, instructions and procedure prescribed in the package insert, '*i*-CHROMA iFOB' has assured chemical safety profile.	'OC Auto Micro FOB Test' is reportedly safe on this count

Discussion of Similarities:

As evident from the table above *i*-CHROMA iFOB (along with *i*-CHROMA Reader) shares a very close similarity with the predicate device OC Auto Micro FOB Test (along with OC Auto Micro 80 Analyzer) when compared on different parameters related to scientific rationale, test principle, intended use(s), indications for use(s), user(s) profile, work flow, performance characteristics, effectiveness, energy used, bio-hazard and environmental compatibility, safety profile etc. This explicit similarity forms a robust foundation for substantial equivalence of *i*-CHROMA iFOB (along with *i*-CHROMA Reader) to the predicate device.

DIFFERENCES			
No.	**Comparison Parameter**	**Test Device (*i*-CHROMA iFOB with *i*-CHROMA Reader)**	**Predicate Device (OC Auto Micro FOB Test with Polymedco OC Auto Micro 80 Analyzer)**
1	Test Platform/ Format	Lateral flow chromatographic fluorescence immunoassay	Automated immunoassay using latex fixation
2	Test Components	➢ *i*-CHROMA iFOB Test Cartridge ➢ *i*-CHROMA iFOB Sample Collection Tube containing the Detection Buffer	➢ Closed tube-type Sampling Bottle containing the Extraction Buffer ➢ Test Reagents (Latex reagent, Buffer, Negative &

		➢ *i*-CHROMA iFOB ID Chip which contains encoded calibration data **&** ➢ *i*-CHROMA Reader	Positive Controls, Wash Concentrate, and Calibrator) **&** ➢ OC Auto Micro 80 Analyzer
3	Test Device	Test Cartridge (Test strip enclosed in a plastic housing)	Sampling Bottle containing an extraction buffer
4	Detection Mechanism	Involves scanning/ measurement of intensity of fluorescence on the processed sample-loaded test cartridge membrane	Involves optical measurement of agglutination of latex particles
5	Quantity of fecal sample delivered into the sample collection device after sampling	Approx. 13 mg (±1.82 mg) of human fecal sample is actually delivered into 1mL detection buffer in the '*i*-CHROMA iFOB Sample Collection Tube'	Approx. 10 mg of human fecal sample is actually delivered into 2 mL extraction buffer in the 'OC Sample Bottle'
6	Correlation between ng Hb/mL fecal sample + detection buffer mixture and µg or mg Hb/g stool	1 ng Hb/mL fecal sample + detection buffer mixture is equivalent to 0.08 µg or 0.00008 mg Hb/g stool	1 ng Hb/mL fecal sample + extraction buffer mixture is equivalent to 0.2 µg or 0.0002 mg Hb/g stool
7	Cut-off in terms of µg or mg hemoglobin per gm of stool	100 ng Hb/mL fecal sample + detection buffer mixture is equivalent to 8 µg or 0.008 mg Hb/g stool	100 ng Hb/mL fecal sample + extraction buffer mixture is equivalent to 20 µg or 0.02 mg Hb/g stool

Discussion of Differences:

i-CHROMA iFOB (along with *i*-CHROMA Reader) differs from the predicate device OC Auto Micro FOB Test (along with OC Auto Micro 80 Analyzer) with respect to the test platform/format, test device & components and detection mechanism.

However, these differences are in accordance with the respective technology platforms on which the test device and the predicate device are based.

i-CHROMA iFOB is a fluorescence immuno-chromatographic assay based on lateral flow format while OC Auto Micro FOB Test is an automated immunoassay using latex fixation. The lateral flow technology is a quite well-established and proven platform for development of modern rapid, sensitive, reliable and user-friendly *in vitro* diagnostic tests.

i-CHROMA iFOB differs from the predicate device in terms of test components. In *i*-CHROMA iFOB, the test components are viz. a 'Test Cartridge', a 'Sample Collection Tube containing Detection Buffer', an 'ID Chip' and the '*i*-CHROMA Reader'

while in OC Auto Micro FOB test, the test components are: a closed tube-type 'OC-Auto Sampling Bottle containing Extraction Buffer', 'Test Reagents' (Latex Reagent, Buffer, Negative & Positive Controls, Wash Concentrate, and Calibrator) and the 'OC Auto Micro 80 Analyzer'.

i-CHROMA iFOB test cartridge and the sample collection tube (containing the detection buffer) collectively carry out the function which is analogous to the role of OC-auto sampling bottle (containing the extraction buffer) and the latex & buffer reagent provided as a part of the predicate test.

In case of *i*-CHROMA iFOB, the ID chip contains encoded calibration data. An ID chip having a lot number matching with that of the test cartridge and the sample collection tube; is inserted into the designated port of the *i*-CHROMA Reader which utilizes the calibration data for computing and converting the test result. In case of OC Auto Micro FOB test, calibration curve needs to be plotted for each measurement by serially diluting the primary calibrator and plotting the known concentrations of human hemoglobin in the control dilutions against the corresponding absorbance values.

i-CHROMA iFOB Control reagents are supplied on demand separately from the test components while negative & positive controls are supplied as components of the OC Auto Micro FOB test.

i-CHROMA iFOB test cartridge (loaded with a test sample processed with the detection buffer) is to be inserted in the *i*-CHROMA Reader which scans it and automatically displays the test result. In case of the predicate device, similar role is played by the OC Auto Micro 80 Analyzer. OC-auto sampling bottle(s) containing the extracted fecal sample(s) is placed on the rack(s) of the OC Auto Micro 80 Analyzer which performs the automated immunoassay and displays the test result.

There is difference between the quantities of fecal sample delivered per sampling into the '*i*-CHROMA iFOB Sample Collection Tube' (13 mg/1mL detection buffer) and the 'OC FIT-Chek Sample Bottle' (10 mg/2mL extraction buffer).

However, this difference does not necessarily affect the equivalence between the two tests adversely.

Both are immunochemical tests having same cut-off but they are based on different test formats/platforms and measurement technologies.

i-CHROMA iFOB is a lateral flow chromatographic fluorescence immunoassay while OC Auto Micro FOB is an automated immunoassay using latex fixation. Moreover, the two tests follow different calibration procedures.

Further, stearic properties and epitope configuration of antibodies used in the test reagent/devices of the two tests may be different leading to difference in their detection abilities and conjugation properties.

Hence substantial equivalence of *i*-CHROMA iFOB with OC Auto Micro FOB can only be determined by analytical method comparison and other performance studies using spiked or clinical fecal samples.

Thus it is undoubtedly established that above differences neither deviate *i*-CHROMA iFOB from being substantially equivalent to the predicate device nor adversely affect the performance, effectiveness and safety of *i*-CHROMA iFOB in any manner.

Conclusions:

In view of the matter mentioned above, it can be positively concluded that *i*-CHROMA iFOB is substantially equivalent to the predicate device OC Auto Micro FOB Test.

Section 13: Proposed Labeling

A. Labels of Test Components and Accessories

1) Test Cartridge Box Label:

(Outer packaging label)

i-CHROMA iFOB

Intended Use: Fluorescence immunochromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples by laboratories and physician offices

This box contains:

Item	Quantity
Test Cartridges	25
ID Chip	1
Package Insert	1
Quick Reference Instructions Sheet	1

Lot No.: FOXGA06 (Example)
Expiration Date: 06.05.2015 (Example)
(Month, Date, Year)

- For *in vitro* diagnostic use only
- Store sealed test cartridges at 4ºC~30ºC.
- Read the package insert carefully and follow the instructions and procedure mentioned therein before performing the test.
- Note : 1 ng/mL = 0.00008 mg/1g stool.

Test results should not be considered valid and accurate unless supported or corroborated with acceptable tests results with *i*-CHROMA iFOB Controls.

Manufactured by:

Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr
Website: www.boditech.co.kr

2) Test Cartridge Pouch Label:

(Immediate packaging label)

i-CHROMA iFOB Test Cartridge

- For *in vitro* diagnostic use only
- Store sealed test cartridge at 4 ~ 30°C.
- If stored in a refrigerator, allow a minimum of 30 minutes for the sealed test cartridge to attain room temperature prior to performing the test.
- Do not unseal the test cartridge until just prior to performing the test.

Lot No.: FOXGA06 (Example)
Expiration Date: 06.05.2015 (Example)
(Month, Date, Year **)**

Manufactured by:
Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr
Website: www.boditech.co.kr

3) ID Chip Label:

	ID Chip
Face	**iFOB**
	LOT: FOXGA06 (Example)
	***i*-CHROMA™**
Back	**ID Chip**

4) Sample Collection Tube Box Label:

(Outer packaging label)

i-CHROMA iFOB
Sample Collection Tube

This box contains:

Item	Quantity
i-CHROMA iFOB Sample Collection Tubes (Each containing 1 mL Detection Buffer)	25

Lot No.: FOXGA06 (Example)

Expiration Date: 06.05.2015 (Example)

(Month, Date, Year)

- For *in vitro* diagnostic use only
- A sample collection tube is meant for mixing the fecal sample with detection buffer.
- Store the sample collection tubes in a refrigerator at 2ºC~8ºC
- Allow a minimum of 30 minutes for the sample collection tube to attain room temperature prior to performing the test.
- Please read the package insert carefully and follow the instructions and procedure mentioned therein before performing the test.

Manufactured by:

Boditech Med Inc.
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.
Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr
Website: www.boditech.co.kr

5) Sample Collection Tube Label:

(Immediate container label)

i-CHROMA iFOB
Sample Collection Tube

Lot No.: FOXGA06 (Example)
Exp. Date: 06.05.2015 (Example)
(Month, Date, Year**)**

Patient Name: …….
Date of Birth: ……..(MMDDYY)
Gender: …….
Time of Collection: …… (Hour: Minute am/pm)
Date of Collection: ……(MMDDYYYY)

6) *i*-CHROMA iFOB Patient Pack Label

(Outer packaging label)

i-CHROMA iFOB Patient Pack

This patient pack contains:

- 1 Patient Instructions Leaflet (for sampling instructions)
- 1 Sample Collection Paper (for fixing onto the toilet bowl)
- 1 Sample Sac containing an absorption pad (for enclosing the sample collection tube after sampling)
- 1 Return Envelop (for submitting the sample collection tube to the laboratory/physician office for testing)

Important:

- Laboratory/Physician office should place one '*i*-CHROMA iFOB Sample Collection Tube' inside the 'Sample Sac' before handing over this patient pack to the patient.
- Do not remove the absorbent pad from the sample sac.

7) Sample Sac Label

SAMPLE SACK

Have you entered 'Patient Information' on the label of Sample Collection Tube?

- Place sample collection tube into this sack.
- Remove blue colored tape from the nick area.
- Fold at the dashed line marked along the nick.
- Press firmly to seal.

Do not remove the absorbent pad from this sample sack.

Clinical Specimen
(Human Fecal Sample)

8) Return Envelope Label

From: _____

_____

_____

Apply 1st Class Postage	Apply 1st Class Postage	Apply 1st Class Postage	Apply 1st Class Postage

Contents: Diagnostic Test Sample

Date of Collection: _____

Time of Collection: _____

Return To: _____

_____

_____

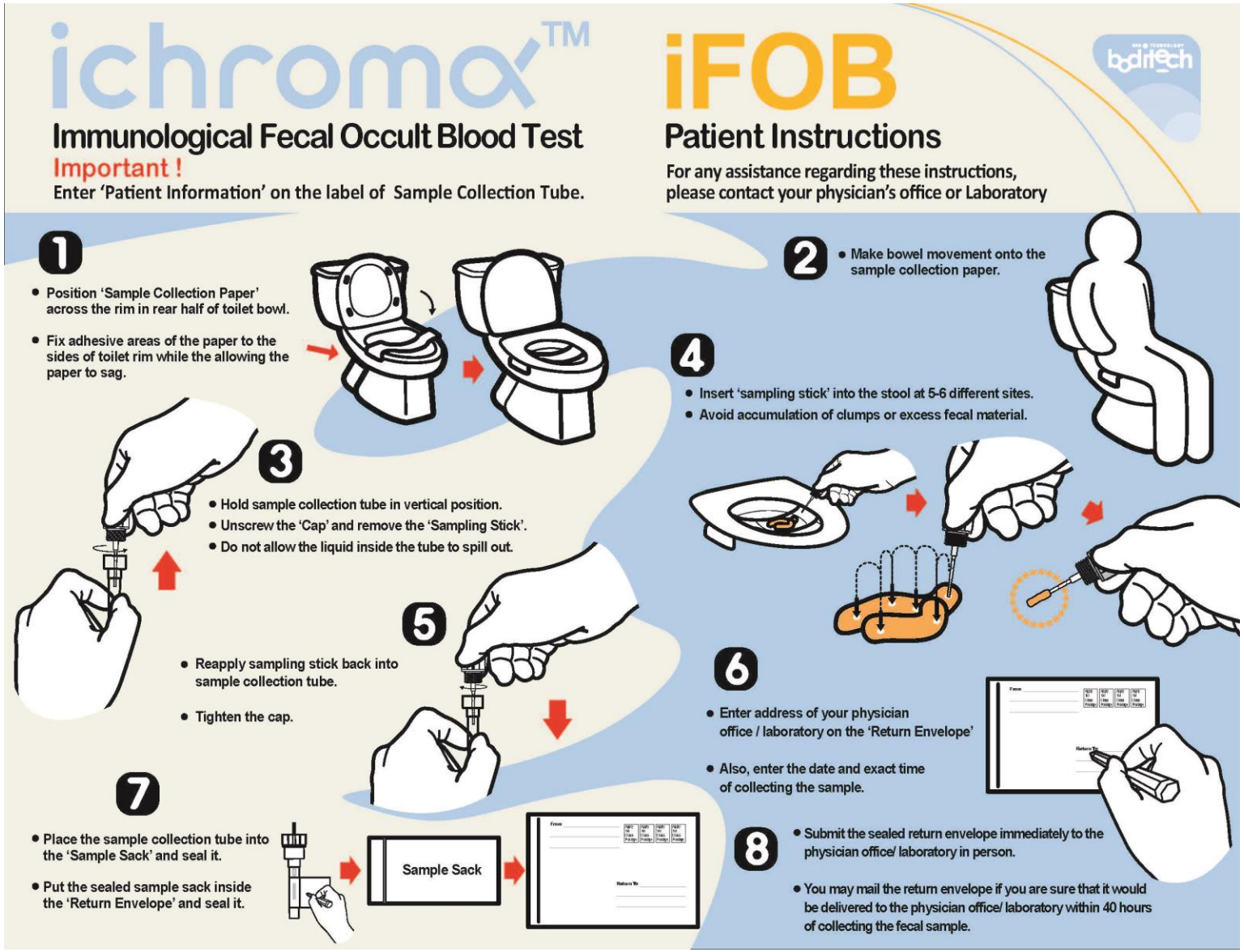
Instructions:

1. Put the sealed sample sack inside this return envelope.
2. Remove the green colored tape.
3. Fold at the dashed line.
4. Press firmly to seal.
5. Submit immediately to the physician office/laboratory in person.
6. You may mail this envelope if you are sure that it would be delivered to the physician office/laboratory within 40 hours of collecting the fecal sample.

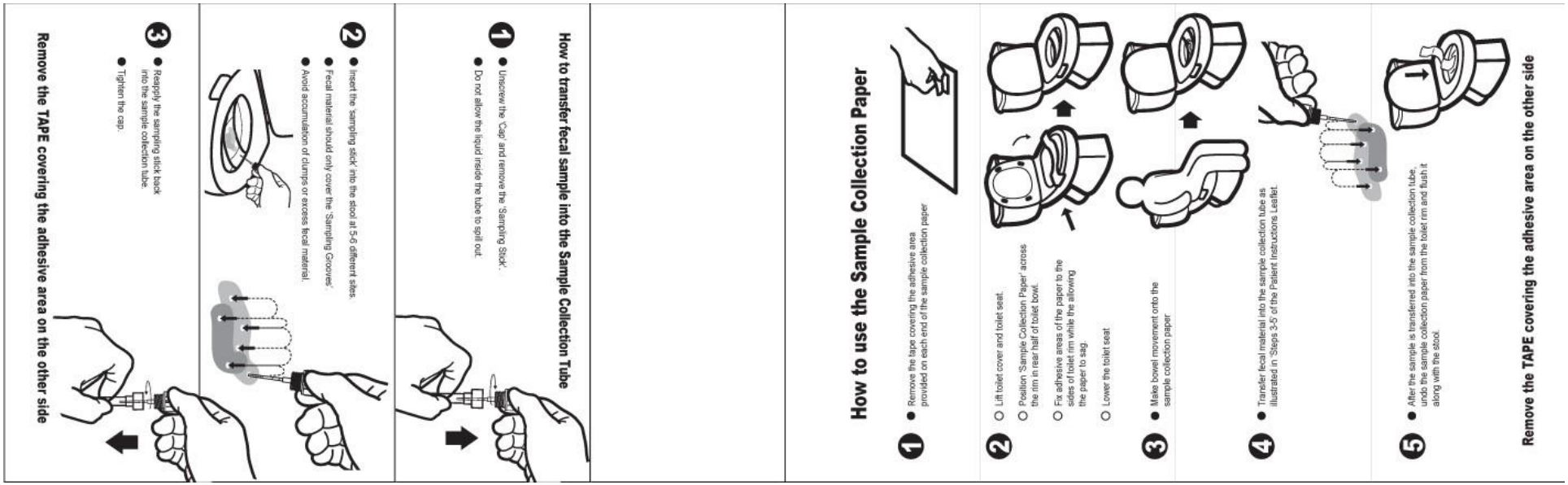
Note: Use of paper envelopes for mailing diagnostic test samples is prohibited by US Postal Service regulations. Hence, use only this envelope approved by US Postal service, for mailing the test sample.

B. Instructional Materials

1) Patient Instructions Leaflet:



2) Sample Collection Paper:



3) *i*-CHROMA iFOB Package Insert:

Please refer to '**Appendix II**: *i*-CHROMA iFOB Package Insert'

4) *i*-CHROMA iFOB Quick Reference Instructions:

Please refer to '**Appendix III**: *i*-CHROMA iFOB Quick Reference Instructions'

5) *i*-CHROMA iFOB Controls Package Insert:

Please refer to '**Appendix IV**: *i*-CHROMA iFOB Controls Package Insert'

6) *i*-CHROMA Reader Operation Manual:

Please refer to '**Appendix V**: *i*-CHROMA Reader Operation Manual'

Section 14: Sterilization and Shelf Life

Sterilization:

(b)(4)Trade Secret Process [redacted].

Shelf Life:

(b)(4)Trade Secret Process [redacted]

(b)(4)Trade Secret Process

[redacted]

Section 18: Analytical Performance Testing (Bench)

(b)(4)Trade Secret Process - Performance Testing

[redacted]

(b)(4)Trade Secret Process - Performance Testing

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Appendix I: *i*-CHROMA iFOB System Information

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1. Background

1.1 Lateral Flow Assay

Immunoassays have been widely used in many important areas of medical practice and pharmaceutical industry such as diagnosis of diseases, therapeutic drug monitoring, clinical pharmacokinetic and bioequivalence studies in drug discovery since the mid-1960s. Clinical immunoassays in connection with medical diagnosis are usually performed either in central laboratorie(s) of hospitals or clinics using a variety of instrument-based technologies or on-site/near-patient (also known as point-of-care/POC) using rapid test techniques.

Rapid immunoassays are commonly designed in two configurations. First type is the 'Flow-through System', which involves multiple steps. The test device based on flow-through mechanism generally uses a reagent-containing matrix layered on a porous material. Test sample is applied to and flows through the porous material, and analyte in the sample reacts with the reagent(s) to produce a detectable signal on the porous material. These devices are generally encased in a plastic housing or casing with calibrations to aid in the detection of the particular analyte. The test procedure may take as long as 20 minutes. One sample is tested per test device.

The second type of rapid immunoassays is the 'Lateral Flow System' which is a single step technique. The test device based on lateral flow mechanism also uses a porous membrane for performing analyte detection. However, instead of drawing the sample through the membrane perpendicularly, the sample is permitted to flow laterally from an application zone to a reaction zone on the membrane surface. The capture reagent is present in the reaction zone, and the captured analyte can be detected by a variety of protocols, including direct visualization of visible moieties associated with the captured analyte. Tests results are obtained in 10-30 minutes after loading the test device with the sample. Lateral flow test devices can be designed so as to test for a single or multiple analyte(s).

As the flow-through type immunoassay involves multiple steps and requires greater operational skill, this format is less commonly used as compared to the lateral flow type.
Lateral flow tests; also known as immunochromatographic strip tests have been a popular tool for performing rapid immunoassays since their introduction in the mid-1980s. Lateral flow tests have been developed using combinations of various features. Hence it is customary to accept a broad definition of lateral flow tests to include any immunochromatographic strip test/device based on fluid migration or flow technology using a paper, nitrocellulose or similar support material with or without being enclosed in a housing/casing. Further, it may be used for testing a single or multiple analyte(s) and the test device may be read either manually or by using an instrument or reader. The lateral flow format is thus so versatile that rapid immunoassay test manufacturers have developed these tests for variety of situations requiring rapid testing.

At present, lateral flow tests are widely used for diagnostic purposes in hospitals, clinics,

physician offices, and clinical laboratories. They are meant for the qualitative and quantitative detection of a wide variety of antigens and antibodies in various biological samples including whole blood, plasma, serum, urine, saliva, sweat, tears, biopsied tissue and fluids. They are also used in veterinary medicine. Apart from diagnostic purposes, lateral flow tests offer an important tool in manufacturing, quality control and product safety assurance in pharmaceutical, biologics and food production. These tests also find important applications in water safety evaluation and environmental testing. More recently lateral flow tests are being developed to measure the products of nucleic acid amplification.

Lateral flow immunochromatographic tests have proved to be an ideal tool for variety of applications by virtue of their following features:

- Simple and user-friendly design/format which enables use by non-technical or non-laboratory personnel and thus supporting point-of-care/home testing
- Minimal operator-dependent steps and easy interpretation of test results
- Short processing time (5-30 minutes to get the results) offers rapid testing
- High sensitivity, specificity and accuracy
- Good stability with shelf-lives of 12-24 months mostly without necessitating refrigeration
- Requires very small volumes of test samples
- Amenable to various types of test samples
- Versatility of applications

Favorable technological and commercial aspects of the lateral flow tests include:

- Established technology which can be integrated with on-board electronics, reading instrument system and information systems
- Relative ease of manufacture because of already developed equipment and processes
- Prospects of easy scale-up to high-volume production
- Relatively low cost and short timeline of product development and regulatory approval
- Huge market potential

Combined with the principles of thin layer and paper chromatography, the development of lateral flow immunoassays is the result of convergence of several technological landmarks tracing back to the 1950s with the invention of first antigen-antibody radioimmunoassay (RIA) reaction by Burson and Yallow. The enzyme immunoassays (EIA) introduced in the 1960s offered significant advantages over the radioimmunoassay in respect of replacement of radioisotopes with enzymes, higher specificities, faster reaction times and longer shelf-lives. The lateral flow technology continued to be refined over the years and established firmly in the late 1980s with the filing of several patents on the lateral flow technology platform. Significant amongst them were those filed by Becton Dickinson & Co, Uniliver and Carter Wallace. Since then over 500 patents have been filed on various aspects of this technology.

The trend towards more decentralized healthcare delivery obviously resulted in the decentralization of laboratory diagnostic services as well. Immunoassays account for approximately 30% of all marketed diagnostic tests. Technological innovations in lateral flow tests have facilitated the move to bring diagnostic testing closer to the patient—be it at home, at work place, in the hospital bedside or the pharmacy. The pharmacies and retail shopping malls are rapidly becoming the focal point for Over-the-Counter (OTC) testing and screening related to heart diseases and diabetes. In current scenario, most of the marketed Point-Of-Care Testing (POCT) systems cover infectious diseases, life style-related conditions like cardiac diseases and diabetes, fertility issues like pregnancy detection and drug abuse detection/monitoring.

Furthermore, the noteworthy aspect of almost all of these lateral flow immunoassays tests is the use of single-use test devices. It is not realistic to expect that any medical practice or clinic would have the storage space, inventory control system and inclination to keep some 20 to 30 different test devices on hand. Therefore considerable research has been ongoing for the past 15 years for a multipurpose POCT platform for lateral flow immunoassays.

Remote monitoring and testing of patients-at-risk; both at home and in hospitals or clinics; is fast-emerging as a primary proactive strategy to keep individuals out of hospital emergency and acute care wards. Point-of-Care testing as the new frontier of health care delivery promises to achieve this objective. Patients with diabetes and many other chronic diseases or conditions as well as the elderly and those suffering from HIV/AIDS are being increasingly targeted for such near-patient testing.

Advances in functional genomics, bioinformatics, microelectronics and miniaturization have dramatically changed the diagnostic test technology in recent years. Improvements in the biomedical engineering-based clinical devices with inputs derived from the information and computer technologies have been opening up new markets for rapid diagnostic test products. Global economic instability and rising healthcare costs coupled with increasing demand for rapid test results to reduce the need and duration of hospitalization has further influenced the development of rapid diagnostic test products. Near-patient testing is one of the most rapidly growing segments as the tests that were once carried out in central laboratories; are now available as near-patient tests. All these factors would have a further positive impact on research, development and commerce of POCT segment.

Though the market is witnessing commercial unveiling of newer and newer near-patient, rapid diagnostic test products based on advanced lateral flow technologies, POC testing has still a long way to go so far its worldwide coverage is concerned. Globally about 10% of the immunoassay-based diagnostic tests are performed in settings other than a hospital or commercial laboratory. In the U.S. alone, there are approximately 41,000 small to medium-sized physician office practices and freestanding alternate-site laboratories, which are licensed under Clinical Laboratory Improvement Amendments (CLIA) for high or moderate complexity testing. Most of these sites do not currently have

immunodiagnostic testing capability. The potential for POC testing and lateral flow immunoassays is enormous and new hope has been placed in microchip and miniaturized systems in this context.

All these terms such as decentralized, rapid, near-patient, point-of-care testing etc. refer to an approach to diagnostic testing that uses light weight, readily portable and easy-to-use devices; designed to perform complex biological tests at the site where they are needed most. Traditionally these tests are usually performed in laboratories equipped with large instruments. The main market-driving force behind the POCT diagnostic products is the enhanced portability and networking capabilities that allow rapid immediate patient care. So far, the commercialization such portable diagnostic devices for POC testing has been restrained by the lack of suitable miniaturized, low power consuming, optical detection systems.

Membrane lateral flow is the technology most commonly adopted in rapid disposable POCT systems. This technology lacks desired sensitivity and in most cases provides only qualitative or Yes/No type test results. Testing of new analytes will not be shifted to POC settings until the results are comparable with those obtained with the tests performed in the central laboratory systems. This would obviously require quantitative measurement of analyte(s) in the test samples. Membrane lateral flow is generally appropriate for qualitative assays, but for technical reasons it does not lend itself to quantitative assays.

The success of lateral flow technology-based POCT techniques depends on the evolution of the technology but is also influenced by how POCT market unfolds. Miniaturization of traditional diagnostic techniques has led to the introduction of a number of innovative point-of-care tests and devices. *In vitro* diagnostics manufacturers have developed and are designing technological innovations that provide more patient-friendly, cost-effective, multiplexed POC testing platforms coupled with high-end software capabilities. Decentralized testing directives aimed at nearer-the-patient testing coupled with newer healthcare trends and novel therapeutics are set to redefine and refocus the role of laboratory diagnostic services in healthcare.

Though development of new age microchip-based diagnostic POCT systems has been a considerably challenging issue, miniaturization of conventional laboratory tests is not new as best exemplified by the Glucose Meter for self-testing of blood glucose by patients and individuals. Such miniaturized versions of conventional laboratory tests are already available for about 70 analytes and there are at least 50 companies selling these miniaturized test products around the world. Development of molecular biology-based tests, decentralization of out-patient testing, increased self-testing and trend towards home-patient testing are fuelling the demand for miniaturization of POCT products and thereby for the next generation of more sophisticated diagnostic devices commonly referred to as chips.

Modern medicine is entering an era characterized by emergence of biomedical therapeutics and devices utilizing the principles of genomics, bioinformatics and miniaturization/ portability of medical devices. These frontiers of medical science are set to revolutionize the diagnosis, treatment and monitoring of diseases such as Alzheimer's

disease, rheumatoid arthritis, cancer, heart diseases, HIV/AIDS, hepatitis C, other contagious and hereditary diseases. Clinical/laboratory testing play a critical role in post-genomic medicine. Molecular immunoassays and cell-based tests are beginning to prove their role in the earlier diagnosis of diseases, improvement in drug efficacy and physicians' ability to monitor the success of the chosen intervention.

Newer diagnostic test methodologies mainly include the DNA probe tests for viruses, bacteria, genetic markers etc. as well as blood and cell-based tests for disease-specific markers such as those for diabetes, cancer, osteoporosis, arthritic conditions and cardiac disease. These new tests would allow physicians to tailor therapeutics derived from combinatorial chemistry, antisense therapy and gene therapies for specific patient and disease. Increased knowledge of disease physiology derived from molecular biology and human genome studies will enhance the position of analytes used in chronic conditions such as cardiovascular disease, autoimmune disorders and diabetes. The function of genes is measured by presence of tangible products - proteins of every size and molecular structure. Thus immunoassays combined with DNA probe studies will have an important place in the new era of disease-based medicine.

For POC tests to become more meaningful and more acceptable to healthcare professionals, they must combine the benefits of new miniaturized technologies with digital capture of test results which are then correlated to algorithms embedded in the device chips which further transform a unique set of test data into an actionable piece of information. A step further would be to make home-testing for chronic diseases interactive so that the patient can be advised to take action when necessary. Similarly, POC information systems can aid the physicians in determining the significance of a laboratory test result. However, all new immunoassays and especially those designed for rapid testing will have to prove themselves on the parameters of medical research, health economics and improved patient outcomes.

1.2 Fecal Occult Blood test

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2. *i*-CHROMA iFOB

2-1 Introduction

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

i-CHROMA iFOB is an *in vitro* diagnostic test intended to be used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology wherein the antigen-antibody complexes formed after mixing the test sample with the detection buffer are captured while migrating through the test cartridge which is scanned by the *i*-CHROMA Reader to compute, convert and display the test result in a qualitative (positive or negative) manner.

2-2 Components of *i*-CHROMA iFOB:

i-CHROMA iFOB consists of a 'Test Cartridge', an 'ID Chip' and a 'Sample Collection Tube' containing the 'Detection Buffer' and *i*-CHROMA Reader.

- The test cartridge contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.

- The detection buffer contains fluorochrome-labeled anti-human hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin (BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. Each sample collection tube contains 1 mL detection buffer. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

- *i*-CHROMA Reader is a fluorometer instrument which scans the sample-loaded *i*-CHROMA iFOB test cartridge and displays the test result. *i*-CHROMA Reader and *i*-CHROMA iFOB test cartridge are compatible only with each other. *i*-CHROMA Reader is marketed/supplied separately on demand.

- The ID chip contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

- Additionally, ‘Patient Packs’ are provided along with the test cartridge box and also separately on demand.

  Each ‘Patient Pack’ contains following items:

  - 1 Patient Instructions Leaflet (for sampling instructions)
  - 1 Sample Collection Paper (for fixing onto the toilet bowl)
  - 1 Sample Sac containing an absorption pad (for enclosing the sample collection tube after sampling)
  - 1 Return Envelop (for submitting the sample collection tube to the laboratory/ physician office for testing)

2-3 *i*-CHROMA iFOB Test Cartridge Format and Structure:

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2-4 *i*-CHROMA iFOB Sample Collection Tube:

Sample Collection Tube is an essential component of *i*-CHROMA iFOB. A box containing 25 pre-filled sample collection tubes is delivered separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

The sample collection tube is a specially designed plastic container. Each sample collection tube contains 1mL Detection Buffer. Apart from being the container for the detection buffer, the sample collection tube serves the following purposes:

i) Proper sampling of the fecal sample
ii) Thorough mixing of the fecal sample with the detection buffer for ensuring complete extraction of the fecal sample
iii) Application of precise quantity of the fecal sample mixture into the 'Sample well' of the *i*-CHROMA iFOB test cartridge

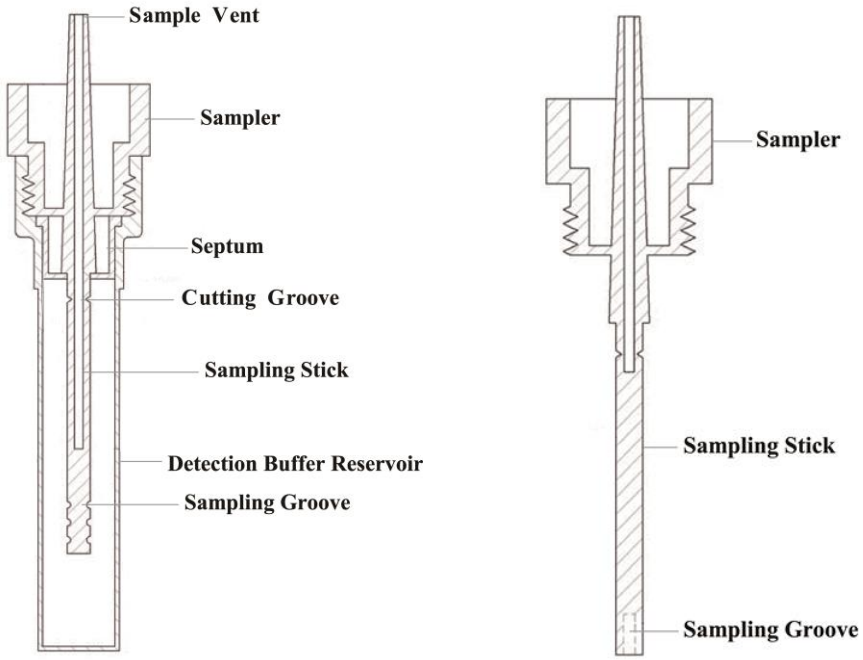

Figure 2: Diagram of *i*-CHROMA iFOB Sample Collection Tube

The sample collection tube is made up of two distinct and detachable components viz. the '**Detection Buffer Reservoir**' and the '**Sampler**'.

The **Detection Buffer Reservoir** is a cylindrical, near-transparent, plastic container similar in shape to a test tube which acts as the vessel for the detection buffer as well as its mixture with the fecal sample.

The open end of the detection buffer reservoir is enlarged and threaded on the inner surface so as to screw-in the sampler.

Just below the enlarged, and threaded open-end of the detection buffer reservoir, a '**Septum**' in the form of a small, cylindrical disc-like, plastic structure with a minute aperture at its center; has been fitted inside the detection buffer reservoir. This septum wipes the excess fecal material from the sampling stick when it passes through the aperture of the septum after sampling. Secondly, as the sampling stick exactly fits into this aperture of the septum, it prevents the mixture of the fecal sample and the detection buffer from splashing out of sample collection tube during shaking/mixing.

The **Sampler** is somewhat an inverted umbrella-like plastic structure. The sampler is in the form of a long stalk called as the '**Sampling Stick**', the upper end of which passes through a '**Cap**' The lower portion of the cap is threaded. It is this threaded portion which screws-in the sampler into the detection buffer reservoir.

The upper $^{2}/_{3}^{rd}$ portion of the sampling stick has been actually made into a hollow tube while the basal $^{1}/_{3}^{rd}$ portion is non-hollow. The surface of the sampling stick in lowermost part of this basal portion is grooved which is called as '**Sampling Grooves**'.

For sampling, the cap is unscrewed and the sampler/sampling stick is removed from the sample collection tube. While removing the sampling stick, the septum remains fitted inside the detection buffer reservoir otherwise there is possibility of the detection buffer spilling out of the reservoir.

The grooved end of the sampling stick is inserted into the fecal sample at 5~6 different sites so as to ensure a representative sampling. Sampling grooves on the sampling stick should be covered with sufficient fecal sample while ensuring that the quantity is not too much.

The sample-ridden sampling stick is then inserted back into the sample collection tube and the cap of the sampler is screwed-in tightly. The excess fecal material is wiped off from the sampling stick when it passes though the septum of the detection buffer reservoir. At this stage, the sampling system of *i*-CHROMA iFOB delivers the fecal material into detection buffer already present in the sample collection tube.

'*i*-CHROMA iFOB Sample Collection Tube' contains 1 mL 'Detection Buffer'. Approximately 13 mg (±1.82 mg) of human fecal sample is actually delivered into the

detection buffer in the '*i*-CHROMA iFOB Sample Collection Tube' following the sampling procedure described as above.

Approximate quantity of fecal sample delivered per sampling into the detection buffer in *i*-CHROMA iFOB sample collection tubes was determined in the following manner **(Table I.1)**:

1. 'Sampler' as well as the 'Septum' of the *i*-CHROMA iFOB sample collection tube were removed from the 'Detection Buffer Reservoir'
2. Weight of the 'Sampler' alone was noted on electronic balance.
3. 'Sampling Stick' was poked into the fecal sample at 5-6 different sites as per standard sampling procedure.
4. The 'Sample-ridden Sampler' was then passed through the 'Septum' and just removed from it to wipe of the excess fecal matter accumulated on the 'Sampling Grooves'.
5. Weight of 'Sample-ridden Sampler' (after passing through and removing from the 'Septum') is noted.
6. Weight of 'Fecal Sample Retained on the Sampler' was calculated by subtracting the weight obtained in Step 2 from the weight obtained in Step 5.
7. This gives 'Approximate Weight of Fecal Sample' delivered into the 1 mL 'Detection Buffer' present in the *i*-CHROMA iFOB sample collection tube after standard sampling procedure.
8. Average of 20 samplings (using 20 different *i*-CHROMA iFOB sample collection tubes) was taken as the 'approximate weight of fecal sample delivered per sampling into the 1mL detection buffer in *i*-CHROMA iFOB sample collection tube.

It is evident from **Table I.1** that approximately 13 mg of fecal sample is delivered into 1mL detection buffer which is pre-dispensed in the *i*-CHROMA iFOB sample collection tube.

Though *i*-CHROMA iFOB is proposed to be a qualitative test offering test results only in terms of 'iFOB Test Negative' or 'iFOB Test Positive' (based on an analytical cut-off of 100 ng/mL; hemoglobin in fecal sample mixed with detection buffer), the underlying measurement/computation of test result is done in terms of ng/mL (ng FOB Hemoglobin per 1mL test sample + detection buffer mixture)

Moreover, some of the analytical performance evaluation studies of *i*-CHROMA iFOB were previously conducted under dual display (i.e. Negative/ Positive + Numerical Test Result in ng/mL) mode of *i*-CHROMA Reader.

So one can understand that the numerical value of *i*-CHROMA iFOB test result (for instance 1 ng/mL i.e. 1ng hemoglobin present in 1mL test sample + detection buffer mixture) is obviously the amount of FOB hemoglobin present in 13 mg fecal sample which was delivered into 1mL detection buffer present in the *i*-CHROMA iFOB sample collection tube.

Thus:

1ng Hb/1ml test sample (+detection buffer) mixture = 1ng Hb/13 mg of fecal sample

It means 1ng FOB hemoglobin is present in 13 mg of fecal sample

Hence 1 g (i.e. 1000 mg) of fecal sample would contain 1000/13 = 76.92 ng Hemoglobin

It means 1 g fecal sample would contain 0.00007692 mg i.e. 0.00008 mg or 0.08 µg Hemoglobin.

Thus *i*-CHROMA iFOB quantitative test result of 1ng/ml means 0.08 µg Hemoglobin is present in 1 gm of the fecal sample.

However, *i*-CHROMA iFOB is proposed to be a qualitative test offering test results only in terms of 'iFOB Test Negative' or 'iFOB Test Positive' based on an analytical cut-off of 100 ng/mL.

Thus a clinical fecal sample containing less than 8 µg i.e. 0.008 mg/g concentration of FOB hemoglobin would test 'iFOB Test Negative' and a clinical fecal sample containing 8 µg i.e. 0.008 mg/g or higher concentration of FOB hemoglobin would test 'iFOB Test Positive' with *i*-CHROMA iFOB test.

Table I.1: Determination of average quantity of fecal sample delivered per sampling into in *i*-CHROMA iFOB sample collection tube.

Serial Number	**Weight of the 'Sampler' alone before Sampling (mg)**	**Weight of the 'Sample-ridden Sampler'** (after wiping off the excess fecal matter by passing through and removing from the 'Septum') **(mg)**	**Weight of Fecal Sample Retained on the Sampler** (i.e. Approximate quantity of fecal sample deliverable into *i*-CHROMA iFOB sample collection tube) **(mg)**
1	1592	1604	12
2	1589	1605	16
3	1592	1606	14
4	1596	1608	12
5	1593	1604	11
6	1593	1607	14
7	1594	1606	12
8	1595	1608	13
9	1591	1607	16
10	1592	1606	14
11	1591	1604	13
12	1590	1605	15
13	1592	1608	16
14	1593	1606	13
15	1593	1605	12
16	1591	1602	11
17	1591	1602	11
18	1597	1607	10
19	1593	1604	11
20	1594	1607	13
Average	1593	1606	13
Standard Deviation	--	--	±1.82

Fecal sample submitted by the patient in *i*-CHROMA iFOB sample collection tube should be tested before 72 hours after sampling if stored at 4º C (2~8º C/35.6~46.4º F) and before 48 hours after sampling if stored at ambient temperature not exceeding 37º C/98.6º F.

Laboratory should test the fecal sample as early as possible within the above time limits after it is received from the patient. However, it is strongly recommended to test the fecal sample immediately after sampling and/or receipt at laboratory if it has been exposed to ambient temperature exceeding 37º C/98.6º F.

Contents of the sample collection tube are shaken well and mixed thoroughly to yield a homogenous suspension for complete extraction of the fecal sample. Fecal sample mixture thus obtained; should be kept standing at least for 10 minutes.

Before loading the fecal sample mixture into the sample well of the *i*-CHROMA iFOB test cartridge, the sample collection tube is held in vertical position afand the sampling stick is cut by bending it the 2-3 times just below the cap i.e. at the '**Cutting Groove**' which is the first designated point below the cap as shown in the figure above. The sample collection tube must be held in an upright position during this stick-cutting process.

After the stick-cutting process, the basal non-hollow portion of the sampling stick will remain suspended in the processed fecal sample mixture while its upper hollow tube-like portion will now open into the detection buffer reservoir.

The fecal sample mixture can now be squeezed out by inverting the sample collection tube. In this position, the fecal sample mixture will squeeze out from the '**Sample Vent**' of the sampler.

Three drops of the fecal sample mixture are loaded into the sample well of the *i*-CHROMA iFOB test cartridge. The sample-loaded test cartridge is then immediately inserted in the cartridge holder of the *i*-CHROMA Reader which scans it after 10 minutes (as per the default reaction time setting i.e. Single Mode) to compute and display the test result.

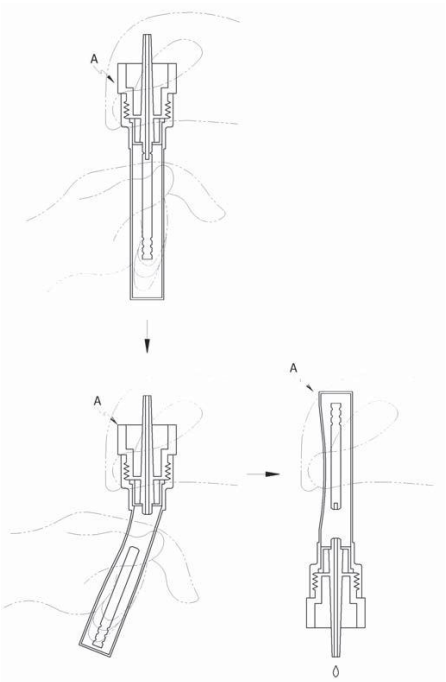

Figure 3: Using the *i*-CHROMA iFOB Sample Collection Tube

2-5 *i*-CHROMA iFOB Test Principle

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human fecal sample is mixed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer bind with hemoglobin in the fecal occult blood (FOB).

When the fecal sample mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, the fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, the more hemoglobin in the human fecal sample, the more complexes get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

The fluorescent light is collected together with the scattered laser light. Pure fluorescence is filtered from the mixture of the scattered and fluorescent light. Intensity of the fluorescence is scanned and converted into an electric signal which correlates to the intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample.

The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (positive or negative) manner based on an analytical cut-off of 100 ng/mL (hemoglobin in fecal sample mixed with detection buffer) which is equivalent to 8µg i.e. 0.008 mg hemoglobin per gram of stool.

i-CHROMA iFOB and *i*-CHROMA Reader are compatible only with each other.

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2.6 *i*-CHROMA iFOB Test Method:

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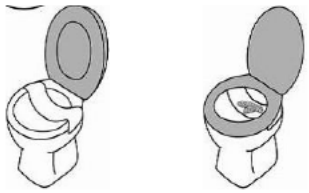
General procedure of *i*-CHROMA iFOB test is as follows:

A. Sample collection by patient:

1) Lift toilet cover and toilet seat.
2) Position and fix sample collection paper to the sides of rim in rear half of toilet bowl, allowing the paper to sag.
3) Make bowel movement on to the collection paper.
4) Do not remove the collection paper from toilet bowl until fecal sample has been transferred into the '*i*-CHROMA iFOB Sample Collection Tube' or a specimen cup.



B. Sampling by patient or test operator:

1) Enter required 'Patient Information' on the label of '*i*-CHROMA iFOB Sample Collection Tube'.
2) Unscrew the cap of sample collection tube and remove the sampler.
3) Insert sampling stick of sampler into the stool at 5-6 different sites.
4) Re-apply sampler back into sample collection tube and tighten its cap.

C. Arranging test setup:

1) Arrange following test components:
   - *i*-CHROMA iFOB Test Cartridge & ID Chip
   - *i*-CHROMA iFOB Sample Collection Tube (containing the fecal sample)
   - *i*-CHROMA Reader (attached with key pad and serial printer)
2) All these test components must have been stored properly under recommended storage conditions.
3) Check whether lot number of the ID chip is exactly same as lot numbers of the test cartridge and the sample collection tube.
4) Ensure that test cartridge and sample collection tube has not passed respective expiration dates.
5) Allow the test components to attain ambient temperature (15~37º C/59~98.6º F) for about 30 min.

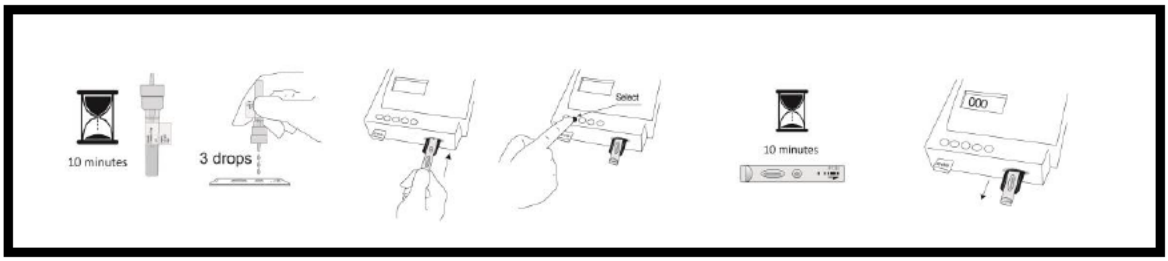
D. Performing 'System Check' on *i*-CHROMA Reader:

1) Arrange '*i*-CHROMA System Check ID Chip & System Check Cartridge'.
2) Turn power switch of *i*-CHROMA Reader 'On'. It will automatically display the default 'MENU'.
3) Select 'Test Mode' and insert 'System Check ID Chip' in the ID chip port.
4) *i*-CHROMA Reader ejects cartridge holder and displays the message alert 'Input Patient ID'.
5) Press 'Select' to skip inputting 'Patient ID'. Message alert 'Insert System Check Cartridge' is displayed.
6) Insert System Check Cartridge in the cartridge holder and press 'Select'.
7) *i*-CHROMA Reader should display 'System Check System OK' indicating overall normal functioning.

E. Testing the patient sample:

1) Shake the sample collection tube (containing fecal sample) about 10 times.
2) Hold it in vertical position and cut the sampling stick by bending the tube 2-3 times just below the cap.
3) Allow the sample collection tube to stand for 10 minutes in vertical position.
4) Turn power switch of *i*-CHROMA Reader 'On'. It automatically displays the default 'MENU'.

5) Select 'Test Mode' and insert '*i*-CHROMA iFOB ID Chip' in the ID chip port.
6) *i*-CHROMA Reader ejects cartridge holder and displays message alert 'Input Patient ID'.
7) Input an 11-digit patient ID correctly based on the patient information and laboratory record system in the following manner:
   - First six digits for patient's date of birth e.g. enter March 9, 2014 as 030914
   - Next two digits for patient's gender e.g. 01 for male and 02 for female
   - Last three digits for serial number of the test as entered/to be entered in record/information management system of the laboratory e.g. enter 'Serial No. 1' as '001'
8) After inputting the patient ID, press 'Select'. Message alert 'Insert iFOB Test Cartridge' is displayed.
9) Remove the '*i*-CHROMA iFOB Test Cartridge' from its original pouch and place it on a flat surface.
10) Invert the sample collection tube and squeeze out precisely three drops of fecal sample mixture into 'Sample Well' of the test cartridge.
11) Immediately insert the sample-loaded test cartridge in the cartridge holder and press 'Select'.
12) *i*-CHROMA Reader will automatically scan the inserted test cartridge after 10 minutes and display test result.
13) If *i*- CHROMA Reader has been set to 'Multi Mode', allow the sample-loaded test cartridge to stand for exactly 10 minutes outside the *i*-CHROMA Reader.
14) After 10 minutes, insert the sample-loaded test cartridge in the cartridge holder and press 'Select'.
15) *i*-CHROMA Reader immediately scans the inserted test cartridge and displays test result.



Details of *i*-CHROMA iFOB test procedure have been described in **Appendix II:** *i*-CHROMA iFOB Package Insert and **Appendix III:** *i*-CHROMA iFOB Quick Reference Instructions.

Detail information regarding operation of *i*-CHROMA Reader has been included in **Appendix IV:** *i*-CHROMA Reader Operation Manual.

Detail information regarding of *i*-CHROMA iFOB Negative & Positive Controls along with the control test procedure has been included in **Appendix V:** *i*-CHROMA iFOB Control Package Insert.

2.7 Production Process of *i*-CHROMA iFOB

(b)(4)Trade Secret Process - Product Specs

[redacted]

(b)(4)Trade Secret Process - Product Specs

[redacted]

(b)(4)Trade Secret Process - Product Specs

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(b)(4)Trade Secret Process - Product Specs

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(b)(4)Trade Secret Process - Product Specs

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3 *i*-CHROMA Reader

3-1 Introduction

i-CHROMA Reader is a custom-configured, portable, desktop, fluorescence-scanning instrument for qualitative detection of fecal occult blood (FOB) in human fecal samples; duly processed and tested by *i*-CHROMA iFOB.

Upon upgrading the software, *i*-CHROMA Reader can also be used for quantitative determination of various other analytes/disease markers when used in conjunction with other *in vitro* diagnostic immunoassay tests manufactured by Boditech Med Inc. *i*-CHROMA Reader and *i*-CHROMA iFOB are compatible only with each other.

i-CHROMA Reader is intended to be used only in conjunction with *i*-CHROMA iFOB for *in vitro* diagnostic purpose by laboratories and physician offices. *i*-CHROMA Reader measures 250 mm (L) x 185 mm (W) x 80 mm (H) in size and weighs 1.2 Kg.

i-CHROMA iFOB test cartridge is loaded with human fecal sample which has been duly mixed with the detection buffer in the '*i*-CHROMA iFOB sample collection tube' as per the standard test procedure recommended by Boditech Med Inc. This sample-loaded test cartridge is inserted in to the cartridge holder of *i*-CHROMA Reader for the purpose of being scanned.

i-CHROMA Reader is designed to extract designated information off the sample-loaded *i*-CHROMA iFOB test cartridge (manufactured by Boditech Med Inc.). *i*-CHROMA Reader includes specific components required to perform this task in a preprogrammed manner.

The *i*-CHROMA iFOB test cartridge contains a test line and a control line both of which have been tagged with capture antibodies. Test line of the test strip has been tagged with 'anti-human hemoglobin antibodies' while the control line has been tagged with 'rabbit immunoglobulin-G'.

The detection buffer (dispensed in the *i*-CHROMA iFOB Sample Collection Tubes) contains the detector antibodies i.e. 'fluorochrome-labeled anti-human hemoglobin antibodies' and 'fluorochrome-labeled anti-rabbit immunoglobulin-G'.

When the fecal sample-detection buffer mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

Complexes of the detector antibody (fluorochrome-labeled anti-human hemoglobin antibody)-analyte (FOB hemoglobin)-capture antibody (anti-human hemoglobin antibody) accumulate at the test line of the test strip.

Similarly, complexes of the detector antibody (fluorochrome-labeled anti-rabbit immunoglobulin-G)-capture antibody (rabbit immunoglobulin-G) accumulate at the control line of the test strip.

One would need an external light source to excite these fluorochrome-labeled complexes accumulated at the test line and the control line so that they would emit characteristic radiation i.e. fluorescence. *i*-CHROMA Reader uses a semiconductor diode laser as the excitation light source.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes accumulated at the test line as well at the control line.

i-CHROMA Reader scans the test cartridge across the test and the control lines while illuminating the cartridge with the laser radiation to measure the intensities of fluorescence generated at the test line and the control line and converts them into electrical signals.

Thus, fluorescence generated at the 'test line' and 'control line' are collected by the optical assembly onto a photo-sensor to convert them into the corresponding electric signals, which are translated by *i*-CHROMA Reader into corresponding curves.

Intensity of the fluorescence generated at the test line is proportional to the concentration of FOB hemoglobin present in the test sample.

This correlation is observed till FOB hemoglobin concentration of 1500 ng/mL beyond which hook/prozone effect comes into play.

However, as *i*-CHROMA reader has been programed to display test results qualitatively only in terms of 'iFOB Test Positive' or 'iFOB Test Negative', test samples with FOB hemoglobin concentrations up to 2000 ng/mL have been found to test positive with '*i*-CHROMA iFOB'.

Thus, summation of whole fluorescence emission at the test line is closely correlated with the concentration of FOB hemoglobin present in the test sample (up to hemoglobin concentration of 1500 ng/mL).

Control line of *i*-CHROMA iFOB test cartridge functions as the built-in procedural control which fairly satisfies the routine quality control requirement of *i*-CHROMA iFOB test(s).

While computing the test result, *i*-CHROMA Reader takes into account the ratio of fluorescence generated at the test line to that at the control line. This ratio further determines quality of the test run.

i-CHROMA Reader automatically calculates ratio of 'Area under Curve'/AUC (above base line) at the 'Test Line' (A_T) to the AUC at the 'Control Line' (A_C).

The on-board microprocessor computes the FOB hemoglobin concentration (in terms of ng/mL) based on a pre-programmed calibration formula encoded in the '*i*-CHROMA iFOB ID Chip inserted in the ID chip port of *i*-CHROMA Reader.

However, *i*-CHROMA Reader would display the test result qualitatively as 'iFOB Test Negative' or 'iFOB Test Positive' based on the cut-off of 100 ng/mL.

The 'ID Chip' provided with *i*-CHROMA test cartridge(s) contains a memory device which contains encoded calibration data. An ID chip having a lot number matching with that of the test cartridge and the sample collection tube is inserted into the designated port of the *i*-CHROMA Reader which utilizes the calibration data for computing the test result(s). Hence the user is not required to perform routine calibration before performing the test.

3-2 Components of *i*-CHROMA Reader

Since *i*-CHROMA Reader has been designed to be a stand-alone device (although network connectivity is also supported), users would use built-in input means only by default. Following is the itemized description of various functional and operational elements which are accessible by the user of *i*-CHROMA Reader.

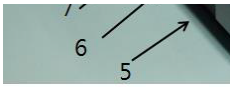
3-2-1 Function/Control Keys:

Operation of *i*-CHROMA Reader is based on five primary functions; each of which is controlled by one or more keys in the key pad provided on the front panel of the *i*-CHROMA Reader.

These keys are used to control the general settings and operation of the *i*-CHROMA Reader. One can adjust the settings, move the cartridge holder in and out of the main body of the instrument and initiate the measurement sequence. With proper combination of key sequences, one can gain access to system-level setting authority.

3-2-2 Display Screen:

The display screen consists of a LCD display device which is based on a black and white 4x18 character display module. Any pertinent information about proper operation of the system would be displayed on the display screen. These include, but not limited to, the patient ID, test result, time, temperature, software version number, procedural and error message alert if any. When in setting mode, the user would interact with the system via the information shown on the display screen.



1. Set of ‘Function/Control Keys’
2. Display Screen
3. ID Chip Port
4. Test Cartridge Port
5. Power ‘On/Off’ Switch
6. RS 232C Port
7. Power Plug Socket

Figure 6: Functional and Operational Elements of *i*-CHROMA Reader

Figure 7: Top View of *i*-CHROMA Reader

Figure 8: Side View of *i*-CHROMA Reader

3-2-3 ID Chip Port:

In Vitro diagnostic test systems are inevitably susceptible to batch-to-batch variations. *i*-CHROMA tests counter this problem by providing means of compensating for the batch-to-batch variations. For this purpose, the *i*-CHROMA test cartridge(s) is supplemented with an ID-Chip having a matching lot number.

The ID chip contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

3-2-4 Test Cartridge Port:

The test cartridge holder ejects out of the main body of *i*-CHROMA Reader from this port. After inserting the sample-loaded test cartridge into the cartridge holder, the ‘Select’ key is to be pressed for scanning the test cartridge by the *i*-CHROMA Reader. The

cartridge holder along with the 'Test Cartridge' moves into the *i*-CHROMA Reader. After the test result is displayed on the display screen, the cartridge holder along with the test cartridge is ejected automatically and stays protruded outside the main body *i*-CHROMA Reader. Upon pressing the 'Select' key or 'In/Out' key (depending on the display message and/or stage of operation), the cartridge holder would retract into *i*-CHROMA Reader.

3-2-5 Power 'On/Off' Switch:

The power switch is provided on the right side of the *i*-CHROMA Reader.

3-2-6 RS 232C Port:

This port serves as both the input and the output port. A keypad is attached to the reader through this port for inputting an 11-digit 'Patient ID' before testing a patient sample. The test result is by default routed through this port to the printer if attached. Without the printer being attached, the output is disregarded. A 'Y' cable is provided to attach the keypad as well as the printer to the **i**-CHROMA Reader through this port. One can utilize this feature to establish a network connection so that another device would capture the printer output for further processing and share the same with other networked system(s). This port could also be used to facilitate the reception of incoming data. One would use this feature to accommodate external control of the system.

3-2-7 Power Plug Socket:

Power plug socket is provided on the right side of the *i*-CHROMA Reader adjacent to the RS232C Port and the power switch.

3-3 Regarding prior FDA clearance of *i*-CHROMA™ Reader:

i-CHROMA Reader has received prior clearance from FDA as the associated instrument of the ***i*-CHROMA CRP Test which has been cleared by FDA** vide **the 510(k) number k062981.**

4. Risk Control Measures Incorporated in *i*-CHROMA iFOB Test System

Risk management has been used for proper identification and effective control of error sources which may be associated with the intended use of *i*-CHROMA iFOB.

Appropriate risk control measures in the form of fail-safe and/or failure alert mechanisms have been incorporated in *i*-CHROMA iFOB test system.

These fail-safe and failure alert mechanisms help assure that *i*-CHROMA iFOB test has an insignificant risk of an erroneous result.

Various fail-safe and/or failure alert mechanisms incorporated in *i*-CHROMA iFOB test system can be broadly classified as follows:

- Appropriate design and physical features to prevent operator errors
- Electronic controls in *i*-CHROMA Reader
- Mechanism for identification and validation of *i*-CHROMA iFOB ID chip
- Unique barcode and mechanism for identification/validation of *i*-CHROMA iFOB test cartridge
- Procedural/Internal control of *i*-CHROMA iFOB
- *i*-CHROMA iFOB external controls

Various fail-safe & failure alert mechanisms and other risk control measures incorporated in the *i*-CHROMA iFOB test system have been described in detail in following appendices:

Appendix VI: System Information and Clinical Testing for CLIA Waiver Application of *i*-CHROMA iFOB

Appendix VII: Risk Analysis of *i*-CHROMA iFOB Test System

Package Insert

i-CHROMA iFOB

For complete information, refer to the following additional instructional materials:

- Operation Manual of '*i*-CHROMA Reader'
- Package Insert of '*i*-CHROMA iFOB Controls'

INTENDED USE

i-CHROMA iFOB in conjunction with *i*-CHROMA Reader is a fluorescence immuno-chromatographic assay system for qualitative detection of fecal occult blood (FOB) in human fecal samples.

i-CHROMA iFOB is an *in vitro* diagnostic test used by laboratories and physician offices for routine physical examination when gastrointestinal bleeding may be suspected.

INTRODUCTION

Colorectal cancer (CRC) is the third most common malignant cancer worldwide and the second leading cause of cancer deaths in the United States. About 143,000 newly-diagnosed cases of CRC and about 52,000 deaths due to the same had been projected in the United States for the year 2012.

Fecal Occult Blood (FOB) is a widely accepted early marker for screening of colorectal cancer. Screening methods for colorectal cancer include the conventional guaiac-based fecal occult blood tests (FOBTs), immunochemical fecal occult blood tests (iFOBTs), barium enema, sigmoidoscopy and colonoscopy.

Conventional FOBTs use the chemical Guaiac, which detects hemoglobin by virtue of its sensitivity to hemoglobin peroxidase activity. Since the late 1970s, these guaiac-based FOBTs have been the primary screening method for colorectal cancer. These tests have a number of limitations such as diet restrictions because of interference from dietary plant peroxidase(s), low sensitivity to clinically significant colorectal neoplasis, non-specificity for human hemoglobin, sample handling and others.

An alternative to conventional guaiac-based FOBTs is immunochemical testing (iFOBTs), which detects only the specific portion of human hemoglobin rather than detecting hemoglobin peroxidase activity, which is prone to interference from dietary plant peroxidase(s). iFOBTs use specific antibodies for capture and detection of FOB hemoglobin in the human fecal samples. iFOBTs thus overcome the critical limitations associated with the conventional guaiac-based FOBTs.

Large randomized controlled clinical trials have shown that iFOB screening can result in decreased colorectal cancer mortality. Over the years, iFOBTs have been slowly replacing the conventional guaiac-based FOBTs. *i*-CHROMA iFOB uses specific monoclonal antibodies for capture and detection of human hemoglobin.

PRINCIPLE

i-CHROMA iFOB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human fecal sample is mixed with the detection buffer in the sample collection tube, the fluorochrome-labeled detector antibodies (anti-hemoglobin) in the detection buffer bind with hemoglobin in the fecal occult blood (FOB).

When the fecal sample mixture is loaded into the sample well on the test cartridge as per the recommended test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (FOB hemoglobin) complexes get captured on to the capture antibodies (anti-hemoglobin) which have been immobilized at the test line on the test strip.

As a result, fluorochrome-labeled complexes of the detector antibody-analyte (FOB hemoglobin)-capture antibody get accumulated at the test line on test cartridge membrane.

Thus, more the hemoglobin in the human fecal sample, more the complexes that get accumulated at the test line on the test cartridge membrane.

Upon inserting the sample-loaded test cartridge in the *i*-CHROMA Reader, the laser light illuminates the test cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of hemoglobin.

Intensity of the fluorescence is scanned and converted into an electric signal which is correlates to intensity of fluorescence and hence to the concentration of FOB hemoglobin in the test sample. The on-board microprocessor computes the FOB hemoglobin concentration based on a pre-programmed calibration.

Computed and converted result is displayed by the *i*-CHROMA Reader in a qualitative (negative/positive) manner based on an analytical cut-off of 100 ng/mL (hemoglobin in fecal sample mixed with detection buffer) which is equivalent to 8µg i.e. 0.008 mg hemoglobin per gram of stool.

COMPONENTS OF TEST SYSTEM

For performing *i*-CHROMA iFOB test, following items are needed:

- *i*-CHROMA iFOB Test Cartridge
- *i*-CHROMA iFOB Sample Collection Tube (containing detection buffer)
- *i*-CHROMA iFOB ID Chip
- *i*-CHROMA Reader with attached Key Pad

'*i*-CHROMA iFOB Test Cartridge' contains a test strip; on the nitrocellulose membrane of which, murine antibodies against human hemoglobin and rabbit immunoglobulin-G have been immobilized at the test line and the control line respectively. Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains the '*i*-CHROMA iFOB ID Chip'.

Each '*i*-CHROMA iFOB Sample Collection Tube' contains 1 mL '*i*-CHROMA iFOB Detection Buffer'. The detection buffer contains fluorochrome-labeled anti-hemoglobin antibodies, fluorochrome-labeled anti-rabbit immunoglobulin-G, bovine serum albumin

(BSA) as a stabilizer, and sodium azide in phosphate buffered saline (PBS) as a preservative. 25 pre-filled sample collection tubes are packed in a box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

i-CHROMA Reader is a fluorometer instrument which scans the sample-loaded *i*-CHROMA iFOB test cartridge and displays the test result. *i*-CHROMA Reader and *i*-CHROMA iFOB test cartridge are compatible only with each other. *i*-CHROMA Reader is marketed/supplied separately on demand.

'*i*-CHROMA iFOB ID chip' contains a memory device that contains encoded calibration data/information for the batch-to-batch (lot-to-lot) variation. With the ID chip inserted in the designated port, *i*-CHROMA Reader reads and utilizes the calibration data regarding the batch/lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

MATERIALS SUPPLIED

Commercial '*i*-CHROMA iFOB' test product comprises:

1) ***i*-CHROMA iFOB Test Cartridge Box**

   Contains:

   - 25 Test Cartridges
   - 1 ID Chip
   - 1 Package Insert

2) ***i*-CHROMA iFOB Sample Collection Tube Box**

   Contains:

   - 25 Sample Collection Tubes ; each containing 1 mL Detection Buffer

Sample collection tubes box is supplied separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.

3) **Patient Packs Box**

   Contains:

   - 25 Patient Packs

Patient pack box is supplied with the test cartridge box.

Each patient pack contains following items:

- 1 Patient Instructions Leaflet (for sampling instructions)
- 1 Sample Collection Paper (for fixing onto the toilet bowl)
- 1 Sample Sac containing an absorbent pad (for enclosing the sample collection tube after sampling)
- 1 Return Envelop (for submitting the sample collection tube to the laboratory/ physician office for testing)

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items are also required for performing *i*-CHROMA iFOB tests. However, these items can be ordered separately from '*i*-CHROMA iFOB' as per requirement.

Contact the manufacturer or authorized supplier for more information.

1) *i*-CHROMA Reader
2) *i*-CHROMA iFOB Controls
3) Capillary Tube Bottle
4) Capillary Tube Grabber
5) Microplate

STORAGE AND STABILITY

***i*-CHROMA iFOB Sample Collection Tube(s)**:

- Must be stored at 2~8º C/35.6~46.4º F in a refrigerator.
- Do not freeze.
- Do not use beyond expiration date.

***i*-CHROMA iFOB Test Cartridge(s):**

- Must be stored in sealed condition at 4~30º C/39.2~86º F.
- Do not freeze.
- Do not use beyond expiration date.

WARNINGS AND PRECAUTIONS

A. General:

- Strictly follow the instructions and test procedure as recommended by the manufacturer; otherwise test results may be misleading or erroneous.
- Place one sample collection tube into the sample sac before handing over the patient pack to the patient so that the patient can collect fecal sample and do the sampling himself/herself.
- Occasionally, laboratory may receive fecal sample which has been collected and submitted in a specimen cup or similar container by the patient.

B. Technical:

- Test should be performed using test cartridge, sample collection tube and ID chip; all having exactly matching lot number. Never interchange test products from different lots.
- Do not use the test cartridge or sample collection tube if it has been already used, damaged or stored under improper conditions.
- Misleading or erroneous test results may be obtained with test components which are past the expiration date or stored improperly or not matching with each other.
- Use *i*-CHROMA iFOB test cartridge and *i*-CHROMA Reader only with each other.

- Fecal sample submitted by the patient in *i*-CHROMA iFOB sample collection tube should be tested before 72 hours after sampling if stored at 4º C (2~8º C/35.6~46.4º F) and before 48 hours after sampling if stored at ambient temperature not exceeding 37º C/98.6º F.
- Fecal sample submitted by the patient in a specimen cup should be tested before 72 hours after sampling if stored at 4º C (2~8º C/35.6~46.4º F) and before 24 hours after sampling if stored at ambient temperature not exceeding 37º C/98.6º F.
- Laboratory should test the fecal sample as early as possible within the above time limits after it is received from the patient.
- However, it is strongly recommended to test the fecal sample immediately after sampling and/or receipt at laboratory if it has been exposed to ambient temperature exceeding 37º C/98.6º F.
- Test cartridge and sample collection tube (containing fecal sample or control) must be allowed to attain ambient temperature (15~37 ºC/59~98.6 ºF) before testing.
- A sample collection tube and test cartridge should be used for testing a sample or control only once and should never be reused.

C. Clinical:

- *i*-CHROMA iFOB is meant for *in vitro* diagnostic use only.
- The test should always be performed upon recommendation of attending physician.
- Test result should not be considered conclusive evidence of presence or absence of gastrointestinal bleeding or disorder.
- The test may yield false negative or false positive results owing to certain technical and clinical factors.

D. Patient Instructions:

- Provide appropriate instructions and guidance to the patient regarding sample collection/sampling procedure, entering required information on the label of sample collection tube and returning the sample collection tube to the laboratory for testing within recommended time limits.
- Patient must be instructed to observe following precautions:
  - Dietary restrictions if any; as advised by attending physician, must be followed by the patient before collecting and submitting fecal sample for testing.
  - Fecal sample should not be collected during or within three days after menstrual period, or if the patient suffers from bleeding hemorrhoids or urinary bleeding.
  - Fecal sample should not come in contact with toilet water and/or urine until collected.

E. Handling and Disposal:

Fecal sample, used test cartridge and used sample collection tube should be considered as potentially infectious and hence must be disposed of in accordance with appropriate local, state or federal requirements.

SYSTEM CHECK MECHANISMS OF *i*-CHROMA READER

A. Preprogrammed 'System Self-check' of *i*-CHROMA Reader:

What it is

- It is a mechanism which routinely checks whether key electronic components representing major functions of the *i*-CHROMA Reader are working in order.

How it is executed

- It is executed automatically whenever the power switch of *i*-CHROMA Reader is turned 'ON'.

What it normally indicates

- Up on turning the power switch on, *i*-CHROMA Reader displays 'Self-test Mode' and then momentarily displays 'OK' and comes in 'MENU' mode.
- This indicates that key electronic components representing major functions of the *i*-CHROMA Reader are working in order.
- You can proceed to perform the tests.

What if it malfunctions?

- If one or more of the key electronic components malfunction, *i*-CHROMA Reader displays any of the error message alerts 'Error 21 Turn Off the Power'-'Error 24 Turn Off the Power' thereby disabling it from further use.
- Contact the manufacturer for technical assistance.

B. Performing 'System Check' on *i*-CHROMA Reader:

Importance

- System Check of *i*-CHROMA Reader must be performed regularly.

Purpose

- To ascertain overall normal functioning of the *i*-CHROMA Reader
- To ascertain whether it would carry out the designated task as intended.

Items specially required

- A set of '*i*-CHROMA System Check Cartridge and System Check ID Chip' is provided with the *i*-CHROMA Reader.

For details

- Refer to the 'Operation Manual of *i*-CHROMA Reader'.

Procedure

- As described under '**D. Performing System Check on *i*-CHROMA Reader**' in the 'Test Procedure' section of this package insert.

When to Perform

- In case of installing the *i*-CHROMA Reader for the first time.
- In case of any concern regarding physical/functional integrity of the Reader
- In case of any question concerning validity or accuracy of test results.
- Before performing the test using *i*-CHROMA Reader after extended period of non-use, changing its operational settings or up-gradation of software.

What the result indicates

- If the result is 'System Check System OK', then:
  - It confirms overall normal functioning of the *i*-CHROMA Reader.
  - *i*-CHROMA iFOB Test results are most likely to be accurate and valid.
  - Proceed for testing the controls or fecal samples.
- If the result is 'System Check Error S1' or 'System Check Error S2', then:
  - Discontinue using the *i*-CHROMA Reader or do not report any test result.
  - Contact the manufacturer for technical assistance.

QUALITY CONTROL

A. External Controls

Importance:

- Controls must be tested regularly if you are using *i*-CHROMA iFOB test under CLIA-waived status.

Purpose:

- To verify whether *i*-CHROMA iFOB test offers expected test results with *i*-CHROMA iFOB controls**.**
- To assure and confirm acceptable performance of *i*-CHROMA iFOB test system.

Items specially required:

- *i*-CHROMA iFOB controls are to be procured separately from the 'Test Cartridge Box' & 'Sample Collection Tube Box'.
- Capillary tubes (10 µL), grabber and microplate are also supplied by the manufacturer on demand.

For details:

- Refer to the package insert of *i*-CHROMA iFOB controls.

Procedure:

- As described under '**E. Testing *i*-CHROMA iFOB Controls**' in test procedure section of this insert.

When to Perform:

- At least once daily before testing fecal samples
- In case of any concern regarding functional integrity of the test cartridge(s) and/or detection buffer in sample collection tube(s)
- In case of any question concerning validity or accuracy of test results
- Before performing the test using any new lot of test components or any new shipment even if it belonged to a previously received lot
- Once every month for routinely checking stability of stored test components.
- If the test is being performed by a new operator
- If the operator has not performed the test within last 7 days.

What the results indicate:

- Control test results should be considered valid/acceptable if '*i*-CHROMA iFOB Negative Control' tests 'iFOB Test Negative' and '*i*-CHROMA iFOB Positive Control' tests 'iFOB Test Positive'.
- **If valid/acceptable results are obtained with both controls, then:**
  - It assures acceptable performance of *i*-CHROMA iFOB test system.
  - Test results with fecal samples are most likely to be accurate and valid.
  - You can proceed to test the fecal samples.
- **If results obtained with any/both controls are invalid/unacceptable, then:**
  - It may be due to one of the following reasons:
    - Proper technique or correct procedure was not followed while testing the controls.
    - Quality/Functional integrity of the controls and /or other components of the test system might have been adversely affected due to improper storage and/or handling.
    - The test system being used may not be performing effectively and hence tests performed on clinical human fecal samples using this test system may yield results of questionable validity and/or accuracy.
  - Test the controls again after correcting any error that might have occurred.
  - If test results with the controls continue to be invalid/unacceptable; then:
    - Do not perform further tests on the fecal samples or do not report any result.
    - Contact the manufacturer for technical assistance.

B. Internal Control

What it is:

- 'Control line' of test cartridge functions as the quality control mechanism which fairly satisfies routine quality control requirement of *i*-CHROMA iFOB test.

How it is executed:

- It is executed automatically whenever a control or fecal sample is tested by *i*-CHROMA iFOB test.

What its normal functioning indicates:

- Internal control mechanism functioned optimally.
- Sufficient quantity of processed test sample was loaded into the sample well.
- The test sample migrated to the control line and test line as required.

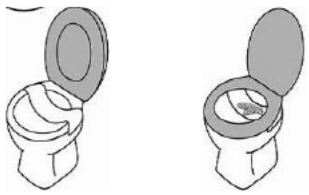
What if it malfunctions?

- In case of malfunction of the internal control due to any reason, *i*-CHROMA Reader displays any of the error message alerts viz. 'Caution! Error', 'iFOB Test Error 26' or 'iFOB Test Error 28' thereby terminating the test.
- Repeat the test using a new test cartridge following correct test procedure.
- If same error message alert(s) is displayed again, contact the manufacturer for technical assistance.

TEST PROCEDURE

A. Sample collection by patient:

1) Lift toilet cover and toilet seat.
2) Position and fix sample collection paper to the sides of rim in rear half of toilet bowl, allowing the paper to sag.
3) Make bowel movement on to the collection paper.
4) Do not remove the collection paper from toilet bowl until fecal sample has been transferred into the '*i*-CHROMA iFOB Sample Collection Tube' or a specimen cup.



B. Sampling by patient or test operator:

1) Enter required 'Patient Information' on the label of '*i*-CHROMA iFOB Sample Collection Tube'.
2) Unscrew the cap of sample collection tube and remove the sampler.
3) Insert sampling stick of sampler into the stool at 5-6 different sites.
4) Re-apply sampler back into sample collection tube and tighten its cap.

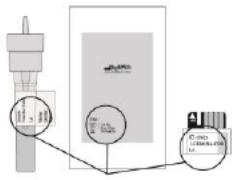
C. Arranging test setup:

1) Arrange following test components:

- *i*-CHROMA iFOB Test Cartridge & ID Chip
- *i*-CHROMA iFOB Sample Collection Tube (containing the fecal sample)
- *i*-CHROMA Reader (attached with key pad and serial printer)

2) All these test components must have been stored properly under recommended storage conditions.
3) Check whether lot number of the ID chip is exactly same as lot numbers of the test cartridge and the sample collection tube.

4) Ensure that test cartridge and sample collection tube has not passed respective expiration dates.
5) Allow the test components to attain ambient temperature (15~37º C/59~98.6º F) for about 30 min.



D. Performing 'System Check' on *i*-CHROMA Reader:

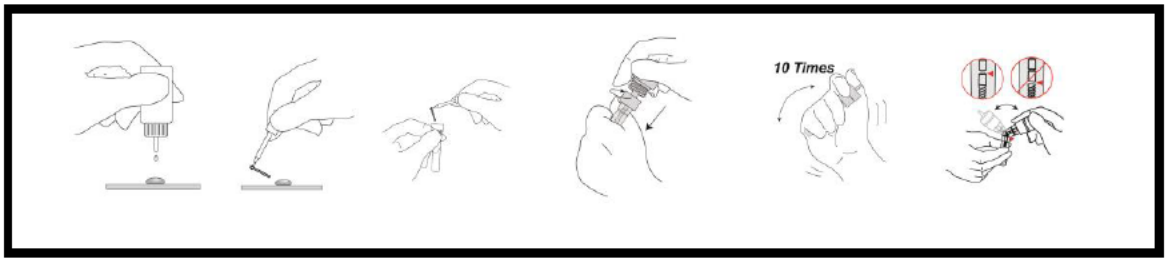
1) Arrange '*i*-CHROMA System Check ID Chip & System Check Cartridge'.
2) Turn power switch of *i*-CHROMA Reader 'On'. It will automatically display the default 'MENU'.
3) Select 'Test Mode' and insert 'System Check ID Chip' in the ID chip port.
4) *i*-CHROMA Reader ejects cartridge holder and displays the message alert 'Input Patient ID'.
5) Press 'Select' to skip inputting 'Patient ID'. Message alert 'Insert System Check Cartridge' is displayed.
6) Insert System Check Cartridge in the cartridge holder and press 'Select'.
7) *i*-CHROMA Reader should display 'System Check System OK' indicating overall normal functioning.

E. Testing *i*-CHROMA iFOB Controls:

1) Arrange the test set up but the sample collection tube should not contain fecal sample.
2) Arrange vials of *i*-CHROMA iFOB 'Negative' and 'Positive' controls as well as capillary tubes, grabber and microplate.
3) Allow the vials to attain ambient temperature (15~37ºC/59~98.6ºF) for about 30 minutes.
4) Unscrew cap of the sample collection tube and remove sampler.
5) Squeeze out 2 drops from the vial of 'Negative' control into a well on the microplate.
6) Hold a capillary tube with the grabber at one end and immerse another end of the tube into the control reagent present in the well of microplate.
7) Ensure that the capillary tube has been completely filled with the control reagent.
8) Carefully drop the filled capillary tube into the sample collection tube such that it falls into the detection buffer reservoir.
9) Re-apply the sampler back into sample collection tube and tighten its cap.
10) Shake the sample collection tube 10 times.

11) Perform further procedure in the manner as described in '**Steps 2-15 under F. Testing human fecal sample**' except that you should skip inputting the patient ID by pressing 'Select' button.

12) Perform the test with 'Positive' control also using new sample collection tube and test cartridge.



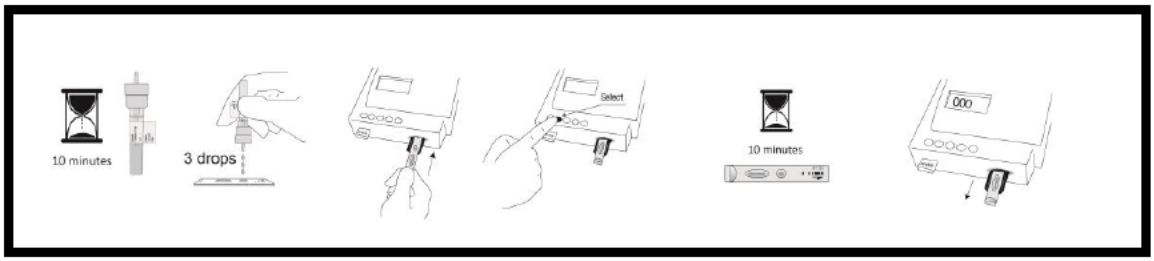
F. Testing human fecal sample:

1) Shake the sample collection tube (containing fecal sample) about 10 times.
2) Hold it in vertical position and cut the sampling stick by bending the tube 2-3 times just below the cap.
3) Allow the sample collection tube to stand for 10 minutes in vertical position.
4) Turn power switch of *i*-CHROMA Reader 'On'. It automatically displays the default 'MENU'.
5) Select 'Test Mode' and insert '*i*-CHROMA iFOB ID Chip' in the ID chip port.
6) *i*-CHROMA Reader ejects cartridge holder and displays message alert 'Input Patient ID'.
7) Input an 11-digit patient ID correctly based on the patient information and laboratory record system in the following manner:
   - First six digits for patient's date of birth e.g. enter March 9, 2014 as 030914
   - Next two digits for patient's gender e.g. 01 for male and 02 for female
   - Last three digits for serial number of the test as entered/to be entered in record/ information management system of the laboratory e.g. enter 'Serial No. 1' as '001'
8) After inputting the patient ID, press 'Select'. Message alert 'Insert iFOB Test Cartridge' is displayed.
9) Remove the '*i*-CHROMA iFOB Test Cartridge' from its original pouch and place it on a flat surface.
10) Invert the sample collection tube and squeeze out precisely three drops of fecal sample mixture into 'Sample Well' of the test cartridge.
11) Immediately insert the sample-loaded test cartridge in the cartridge holder in the direction denoted by the 'arrow mark' on face of the cartridge and press 'Select'. Push the test cartridge gently all the way inside the test cartridge holder.
12) *i*-CHROMA Reader will automatically scan the inserted test cartridge after 10 minutes and display test result.

13) If *i*- CHROMA Reader has been set to 'Multi Mode', allow the sample-loaded test cartridge to stand for exactly 10 minutes outside the *i*-CHROMA Reader.

14) After 10 minutes, insert the sample-loaded test cartridge in the cartridge holder and press 'Select'.

15) *i*-CHROMA Reader immediately scans the inserted test cartridge and displays test result.



CATEGORIZATION AND INTERPRETATION OF TEST RESULTS

- Cut-off of *i*-CHROMA iFOB is 100 ng/mL (hemoglobin in fecal sample mixed with detection buffer) which is equivalent to 8µg i.e. 0.008 mg hemoglobin per gram of stool.
- Thus a clinical fecal sample containing less than 8 µg i.e. 0.008 mg/g concentration of hemoglobin would test 'iFOB Test Negative' and a clinical fecal sample containing 8 µg i.e. 0.008 mg/g or higher concentration of hemoglobin would test 'iFOB Test Positive' with *i*-CHROMA iFOB test.
- **Valid Results:**
  - Fecal sample test results should be considered valid if quality control results with both *i*-CHROMA iFOB controls on that day are also valid/acceptable.
  - Report valid test results to the attending physician for correct interpretation and appropriate medical intervention.
- **Invalid Results:**
  - Fecal sample test results should be considered invalid if quality control results with any or both *i*-CHROMA iFOB controls on that day are invalid/unacceptable.
  - Do not report invalid test results.
  - Repeat quality control tests after correcting any error that might have occurred as described in the section 'External Controls' in this package insert.
  - If test results with the controls continue to be invalid/unacceptable; then:
    - Do not perform further tests on the fecal samples or do not report any result.
    - Contact the manufacturer for technical assistance.
- **Indeterminate Results:**
  - Fecal sample test result should be considered indeterminate if it is displayed as one of the following 'Error Message Alerts' but the test results of both *i*-CHROMA iFOB controls on that day are valid/acceptable.

- ‘Caution! Barcode Error’
- ‘Caution! Error’
- ‘iFOB Test Error 26’
- ‘iFOB Test Error 27’
- ‘iFOB Test Error 28’
- ‘iFOB Test Error 29’

- Repeat the test using a new *i*-CHROMA iFOB test cartridge and/or correcting any operator error that might have occurred.
- If same error message alert continues to be displayed, contact the manufacturer for technical assistance.

PERFORMANCE CHARACTERISTICS

1. **Cut-off:** Cut-off of *i*-CHROMA iFOB is 100.0 ng/mL (hemoglobin in human fecal sample mixed with detection buffer) which is equivalent to 8µg i.e. 0.008 mg hemoglobin per gram of stool.
2. **Prozone effect:** *i*-CHROMA iFOB showed no prozone effect upto 2000 ng/mL (hemoglobin in human fecal sample mixed with detection buffer) which is equivalent to 160 µg i.e. 16 mg hemoglobin per gram of stool.
3. **Sensitivity to human hemoglobin variant:** *i*-CHROM iFOB has been found to be equally sensitive to ‘Hemoglobin S’ as the human hemoglobin variant associated with sickle cell anemia.
4. **Cross-reactivity:** *i*-CHROMA iFOB showed no significant cross-reactivity with animal hemoglobin (bovine, chicken, fish, equine, goat, swine, rabbit, and sheep origin).
5. **Interference:** *i*-CHROMA iFOB showed no significant interference from endogenous substances (Ascorbic Acid, Bilirubin, Albumin and Myoglobin).
6. **Precision:** *i*-CHROMA iFOB test results showed high degree of repeatability as well as reproducibility under different variability conditions.
7. **Comparability:** Test results of method comparison studied performed on several spiked as well as clinical human fecal samples showed acceptable level of agreement between *i*-CHROMA iFOB and the predicate method OC Auto Micro FOB Test (Polymedco Inc., USA).

LIMITATIONS OF THE TEST SYSTEM

i-CHROMA iFOB provides accurate and reliable test results subject to the following constraints:

- Accuracy and reliability of test results is highly dependent on proper handling/storage of test components and test samples as well as strict adherence to the correct testing and quality control procedures described in this insert.
- The test may yield false positive results due to cross-reactions of some components of the fecal sample or the fecal occult blood with the capture/detector antibodies and/or

non-specific adhesion of certain components (having similar epitopes) with these antibodies.

- The test may also yield false negative results; the most common factor being non-responsiveness of the antigen to the capture/detector antibodies due to its epitopes being masked by some unknown components such that the antigen cannot be detected or captured by the antibodies. False negative results may also be obtained due to instability or degradation of the hemoglobin antigen with time and/or temperature making it unrecognizable by the antibodies.
- Other factors causing erroneous/misleading results include technical/procedural errors, degradation of the test components/reagents as well as presence of interfering substances in the test samples.
- The user should neither arrive at any conclusion nor take any decision of medical/therapeutic importance after knowing the test result without first consulting the attending physician.
- Any clinical diagnosis and consequent decision of medical/therapeutic importance based on the test result(s) must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

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1. Ferlay J, Bray F, Pisani P, Parkin DM. GLOBOCAN 2020: Cancer incidence, motality and Prevalence worldwide. IARC CancerBase no. 5, version 2.0. Lyon, France: IARC Pr; 2004.
2. Arnold CN, Goel A, Blum HE, Boland CR. Molecular pathogenesis of colorectal cancer: implications for molecular diagnosis. Cancer 2005;104:2035-2047.
3. Mandel JS, Bond JH, Church TR, Snover DC, Bradley GM, Schuman LM, et al. Reducing mortality from colorectal cancer by scrrning for fecal occult blood. Minnesota Colon Cancer Control study. N Engl J Med 1993; 328:1365-1371
4. Kronborg O, Fenger C, Olden J, Jorgensen OD, Sondergaard O. Randomised study of screening for colorectal cancer with fecal occult blood test. Lancet 1996; 384: 1467-1471.
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6. Rozen P, Waked A, Vilkin A, et al. Evaluation of a desk top instrument for the automated development and immunochemical quantification of fecal occult blood. Med Sci Moint 2006; 12(6):MT27-32.
7. Oh SW, Moon JD, Park SY, et al. Evaluation of fluorescence hsCRP immunoassay for point of care testing. Clin Chim Acta 2005; 356:172-177.

Note: Please refer to the table below to identify various symbols on the product labels

	Read instructions for use
	Use by
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
IVD	*In vitro* diagnostic medical device
	Temperature limitation
	Do not Reuse

For technical assistance please contact:
Boditech Med Inc.'s Technical Services
Phone: + 82 33 243 1400
E-mail: support@boditech.co.kr

Boditech Med Incorporated
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.

Phone No.: +82 33 243 1400
Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr

Website: www.boditech.co.kr

Quick Reference Instructions

i-CHROMA iFOB

For complete information, refer to the following instructional material.

- Package Insert of *i*-CHROMA iFOB
- Package Insert of *i*-CHROMA iFOB Controls
- Operation Manual of *i*-CHROMA Reader

Which items you need for the test

- *i*-CHROMA iFOB Test Cartridge
- *i*-CHROMA iFOB Sample Collection Tube
- *i*-CHROMA Reader with attached Key Pad

  Following items are additionally required for quality control tests
- *i*-CHROMA iFOB Negative & Positive Controls
- Capillary Tubes (10 µL)
- Grabber
- Microplate

How you may receive and store the test sample(s)

Fecal sample submitted in *i*-CHROMA iFOB Sample Collection Tube:

- May be stored at ambient temperature (≤ 37º C/98.6º F) for up to 48 hours or at 2~8º C/35.6~46.4º F in a refrigerator for up to 72 hours after sampling by patient.
- Do not freeze.

Fecal sample submitted in a specimen cup:

- May be stored at ambient temperature (≤ 37º C/98.6º F) for up to 24 hours or at 2~8º C/35.6~46.4º F in a refrigerator for up to 72 hours after sampling by patient.
- Do not freeze.

How you should store the test products

***i*-CHROMA iFOB Sample Collection Tubes**:

- Must have been stored at 2~8º C/35.6~46.4º F in a refrigerator. Do not freeze.
- Do not use beyond expiration date.
- Use for mixing a fecal sample or a control only once. Never reuse.

***i*-CHROMA iFOB Test Cartridges:**

- Must have been stored in sealed condition at 4~30º C/39.2~86º F. Do not freeze.
- Do not use beyond expiration date.
- Use for testing a fecal sample or a control only once. Never reuse.

***i*-CHROMA iFOB Controls**:

- Vials of Negative and Positive controls must have been stored at 2~8ºC/ 35.6~46.4ºF in a refrigerator. Do not freeze.
- Do not use beyond one month after the vials are opened for the first time.
- Do not use beyond expiration date.

***i*-CHROMA iFOB ID Chip and *i*-CHROMA Reader**:

- Always store and use at ambient temperature (15~37º C/59~98.6º F).
- Store properly and handle gently to avoid any physical damage.
- Keep away from moisture, heat, direct sunlight, vibrations and magnetic field.

System Check Mechanisms of *i*-Chroma Reader

A. Preprogrammed 'System Self-check' of *i*-CHROMA Reader:

What it is

- It is a mechanism which routinely checks whether key electronic components representing major functions of the *i*-CHROMA Reader are working in order.

How it is executed

- It is executed automatically whenever the power switch of *i*-CHROMA Reader is turned 'ON'.

What it normally indicates

- Up on turning the power switch on, *i*-CHROMA Reader displays 'Self-test Mode' and then momentarily displays 'OK' and comes in 'MENU' mode.
- This indicates that key electronic components representing major functions of the *i*-CHROMA Reader are working in order.
- You can proceed to perform the tests.

What if it malfunctions?

- If one or more of the key electronic components malfunction, *i*-CHROMA Reader displays any of the error message alerts 'Error 21 Turn Off the Power'-'Error 24 Turn Off the Power' thereby disabling it from further use.
- Contact the manufacturer for technical assistance.

B. Performing 'System Check' on *i*-CHROMA Reader:

Importance

- System Check of *i*-CHROMA Reader must be performed regularly.

Purpose

- To ascertain overall normal functioning of the *i*-CHROMA Reader
- To ascertain whether it would carry out the designated task as intended.

Items specially required

- A set of '*i*-CHROMA System Check Cartridge and System Check ID Chip' is provided with the *i*-CHROMA Reader.

For details

- Refer to the 'Operation Manual of *i*-CHROMA Reader'.

Procedure

- As described under '**D. Performing System Check on *i*-CHROMA Reader**' in the 'Test Procedure' section of this instruction guide.

When to Perform

- In case of installing the *i*-CHROMA Reader for the first time.
- In case of any concern regarding physical/functional integrity of the Reader
- In case of any question concerning validity or accuracy of test results.
- Before performing the test using *i*-CHROMA Reader after extended period of non-use, changing its operational settings or up-gradation of software.

What the result indicates

- If the result is 'System Check System OK', then:
  - It confirms overall normal functioning of the *i*-CHROMA Reader.
  - *i*-CHROMA iFOB Test results are most likely to be accurate and valid.
  - Proceed for testing the controls or fecal samples.
- If the result is 'System Check Error S1' or 'System Check Error S2', then:
  - Discontinue using the *i*-CHROMA Reader or do not report any test result.
  - Contact the manufacturer for technical assistance.

Quality Control

A. External Controls

Importance:

- Controls must be tested regularly if you are using *i*-CHROMA iFOB test under CLIA-waived status.

Purpose:

- To verify whether *i*-CHROMA iFOB test offers expected test results with *i*-CHROMA iFOB controls**.**
- To assure and confirm acceptable performance of *i*-CHROMA iFOB test system.

Items specially required:

- *i*-CHROMA iFOB controls are to be procured separately from the 'Test Cartridge Box' & 'Sample Collection Tube Box'.
- Capillary tubes (10 µL), grabber and microplate are also supplied by the manufacturer on demand.

For details:

- Refer to the package insert of *i*-CHROMA iFOB controls.

Procedure:

- As described under '**E. Testing *i*-CHROMA iFOB Controls**' in test procedure section of this instruction guide.

When to Perform:

- At least once daily before testing fecal samples
- In case of any concern regarding functional integrity of the test cartridge(s) and/or detection buffer in sample collection tube(s)
- In case of any question concerning validity or accuracy of test results
- Before performing the test using any new lot of test components or any new shipment even if it belonged to a previously received lot
- Once every month for routinely checking stability of stored test components.
- If the test is being performed by a new operator
- If the operator has not performed the test within last 7 days.

What the results indicate:

- Control test results should be considered valid/acceptable if '*i*-CHROMA iFOB Negative Control' tests 'iFOB Test Negative' and '*i*-CHROMA iFOB Positive Control' tests 'iFOB Test Positive'.
- **If valid/acceptable results are obtained with both controls, then:**
  - It assures acceptable performance of *i*-CHROMA iFOB test system.
  - Test results with fecal samples are most likely to be accurate and valid.
  - You can proceed to test the fecal samples.
- **If results obtained with any/both controls are invalid/unacceptable, then:**
  - It may be due to one of the following reasons:
    - Proper technique or correct procedure was not followed while testing the controls.
    - Quality/Functional integrity of the controls and /or other components of the test system might have been adversely affected due to improper storage and/or handling.
    - The test system being used may not be performing effectively and hence tests performed on clinical human fecal samples using this test system may yield results of questionable validity and/or accuracy.
  - Test the controls again after correcting any error that might have occurred.
  - If test results with the controls continue to be invalid/unacceptable; then:
    - Do not perform further tests on the fecal samples or do not report any result.
    - Contact the manufacturer for technical assistance.

B. Internal Control

What it is:

- 'Control line' of test cartridge functions as the quality control mechanism which fairly satisfies routine quality control requirement of *i*-CHROMA iFOB test.

How it is executed:

- It is executed automatically whenever a control or fecal sample is tested by *i*-CHROMA iFOB test.

What its normal functioning indicates:

- Internal control mechanism functioned optimally.
- Sufficient quantity of processed test sample was loaded into the sample well.
- The test sample migrated to the control line and test line as required.

What if it malfunctions?

- In case of malfunction of the internal control due to any reason, *i*-CHROMA Reader displays any of the error message alerts viz. 'Caution! Error', 'iFOB Test Error 26' or 'iFOB Test Error 28' thereby terminating the test.
- Repeat the test using a new test cartridge following correct test procedure.
- If same error message alert(s) is displayed again, contact the manufacturer for technical assistance.

Test Procedure

A. Sample collection by patient:

1) Lift toilet cover and toilet seat.
2) Position and fix sample collection paper to the sides of rim in rear half of toilet bowl, allowing the paper to sag.
3) Make bowel movement on to the collection paper.
4) Do not remove the collection paper from toilet bowl until fecal sample has been transferred into the '*i*-CHROMA iFOB Sample Collection Tube' or a specimen cup.

B. Sampling by patient or test operator:

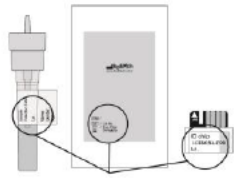
1) Enter required 'Patient Information' on the label of '*i*-CHROMA iFOB Sample Collection Tube'.
2) Unscrew the cap of sample collection tube and remove the sampler.
3) Insert sampling stick of sampler into the stool at 5-6 different sites.
4) Re-apply sampler back into sample collection tube and tighten its cap.

C. Arranging test setup:

1) Arrange following test components:

- *i*-CHROMA iFOB Test Cartridge & ID Chip
- *i*-CHROMA iFOB Sample Collection Tube (containing the fecal sample)
- *i*-CHROMA Reader (attached with key pad and serial printer)

2) All these test components must have been stored properly under recommended storage conditions.
3) Check whether lot number of the ID chip is exactly same as lot numbers of the test cartridge and the sample collection tube.
4) Ensure that test cartridge and sample collection tube has not passed respective expiration dates.
5) Allow the test components to attain ambient temperature (15~37º C/59~98.6º F) for about 30 min.

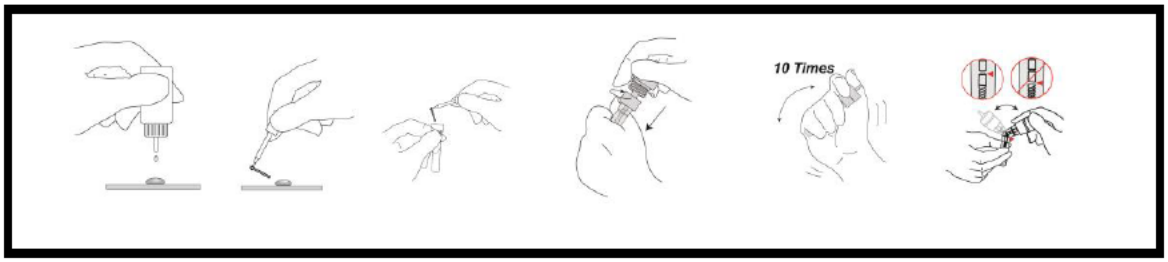


D. Performing 'System Check' on *i*-CHROMA Reader:

1) Arrange '*i*-CHROMA System Check ID Chip & System Check Cartridge'.
2) Turn power switch of *i*-CHROMA Reader 'On'. It will automatically display the default 'MENU'.
3) Select 'Test Mode' and insert 'System Check ID Chip' in the ID chip port.
4) *i*-CHROMA Reader ejects cartridge holder and displays the message alert 'Input Patient ID'.
5) Press 'Select' to skip inputting 'Patient ID'. Message alert 'Insert System Check Cartridge' is displayed.
6) Insert System Check Cartridge in the cartridge holder and press 'Select'.
7) *i*-CHROMA Reader should display 'System Check System OK' indicating overall normal functioning.

E. Testing *i*-CHROMA iFOB Controls:

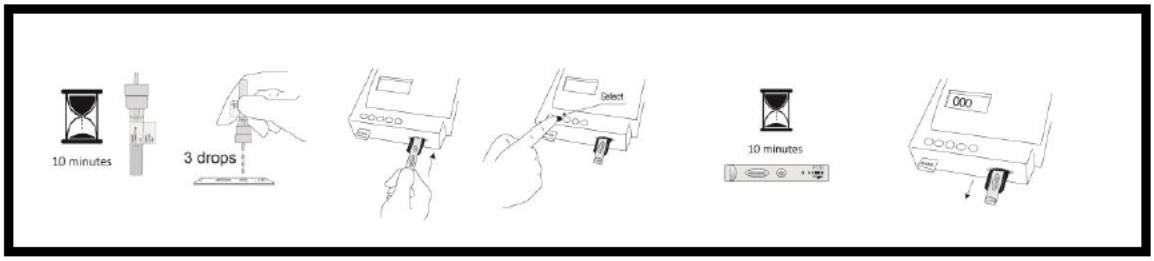
1) Arrange the test set up but the sample collection tube should not contain fecal sample.
2) Arrange vials of *i*-CHROMA iFOB 'Negative' and 'Positive' controls as well as capillary tubes, grabber and microplate.
3) Allow the vials to attain ambient temperature (15~37ºC/59~98.6ºF) for about 30 minutes.
4) Unscrew cap of the sample collection tube and remove sampler.
5) Squeeze out 2 drops from the vial of 'Negative' control into a well of on the microplate.
6) Hold a capillary tube with the grabber at one end and immerse another end of the tube into the control reagent present in the well of microplate.
7) Ensure that the capillary tube has been completely filled with the control reagent.
8) Carefully drop the filled capillary tube into the sample collection tube such that it falls into the detection buffer reservoir.
9) Re-apply the sampler back into sample collection tube and tighten its cap.
10) Shake the sample collection tube 10 times.
11) Perform further procedure in the manner as described in '**Steps 2-15 under F. Testing human fecal sample**' except that you should skip inputting the patient ID by pressing 'Select' button.
12) Perform the test with 'Positive' control also using new sample collection tube and test cartridge.



F. Testing human fecal sample:

1) Shake the sample collection tube (containing fecal sample) about 10 times.
2) Hold it in vertical position and cut the sampling stick by bending the tube 2-3 times just below the cap.
3) Allow the sample collection tube to stand for 10 minutes in vertical position.
4) Turn power switch of *i*-CHROMA Reader 'On'. It automatically displays the default 'MENU'.
5) Select 'Test Mode' and insert '*i*-CHROMA iFOB ID Chip' in the ID chip port.
6) *i*-CHROMA Reader ejects cartridge holder and displays message alert 'Input Patient ID'.

7) Input an 11-digit patient ID correctly based on the patient information and laboratory record system in the following manner:
   - First six digits for patient's date of birth e.g. enter March 9, 2014 as 030914
   - Next two digits for patient's gender e.g. 01 for male and 02 for female
   - Last three digits for serial number of the test as entered/to be entered in record/ information management system of the laboratory e.g. enter 'Serial No. 1' as '001'
8) After inputting the patient ID, press 'Select'. Message alert 'Insert iFOB Test Cartridge' is displayed.
9) Remove the '*i*-CHROMA iFOB Test Cartridge' from its original pouch and place it on a flat surface.
10) Invert the sample collection tube and squeeze out precisely three drops of fecal sample mixture into 'Sample Well' of the test cartridge.
11) Immediately insert the sample-loaded test cartridge in the cartridge holder in the direction denoted by the 'arrow mark' on face of the cartridge and press 'Select'. Push the test cartridge gently all the way inside the test cartridge holder.
12) *i*-CHROMA Reader will automatically scan the inserted test cartridge after 10 minutes and display test result.
13) If *i*- CHROMA Reader has been set to 'Multi Mode', allow the sample-loaded test cartridge to stand for exactly 10 minutes outside the *i*-CHROMA Reader.
14) After 10 minutes, insert the sample-loaded test cartridge in the cartridge holder and press 'Select'.
15) *i*-CHROMA Reader immediately scans the inserted test cartridge and displays test result.



Categorization and Interpretation of Test Results

- Cut-off of *i*-CHROMA iFOB is 100 ng/mL (hemoglobin in fecal sample mixed with detection buffer) which is equivalent to 8µg i.e. 0.008 mg hemoglobin per gram of stool.
- Thus a clinical fecal sample containing less than 8 µg i.e. 0.008 mg/g concentration of hemoglobin would test 'iFOB Test Negative' and a clinical fecal sample containing 8 µg i.e. 0.008 mg/g or higher concentration of hemoglobin would test 'iFOB Test Positive' with *i*-CHROMA iFOB test.

- **Valid Results:**
  - Fecal sample test results should be considered valid if quality control results with both *i*-CHROMA iFOB controls on that day are also valid/acceptable.
  - Report valid test results to the attending physician for correct interpretation and appropriate medical intervention.
- **Invalid Results:**
  - Fecal sample test results should be considered invalid if quality control results with any or both *i*-CHROMA iFOB controls on that day are invalid/unacceptable.
  - Do not report invalid test results.
  - Repeat quality control tests after correcting any error that might have occurred as described in the section 'External Controls' in this instruction guide.
  - If test results with the controls continue to be invalid/unacceptable; then:
    - Do not perform further tests on the fecal samples or do not report any result.
    - Contact the manufacturer for technical assistance.
- **Indeterminate Results:**
  - Fecal sample test result should be considered indeterminate if it is displayed as one of the following 'Error Message Alerts' but the test results of both *i*-CHROMA iFOB controls on that day are valid/acceptable.
    - 'Caution! Barcode Error'
    - 'Caution! Error'
    - 'iFOB Test Error 26'
    - 'iFOB Test Error 27'
    - 'iFOB Test Error 28'
    - 'iFOB Test Error 29'
  - Repeat the test using a new *i*-CHROMA iFOB test cartridge and/or correcting any operator error that might have occurred.
  - If same error message alert continues to be displayed, contact the manufacturer for technical assistance.

For technical assistance please contact:

Boditech Med Inc.'s Technical Services
Phone: + 82 33 243 1400
E-mail: support@boditech.co.kr

Boditech Med Incorporated
43, Geodudanji 1-gil, Dongnae-myeon,
Chuncheon-si, Gang-won-do, 200-883,
REPUBLIC OF KOREA.

Phone No.: +82 33 243 1400

Fax No.: +82 33 243 9373
E-mail: support@boditech.co.kr
Website: www.boditech.co.kr

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

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VI.3 Accuracy of *i*-CHROMA iFOB in intended use settings:

(In Comment No. 3c of K132167 Hold Letter, FDA had sought explanation regarding the criteria adopted for categorization of 'Invalid' & 'Indeterminate' test results and statistical treatment of such results as applied to the clinical studies which we had described under 'Appendix VI: CLIA Waiver Clinical Testing' of the K132167 original submission.)

- In our Submission Issue Q-Sub (Q1313168), we have already provided the explanation sought by FDA.
- In Q131368 Final Review Memo dated December 11, 2013, FDA pointed out some discrepancies in the criteria applied to invalid results as well as statistical treatment of data of above studies and recommended new clinical studies at three hospitals or intended use sites.

(We agree with the discrepancies in our earlier clinical studies. As we have newly performed the clinical method comparison studies as recommended by FDA, the clinical study/data previously submitted under 'Appendix VI: CLIA Waiver Clinical Testing' may be disregarded.)

(In Q131368 Final Review Memo dated December 11, 2013 and an E-mail response dated December 24, 2013, FDA has suggested clinical method comparison studies in three hospitals or intended use sites (with at least one site in US) on fecal samples obtained from asymptomatic individuals (with negative diagnoses) and high risk individuals (with positive diagnoses) who have already been screened with colonoscopy/biopsy.)

Purpose of study:

- Clinical testing was carried out to demonstrate accuracy of *i*-CHROMA iFOB at the hands of intended operators through prospective testing using patient samples collected in the intended testing environment.

Clinical testing sites:

- Clinical testing of *i*-CHROMA iFOB was conducted at following three sites at different demographic locations:
  - (b)(4)Trade Secret Process [redacted], Republic of Korea
  - (b)(4)Trade Secret Process [redacted], Republic of Korea
  - (b)(4)Trade Secret Process [redacted] USA
- These sites were selected to closely replicate the clinical setting actually intended for proposed clinical use of *i*-CHROMA iFOB.
- Details of these clinical testing sites are as follows:

Study site 1:

(b)(4)Trade Secret Process [redacted]

(b)(4)Trade Secret Process [redacted]

Study site 2:

Site Number: CSS-2

(b)(4)Trade Secret Process [redacted] Republic of Korea

(b)(4)Trade Secret Process [redacted]

Study site 3:

Site Number: CSS-3

(b)(4)Trade Secret Process [redacted], USA

(b)(4)Trade Secret Process [redacted]

Clinical investigators:

- Clinical investigators were not involved in the clinical testing of *i*-CHROMA iFOB conducted at the three testing sites.

Operators:

- It was aimed to enroll 3 operators at each testing site so as to have the participation of a minimum of 9 operators in total over the three clinical testing sites.
- At the two Korean sites (Study Site No. CSS-1 & CSS-2), special arrangements were made to ensure that *i*-CHROMA iFOB testing was performed by operators other than the regular laboratory technical staff performing routine clinical laboratory tests at these sites.
- These new operators were either biomedical laboratory science or clinical pathology undergraduate students doing internship at these hospitals or the staff serving in other support functions like administration, office assistance, nursing/patient counselling etc. at these hospitals.
- At the (b)(4)Trade Secret Process [redacted] (Study Site No. CSS-1), eight laboratory technicians were available which included two biomedical laboratory science interns. These two intern students and one person from amongst the support staff were enrolled as *i*-CHROMA iFOB operators.
- At the (b)(4)Trade Secret Process [redacted] (Study Site No. CSS-2), four laboratory technicians were available which included one clinical pathology intern student. The

intern student and two persons from amongst the support staff were enrolled as *i*-CHROMA iFOB operator.

- Thus, these new operators had minimum or no qualifications and/or previous training/experience relevant to laboratory clinical testing.
- At the US study site (Site No. CSS-3), operators with least level of academic qualifications and professional training/experience from amongst the operators available at the site, were enrolled to participate in the study.
- However, OC Auto Micro FOB testing was performed by the technician/professional-in-charge of the analyzer at the respective sites.
- **Table VI.3.A** shows the number of operators available and number of operators enrolled to participate in clinical testing of *i*-CHROMA iFOB at the designated testing.

Table VI.3.A: Site-wise availability, enrolment and participation of operators for the clinical testing study of *i*-CHROMA iFOB

Site No.	Clinical testing site	Number of operators at the testing site	
		Available	Chosen to enroll & participate in the clinical testing
CSS-1	(b)(4)Trade Secret [redacted] Process [redacted] Republic of Korea	06 + 2*	**2*** (CSS1-O1 & CSS1-O2) **+ 1Δ** (CSS1-O3)
CSS-2	(b)(4)Trade Secret Process [redacted] Republic of Korea	03 + 1*	**1*** (CSS2-O1) **+ 2Δ** (CSS2-O2 & CSS2-O3)
CSS-3	(b)(4)Trade Secret Process [redacted], USA	04	**03** (CSS3-O1, CSS3-O2 & CSS3-O3)
	Total	**16**	**09**

* *These operators were either biomedical laboratory science or clinical pathology undergraduate students doing internship at these hospitals.*

Δ *These operators were the staff serving in other support functions like nursing, administration, office assistance, patient counselling etc. at these hospitals.*

- Details of education, occupation, training/experience etc. of the enrolled operators have been provided in **Table VI.3.B**
- Details of education, occupation, training/experience etc. of the operators that were available at the testing sites but not enrolled for the study, have been provided in **Table VI.3.C**

Table VI.3.B: Details of education, occupation, training/experience etc. of the operators enrolled for the clinical testing of *i*-CHROMA iFOB				
Study site	**Information**	**Operators enrolled for & participated in the clinical study**		
		Operator CSS1-O1	**Operator CSS1-O2**	**Operator CSS1-O3**
CSS-1: (b)(4)Trade Secret Process [redacted], Republic of Korea	**Education**	Biomedical Laboratory Science Undergraduate student	Biomedical Laboratory Science Undergraduate student	Bachelor in Physics
	Occupation	Medical Laboratory Intern	Medical Laboratory Intern	Hospital General Support Staff
	Training and/ or Experience	Very little professional experience of clinical laboratory testing	Very little professional experience of clinical laboratory testing	No professional experience of clinical laboratory testing
CSS-2: (b)(4)Trade Secret Process [redacted], Republic of Korea	**Education**	Clinical Pathology Undergraduate student	Diploma in Nursing	Bachelor of Hospital Administration
	Occupation	Medical Laboratory Intern	Hospital Nurse	Hospital Assistant
	Training and/ or Experience	Very little professional experience of clinical laboratory testing	No professional experience of clinical laboratory testing	No professional experience of clinical laboratory testing
CSS-3: (b)(4)Trade Secret Process [redacted], USA	**Education**	Bachelor in Bioscience	Two year college education	Bachelor in Bioscience
	Occupation	Medical Technician	Medical Technician	Medical Technician
	Training and/or Experience	ASCP certification with three years professional experience	ASCP certification with one year professional experience	ASCP certification

Table VI.3.C: Details of education, occupation, training/experience etc. of the operators that were available at the testing sites but not enrolled for the clinical testing				
Study site	**Information**	**Operators enrolled for & participated in the clinical study**		
		Operator CSS1-O4	**Operator CSS1-O5**	**Operator CSS1-O6**
CSS-1: (b)(4)Trade Secret Process [redacted] Republic of Korea	**Education**	Bachelor in Biomedical Laboratory Science	Bachelor in Clinical Pathology	Bachelor in Clinical Pathology
	Occupation	Senior Medical Laboratory Technician	Senior Medical Laboratory Technician	Medical Laboratory Technician
	Training and/ or Experience	12 years professional experience	7 years professional experience	5 years professional
CSS-1: (b)(4)Trade Secret Process [redacted] Republic of Korea		**Operator CSS1-O7**	**Operator CSS1-O8**	**Operator CSS1-O9**
	Education	Bachelor in Clinical Pathology	Bachelor in Clinical Pathology	Bachelor in Biomedical Laboratory Science
	Occupation	Medical Laboratory Technician	Medical Laboratory Technician	Medical Laboratory Technician
	Training and/ or Experience	5 years professional experience	2 years professional experience	4 years professional experience
CSS-2: (b)(4)Trade Secret Process [redacted] Republic of Korea		**Operator CSS2-O4**	**Operator SS2-O5**	**Operator CSS2-O6**
	Education	Bachelor in Clinical Pathology	Bachelor in Clinical Pathology	Bachelor in Biomedical Laboratory Science
	Occupation	Medical Laboratory Technician	Medical Laboratory Technician	Medical Laboratory Technician
	Training and/ or Experience	6 years professional experience	2 years professional experience	5 years professional experience
CSS-3: (b)(4)Trade Secret Process [redacted]J, USA		**Operator CSS3-O4**	--	--
	Education	Bachelor Degree	--	--
	Occupation	Medical Technician	--	--
	Training and/or Experience	ASCP certification with five years professional experience	--	--

Sample selection, collection/sampling, shipping and storage:

- The study was performed on clinical fecal samples of individuals who had already been screened with colonoscopy in recent past.
- At the two Korean study sites i.e. CSS-1 and CSS-2, fecal samples were obtained from individuals who had been screened with colonoscopy during last two years as a part of the annual colorectal cancer checkup program offered by **N**ational **H**ealth **I**nsurance **S**ervice (www.nhis.or.kr) of the Korean Government.
- At the US study site i.e. CSS-3 also, fecal samples were obtained from individuals who had already been screened with colonoscopy/biopsy as per knowledge of administration of the testing site.
- Fecal samples of individuals meeting following criteria were used for the method comparison study.
    - Individuals (males and females) above 50 years of age
    - High-risk individuals (subjects with positive diagnoses i.e. diagnosed with ulcerative colitis, Crohn's disease, rectal adenomas/adenomatous polyps, Gardner syndrome, colorectal cancer etc.)
    - Asymptomatic individuals (subjects with negative diagnoses i.e. individuals without any of the above clinical conditions)
- However following categories of fecal samples were excluded from amongst the fecal samples meeting the above-mentioned inclusion criteria:
    - Fecal samples of patients suffering from bleeding hemorrhoids.
    - Fecal samples of patients suffering from constipation bleeding.
    - Fecal samples of patients suffering from urinary bleeding.
- Fecal samples of individuals meeting the above selection criteria were obtained with the assistance from the testing sites.
- In some cases, fecal samples were obtained from the individuals in specimen cups which were submitted to the respective testing sites on the same day within 6 hours after collection.
- From each sample submitted in specimen cup, sampling was done in '*i*-CHROMA iFOB Sample Collection Tube' as well as 'OC Auto Sample Bottle' immediately after receiving the sample at the testing site.
- In some cases, '*i*-CHROMA iFOB Sample Collection Tube' and 'OC Auto Micro Sample Collection Tube' were provided to the concerned individual for sampling at home and arrangements were made such that these sample collection devices were received at the respective testing sites on the same day on which sampling was done.
- Fecal samples consecutively received by respective testing site were code-numbered.
- Demographic details of the patient corresponding to each code-numbered sample were also noted separately in confidential records immediately upon receipt of the sample at the testing sites.

- After record-entry, the samples were stored in low temperature conditions (2~8 ºC) till the tests were performed.
- *i*-CHROMA iFOB testing was mostly performed on the same day on which the sample(s) was received at the testing site.
- OC Auto Micro FOB testing was performed at intervals of 1- 4 days after sampling so as to accumulate adequate number of sample bottles for filling the analyzer rack.
- It was ensured that the time interval between sample collection/sampling and sample testing as well as the shipping, handling, storage, and testing conditions were in accordance with the allowable/permissible conditions keeping in mind the stability of human fecal samples as well as performance of both test systems.

Clinical testing methodology:

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Testing and quality control procedure:

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Statistical analysis of study results:

(b)(4)Trade Secret Process

[redacted]

Performance criteria:

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Table VI.3.D: Results of clinical method comparison study of *i*-CHROMA iFOB

Study Site CSS-1: (b)(4)Trade Secret Process [redacted], South Korea

Study Period: January 6, 2014 – February 14, 2014 ***i*-CHROMA iFOB Lot No.:** FOYKA10

Manufacturing Date: November 7, 2013 **Expiry Date:** July 7, 2015

***i*-CHROMA iFOB Lot No.:** PFR13K293714 **Operator CSS1-O1:** (b)(4)Trade [redacted]

Operator CSS1-O2: (b)(4)Trade [redacted] **Operator CSS1-O3:** (b)(4)Trade Secret

OC Auto Micro FOB Lot No.: 38838 **Expiry Date:** February 2015

Serial Number of Testing	*i*-CHROMA iFOB Test Operator	Clinical Sample Code Number	Colonoscopic /Clinical Status of the Test Sample	*i*-CHROMA iFOB Test Result	OC Auto Micro FOB Test Result	
					Qualitative Test Result	Quantitative Test Result (ng/mL)
01	**Operator CSS1-O1**	**CSS1-001**	Positive	Positive	Positive	951
02		**CSS1-002**	Positive	Positive	Positive	253
03		**CSS1-003**	Negative	Negative	Negative	18
04		**CSS1-004**	Negative	Negative	Negative	91
05		**CSS1-005**	Positive	Positive	Positive	174
06		**CSS1-006**	Positive	Positive	Positive	491
07		**CSS1-007**	Negative	Negative	Negative	84
08		**CSS1-008**	Negative	Negative	Negative	45
09		**CSS1-009**	Positive	Positive	Positive	136
10		**CSS1-010**	Negative	Negative	Negative	65
11		**CSS1-011**	Positive	Positive	Positive	651
12		**CSS1-012**	Positive	Positive	Positive	332
13		**CSS1-013**	Negative	Negative	Negative	40
14		**CSS1-014**	Negative	Negative	Negative	75
15		**CSS1-015**	Positive	Positive	Positive	285
16		**CSS1-016**	Negative	Negative	Negative	19
17		**CSS1-017**	Positive	Positive	Positive	102
18		**CSS1-018**	Negative	Negative	Negative	79
19		**CSS1-019**	Negative	Positive	Negative	94
20		**CSS1-020**	Negative	Negative	Negative	38
21		**CSS1-021**	Negative	Negative	Negative	58
22		**CSS1-022**	Positive	Positive	Positive	711
23		**CSS1-023**	Negative	Negative	Negative	65
24		**CSS1-024**	Positive	Positive	Positive	140
25		**CSS1-025**	Negative	Negative	Negative	37
26		**CSS1-026**	Positive	Positive	Positive	251
27		**CSS1-027**	Negative	Negative	Negative	77
28		**CSS1-028**	Positive	Positive	Positive	373
29		**CSS1-029**	Negative	Negative	Negative	65
30		**CSS1-030**	Negative	Negative	Negative	71
31		**CSS1-031**	Negative	Negative	Negative	41
32		**CSS1-032**	Positive	Positive	Positive	185

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***Continued* Table VI.3.D:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-1: (b)(4)Trade Secret Process [redacted], South Korea						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
33	**Operator CSS1-O1**	**CSS1-033**	Negative	Negative	Negative	43
34		**CSS1-034**	Negative	Negative	Negative	94
35		**CSS1-035**	Negative	Negative	Negative	54
36		**CSS1-036**	Positive	Positive	Positive	877
37		**CSS1-037**	Positive	Positive	Positive	384
38		**CSS1-038**	Negative	Negative	Negative	38
39		**CSS1-039**	Negative	Negative	Negative	11
40	**Operator CSS1-O2**	**CSS1-040**	Positive	Positive	Positive	1002
41		**CSS1-041**	Positive	Positive	Positive	123
42		**CSS1-042**	Negative	Negative	Negative	60
43		**CSS1-043**	Positive	Positive	Positive	863
44		**CSS1-044**	Negative	Negative	Negative	75
45		**CSS1-045**	Negative	Negative	Negative	32
46		**CSS1-046**	Positive	Positive	Positive	252
47		**CSS1-047**	Negative	Negative	Negative	67
48		**CSS1-048**	Positive	Positive	Positive	561
49		**CSS1-049**	Negative	Negative	Negative	76
50		**CSS1-050**	Positive	Positive	Positive	433
51		**CSS1-051**	Negative	Negative	Negative	64
52		**CSS1-052**	Positive	Positive	Positive	843
53		**CSS1-053**	Positive	Positive	Positive	473
54		**CSS1-054**	Negative	Negative	Negative	49
55		**CSS1-055**	Negative	Negative	Negative	34
56		**CSS1-056**	Positive	Positive	Positive	585
57		**CSS1-057**	Positive	Positive	Positive	217
58		**CSS1-058**	Negative	Negative	Negative	85
59		**CSS1-059**	Negative	Negative	Negative	54
60		**CSS1-060**	Positive	Positive	Positive	130
61		**CSS1-061**	Negative	Negative	Negative	41
62		**CSS1-062**	Positive	Positive	Positive	114
63		**CSS1-063**	Negative	Negative	Negative	81
64		**CSS1-064**	Positive	Positive	Positive	158
65		**CSS1-065**	Negative	Negative	Negative	20
66		**CSS1-066**	Negative	Negative	Negative	43
67		**CSS1-067**	Positive	Positive	Positive	914
68		**CSS1-068**	Negative	Negative	Negative	50

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***Continued* Table VI.3.D:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-1: (b)(4)Trade Secret Process [redacted], South Korea						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
69	**Operator CSS1-O2**	**CSS1-069**	Negative	Negative	Negative	74
70		**CSS1-070**	Negative	Negative	Negative	39
71		**CSS1-071**	Positive	Positive	Positive	127
72		**CSS1-072**	Negative	Negative	Negative	83
73		**CSS1-073**	Negative	Negative	Negative	79
74		**CSS1-074**	Negative	Negative	Negative	94
75		**CSS1-075**	Positive	Positive	Positive	484
76		**CSS1-076**	Positive	Positive	Positive	149
77		**CSS1-077**	Negative	Negative	Negative	31
78		**CSS1-078**	Positive	Positive	Positive	676
79		**CSS1-079**	Positive	Positive	Positive	199
80		**CSS1-080**	Positive	Positive	Positive	702
81		**CSS1-081**	Negative	Negative	Negative	33
82		**CSS1-082**	Positive	Positive	Positive	253
83		**CSS1-083**	Negative	Negative	Negative	63
84	**Operator CSS1-O3**	**CSS1-084**	Positive	Positive	Positive	258
85		**CSS1-085**	Positive	Positive	Positive	396
86		**CSS1-086**	Negative	Negative	Negative	27
87		**CSS1-087**	Negative	Negative	Negative	35
88		**CSS1-088**	Positive	Positive	Positive	907
89		**CSS1-089**	Negative	Negative	Negative	23
90		**CSS1-090**	Negative	Negative	Negative	20
91		**CSS1-091**	Positive	Positive	Positive	478
92		**CSS1-092**	Positive	Positive	Positive	518
93		**CSS1-093**	Positive	Positive	Positive	439
94		**CSS1-094**	Negative	Negative	Negative	40
95		**CSS1-095**	Positive	Positive	Positive	419
96		**CSS1-096**	Negative	Negative	Negative	41
97		**CSS1-097**	Positive	Positive	Positive	233
98		**CSS1-098**	Negative	Negative	Negative	26
99		**CSS1-099**	Negative	Negative	Negative	22
100		**CSS1-100**	Negative	Negative	Negative	27
101		**CSS1-101**	Positive	Positive	Positive	117
102		**CSS1-102**	Positive	Positive	Positive	103
103		**CSS1-103**	Negative	Negative	Negative	72
104		**CSS1-104**	Positive	Positive	Positive	818

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***Continued* Table VI.3.D:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-1: (b)(4)Trade Secret Process [redacted] South Korea						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
105	**Operator CSS1-O3**	**CSS1-105**	Negative	Negative	Negative	64
106		**CSS1-106**	Negative	Negative	Negative	38
107		**CSS1-107**	Positive	Positive	Positive	218
108		**CSS1-108**	Positive	Positive	Positive	118
109		**CSS1-109**	Negative	Negative	Negative	49
110		**CSS1-110**	Negative	Negative	Negative	40
111		**CSS1-111**	Positive	Positive	Positive	428
112		**CSS1-112**	Negative	Negative	Positive	108
113		**CSS1-113**	Positive	Positive	Positive	742
114		**CSS1-114**	Positive	Positive	Positive	512
115		**CSS1-115**	Positive	Positive	Positive	846
116		**CSS1-116**	Negative	Negative	Negative	63
117		**CSS1-117**	Negative	Negative	Negative	14

Table VI.3.E: Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-2: (b)(4)Trade Secret Process [redacted] South Korea						
Study Period: January 8 2014 – February 20, 2014 ***i*-CHROMA iFOB Lot No.:** FOYKA10 **Manufacturing Date:** November 7, 2013 **Expiry Date:** July 7, 2015 ***i*-CHROMA iFOB Lot No** PFR13K293712 **Operator CSS2-O1:** (b)(4)Trade [redacted] **Operator CSS2-O2:** (b)(4)Trade Secret [redacted] **Operator CSS2-O3:** (b)(4)Trade Secret [redacted] **OC Auto Micro FOB Lot No.:** 38838 **Expiry Date:** February 2015						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
01	**Operator CSS2-O1**	**CSS2-001**	Negative	Negative	Negative	24
02		**CSS2-002**	Positive	Positive	Positive	845
03		**CSS2-003**	Negative	Negative	Negative	67
04		**CSS2-004**	Positive	Positive	Positive	296
05		**CSS2-005**	Positive	Positive	Positive	466
06		**CSS2-006**	Negative	Negative	Negative	74
07		**CSS2-007**	Positive	Positive	Positive	913
08		**CSS2-008**	Negative	Negative	Negative	54
09		**CSS2-009**	Positive	Positive	Positive	132

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***Continued* Table VI.3.E:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-2: (b)(4)Trade Secret Process [redacted], South Korea						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
10	**Operator CSS2-O1**	**CSS2-010**	Negative	Negative	Negative	45
11		**CSS2-011**	Negative	Positive	Negative	97
12		**CSS2-012**	Positive	Positive	Positive	185
13		**CSS2-013**	Positive	Positive	Positive	644
14		**CSS2-014**	Negative	Negative	Negative	87
15		**CSS2-015**	Positive	Positive	Positive	795
16		**CSS3-016**	Negative	Negative	Negative	43
17		**CSS2-017**	Negative	Negative	Negative	54
18		**CSS2-018**	Negative	Negative	Negative	65
19		**CSS2-019**	Positive	Positive	Positive	885
20		**CSS2-020**	Negative	Negative	Negative	56
21		**CSS2-021**	Negative	Negative	Negative	21
22		**CSS2-022**	Positive	Positive	Positive	295
23		**CSS2-023**	Positive	Positive	Positive	174
24		**CSS2-024**	Negative	Negative	Negative	84
25		**CSS2-025**	Negative	Negative	Negative	46
26		**CSS2-026**	Positive	Positive	Positive	159
27		**CSS2-027**	Negative	Negative	Negative	54
28		**CSS2-028**	Positive	Positive	Positive	216
29		**CSS2-029**	Negative	Negative	Negative	68
30		**CSS2-030**	Negative	Negative	Negative	63
31		**CSS2-031**	Positive	Positive	Positive	107
32		**CSS2-032**	Positive	Positive	Positive	165
33		**CSS2-033**	Negative	Negative	Negative	85
34		**CSS2-034**	Negative	Negative	Negative	99
35		**CSS2-035**	Positive	Positive	Positive	654
36		**CSS2-036**	Negative	Negative	Negative	46
37		**CSS2-037**	Positive	Positive	Positive	158
38		**CSS2-038**	Positive	Positive	Positive	387
39		**CSS2-039**	Negative	Negative	Negative	42
40		**CSS2-040**	Positive	Positive	Positive	495
41		**CSS2-041**	Negative	Negative	Negative	18
42		**CSS2-042**	Positive	Positive	Positive	167
43	**Operator CSS2-O2**	**CSS2-043**	Negative	Negative	Negative	38
44		**CSS2-044**	Positive	Positive	Positive	879
45		**CSS2-045**	Positive	Positive	Positive	694

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***Continued* Table VI.3.E:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-2: (b)(4)Trade Secret Process [redacted], South Korea						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
46	**Operator CSS2-O2**	**CSS2-046**	Negative	Negative	Negative	57
47		**CSS2-047**	Positive	Positive	Positive	916
48		**CSS2-048**	Negative	Negative	Negative	97
49		**CSS2-049**	Negative	Negative	Negative	39
50		**CSS2-050**	Positive	Positive	Positive	1077
51		**CSS2-051**	Negative	Negative	Negative	87
52		**CSS2-052**	Positive	Positive	Positive	954
53		**CSS2-053**	Negative	Negative	Negative	45
54		**CSS2-054**	Positive	Positive	Positive	145
55		**CSS2-055**	Positive	Positive	Positive	684
56		**CSS2-056**	Positive	Positive	Positive	439
57		**CSS2-057**	Negative	Negative	Negative	82
58		**CSS2-058**	Positive	Positive	Positive	124
59		**CSS2-059**	Negative	Positive	Negative	96
60		**CSS2-060**	Positive	Positive	Positive	111
61		**CSS2-061**	Positive	Positive	Positive	247
62		**CSS2-062**	Negative	Negative	Negative	68
63		**CSS2-063**	Negative	Negative	Negative	43
64		**CSS2-064**	Negative	Negative	Negative	38
65		**CSS2-065**	Positive	Positive	Positive	846
66		**CSS2-066**	Positive	Positive	Positive	315
67		**CSS2-067**	Positive	Negative	Positive	108
68		**CSS2-068**	Negative	Negative	Negative	28
69		**CSS2-069**	Positive	Positive	Positive	943
70		**CSS2-070**	Negative	Negative	Negative	16
71		**CSS2-071**	Positive	Positive	Positive	154
72		**CSS2-072**	Negative	Negative	Negative	75
73		**CSS2-073**	Negative	Negative	Negative	83
74		**CSS2-074**	Positive	Positive	Positive	862
75		**CSS2-075**	Negative	Negative	Negative	72
76		**CSS2-076**	Positive	Positive	Positive	533
77		**CSS2-077**	Negative	Negative	Negative	66
78		**CSS2-078**	Negative	Negative	Negative	46
79		**CSS2-079**	Positive	Positive	Positive	617
80	**Operator CSS2-O3**	**CSS2-080**	Negative	Negative	Negative	91
81		**CSS2-081**	Negative	Negative	Negative	36

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***Continued* Table VI.3.E:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-2: (b)(4)Trade Secret Process [redacted], South Korea						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
82	**Operator CSS2-O3**	**CSS2-082**	Positive	Positive	Positive	249
83		**CSS2-083**	Negative	Negative	Negative	78
84		**CSS2-084**	Positive	Positive	Positive	173
85		**CSS2-085**	Negative	Negative	Negative	64
86		**CSS2-086**	Negative	Negative	Negative	17
87		**CSS2-087**	Positive	Positive	Positive	244
88		**CSS2-088**	Negative	Negative	Negative	94
89		**CSS2-089**	Positive	Positive	Positive	394
90		**CSS2-090**	Negative	Negative	Negative	58
91		**CSS2-091**	Negative	Negative	Negative	61
92		**CSS2-092**	Positive	Positive	Positive	421
93		**CSS2-093**	Positive	Positive	Positive	264
94		**CSS2-094**	Negative	Negative	Negative	72
95		**CSS2-095**	Negative	Negative	Negative	91
96		**CSS2-096**	Negative	Negative	Negative	34
97		**CSS2-097**	Positive	Positive	Positive	139
98		**CSS2-098**	Positive	Positive	Positive	711
99		**CSS2-099**	Negative	Negative	Negative	16
100		**CSS2-100**	Positive	Positive	Positive	976
101		**CSS2-101**	Negative	Negative	Negative	82
102		**CSS2-102**	Negative	Negative	Negative	42
103		**CSS2-103**	Positive	Positive	Positive	841
104		**CSS2-104**	Positive	Positive	Positive	146
105		**CSS2-105**	Negative	Negative	Negative	91
106		**CSS2-106**	Positive	Positive	Positive	290
107		**CSS2-107**	Negative	Negative	Negative	67
108		**CSS2-108**	Negative	Negative	Negative	84
109		**CSS2-109**	Negative	Negative	Negative	77
110		**CSS2-110**	Positive	Positive	Positive	167
111		**CSS2-111**	Negative	Negative	Negative	28
112		**CSS2-112**	Negative	Negative	Negative	94
113		**CSS2-113**	Positive	Positive	Positive	529
114		**CSS2-114**	Negative	Negative	Negative	56
115		**CSS2-115**	Positive	Positive	Positive	876
116		**CSS2-116**	Positive	Positive	Positive	599
117		**CSS2-117**	Positive	Positive	Positive	758

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***Continued* Table VI.3.E:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-2: (b)(4)Trade Secret Process [redacted], South Korea						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
118	**Operator CSS2-O3**	**CSS2-118**	Negative	Negative	Negative	43
119		**CSS2-119**	Negative	Negative	Negative	56
120		**CSS2-120**	Positive	Positive	Positive	852
121		**CSS2-121**	Positive	Positive	Positive	285
122		**CSS2-122**	Negative	Negative	Negative	40
123		**CSS2-123**	Negative	Negative	Negative	64

Table VI.3.F: Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-3: Manhattan Labs , Pine Brook, NJ, USA						
Study Period: January 13, 2014 – January 31, 2014 ***i*-CHROMA iFOB Lot No.:** FOYKA10 **Manufacturing Date:** November 19, 2013 **Expiry Date:** July 19, 2015 ***i*-CHROMA iFOB Lot No.:** PFR13J183123 **Operator CSS3-O1:** C. Bolkar **Operator CSS3-O2:** D. Allegrino **Operator CSS3-O3:** J. Mahoney **OC Auto Micro FOB Lot No.:** 29209 **Expiry Date:** March 2014						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
01	**Operator CSS3-O1**	**1**	Positive	Positive	Positive	136
02		**2**	Positive	Positive	Positive	191
03		**3**	Negative	Negative	Negative	33
04		**4**	Negative	Negative	Negative	54
05		**5**	Positive	Positive	Positive	879
06		**6**	Negative	Negative	Negative	43
07		**7**	Negative	Negative	Negative	28
08		**8**	Negative	Negative	Negative	22
09		**9**	Negative	Negative	Negative	30
10		**10**	Positive	Positive	Positive	108
11		**11**	Negative	Negative	Negative	68
12		**12**	Negative	Negative	Negative	78
13		**13**	Positive	Positive	Positive	875
14		**14**	Positive	Positive	Positive	646
15		**15**	Negative	Negative	Negative	82
16		**16**	Negative	Negative	Negative	29

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***Continued* Table VI.3.F:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-3: (b)(4)Trade Secret Process USA						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
17	**Operator CSS3-O1**	**17**	Positive	Positive	Positive	282
18		**18**	Positive	Positive	Positive	845
19		**19**	Negative	Negative	Negative	94
20		**20**	Negative	Negative	Negative	68
21		**21**	Positive	Positive	Positive	564
22		**22**	Negative	Negative	Negative	75
23		**23**	Positive	Positive	Positive	242
24		**24**	Negative	Negative	Negative	48
25		**25**	Negative	Negative	Negative	43
26		**26**	Positive	Positive	Positive	118
27		**27**	Negative	Negative	Negative	56
28	**Operator CSS3-O2**	**28**	Positive	Positive	Positive	554
29		**29**	Negative	Negative	Negative	44
30		**30**	Negative	Negative	Negative	39
31		**31**	Negative	Negative	Negative	22
32		**32**	Negative	Negative	Negative	98
33		**33**	Negative	Negative	Negative	74
34		**34**	Negative	Negative	Negative	46
35		**35**	Positive	Positive	Positive	414
36		**36**	Negative	Negative	Negative	16
37		**37**	Negative	Negative	Negative	49
38		**38**	Positive	Positive	Positive	119
39		**39**	Negative	Negative	Negative	87
40		**40**	Negative	Negative	Negative	16
41		**41**	Positive	Positive	Positive	168
42		**42**	Negative	Negative	Negative	79
43		**43**	Positive	Positive	Positive	246
44		**44**	Negative	Negative	Negative	49
45		**45**	Positive	Positive	Positive	546
46		**46**	Positive	Positive	Positive	654
47		**47**	Negative	Negative	Negative	58
48		**48**	Negative	Negative	Negative	92
49		**49**	Negative	Negative	Negative	11
50		**50**	Positive	Positive	Positive	886
51		**51**	Negative	Negative	Negative	38
52		**52**	Negative	Negative	Negative	85

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***Continued* Table VI.3.F:** Results of clinical method comparison study of *i*-CHROMA iFOB						
Study Site CSS-3: (b)(4)Trade Secret Process USA						
Serial Number of Testing	***i*-CHROMA iFOB Test Operator**	**Clinical Sample Code Number**	**Colonoscopic /Clinical Status of the Test Sample**	***i*-CHROMA iFOB Test Result**	**OC Auto Micro FOB Test Result**	
					Qualitative Test Result	**Quantitative Test Result** (ng/mL)
53	**Operator CSS3-O2**	**53**	Positive	Positive	Positive	562
54		**54**	Negative	Negative	Negative	95
55		**55**	Negative	Positive	Negative	98
56		**56**	Positive	Positive	Positive	1026
57		**57**	Negative	Negative	Negative	78
58		**58**	Negative	Negative	Negative	53
59		**59**	Positive	Positive	Positive	213
60		**60**	Negative	Negative	Negative	24
61		**61**	Negative	Negative	Negative	96
62		**62**	Positive	Positive	Positive	298
63		**63**	Positive	Positive	Positive	946
64	**Operator CSS3-O3**	**64**	Negative	Negative	Negative	72
65		**65**	Positive	Positive	Positive	735
66		**66**	Positive	Positive	Positive	111
67		**67**	Positive	Positive	Positive	213
68		**68**	Negative	Negative	Negative	66
69		**69**	Positive	Positive	Positive	857
70		**70**	Negative	Negative	Negative	49
71		**71**	Negative	Negative	Negative	67
72		**72**	Negative	Negative	Negative	53
73		**73**	Positive	Positive	Positive	165
74		**74**	Positive	Positive	Positive	415
75		**75**	Negative	Negative	Negative	81
76		**76**	Negative	Negative	Negative	52
77		**77**	Positive	Positive	Positive	120
78		**78**	Negative	Negative	Negative	35
79		**79**	Negative	Negative	Negative	49
80		**80**	Negative	Negative	Negative	58
81		**81**	Positive	Positive	Positive	258
82		**82**	Positive	Positive	Positive	835
83		**83**	Negative	Negative	Negative	25

Table VI.3.G: Site-wise and operator-wise number of clinical fecal samples tested during clinical method comparison study of *i*-CHROMA iFOB

Study Site	Operator-wise number of clinical fecal samples tested											
	Operator 1			Operator 2			Operator 3			Operator 1+2+3		
	Positive	Negative	Total	Positive	Negative	Total	Positive	Negative	Total	Positive	Negative	Total
CSS-1: [redacted] b [redacted] Republic of Korea	16	23	**39**	21	23	**44**	18	16	**34**	55	62	**117**
CSS-2: (b)(4)Trade Secret Process [redacted], Republic of Korea	20	22	**42**	19	18	**37**	19	25	**44**	58	65	**123**
CSS-3: (b)(4)Trade Secret Process [redacted] USA	11	16	**27**	13	23	**36**	09	11	**20**	33	50	**83**
									Total	**146**	**177**	**323**

Table VI.3.H: Statistical analysis of clinical method comparison study of *i*-CHROMA iFOB

Study site	Waiver Method (WM)	Comparative Method (CM)			Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
		OC Auto Micro FOB					
	i-CHROMA iFOB	Positive Results	Negative Results	Total Results			
CSS-1	**Positive Results**	**54**	01	55	**98.29%**	**98.18%** (90.40% - 99.68%)	**98.39%** (91.41% - 99.72%)
	Negative Results	01	**61**	62			
	Total Results	**55**	**62**	**117**			
CSS-2	**Positive Results**	**57**	02	59	**97.56%**	**98.3%** (90.86% - 99.70%)	**96.9%** (89.46% - 99.15%)
	Negative Results	01	**63**	64			
	Total Results	**58**	**65**	**123**			
CSS-3	**Positive Results**	**33**	01	34	**98.79%**	**100%** (89.58% - 100%)	**98.00%** (89.51% - 99.65%)
	Negative Results	00	**49**	49			
	Total Results	**33**	**50**	**83**			
CSS-1+CSS-2 +CSS-3	**Positive Results**	**144**	04	148	**98.14%**	**98.63%** (94.14% - 99.62%)	**97.74%** (94.33% - 99.12%)
	Negative Results	02	**173**	175			
	Total Results	**146**	**177**	**323**			

Results of VI.3.2 Determination of performance of *i*-CHROMA iFOB at analyte concentrations near the cutoff:

- Site-wise as well as combined information regarding the percent of the positive and negative results obtained with 60 aliquots of the weak positive sample and 60 aliquots of the weak negative sample tested by *i*-CHROMA iFOB have been shown in **Table VI.3.I**
- No invalid or indeterminate result was obtained in this part of the study.

Table VI.3.I: *i*-CHROMA iFOB Test Results of 60 aliquots of the Weak Positive Sample and 60 aliqouts of the Weak Negative Sample tested at each study site of clinical method comparison study of *i*-CHROMA iFOB

Number and Name of Testing Site	Operator	Number of Aliquots Tested		*i*-CHROMA iFOB (WM) Test Results			
				Aliquots of the Weak Positive Sample		Aliquots of the Weak Negative Samples	
		Aliquots of Weak Positive Sample	Aliquots of Weak Negative Sample	True Positive Results	False Negative Results	True Negative Results	False Positive Results
CSS-1 (b)(4)Trade Secret Process [redacted] Republic of Korea	Operator CSS1-O1	20	20	20	00	20	00
	Operator CSS1-O2	20	20	19	01	20	00
	Operator CSS1-O3	20	20	19	01	19	01
	Total	**60**	**60**	**58 (96.66%)**	**02 (3.33%)**	**59 (98.33%)**	**01 (1.66%)**
CSS-2 (b)(4)Trade Secret Process [redacted] Republic of Korea	Operator CSS2-O1	20	20	19	01	18	02
	Operator CSS2-O2	20	20	18	02	20	00
	Operator CSS2-O3	20	20	20	00	20	00
	Total	**60**	**60**	**57 (95%)**	**03 (5%)**	**58 (96.66%)**	**02 (3.33%)**
CSS-3 (b)(4)Trade Secret [redacted] USA	Operator CSS3-O1	20	20	20	00	19	01
	Operator CSS3-O2	20	20	20	00	20	00
	Operator CSS3-O3	20	20	19	01	18	02
	Total	**60**	**60**	**59 (98.33%)**	**01 (1.66%)**	**57 (95%)**	**03 (5%)**
Testing Sites CSS-1 + CSS-2 + CSS-3	**Grand Total**	**180**	**180**	**174 (96.66%)**	**06 (3.33%)**	**174 (96.66%)**	**06 (3.33%)**

- Site-wise as well as combined estimates of percent of positive results (obtained with aliquots of the weak positive sample) and percent of negative results (obtained with aliquots of the weak negative sample) along with respective two-sided 95% confidence intervals have been shown in **Table VI.3.J**.

Table VI.3.J: Site-wise as well as combined estimates of percent of positive results (obtained with aliquots of the weak positive sample) and percent of negative results (obtained with aliquots of the weak negative sample) along with respective two-sided 95% confidence intervals tested with *i*-CHROMA iFOB				
Type of Weak Sample Tested by *i*-CHROMA iFOB	**Percent of positive and negative Results (along with 95% confidence intervals) obtained with *i*-CHROMA iFOB**			
	Site CSS-1 (b)(4)Trade Secret Process [redacted] Republic of Korea	**Site CSS-2** (b)(4)Trade Secret Process [redacted] Republic of Korea	**Site CSS-3** (b)(4)Trade Secret Process [redacted] USA	**Site CSS-1 + Site CSS-2 + Site CSS-3**
60 Aliquots of Weak Positive Sample	**96.67%** (88.64%-99.08%)	**95%** (86.30%-98.29%)	**98.33%** (91.15%-99.71%)	**96.67%** (92.92%-98.46%)
60 Aliquots of Weak Negative Sample	**98.33%** (91.15%-99.71%)	**96.67%** (88.64%-99.08%)	**95%** (86.30%-98.29%)	**96.67%** (92.92%-98.46%)

- The differences in percent of positive results (for the weak positive sample) among the three sites and also the differences in percent of negative results (for the weak negative sample) among the three testing sites were not found to be statistically significant at alpha = 0.05.

Operators' Feedback:

- In order to evaluate the simplicity of *i*-CHROMA iFOB test as a whole and ease of operation of *i*-CHROMA Reader in particular and also to evaluate the ease of understanding the proposed instructional material of *i*-CHROMA iFOB, a questionnaire containing multiple choice questions related to above aspects of the test, was given to each operator participated in the clinical method comparison study of *i*-CHROMA iFOB.
- Feedback was obtained from each operator after completion of his/her role in the study.
- Test operators who participated in the clinical study conducted at the two Korean sites (Study Site No.CSS-1 & CSS-2) were provided with Korean language version of the questionnaire while operators at the USA site (Study Site No. CSS-3) were provided with proper English draft of the same.
- Content of the operator questionnaire as well as site-wise/operator-wise and combined feedback have been shown in **Table VI.3.K**.

Table VI.3.K: Content of the operator questionnaire as well as site-wise/operator-wise and combined feedback obtained from test operators participated in the clinical method comparison study of *i*-CHROMA iFOB

Que. No.	Question with Options	Clinical Study Sites			Combined Responses
		Site CSS-1	Site CSS-2	Site CSS-3	
		3 Operators	3 Operators	3 Operators	9 Operators
1	**How it was to understand the test instructions.**				
a	Very easy	02	03	03	**08**
b	Easy	01	00	00	**01**
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
2	**How it was to follow the test instructions.**				
a	Very easy	02	03	03	**08**
b	Easy	01	00	00	**01**
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
3	**How it was to apply the fecal sample mixture into 'sample well' of the test cartridge correctly.**				
a	Very easy	03	03	03	**09**
b	Easy	--	--	--	--
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
4	**How it was to test the i-CHROMA iFOB external controls.**				
a	Very easy	01	02	02	**05**
b	Easy	02	01	01	**04**
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
5	**How it was to operate the *i*-CHROMA Reader.**				
a	Very easy	02	02	03	**07**
b	Easy	01	01	00	**02**
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--

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Continued **Table VI.3.K:** Content of the operator questionnaire as well as site-wise/ operator-wise and combined feedback obtained from test operators participated in the clinical method comparison study of *i*-CHROMA iFOB

Que. No.	Question with Options	Clinical Study Sites			Combined Responses
		Site CSS-1	Site CSS-2	Site CSS-3	
		3 Operators	3 Operators	3 Operators	9 Operators
6	**How it was to read/understand the normal procedural message alerts displayed by *i*-CHROMA Reader.**				
a	Very easy	03	03	03	**09**
b	Easy	--	--	--	--
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
7	**How it was to read and understand the test results displayed by *i*-CHROMA Reader.**				
a	Very easy	03	03	03	**09**
b	Easy	--	--	--	--
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
8	**How it was to read and understand the error message alerts; if any displayed by *i*-CHROMA Reader.**				
a	Very easy	--	--	--	--
b	Easy	--	--	--	--
c	Somewhat difficult	--	--	--	--
d	Difficult	--	--	--	--
e	Very difficult	--	--	--	--
f	I did not encounter any error message alert	03	03	03	**09**
9	**How it was to perform the overall testing process.**				
a	Very simple	01	02	02	**05**
b	Simple	02	01	01	**04**
c	Somewhat complex	--	--	--	--
d	Complex	--	--	--	--
e	Highly complex	--	--	--	--
10	**How the instructional material explains what to do if a test result is invalid?**				
a	Very clearly	02	02	03	**07**
b	Clearly	01	01	00	**02**
c	Ambiguously	--	--	--	--
d	Vaguely	--	--	--	--
e	Not at all	--	--	--	--

Continued from previous page:

Table VI.3.K: Content of the operator questionnaire as well as site-wise/operator-wise and combined feedback obtained from test operators participated in the clinical method comparison study of *i*-CHROMA iFOB

Que. No.	Question with Options	Clinical Study Sites			Combined Responses
		Site CSS-1	Site CSS-2	Site CSS-3	
		3 Operators	3 Operators	3 Operators	9 Operators
11	**How the instructional material explains what to do if any error message alert is displayed by the *i*-CHROMA Reader?**				
a	Very clearly	02	02	03	**07**
b	Clearly	01	01	00	**02**
c	Ambiguously	--	--	--	--
d	Vaguely	--	--	--	--
e	Not at all	--	--	--	--
12	**You could perform the test properly the first time after …..**				
a	Merely reading the instructional material	02	03	03	**08**
b	Reading the instructional material as well as contacting the technical assistance services of the manufacturer	01	00	00	**01**
c	Discussing the test with other test operator(s)	--	--	--	--
d	Taking help from other test operator(s)	--	--	--	--

Conclusion:

- Considering the acceptance/performance criteria, results of the clinical testing study establish the accuracy of *i*-CHROMA iFOB as a qualitative in-vitro diagnostic fecal occult blood test for its proposed use in clinical settings.

VI.4 Labeling/Instructional material consistent with simple feature of *i*-CHROMA iFOB:

Labels of various components of *i*-CHROMA iFOB test system have been outlined in 'Section 13: Proposed Labelling'.

Appropriate instructional materials consistent with the proposed 'CLIA Waiver' application of *i*-CHROMA iFOB test system, have been included in Appendix II – V as per following details:

Appendix II: *i*-CHROMA iFOB Test Package Insert

Appendix III: *i*-CHROMA iFOB Test Quick Reference Instructions (QRI)

Appendix IV: *i*-CHROMA iFOB Control Package Insert

Appendix V: *i*-CHROMA Reader Operational Manual