Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K062187 - 827 pages
COMPANY:	NATIONAL DIAGNOSTIC PRODUCTS (NATIDIAGPROD)
PRODUCT:	SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER (NBW)
SUMMARY:	Product: BETACHEK GLUCOSE TEST
DATE REQUESTED:	Sep 6, 2016
DATE PRINTED:	Sep 6, 2016
Note:	Printed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

MAR 2 4 2009

510(k) Summary k062187

a) According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1. Submitter's Name: National Diagnostic Products (Aust) Pty Ltd

Address:	22/39 Herbert Street, St.Leonards NSW 2065, Australia
Phone:	+61 2 94328100
Fax:	+61 2 94361151
Contact Person:	Brandon Bransgrove
Date Prepared:	March 24, 2009

2.

Device Name:	Betachek Blood Glucose Test
Proprietary/Trade name:	Betachek Blood Glucose Test
Common Name:	Glucose Test System
Classification Name:	Glucose Test System
Device Classification:	II
Regulation Number:	21 CFR 862.1345
Classification Panel:	Clinical Chemistry (75)
Product Code:	CGA (Glucose Oxidase, Glucose)

3.

Predicate Device Name:	Chemcard Glucose Test
Manufacturer:	CHEM-ELEC, INC
510 (K) Number:	K943503

4. Description of the Device
Reagent test principle – glucose oxidase

5. Intended Use

Betachek Blood Glucose Test is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

Any abnormal results should be verified by a medical professional, such as a physician, and confirmed with a quantitative, laboratory reference method. Only a trained medical professional can determine if an individual has diabetes. A test result within the normal range does not exclude the possibility that the individual has diabetes or pre-diabetes. Any individual who is concerned that he or she may have diabetes or pre-diabetes should seek the advice of a physician.
Betachek Blood Glucose Test is not intended to be used for children or by individuals who are diabetic or pregnant.

This test can not be used to screen or diagnose diabetes.
It should not be used for children or by individuals who are diabetic or pregnant.
This test is only intended for individual use at home.
It is not for use as part of a screening program in a healthcare setting or any other setting.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6. Substantial Equivalence

Similarities		
Item	**Device**	**Predicate**
	Betachek Blood Glucose Test	**Chemcard Glucose Test**
Detection Method	Enzyme linked colour change	Enzyme linked colour change
Sample	Finger stick blood sample	Finger stick blood sample
Sample Volume	1 drop (no sample premeasurement)	1 drop (no sample premeasurement)
Enzyme 1	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Enzyme 2	Peroxidase	Peroxidase
Dye	TMB, APAC, DCP	TMB
Instrument required	No	No
Intended use	a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.	a semi-quantitative glucose test intended to be used by a person who has not been diagnosed as diabetic to measure his or her fasting glucose level in order to determine whether the fasting glucose level is abnormal
Operating Temperature	18 – 35° C	18 – 35° C
Test Range	50 mg/dL – 150 mg/dL	50 mg/dL – 150 mg/dL
Test Time	3 minute	3 minutes
Number of colour blocks	5	5

Differences		
Item	**Device**	**Predicate**
	Betachek Blood Glucose Test	**Chemcard Glucose Test**
Format	Test strip	Test Card
User steps	Blood wiped at 1 minute and result read after 3minutes.	Card Peeled at 3 minutes and result must read within 30 seconds.
Hematocrit Range	35% - 55%	Unknown

7. Performance Characteristics

Betachek Blood Glucose Test has the same intended use and technological characteristics as the predicate device and clinical evaluations demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Therefore, Betachek Blood Glucose Test is substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 24 2009

National Diagnostic Products
c/o Mr. Brandon Bransgrove
7-9 Merriwa Street, Gordon
Sydney, NSW, 2072
Australia

Re: k062187
Trade Name: Betachek Blood Glucose (Sugar) test
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: December 22, 2008
Received: December 24, 2008

Dear Mr. Bransgrove:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Indication for Use

510(k) Number: K062187

Device Name: BETACHEK BLOOD GLUCOSE (SUGAR) TEST

Indication For Use:

Betachek Blood Glucose (Sugar) is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

Any abnormal results should be verified by a medical professional, such as a physician, and confirmed with a quantitative, laboratory reference method. Only a trained medical professional can determine if an individual has diabetes. A test result within the normal range does not exclude the possibility that the individual has diabetes or pre-diabetes. Any individual who is concerned that he or she may have diabetes or pre-diabetes should seek the advice of a physician.

Betachek Blood Glucose Test is not intended to be used for children or by individuals who are diabetic or pregnant.

This test can not be used to screen or diagnose diabetes.
It should not be used for children or by individuals who are diabetic or pregnant.
This test is only intended for individual use at home.
It is not for use as part of a screening program in a healthcare setting or any other setting.

Prescription Use ____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ☑ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062187

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

April 22, 2009

National Diagnostic Products
c/o Brandon Stephen Bransgrove
7-9 Merriwa St. Gordon
Sydney, Australia 2072

Document No: k062187
Re: k062187
Received: August 7, 2006

Categorization Notification (Waived)

Regulations codified at 42 CFR 493.15 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test system or assay for the analyte is categorized below:

Test System/Analyte (s) : (SEE ATTACHMENT)

Waived status is applicable to test systems and their instructions approved by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for the evaluation of waiver. If you change the test system name or your company's name or if a distributor's name replaces your name, you must request another categorization by sending in the revised labeling along with a letter to FDA referencing the document number above.

This complexity categorization is effective as of the date of this notification and will be reported on FDA's home page http://www.fda.gov/cdrh/clia. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. It will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice.

If you have any questions regarding this complexity categorization, please contact Carol Benson at 240-276-0396.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

ATTACHMENT

Document Number : k062187

Test System: National Diagnostic Products Betachek Blood Glucose (Sugar) Test
Analyte : Whole Blood Qualitative Dipstick Glucose
Complexity : WAIVED

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

CLIA Routing Slip

Document No : k062187

Re : k062187

Division: DCTD
Branch: CHTB

Applicant: National Diagnostic Products
Trade Name: Betachek glucose test

DMC Date Received: August 7, 2006
Division Date Received: August 10, 2006

OTC Phone Number: (866) 475-0992

Categorization Information

CLIA Reviewer: Vicki Moyer [VYM]
Date Review Completed: April 17, 2009

Date Branch Concurred: 4-22-09 (CLB)
Date Coordinator Concurred: APR 22 2009
Effective Date:

Test Systems/Analytes/Grading

(See Attachment)

APR 24 2009

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

ATTACHMENT

Document Number : k062187

Test System: National Diagnostic Products Betachek Blood Glucose (Sugar) test
Analyte : Whole Blood Qualitative Dipstick Glucose
Complexity : WAIVED [0]
Rationale : WVD-002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK
Blood Glucose Test

NDP

tests

BETACHEK® Blood Glucose (Sugar) Test

High blood sugar may be a sign of Pre-Diabetes or Diabetes.

Individuals who are concerned they may have Diabetes or Pre-Diabetes should seek the advice of a physician.
Betachek Blood Glucose Test is a way to estimate your fasting plasma glucose (blood sugar)

This test can not be used to screen or diagnose diabetes. It should not be used for children or by individuals who are diabetic or pregnant. This test is only intended for individual use at home. It is not for use as part of a screening program in a healthcare setting or any other setting

Betachek Blood Glucose Test is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

BETACHEK
Blood Glucose Test

NDP

tests

BETACHEK® Blood Glucose (Sugar) Test

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Contents:
2 Betachek tests 2 [illegible]
2 Alcohol Swabs 2 Micro Wipes 30 [illegible]

Distributed exclusively by:
Sydney, New York 10-8[illegible]

Manufactured by: National Diagnostics Products
22/9 Pendant Street, St Ubarrans NSW 2085
Sydney, Australia

Helpline: 866 475 0992 (9AM - 5PM PST)
Notice: Color interpretation Required

BETACHEK
Blood Glucose Test

LOT
EXP

Insert UPC Barcode
009568000415

BDTB-USA-3

Box packaging
4/15/09

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Blood Glucose Test
Instructions for use

Read instructions carefully before use

Betachek Helpline:
866-475 0992
(9 AM to 5 PM PST).

Before you perform the test:

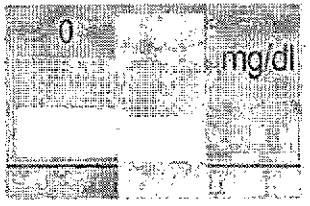
You should perform the test before breakfast, and after you have not eaten for at least 8 hours.

Have a watch or timer ready.

Contents:

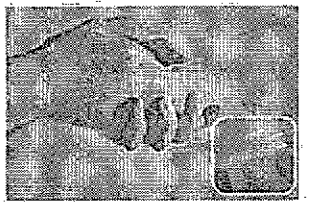
Step 1:

Compare the test strip in the package to the color chart on the outside of the package. The test zone should match the label color for 0. It should not be blue. If you are unsure if the test strip is in good condition, you should call the toll-free phone number for technical assistance.



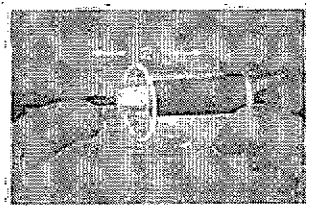
Step 2:

Wash hands with warm water and dry thoroughly. Place the contents of the test kit on a firm, clean surface. Use the alcohol swab provided to wipe the tip of your middle finger.



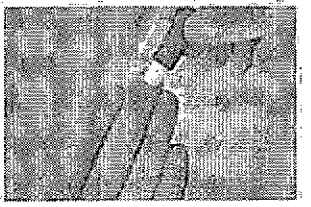
Step 3:

Hold the lancet as shown and twist off the protective cap.



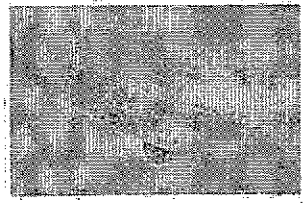
Step 4:

Use the photo as a guide to help you position the lancet on your finger tip. Push the lancet into the finger until you hear a click.



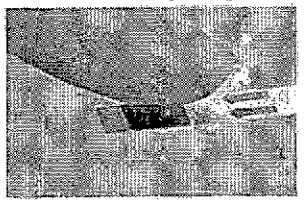
Step 5:

Hold your finger down and allow the blood to flow until you have a large hanging drop of blood. DO NOT SQUEEZE your finger. Get ready to start timing.

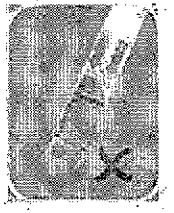


Step 6:

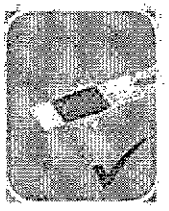
With the test strip on a firm surface, place the drop of blood on the test zone of the test strip. Start the timing for 1 minute.



Check



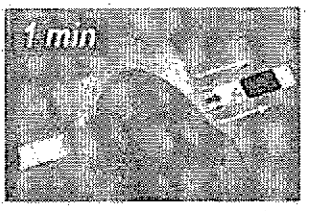
Do not smear or dab blood.



Ensure both test pads are fully covered.

Step 7:

After exactly 1 minute wipe the blood off the test zone using the tissue provided.

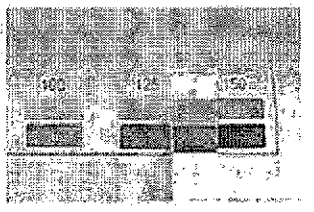


Step 8:

Now wait 2 minutes.
Next, compare your test strip to the color chart on the label.

See section: How do I read my result?

Do not read the result after 5 minutes as the test zone will start to fade.



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK® BLOOD GLUCOSE TEST

What is this Test for?

Betachek® Blood Glucose Test is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

Any abnormal results should be verified by a medical professional, such as a physician, and confirmed with a quantitative, laboratory reference method. Only a trained medical professional can determine if an individual has diabetes. A test result within the normal range does not exclude the possibility that the individual has diabetes or pre-diabetes. Any individual who is concerned that he or she may have diabetes or pre-diabetes should seek the advice of a physician.

> This test can not be used to screen or diagnose diabetes.
> It should not be used for children or by individuals who are diabetic or pregnant.
> This test is only intended for individual use at home.
> It is not for use as part of a screening program in a healthcare setting or any other setting.

Background

Type 2 Diabetes: It is estimated that 30% of people with diabetes in the US remain undiagnosed. This is because when a person first develops diabetes it is common for them to have no signs of sickness. They do however have high levels of glucose in their blood. Often diabetes is only discovered many years later when the effects on health have already occured. It is therefore important to seek the advice of a medical professional if you have concerns about your risk for diabetes.

Pre-Diabetes: In addition to undiagnosed diabetes, the American Diabetes Association (ADA) estimates that 54 million people in the US (18%) have pre-diabetes (plasma glucose levels 100-125 mg/dl). The ADA and National Institute of Diabetes and Digestive and Kidney Diseases believe that people with pre-diabetes can delay or *prevent* diabetes if they begin treatment early[1]. Treatment can often involve simple measures such as diet and exercise.

Betachek® Blood Glucose Test is a convenient way to estimate your fasting plasma glucose (blood sugar) in just 3 minutes. People with concerns about their health should consult with a medical professional.

How Does the Test Work?

The test zone consists of two test pads containing sensitive chemicals. (see picture under step 1 overleaf)

When finger stick blood is applied to this zone, the chemicals react with the glucose in the blood. The reaction produces a color change that varies with the amount of glucose in the blood.

Precautions

- Read all of the test instructions before performing a test.
- Follow each step exactly.
- You must not eat for 8 hours before testing.
- Use the test strips only between 64 and 95°F
- Do not refrigerate or freeze the test strips.
- Use the test strip immediately after it is removed from the container.
- Only use blood from your finger.
- Blood drop must evenly cover the test zone – see picture following step 6.
- Each test can only be used once.

Things that can give you and incorrect result:

- Eating before performing the test.
- Incorrect timing
- Placing the drop of blood on the test strip incorrectly
- Smearing the blood unevenly.
- Adding more blood after the test timing has started.

Before performing a test

Before performing a test check the color of the test zone matches the color of the '0' on the color chart. If the test zone is blue, the strip is damaged and should not be used. Call customer service.

What is Included in the test kit?

2 tests, 2 single use lancets, 1 label on container with color chart, tissue, alcohol swab, 1 package insert.

What is not Included but Needed?

A watch with a second hand or a timer.

When Should I Test?

The test should be performed before breakfast.
Do not eat or drink for 8 hours before testing (you may drink water only).

How do I Run a Test?

Follow the step by step instructions, using the quick guide.

How do I Read the Result?

- Compare the 2 colors on your test strip to the color chart on the package. Use both colors to help you read your results.
- Use natural light for best results.

damaged and should not be used. Call customer service.

What is Included in the test kit?

2 tests, 2 single use lancets, 1 label on container with color chart, tissue, alcohol swab, 1 package insert.

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Do not eat or drink for 8 hours before testing (you may drink water only).

How do I Run a Test?

Follow the step by step instructions, using the quick guide.

How do I Read the Result?

- Compare the 2 colors on your test strip to the color chart on the package. Use both colors to help you read your results.
- Use natural light for best results.

- Select the color block that is the closest match to your test strip. The closest match may be darker.

What should I do if I have trouble deciding on the best color block match?

Choose the color block that is the closest match. Ask a friend or relative to assist you.

What should I do if my test result is in between 2 color blocks?

Choose the color block that is the closest match. The closest match may a darker color block.

What should I do if my test result is very dark or darker than the 150 mg/dl color block?

A test result greater than 150 mg/dl will be very dark.

If you still need assistance, call the Betachek Helpline at 800-830 0977.

Expected Results

Results	Fasting Plasma Glucose (FPG) (mg/dl)
Abnormally Low	50
Normal	75, 100
Abnormal	125, 150

- If your result most closely matches the 50 mg/dl color block, your fasting plasma glucose today is abnormally low. You should have something to eat. You should consider seeking the advice of a medical professional.
- If your result most closely matches either the 75 or 100 mg/dl color blocks, your testing plasma glucose today is in the normal range. You should seek the advice of a medical professional if you still have concerns about your health.
- If you result most closely matches the 125 or 150 mg/dl color blocks, your fasting plasma glucose today is abnormally high and in the pre-diabetes or diabetes range. You should seek the advice of a medical professional for further evaluation.

Performance Characteristics

In a study of 156 consumers and laboratory professionals who performed the Betachek Blood Glucose test, consumers obtained the same test results as professionals greater than 97% of the time.

More information on diabetes and pre diabetes can be found at:
www.diabetes.org/pre-diabetes.jsp
(NDP is not affiliated with the ADA)

Betachek Helpline: 866-475 0992
(9 AM to 5 PM PST).

Version: BGT-US-009
Issued date: APRIL 09

[1] Cardenas C, Colle E et al., Prevalence of Diabetes and Impaired Fasting Glucose in Adults in the U.S. Population *Diabetes Care* 29:1253-1255, 2006
[2] American Diabetes Association, The Prevention or Delay of Type 2 Diabetes, *Diabetes Care* 25:742-749, 2002

[3] American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus, *Diabetes Care* 29:S43-S48, 2006

Manufactured by:
National Diagnostic Products
22/39 Herbert Street,
St.Leonards NSW 2065
Sydney Australia
www.betachek.com

Formatted so it could be printed for file. 4/15/09

Questions? Contact FDA/CDRH/OSE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118.

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Helpline 866-475-0992
(9am to 5pm PST)

BETACHEK®
Blood Glucose Test
instructions for use

Read instructions carefully before use

Betachek Helpline:
866.475.0992
(9 AM to 5 PM PST).

Before you perform the test:

You should perform the test before breakfast and after you have not eaten for at least 8 hours.

Have a watch or timer ready

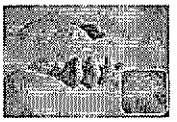
Contents:

Step 1:

Compare the test strip in the package to the color chart on the outside of the package. The test zone should match the label color for 0. It should not be blue. If you are unsure if the test strip is in good condition, you should call the toll-free phone number for technical assistance.

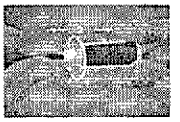
Step 2:

Wash hands with warm water and dry thoroughly. Place the contents of the test kit on a firm, clean surface. Use the alcohol swab provided to wipe the tip of your middle finger.



Step 3:

Hold the lancet as shown and twist off the protective cap.

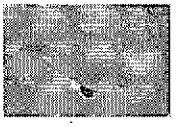


Step 4:

Use the photo as a guide to help you position the lancet on your finger tip. Push the lancet into the finger until you hear a click.

Step 5:

Hold your finger down and allow the blood to flow until you have a large hanging drop of blood. DO NOT SQUEEZE your finger. Get ready to start timing.



Step 6:

With the test strip on a firm surface, place the drop of blood on the test zone of the test strip. Start the timing for 1 minute.

Check

Do not smear or dab blood

Ensure both test pads are fully covered.

Step 7:

After exactly 1 minute wipe the blood off the test zone using the tissue provided.

Step 8:

Now wait 2 minutes.
Next, compare your test strip to the color chart on the label.

See section: How do I read my result?

Do not read the result after 5 minutes as the test zone will start to fade.

BETACHEK® BLOOD GLUCOSE TEST

What is this Test for?
Betachek® Blood Glucose Test is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

Any abnormal results should be verified by a medical professional, such as a physician, and confirmed with a quantitative, laboratory reference method. Only a trained medical professional can determine if an individual has diabetes. A test result within the normal range does not exclude the possibility that the individual has diabetes or pre-diabetes. Any individual who is concerned that he or she may have diabetes or pre-diabetes should seek the advice of a physician.

> This test can not be used to screen or diagnose diabetes.
> It should not be used for children or by individuals who are diabetic or pregnant.
> This test is only intended for individual use at home.
> It is not for use as part of a screening program in a healthcare setting or any other setting.

Background
Type 2 Diabetes: It is estimated that 30% of people with diabetes in the US remain undiagnosed. This is because, when a person first develops diabetes it is common for them to have no signs of sickness. They do however have high levels of glucose in their blood. Often diabetes is only discovered many years later when the effects on health have already occurred. It is therefore important to seek the advice of a medical professional if you have concerns about your risk for diabetes.
Pre-Diabetes: In addition to undiagnosed diabetes, the American Diabetes Association (ADA) estimates that 54 million people in the US (18%) have pre-diabetes (plasma glucose levels 100-125 mg/dl). The ADA and National Institute of Diabetes and Digestive and Kidney Diseases believe that people with pre-diabetes can delay or prevent diabetes if they begin treatment early[1]. Treatment can often involve simple measures such as diet and exercise.

Betachek® Blood Glucose Test is a convenient way to estimate your fasting plasma glucose (blood sugar) in just 3 minutes. People with concerns about their health should consult with a medical professional.

How Does the Test Work?
The test zone consists of two test pads containing sensitive chemicals. (see picture under step 1 overleaf)

When finger stick blood is applied to this zone, the chemicals react with the glucose in the blood. The reaction produces a color change that varies with the amount of glucose in the blood.

Precautions
- Read all of the test instructions before performing a test.
- Follow each step exactly.
- You must not eat for 8 hours before testing.
- Use the test strips only between 64 and 95°F
- Do not refrigerate or freeze the test strips.
- Use the test strip immediately after it is removed from the container.
- Only use blood from your finger
- Blood drop must evenly cover the test zone – see picture following step 6.
- Each test can only be used once.

Things that can give you and incorrect result:
- Eating before performing the test
- Incorrect timing
- Placing the drop of blood on the test strip incorrectly
- Smearing the blood unevenly.
- Adding more blood after the test timing has started.

Before performing a test
Before performing a test check the color of the test zone matches the color of the '0' on the color chart. If the test zone is blue, the strip is damaged and should not be used. Call customer service.
What is included in the test kit?
2 tests, 2 single use lancets, 1 label on container with color chart, tissue, alcohol swab, 1 package insert.

What is not included but Needed?
A watch with a second hand or a timer.

When Should I Test?
The test should be performed before breakfast.
Do not eat or drink for 8 hours before testing (you may drink water only).
How do I Run a Test?
Follow the step by step instructions, using the quick guide.

How do I Read the Result?
- Compare the 2 colors on your test strip to the color chart on the package. Use both colors to help you read your results.
- Use natural light for best results.
- Select the color block that is the closest match to your test strip. The closest match may be darker.

What should I do if I have trouble deciding on the best color block match?
Choose the color block that is the closest match. Ask a friend or relative to assist you.

What should I do if my test result is in between 2 color blocks?
Choose the color block that is the closest match. The closest match may a darker color block

What should I do if my test result is very dark or darker than the 150 mg/dL color block?
A test result greater than 150 mg/dL will be very dark

If you still need assistance, call the Betachek Helpline at 866-930 0977.

Expected Results

Results*	Fasting Plasma Glucose (FPG) (mg/dl)
Abnormally Low	50
Normal	75, 100
Abnormal	125, 150

- If your result most closely matches the 50 mg/dL color block, your fasting plasma glucose today is abnormally low. You should have something to eat. You should consider seeking the advice of a medical professional.
- If your result most closely matches either the 75 or 100 mg/dL color blocks, your fasting plasma glucose today is in the normal range. You should seek the advice of a medical professional if you still have concerns about your health.
- If you result most closely matches the 125 or 150 mg/dL color blocks, your fasting plasma glucose today is abnormally high and in the pre-diabetes or diabetes range. You should seek the advice of a medical professional for further evaluation.

Performance Characteristics
In a study of 156 consumers and laboratory professionals who performed the Betachek Blood Glucose test, consumers obtained the same test results as professionals greater than 97% of the time.

More information on diabetes and pre diabetes can be found at:
www.diabetes.org
www.diabetes.org/pre-diabetes.jsp
(NDP is not affiliated with the ADA)

Betachek Helpline: 866-475 0992
(9 AM to 5 PM PST).

Version: BGT-US-008FU
Issued date: MAR 2009

[1] Karstoft K, Clouet-Foraison N, et al. Prevalence of diabetes and impaired fasting glucose in adults in the U.S. Hispanic Health Care. Diabetes Care 29:1283-1288, 2006
[2] American Diabetes Association. Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 29:S43-S48, 2006
[3] American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 29:S43-S48, 2006

Formatted so that it could be printed.

4/15/09

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Moyer, Vicki

From: Brandon Bransgrove [BrandonBransgrove@ndp.com.au]
Sent: Monday, April 13, 2009 9:46 PM
To: Moyer, Vicki
Cc: Delfina Mihaila
Subject: RE: k062187 final labeling
Attachments: BGT-US-009 IFU P2.pdf; BDTB-USA-3.pdf; BGT-US-009 IFU P1.pdf

Hi Vicki,

I hope you had a Happy Easter.

Here are the changes you requested. Let me know if you need any other changes.

Regards,

Brandon Bransgrove
National Diagnostic Products
22/39 Herbert Street,
St.Leonards NSW 2065
Sydney Australia
www.betachek.com
Tel: 612 9432 8100
Fax 612 9436 1151

From: Moyer, Vicki [mailto:Vicki.Moyer@fda.hhs.gov]
Sent: Monday, 6 April 2009 11:10 PM
To: Brandon Bransgrove
Cc: Delfina Mihaila; Moyer, Vicki
Subject: RE: k062187 final labeling

Hello Brandon-
Thanks for sending this version of the test instructions.

Unfortunately, when I print it out the size of the lettering is extremely small. Is there a way you can format it to print on 2 pages?
Also I noticed that the name and place of business of the manufacturer or distributor is not included. This is required information as per 21CFR (Code of Federal Regulations) 21 part 809.10. Can you please add this information and send it to me?

Upon re-reviewing the box label, I see that the name and place of business appears to be present but it is too small when I print out the version you provided. It is possible that the actual box is in larger lettering, but for my review I need to be able to read it and document it in our database. Also, it must say "manufactured by" or "distributed by" and the manufacturer symbol can not be used in over-the-counter devices. Please provide a larger and revised version so that I can complete the review and CLIA categorization for your device.

I apologize for these oversights. Please let me know if you need further assistance in understanding or responding to my requests.

Best regards,
Vicki

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Vicki Moyer
OIVD-FDA

From: Brandon Bransgrove [mailto:BrandonBransgrove@ndp.com.au]
Sent: Thursday, April 02, 2009 7:05 PM
To: Moyer, Vicki
Cc: Delfina Mihaila
Subject: RE: k062187 final labeling

Hi Vicki,

Here it is, this should print out.

Regards,

Brandon Bransgrove
National Diagnostic Products
22/39 Herbert Street,
St.Leonards NSW 2065
Sydney Australia
www.betachek.com
Tel: 612 9432 8100
Fax 612 9436 1151

From: Moyer, Vicki [mailto:Vicki.Moyer@fda.hhs.gov]
Sent: Friday, 3 April 2009 3:17 AM
To: Brandon Bransgrove
Cc: Delfina Mihaila
Subject: k062187 final labeling

Hello Brandon and Delfinia-
In order to complete the last few administrative steps of the review and CLIA categorization, can you please provide a version of the package insert that I can print on standard letter paper (8 1/2 x 11 inches)?

Thank you.
Best regards,
Vicki

Vicki Moyer
OIVD-FDA

From: Brandon Bransgrove [mailto:BrandonBransgrove@ndp.com.au]
Sent: Friday, March 27, 2009 12:32 AM
To: Moyer, Vicki
Cc: Delfina Mihaila
Subject:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Hi Vicki,

Please find attached the updated labelling (change to helpline number).

Regards,

Brandon Bransgrove
National Diagnostic Products
22/39 Herbert Street,
St.Leonards NSW 2065
Sydney Australia
www.betachek.com
Tel: 612 9432 8100
Fax 612 9436 1151

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Blood Glucose Test

NBP

BETACHEK
Blood Glucose (Sugar) Test

High blood sugar may be a sign of Pre-Diabetes or Diabetes.

Individuals who are concerned they may have Diabetes or Pre-Diabetes should seek the advice of a physician.
Betachek Blood Glucose Test is a way to estimate your fasting plasma glucose (blood sugar).

This test can not be used to screen or diagnose diabetes. It should not be used for children or by individuals who are diabetic or pregnant. This test is only intended for individual use at home. It is not for use as part of a screening program in a healthcare setting or any other setting.

Betachek Blood Glucose Test is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

BETACHEK
Blood Glucose Test

NBP

BETACHEK
Blood Glucose (Sugar) Test

High blood sugar may be a sign of Pre-Diabetes or Diabetes.

Individuals who are concerned they may have Diabetes or Pre-Diabetes should seek the advice of a physician.
Betachek Blood Glucose Test is a way to estimate your fasting plasma glucose (blood sugar).

This test can not be used to screen or diagnose diabetes. It should not be used for children or by individuals who are diabetic or pregnant. This test is only intended for individual use at home. It is not for use as part of a screening program in a healthcare setting or any other setting.

LOT
EXP

Insert UPC Barcode
0099980004115

BETACHEK
Blood Glucose Test

NBP

www.betachek.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Submitter:
Brandon Stephen Bransgrove
Product Manager
National Diagnostic Products
laboratories
7-9 Merriwa Street
Gordon
Sydney, NSW, 2072, AS
Phone: +61 294 184777
Fax: +61 294 184747

July 2, 2008

Attn: CeSub Team
Center for Devices and Radiological Health
Document Mail Center
HFZ-401
9200 Corporate Blvd.
Rockville, MD 20850

Dear Sir or Madam:

This submission dated July 2, 2008, is filed pursuant to the In Vitro Diagnostic Device Evaluation and Safety program's Electronic Review (eReview).

The submission is a Supplement to K062187.

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,

Brandon Stephen Bransgrove
Product Manager
National Diagnostic Products

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Submission Report

Section: Main Menu

Welcome

Welcome to the CDRH Electronic Submissions Software (CeSub)

This software application is intended to automate the current paper submission process. This software contains a number of data capturing tools and helpful dialog boxes to reduce redundant responses for you, and to allow us to capture data in a more useful, structured format. These benefits will enable CDRH to improve our review process and reduce lengthy review times.

For your convenience, an email account has been established to support any questions that you may have regarding the use of this software. Please email any questions or comments to the CeSub team at: **cdrhesub@cdrh.fda.gov.** Please be sure to include your name, company name and contact information in the email.

Thank you again for using our electronic product reporting software. We look forward to hearing from you soon.

What type of product is this submission referring to? *
In Vitro Diagnostic Device

Welcome (Cont.)

Section: Admin

1.0 Type of Submission

Introduction

Department of Health and Human Services
Food and Drug Administration

CDRH PreMarket Review Submission Cover Sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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)
. Submission Sub-Type	*	Supplement
- Submission Sub-Sub-Type		
Enter the original submission number.	*	K062187
Is this a bundled submission?		

User Fee Payment ID Number	

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

2.0 Contact Information

Note:	*Contains Information on the Applicable Contacts*

Section B	**Primary Submitter, Applicant, or Sponsor**

Contact Information		*
Contact Information:		
Contact Name	Mr. Brandon Stephen Bransgrove	
Occupation Title	Product Manager	
Email Address	brandon@ndp.com.au	
Establishment Information:		
Establishment Name	National Diagnostic Products	
Division Name	laboratories	
FDA Establishment Identifier (FEI)		
Central File Number (CFN)		
Registration Number		
Owner/Operator Number		
Physical Location:		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Address	7-9 Merriwa Street Gordon Sydney, NSW, 2072, AS
Telephone Number	(+61) 294-1847 Ext: 77
Fax Number	(+61) 294-1847 Ext: 47
Mailing Location:	
Address	7-9 Merriwa Street Gordon Sydney, NSW, 2072, AS

Section C	**Applicant Correspondent or Secondary Contact**

Note:	*For example, the application correspondent could be a consultant, if different than above.*
Contact information	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Physical Location:	
Address	
Telephone Number	
Fax Number	

Section: Supplement

1.0 Deficiencies and Responses

Item: 1

Enter the deficiency that you are responding to. *
Question 1 of Review of S1 response (3.11.2007), from Vicki Moyer 1. Method Comparison: Copyright Protected [redacted] [redacted] [redacted] [redacted] [redacted].

Enter or attach the response to the deficiency. *
Please see attached.

File Attachment 1	Reply to question 1 of Review of S1 response
File Attachment 2	Betachek GT Method Comparison Test Report

Item: 2

Enter the deficiency that you are responding to. *

Question 2 of Review of S1 response (3.11.2007), from Vicki Moyer

2. Lay user study:

a. (b)(4) [redacted].

Enter or attach the response to the deficiency. *

Please see attached.

File Attachment 1	Betachek GT Feedback Questionnaire
File Attachment 2	Reply to question 2 of Review of S1 response

Item: 3

Enter the deficiency that you are responding to. *

Question 3 of Review of S1 response (3.11.2007), from Vicki Moyer

3. (b)(4) [redacted].

Enter or attach the response to the deficiency. *

Please find attached the (b)(4) [redacted] Studies Report.

File Attachment 1	Betachek GT Hematocrit Study

Item: 4

Enter the deficiency that you are responding to. *

Question 4 of Review of S1 response (3.11.2007), from Vicki Moyer

4. (b)(4) [redacted]

a. (b)(4) [redacted].

b. (b)(4) [redacted]

c. (b)(4) [redacted].

Enter or attach the response to the deficiency. *

Please see attached.	
File Attachment 1	Reply to question 4 of Review of S1 response

Item: 5

Enter the deficiency that you are responding to. *

Question 5 of Review of S1 response (3.11.2007), from Vicki Moyer

5. (b)(4) [redacted]

[redacted].

(b)(4) [redacted].

Enter or attach the response to the deficiency. *

Please see attached.	
File Attachment 1	Reply to question 5 of Review of S1 response

Item: 6

Enter the deficiency that you are responding to. *

Question 6 of Review of S1 response (3.11.2007), from Vicki Moyer

6. (b)(4) [redacted] y

a. (b)(4) [redacted]?

b. (b)(4) [redacted]

Enter or attach the response to the deficiency. *

Please see attached.	
File Attachment 1	Reply to question 6 of Review of S1 response

Item: 7

Enter the deficiency that you are responding to. *

Question 7 of Review of S1 response (3.11.2007), from Vicki Moyer

7 (b)(4) [redacted]

(b)(4) [redacted]

Enter or attach the response to the deficiency. *

Please see attached.	
File Attachment 1	Reply to question 7 of Review of S1 response

Item: 8

Enter the deficiency that you are responding to. *
Question 8 of Review of S1 response (3.11.2007), from Vicki Moyer 8. (b)(4) [redacted]

Enter or attach the response to the deficiency. *	
Please see attached.	
File Attachment 1	Betachek GT IFU p1.
File Attachment 2	Betachek GT IFU p2.

Item: 9

Enter the deficiency that you are responding to. *
Question 9 of Review of S1 response (3.11.2007), from Vicki Moyer 9. (b)(4) [redacted].

Enter or attach the response to the deficiency. *	
Please see attached.	
File Attachment 1	Summary

Item: 10

Enter the deficiency that you are responding to. *
Question 10 of Review of S1 response (3.11.2007), from Vicki Moyer 10. (b)(4) [redacted]

Enter or attach the response to the deficiency. *	
Please see attached.	
File Attachment 1	Reply to question 10 of Review of S1 response

Item: 11

Enter the deficiency that you are responding to. *

Question 11 of Review of S1 response (3.11.2007), from Vicki Moyer

11 (b)(4) [redacted]

[redacted] of

i.Not fasting (will results be too high or too low?)

ii (b)(4) [redacted]

d (b)(4) [redacted]

Enter or attach the response to the deficiency.	*
Please see attached.	
File Attachment 1	Reply to question 11 of Review of S1 response

Item: 12

Enter the deficiency that you are responding to.	*

e-mail letter (30.11.2007), from Vicki Moyer

(b)(4) [redacted]

- [redacted]
- [redacted]

[redacted]

Enter or attach the response to the deficiency. *	
Please see attached.	
File Attachment 1	Reply to e-mail letter 30.11.2007

Item: 13

Enter the deficiency that you are responding to. *
e-mail letter (19.12.2007), from Vicki Moyer (b)(4) [redacted] [redacted].

Enter or attach the response to the deficiency. *	
Please see attached.	
File Attachment 1	Reply to e-mail letter 19.12.2007
File Attachment 2	(b)(4) [redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Annex 4: Betachek GLUCOSE TEST Feedback Questionnaire

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Hematocrit Studies Report

(b)(4)

A. STUDY DESIGN

1. Introduction

(b)(4)

2. Scope

Betachek Glucose Test Strips

3. Study Objectives

The specific objectives are as follows:

(b)(4) .

4. Comparative Method

(b)(4)

The system is calibrated to a NIST standard.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Hematocrit Studies Report

5. Equipments and materials

(b)(4)

[redacted]

6. Description of studies

(b)(4)

[redacted]

7. Quality assurance and safety requirements

(b)(4)

[redacted]

8. Effect of hematocrit evaluation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Hematocrit Studies Report

8.1 General requirements

(b)(4)

[redacted]

8.2. Samples requirements

(b)(4)

[redacted]

Table 1
Hematocrit and glucose concentrations to be used to evaluate the effect of hematocrit on the glucose reading.

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Hematocrit Studies Report

8.3. Environment requirements

(b)(4)

[redacted]

8.4 Reagent system

(b)(4)

[redacted]

8.5 Evaluation procedure

8.5.1 Strips preparation

(b)(4)

[redacted]

8.5.3 Quality Control

(b)(4)

[redacted]

8.5.4 Measurement procedure

All results should be recorded (Annex 3,4,5).

a) (b)(4)

b)

c)

d)

e)

f)

g)

h)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The reference method results and the Betachek GT results will be recorded on separate forms to prevent results being disclosed between technicians.

9. Data analysis and presentation

9.1 Drift analysis

(b)(4)

[redacted]

(b)(4)

[redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Hematocrit Studies Report

B. RESULTS

Betachek GT - Effect of Hematocrit

(b)(4)

[redacted]

Level 2

(b)(4)

[redacted]

Level 3

(b)(4)

[redacted]

Level 4

(b)(4)

[redacted]

C. CONCLUSION

(b)(4)

[redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Hematocrit Studies Report

(b)(4)

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Hematocrit Studies Report

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

BETACHEK GLUCOSE TEST

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

What is this Test for?
Betachek Glucose Test is intended as a screening test for the early detection of abnormal fasting plasma glucose (FPG) levels. Abnormal fasting glucose levels can be a sign of diabetes or other health problems. The test uses a drop of capillary blood to provide a preliminary semi-quantitative result. Any abnormal result should be confirmed by a doctor using a quantitative laboratory based method. The test is not intended to provide a formal diagnosis of diabetes. A formal diagnosis can only be made by a doctor. The test is for over-the-counter use.

Background
Type 2 Diabetes: It is estimated that 30% of people with diabetes in the US remain undiagnosed[1]. This is because when a person first develops diabetes it is common for them to have no signs of sickness. They do however have high levels of glucose in their blood which over time badly damages many parts of the body. Often Diabetes is only discovered many years later when the damage has occurred. This damage can be prevented if high glucose levels are reduced by early treatment. It is therefore important to check your blood glucose level regularly and if it is high, to seek treatment before it causes serious health problems that cannot be reversed.
Pre-Diabetes: In addition to undiagnosed diabetes, the American Diabetes Association (ADA) estimates that 54 million people in the US (18%) have pre-diabetes (glucose levels 100-125 mg/dl). The ADA and National Institute of Diabetes and Digestive and Kidney Diseases believe that people with pre-diabetes can delay or *prevent* diabetes if they begin treatment early[2]. Treatment can often involve simple measures such as diet and exercise.

Betachek® Diabetes Test is a convenient and effective way to measure glucose levels in just 3 minutes. Individuals who obtain an abnormal result should see their doctor for further testing.

How Does the Test Work?
The test zone consists of two test pads containing sensitive chemicals. When blood is applied to this zone, the chemicals react with the glucose in the blood. The reaction produces a colour change that varies with the amount of glucose in the blood. The test uses the enzymes Glucose Oxidase and Peroxidase which along with color forming chemicals and non-reactive ingredients is contained in the test zone.

Chemical Composition
Each Betachek® GT test strip contains (Quantity/cm²): Glucose Oxidase 0.08 U, Peroxidase 9.4 µg, TMB 77 µg, o-Tolidine 81µg, DCP 20 µg, Stabiliser 0.12 mg, APAC 15 µg, Inert ingredients 2.20 mg (w/w).

Precautions and Limitations of the Test
Failure to fast will produce invalid high results. For *in vitro* diagnostic use only. Use the test strips only between 64 and 95˚F (18 and 35˚C). Running a test below 64˚F will give low results and running a test above 95˚F will produce high results. There is no need to refrigerate this product, however if refrigerated, do not use the test until it has warmed to room temperature. Failure to do so could lead to low results. Use only fresh capillary whole blood from a finger stick. The test strips are for single use only. *Incorrect timing* – leaving the blood on too long will increase the result and wiping the blood too early will decrease the result. Blood drop must cover the test zone – see inset picture with tick. Smearing too little blood will lead to uneven color development that will not be readable. Blood cannot be added after timing has started – repeat with new test. The test is not intended for use by individuals who are pregnant. As the reading range is 50 - 150 mg/dl, the test should not be used by people with diabetes to monitor their glucose levels or adjust any treatment.

Storage and Handling
Store Betachek® GT Test Strips in their original container in a cool, dry place between 39-86˚F (4-30˚C). Do not freeze. Use the test strip immediately after it is removed from the container. Always replace the cap quickly.

Quality Checks
The test strips can be checked against the '0' (unreacted) color block to see they are in good condition. If there is any sign of blue, the strip should not be used.

What is Included?
2 tests, 2 single use lancets, 1 label on container with color chart, tissue, alcohol swab, 1 package insert.

What is not Included but Needed?
A watch with a second hand or a timer.

Measurement Range
The measurement range is 50 – 150 mg/dl (2.8 – 8.3 mmol/l).

When Should I Test?
An ideal time to test is before breakfast. Do not eat or drink for 8 hours before testing (you may drink water only).

How do I Run a Test?
Have a timer ready.
See the step by step color instructions numbered 1-7.

How do I Read the Result?
Results are obtained by comparing the test zone to the color chart on the label. Use natural light for best results. If the test zone color lies between two color blocks on the chart e.g. a color that appears to be between the 75 and the 100 mg/dl color blocks, then your result is in the range 75-100 mg/dl.
A test zone lighter than 50mg/dl, is less than 50mg/dl. A test zone darker than 150 mg/dl is greater than 150mg/dl.

Expected Results

Results[3]	**Fasting Plasma Glucose (FPG) (mg/dl)**
Abnormally Low	<75
Normal	75 - 100
Abnormal	> 100

If the test zone color is *darker* than the 100 mg/dl color block then your result is abnormal. Results less than 75 mg/dl are considered abnormally low. Abnormal results should be confirmed by re-testing – seek advice from a physician or medical professional.

Do I Need to Test Again?
Blood glucose should be checked annually by individuals who are any of the following: obese; have a first-degree relative with diabetes; are members of a high-risk ethnic population (Indian, African, Hispanic, Native American, Aboriginal, Pacific-Islander, Asian). Also those who have delivered a baby weighing more than 9 pounds; have had gestational diabetes; have high blood pressure; have HDL cholesterol levels ≤ 35mg/dl or triglyceride levels ≥ 250mg/dl; or who, on previous testing had impaired glucose tolerance or impaired fasting glucose. All adults older than 45 years of age should test every three years.

Performance Characteristics
Accuracy
Diabetes experts have suggested that glucose devices should agree within 15 mg/dL of a laboratory method when the glucose concentration is lower than 75 mg/dL, and within 20% of a laboratory method when the glucose concentration is 75 mg/dL or higher. The chart below displays how often the Betachek Glucose Test achieves this goal. The chart is based on a study done on 124 patients to see how well Betachek Glucose Test compared to laboratory results.

For glucose results lower than 75 mg/dL, the percentage (and number) of Betachek Glucose Test results that matched the laboratory method within 15 mg/dL :	(22/22) 100%
For glucose results at 75 mg/dL or higher, the percent (and number) of meter results that match the laboratory method within 20%:	(214/225) 95%

Note: When Betachek Glucose Test results are compared to the laboratory results, results below 75 mg/dL are compared in mg/dL.

Precision
The within – lot precision of Betachek GT strips was determined for three lots of strips. Three different glucose levels were used, covering a range 50-150mg/dL. CV's for lots ranged from 0 to 4.8%.

More information on diabetes and pre diabetes can be found at:
www.diabetes.org and www.diabetes.org/pre-diabetes.jsp
Betachek Helpline: xxxx xxxxxxxxx

Version BGT-US-003 NOV 2007

[1] Catherine C. Cowie et al., Prevalence of Diabetes and Impaired Fasting Glucose in Adults in the U.S. Population *Diabetes Care* 29:1263-1268, 2006
[2] American Diabetes Association, The Prevention or Delay of Type 2 Diabetes. Diabetes Care 25:742-749, 2002

[3] American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus, *Diabetes Care* 29:S43-S48, 2006

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK®
Glucose Test

Instructions for use

⚠ IMPORTANT!
Read instructions carefully. You need a timer or watch with second hand ready. This test has an important timing step that must be followed exactly to ensure accurate results.

Before you perform the test:

Ensure you have ***not eaten*** for at least 8 hours.
(You may drink water only)

1. Wash hands and dry thoroughly.

Use the alcohol swab provided to wipe the fingertip. Allow to dry before testing.

2. Twist off protective lancet cap.

3. Push the lancet firmly into the finger until you hear a 'click'.

4. Gently squeeze your finger until you have a large hanging drop of blood. ***Get ready to start timing.***

5. Have your timer ready
Place a drop of blood onto the test zone and immediately start timing.
Check - see pictures in boxes
Ensure both test pads are fully covered. Do not smear or dab blood thinly.

6. After exactly 1 minute wipe the blood off the test zone, using the tissue provided.

7. Wait 2 minutes after wiping and then match the test zone against the label color chart for the result.
See section: How do I read the result?

You have 5 minutes to read the result.
Do not read the result after 5 minutes as the test zone will start to fade.

What does my result mean?

If the test zone color is *darker* than the 100 mg/dl color block on the label then your result is abnormal and you should see your doctor for a laboratory based test. See section: Expected Results

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

(b)(4)

[redacted]

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Betachek GT Method Comparison Test Report

6. Equipment and materials

EQUIPMENT	MATERIALS
(b)(4) [redacted]	

7. Reference Measurement Procedure

(b)(4) [redacted]

8. Quality assurance and safety requirements

(b)(4) [redacted]

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Betachek GT Method Comparison Test Report

9. Subject Eligibility

9.1. Study population

(b)(4)

[redacted]

(b)(4)

[redacted]

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Table 23 Glucose concentrations of samples for system accuracy evaluation

(b)(4) [redacted]

(b)(4) [redacted]

10.3. Environment requirements

The evaluation should be performed at a temperature of (b)(4) [redacted] The experiments will be performed at (b)(4) [redacted] .

10.4 Reagent system

(b)(4) [redacted]

10.5 Evaluation procedure

The requirements specified in ISO 15197: 2003, part 7.3 apply.

10.5.1 Subject's information

(b)(4) [redacted]

10.5.2 Strips preparation

Randomly select (b)(4) [redacted]).

10.5.3 Quality Control

(b)(4) [redacted]

10.5.4 Measurement procedure

All results should be recorded (Annexes4-8).

a) (b)(4) [redacted]

b)

c)

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

d) (b)(4) [redacted]

e) [redacted]

(b)(4) [redacted]

Procedure:

(b)(4) [redacted]

11. Data analysis and presentation

11.1 Drift analysis

(b)(4) [redacted]

11.2 Outliers

11.2.1 Within-method outliers

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Method Comparison Test Report

(b)(4)

The samples that are flagged by both the absolute and relative tests are between-method outliers.

11.3 Anomalous results

Should any anomalous results arise, they will be deal with as follows:

(b)(4)

11.4 Data analysis

11.4.1 System accuracy analysis

a) (b)(4)

b)

c)

11.4.2 Regression analysis

(b)(4)

11.5 Data presentation

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Betachek GT Method Comparison Test Report

The following information shall be reported:

a) (b)(4) [redacted]
b)
c)
d)
e)
f) (b)(4) [redacted]
(b)(4) [redacted]
g)
h)
i)
j)
k) (b)(4) [redacted]

12. Acceptability criteria

The acceptability criteria for accuracy of Betachek GT strips are found in ISO 15197:2003 *In vitro* diagnostic tests system- Requirements for self-testing in managing diabetes mellitus.

(b)(4) [redacted]

13. Miscellaneous

13.1 Investigation centers

The collection of specimens and testing will take place at:

(b)(4) [redacted]

13.2 Study coordinators and investigators

(b)(4) [redacted]

Study Investigators:

(b)(4) [redacted]

(b)(4) [redacted]

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Betachek GT Method Comparison Test Report

Contact details:

(b)(4)

[redacted]

13.3 Training and Competences

(b)(4)

[redacted]

- (b)(4)

[redacted]

- [redacted]
- [redacted]

Annex 1.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Method Comparison Test Report

Information Letter

(b)(4)

[redacted]

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(b)(4)

[redacted]

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Betachek GT Method Comparison Test Report

(b)(4)

YSI 2300 Stat Plus Analyser

(b)(4)

Membrane integrity Test	(b)(4)			
Control 1				
Control 2				

	Range	Test 1 (morning)	Test 2 (afternoon)	Accept/Reject
Temperature	(b)(4)			

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Method Comparison Test Report

(b)(4)

[redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

(b)(4)

[redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

(b)(4)

[redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

(b)(4)

[redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

(b)(4)

[redacted]

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Betachek GT Method Comparison Test Report

Subject no.	YSI 2300	Betachek GT	YSI 2300	Date of birth(day/month/year)	Sex	Hematocrit	Disease status

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

Subject no	YSI 2300	Betachek GT	YSI 2300	Date of birth(day/month/year)	Sex	Hematocrit	Disease status

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

Subject no	YSI 2300	Betachek GT	YSI 2300	Date of birth(day/month/year)	Sex	Hematocrit	Disease status

(b)(4)

[redacted]

C. CONCLUSION

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

(b)(4) [redacted]

The excluded results are explained in tables below:

Subject No.	Reason for exclusion
(b)(4) [redacted]	

(b)(4) [redacted]

Subject no.	YSI 2300	Betachek GT	YSI 2300
(b)(4) [redacted]			

Also, it was found a drift (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Method Comparison Test Report

(b)(4) [redacted].

The results affected by drift are presented below:

Subject no.	YSI 2300	Betachek GT	YSI 2300
(b)(4) [redacted]			

(b)(4) [redacted]

A summary of outlier results is presented below:

Outliers	Subject no.	YSI 2300	Betachek GT	YSI 2300
(b)(4) [redacted]				

The glucose concentrations, (b)(4) [redacted]

Table 24
Samples distribution for system accuracy evaluation

(b)(4) [redacted]

The age of the subjects ranged between (b)(4) [redacted] (b)(4) [redacted].

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Method Comparison Test Report

The between methods outliers are plotted with a red symbol.

Figure 1

(b)(4)

[redacted]

Linear regression (ordinary linear regression) for Betachek GT compared with YSI 2300 is presented in Figure 2.

Figure 2

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Method Comparison Test Report

(b)(4) [redacted]

Table 25
Regression statistics of Betachek GT against YSI 2300

(b)(4) [redacted]

Tables 26 and 27 present the accuracy of Betachek GT segregated for glucose levels

(b)(4) [redacted]

Table26 Betachek GT accuracy for glucose concentrations (b)(4) [redacted] samples were tested in this range)

(b)(4) [redacted]

Table 27 Betachek GT accuracy for glucose concentrations ([redacted] samples were tested in this range)

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

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Betachek GT Method Comparison Test Report

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Reply to e-mail letter (19.12.2007), from Vicki Moyer

In the method comparison studies performed with (b)(4) [redacted]

We consider that this was due to random sampling of nonfasting individuals.

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Reply to e-mail letter (30.11.2007), from Vicki Moyer

The method comparison procedure described in ISO 15197 specifies that measurement with a reference method to be performed in duplicates before and after measurements with the device subjected to evaluation.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Reply to question 1 of Review of S1 response (3.11.2007), from Vicki Moyer

a

(b)(4) [redacted]

Subject No.	Reason for exclusion
(b)(4) [redacted]	

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

The results affected by drift are presented below:

(b)(4) [redacted]			

(b)(4) [redacted]

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Reply to question 10 of Review of S1 response (3.11.2007), from Vicki Moyer

Please see revised IFU – precautions and limitations.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Reply to question 11 of Review of S1 response (3.11.2007), from Vicki Moyer

a. Agreed.

b. see precautions and limitations

(b)(4) [redacted]

c. (b)(4) [redacted]

d. [redacted]

(b)(4) [redacted]

e. Please find below the revised section on Accuracy

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Reply to question 2 of Review of S1 response (3.11.2007), from Vicki Moyer

(b)(4)

[redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Reply to question 4 of Review of S1 response (3.11.2007), from Vicki Moyer

(b)(4)

	Level 1 (mg/dL)	Level 2 (mg/dL)	Level 3 (mg/dL)
START			

(b)(4)

(b)(4)

The actual intervals represented by each level are summarised in the table below:

Results Table	***Table 1 (target intervals)***

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Reply to question 5 of Review of S1 response (3.11.2007), from Vicki Moyer

a. Day-to-day precision studies
YSI 2300 results

(b)(4) [redacted]

	Level 1 (mg/dL)	Level 2 (mg/dL)
(b)(4) [redacted]		
Average	**70.5**	**120.2**

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Reply to question 6 of Review of S1 response (3.11.2007), from Vicki Moyer

(b)(4)

	Level 1 (mg/dL)	Level 2 (mg/dL)	Level 3 (mg/dL)
(b)(4)			

Lot: Betachek GT 446385
YSI 2300 results

	Level 1 (mg/dL)	Level 2 (mg/dL)	Level 3 (mg/dL)
(b)(4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Lot: Betachek GT 447185
YSI 2300 results

	Level 1 (mg/dL)	Level 2 (mg/dL)	Level 3 (mg/dL)
(b)(4) [redacted]			

The results are presented in tables in order of glucose concentration. The actual testing was performed in random order, as follows:

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Reply to question 7 of Review of S1 response (3.11.2007), from Vicki Moyer

Sensitivity Study

(b)(4) [redacted]

For each sample

a) (b)(4) [redacted]

b)

c)

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

510 (k) Summary

a) According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1.	Submitter's Name:	National Diagnostic Products (Aust) Pty Ltd
	Address:	22/39 Herbert Street, St.Leonards NSW 2065, Australia
	Phone:	+61 2 94328108
	Fax:	+61 2 94361151
	Contact Person:	Brandon Bransgrove
	Date Prepared:	April 21 2008
2.	Device Name:	Betachek Glucose Test
	Proprietary/Trade name:	Betachek Glucose Test
	Common Name:	Glucose Test System
	Classification Name:	Glucose Test System
	Device Classification:	II
	Regulation Number:	21 CFR 862.1345
	Classification Panel:	Clinical Chemistry (75)
	Product Code:	CGA (Glucose Oxidase, Glucose)
3.	Predicate Device Name:	Chemcard Glucose Test
	Manufacturer:	CHEM-ELEC, INC
	510 (K) Number:	K943503

4. Description of the Device
Reagent test principle – glucose oxidase

5. Intended Use

Betachek Glucose Test is a semi-quantitative glucose test intended to be used by a person who has not been diagnosed as diabetic to measure his or her fasting glucose level in order to determine whether the fasting glucose level is abnormal. This device cannot be used to diagnose or monitor diabetes, or other medical problems. Abnormal results should be verified by a physician.
The test is not intended for use by individuals who are pregnant.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

6. Substantial Equivalence

Similarities		
Item	**Device**	**Predicate**
	Betachek Glucose Test	**Chemcard Glucose Test**
Detection Method	Enzyme linked colour change	Enzyme linked colour change
Sample	Finger stick blood sample	Finger stick blood sample
Sample Volume	1 drop (no sample premeasurement)	1 drop (no sample premeasurement)
Enzyme 1	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Enzyme 2	Peroxidase	Peroxidase
Dye	TMB, o-Tolidine, DCP	TMB
Instrument required	No	No
Intended use	a semi-quantitative glucose test intended to be used by a person who has not been diagnosed as diabetic to measure his or her fasting glucose level in order to determine whether the fasting glucose level is abnormal	a semi-quantitative glucose test intended to be used by a person who has not been diagnosed as diabetic to measure his or her fasting glucose level in order to determine whether the fasting glucose level is abnormal
Operating Temperature	18 – 35° C	18 – 35° C
Test Range	50 mg/dL – 150 mg/dL	50 mg/dL – 150 mg/dL
Test Time	3 minute	3 minutes
Number of colour blocks	5	5

Differences		
Item	**Device**	**Predicate**
	Betachek Glucose Test	**Chemcard Glucose Test**
Format	Test strip	Test Card
User steps	Blood wiped at 1 minute and result read after 3minutes.	Blood pre-filter peeled at exactly 3 minutes and result must read within 30 seconds.
Hematocrit Range	35% - 55%	Unknown

7. Performance Characteristics

Betachek Glucose Test has the same intended use and technological characteristics as the predicate device and clinical evaluations demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Therefore, Betachek Glucose Test is substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

April 22, 2009

National Diagnostic Products
c/o Brandon Stephen Bransgrove
7-9 Merriwa St. Gordon
Sydney, Australia 2072

Document No: k062187
Re: k062187
Received: August 7, 2006

Categorization Notification (Waived)

Regulations codified at 42 CFR 493.15 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test system or assay for the analyte is categorized below:

Test System/Analyte (s) : (SEE ATTACHMENT)

Waived status is applicable to test systems and their instructions approved by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for the evaluation of waiver. If you change the test system name or your company's name or if a distributor's name replaces your name, you must request another categorization by sending in the revised labeling along with a letter to FDA referencing the document number above.

This complexity categorization is effective as of the date of this notification and will be reported on FDA's home page http://www.fda.gov/cdrh/clia. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. It will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice.

If you have any questions regarding this complexity categorization, please contact Carol Benson at 240-276-0396.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

ATTACHMENT

Document Number : k062187

Test System : National Diagnostic Products Betachek Blood Glucose (Sugar) Test
Analyte : Whole Blood Qualitative Dipstick Glucose
Complexity : WAIVED

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

CLIA Routing Slip

Document No : k062187

Re : k062187

Division: DCTD
Branch: CHTB

Applicant: National Diagnostic Products
Trade Name: Betachek glucose test

DMC Date Received: August 7, 2006
Division Date Received: August 10, 2006

OTC Phone Number: (866) 475-0992

Categorization Information

CLIA Reviewer: Vicki Moyer [VYM]
Date Review Completed: April 17, 2009

Date Branch Concurred: 4-22-09 (CLB)
Date Coordinator Concurred: APR 22 2009
Effective Date:

Test Systems/Analytes/Grading

(See Attachment)

APR 24 2009

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

ATTACHMENT

Document Number : k062187

Test System: National Diagnostic Products Betachek Blood Glucose (Sugar) test
Analyte : Whole Blood Qualitative Dipstick Glucose
Complexity : WAIVED [0]
Rationale : WVD-002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK®
Blood Glucose Test

NDP

2 tests

BETACHEK®
Blood Glucose (Sugar) Test

High blood sugar may be a sign of Pre-Diabetes or Diabetes.

Individuals who are concerned they may have Diabetes or Pre-Diabetes should seek the advice of a physician.
Betachek Blood Glucose Test is a way to estimate your fasting plasma glucose (blood sugar)

This test can not be used to screen or diagnose diabetes. It should not be used for children or by individuals who are diabetic or pregnant. This test is only intended for individual use at home. It is not for use as part of a screening program in a healthcare setting or any other setting

BETACHEK®
Blood Glucose Test

Betachek Blood Glucose Test is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

NDP

2 tests

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BETACHEK®
Blood Glucose Test

Contents:
2 Betachek Tests, 2 [illegible] Lancets, 2 Alcohol Swabs, 2 Medical Wipes & Result Chart

In vitro diagnostic use
Store between 39-86°F

Manufactured by: National Diagnostic Products
22/39 Herbert Street, St Leonards NSW 2065
Sydney Australia

Helpline: 866 4750992 (9AM - 5PM PST)
Notice: Color interpretation Required

LOT
EXP
Ref: 009568000415

Insert UPC Barcode
009568000415

BDTB-USA-3

Box packaging
4/15/09

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK®
Blood Glucose Test
Instructions for use

Read instructions carefully before use

Betachek Helpline:
866-475 0992
(9 AM to 5 PM PST).

Before you perform the test:

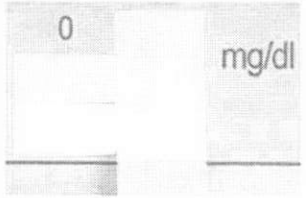
You should perform the test before breakfast and after you have not eaten for at least 8 hours.

Have a watch or timer ready

Contents:

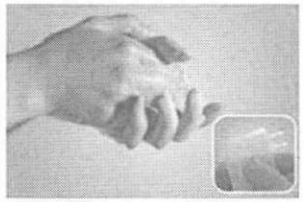
Step 1:

Compare the test strip in the package to the color chart on the outside of the package. The test zone should match the label color for 0. It should not be blue. If you are unsure if the test strip is in good condition, you should call the toll-free phone number for technical assistance.



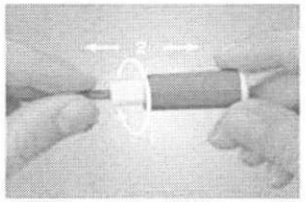
Step 2:

Wash hands with warm water and dry thoroughly. Place the contents of the test kit on a firm, clean surface. Use the alcohol swab provided to wipe the tip of your middle finger.



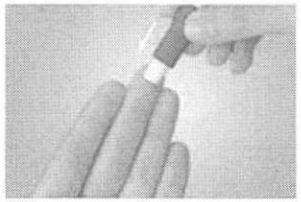
Step 3:

Hold the lancet as shown and twist off the protective cap.



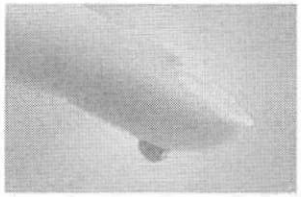
Step 4:

Use the photo as a guide to help you position the lancet on your finger tip. Push the lancet into the finger until you hear a click.



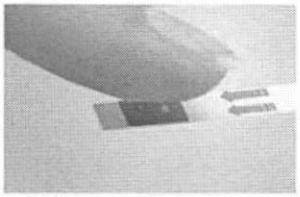
Step 5:

Hold your finger down and allow the blood to flow until you have a large hanging drop of blood. DO NOT SQUEEZE your finger. Get ready to start timing.



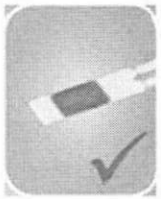
Step 6:

With the test strip on a firm surface, place the drop of blood on the test zone of the test strip. Start the timing for 1 minute.



Check

Do not smear or dab blood



Ensure both test pads are fully covered.

Step 7:

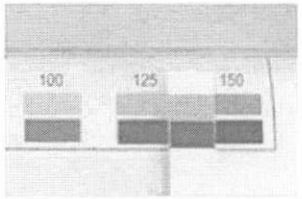
After exactly 1 minute wipe the blood off the test zone using the tissue provided.

Step 8:

Now wait 2 minutes.
Next, compare your test strip to the color chart on the label.

See section: How do I read my result?

Do not read the result after 5 minutes as the test zone will start to fade.



Formatted so it could be printed for the file 4/15/09 (YM)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

BETACHEK®
BLOOD GLUCOSE TEST

What is this Test for?

Betachek® Blood Glucose Test is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

Any abnormal results should be verified by a medical professional, such as a physician, and confirmed with a quantitative, laboratory reference method. Only a trained medical professional can determine if an individual has diabetes. A test result within the normal range does not exclude the possibility that the individual has diabetes or pre-diabetes. Any individual who is concerned that he or she may have diabetes or pre-diabetes should seek the advice of a physician.

> This test can not be used to screen or diagnose diabetes.
> It should not be used for children or by individuals who are diabetic or pregnant.
> This test is only intended for individual use at home.
> It is not for use as part of a screening program in a healthcare setting or any other setting.

Background

Type 2 Diabetes: It is estimated that 30% of people with diabetes in the US remain undiagnosed. This is because when a person first develops diabetes it is common for them to have no signs of sickness. They do however have high levels of glucose in their blood. Often diabetes is only discovered many years later when the effects on health have already occurred. It is therefore important to seek the advice of a medical professional if you have concerns about your risk for diabetes.

Pre-Diabetes: In addition to undiagnosed diabetes, the American Diabetes Association (ADA) estimates that 54 million people in the US (18%) have pre-diabetes (plasma glucose levels 100-125 mg/dl). The ADA and National Institute of Diabetes and Digestive and Kidney Diseases believe that people with pre-diabetes can delay or *prevent* diabetes if they begin treatment early[1]. Treatment can often involve simple measures such as diet and exercise.

Betachek® Blood Glucose Test is a convenient way to estimate your fasting plasma glucose (blood sugar) in just 3 minutes. People with concerns about their health should consult with a medical professional.

How Does the Test Work?

The test zone consists of two test pads containing sensitive chemicals. (see picture under step 1 overleaf)

When finger stick blood is applied to this zone, the chemicals react with the glucose in the blood. The reaction produces a color change that varies with the amount of glucose in the blood.

Precautions

- Read all of the test instructions before performing a test.
- Follow each step exactly.
- You must not eat for 8 hours before testing.
- Use the test strips only between 64 and 95°F
- Do not refrigerate or freeze the test strips.
- Use the test strip immediately after it is removed from the container.
- Only use blood from your finger
- Blood drop must evenly cover the test zone – see picture following step 6.
- Each test can only be used once.

Things that can give you and incorrect result:

- Eating before performing the test
- Incorrect timing
- Placing the drop of blood on the test strip incorrectly
- Smearing the blood unevenly.
- Adding more blood after the test timing has started.

Before performing a test

Before performing a test check the color of the test zone matches the color of the '0' on the color chart. If the test zone is blue, the strip is damaged and should not be used. Call customer service.

What is Included in the test kit?

2 tests, 2 single use lancets, 1 label on container with color chart, tissue, alcohol swab, 1 package insert.

What is not Included but Needed?

A watch with a second hand or a timer.

When Should I Test?

The test should be performed before breakfast.
Do not eat or drink for 8 hours before testing (you may drink water only).

How do I Run a Test?

Follow the step by step instructions, using the quick guide.

How do I Read the Result?

- Compare the 2 colors on your test strip to the color chart on the package. Use both colors to help you read your results.
- Use natural light for best results.

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- Compare the 2 colors on your test strip to the color chart on the package. Use both colors to help you read your results.
- Use natural light for best results.

- Select the color block that is the closest match to your test strip. The closest match may be darker.

What should I do if I have trouble deciding on the best color block match?

Choose the color block that is the closest match. Ask a friend or relative to assist you.

What should I do if my test result is in between 2 color blocks?

Choose the color block that is the closest match. The closest match may a darker color block.

What should I do if my test result is very dark or darker than the 150 mg/dL color block?

A test result greater than 150 mg/dL will be very dark.

If you still need assistance, call the Betachek Helpline at 800-830 0977.

Expected Results

Results	Fasting Plasma Glucose (FPG) (mg/dl)
Abnormally Low	50
Normal	75, 100
Abnormal	125, 150

- If your result most closely matches the 50 mg/dL color block, your fasting plasma glucose today is abnormally low. You should have something to eat. You should consider seeking the advice of a medical professional.
- If your result most closely matches either the 75 or 100 mg/dL color blocks, your testing plasma glucose today is in the normal range. You should seek the advice of a medical professional if you still have concerns about your health.
- If you result most closely matches the 125 or 150 mg/dL color blocks, your fasting plasma glucose today is abnormally high and in the pre-diabetes or diabetes range. You should seek the advice of a medical professional for further evaluation.

Performance Characteristics

In a study of 156 consumers and laboratory professionals who performed the Betachek Blood Glucose test, consumers obtained the same test results as professionals greater than 97% of the time.

More information on diabetes and pre diabetes can be found at:
www.diabetes.org
www.diabetes.org/pre-diabetes.jsp
(NDP is not affiliated with the ADA)

Betachek Helpline: 866-475 0992
(9 AM to 5 PM PST).

Version: BGT-US-009
Issued date: APRIL 09

[1] Cathrine C. Cowie et al., Prevalence of Diabetes and Impaired Fasting Glucose in Adults in the U.S. Population *Diabetes Care* 29:1263-1268, 2006
[2] American Diabetes Association, The Prevention or Delay of Type 2 Diabetes, *Diabetes Care* 25:742-749, 2002

[3] American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus, *Diabetes Care* 29:S43-S48, 2006

Manufactured by:
National Diagnostic Products
22/39 Herbert Street,
St.Leonards NSW 2065
Sydney Australia
www.betachek.com

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4/15/09
(1m)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Helpline 866-475-0992
(9am to 5pm PST)

BETACHEK®
Blood Glucose Test
Instructions for use

Read instructions carefully before use

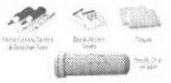
Betachek Helpline:
866-475 0992
(9 AM to 5 PM PST).

Before you perform the test:

You should perform the test before breakfast and after you have not eaten for at least 8 hours.

Have a watch or timer ready

Contents.



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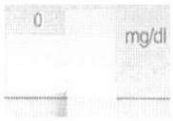
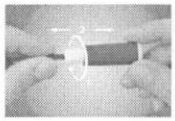


Step 2:

Wash hands with warm water and dry thoroughly. Place the contents of the test kit on a firm, clean surface. Use the alcohol swab provided to wipe the tip of your middle finger.

Step 3:

Hold the lancet as shown and twist off the protective cap



Step 4:

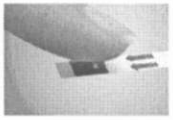
Use the photo as a guide to help you position the lancet on your finger tip. Push the lancet into the finger until you hear a click.

Step 5:

Hold your finger down and allow the blood to flow until you have a large hanging drop of blood. DO NOT SQUEEZE your finger. Get ready to start timing.

Step 6:

With the test strip on a firm surface, place the drop of blood on the test zone of the test strip. Start the timing for 1 minute.



Check

Do not smear or dab blood

Ensure both test pads are fully covered.

Step 7:

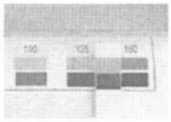
After exactly 1 minute wipe the blood off the test zone using the tissue provided.

Step 8:

Now wait 2 minutes.
Next, compare your test strip to the color chart on the label.

See section: How do I read my result?

Do not read the result after 5 minutes as the test zone will start to fade.



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What should I do if my test result is very dark or darker than the 150 mg/dl color block?

A test result greater than 150 mg/dl will be very dark

If you still need assistance, call the Betachek Helpline at 888-830 8977.

Expected Results

Results*	Fasting Plasma Glucose (FPG) (mg/dl)
Abnormally Low	50
Normal	75, 100
Abnormal	125, 150

- If your result most closely matches the 50 mg/dl color block, your fasting plasma glucose today is abnormally low. You should have something to eat. You should consider seeking the advice of a medical professional.
- If your result most closely matches either the 75 or 100 mg/dl color blocks, your fasting plasma glucose today is in the normal range. You should seek the advice of a medical professional if you still have concerns about your health.
- If you result most closely matches the 125 or 150 mg/dl color blocks, your fasting plasma glucose today is abnormally high and in the pre-diabetes or diabetes range. You should seek the advice of a medical professional for further evaluation.

Performance Characteristics

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www.diabetes.org
www.diabetes.org/are-diabetes.jsp
(NDP is not affiliated with the ADA.)

Betachek Helpline: 866-475 0992
(9 AM to 5 PM PST).

Version: BGT-US-008FU
Issued date: MAR 2009

[1] Catherine C. Cowie et al., Prevalence of Diabetes and Impaired Fasting Glucose in Adults in the U.S. Population, Diabetes Care 29:1263-1268, 2006
[2] American Diabetes Association, Tip Prevention or Delay of Type 2 Diabetes, Diabetes Care 25:742-749, 2002

[3] American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus, Diabetes Care 29:S43-S48, 2006

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4/15/09 (JM)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Moyer, Vicki

From: Brandon Bransgrove [BrandonBransgrove@ndp.com.au]
Sent: Monday, April 13, 2009 9:46 PM
To: Moyer, Vicki
Cc: Delfina Mihaila
Subject: RE: k062187 final labeling
Attachments: BGT-US-009 IFU P2.pdf; BDTB-USA-3.pdf; BGT-US-009 IFU P1.pdf

Hi Vicki,

I hope you had a Happy Easter.

Here are the changes you requested. Let me know if you need any other changes.

Regards,

Brandon Bransgrove
National Diagnostic Products
22/39 Herbert Street,
St.Leonards NSW 2065
Sydney Australia
www.betachek.com
Tel: 612 9432 8100
Fax 612 9436 1151

From: Moyer, Vicki [mailto:Vicki.Moyer@fda.hhs.gov]
Sent: Monday, 6 April 2009 11:10 PM
To: Brandon Bransgrove
Cc: Delfina Mihaila; Moyer, Vicki
Subject: RE: k062187 final labeling

Hello Brandon-
Thanks for sending this version of the test instructions.

Unfortunately, when I print it out the size of the lettering is extremely small. Is there a way you can format it to print on 2 pages?
Also I noticed that the name and place of business of the manufacturer or distributor is not included. This is required information as per 21CFR (Code of Federal Regulations) 21 part 809.10. Can you please add this information and send it to me?

Upon re-reviewing the box label, I see that the name and place of business appears to be present but it is too small when I print out the version you provided. It is possible that the actual box is in larger lettering, but for my review I need to be able to read it and document it in our database. Also, it must say "manufactured by" or "distributed by" and the manufacturer symbol can not be used in over-the-counter devices. Please provide a larger and revised version so that I can complete the review and CLIA categorization for your device.

I apologize for these oversights. Please let me know if you need further assistance in understanding or responding to my requests.

Best regards,
Vicki

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Vicki Moyer
OIVD-FDA

From: Brandon Bransgrove [mailto:BrandonBransgrove@ndp.com.au]
Sent: Thursday, April 02, 2009 7:05 PM
To: Moyer, Vicki
Cc: Delfina Mihaila
Subject: RE: k062187 final labeling

Hi Vicki,

Here it is, this should print out.

Regards,

Brandon Bransgrove
National Diagnostic Products
22/39 Herbert Street,
St.Leonards NSW 2065
Sydney Australia
www.betachek.com
Tel: 612 9432 8100
Fax 612 9436 1151

From: Moyer, Vicki [mailto:Vicki.Moyer@fda.hhs.gov]
Sent: Friday, 3 April 2009 3:17 AM
To: Brandon Bransgrove
Cc: Delfina Mihaila
Subject: k062187 final labeling

Hello Brandon and Delfinia-
In order to complete the last few administrative steps of the review and CLIA categorization, can you please provide a version of the package insert that I can print on standard letter paper (8 1/2 x 11 inches)?

Thank you.
Best regards,
Vicki

Vicki Moyer
OIVD-FDA

From: Brandon Bransgrove [mailto:BrandonBransgrove@ndp.com.au]
Sent: Friday, March 27, 2009 12:32 AM
To: Moyer, Vicki
Cc: Delfina Mihaila
Subject:

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Hi Vicki,

Please find attached the updated labelling (change to helpline number).

Regards,

Brandon Bransgrove
National Diagnostic Products
22/39 Herbert Street,
St.Leonards NSW 2065
Sydney Australia
www.betachek.com
Tel: 612 9432 8100
Fax 612 9436 1151

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 4 2009

National Diagnostic Products
c/o Mr. Brandon Bransgrove
7-9 Merriwa Street, Gordon
Sydney, NSW, 2072
Australia

Re: k062187
Trade Name: Betachek Blood Glucose (Sugar) test
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: December 22, 2008
Received: December 24, 2008

Dear Mr. Bransgrove:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Indication for Use

510(k) Number: K062187

Device Name: BETACHEK BLOOD GLUCOSE (SUGAR) TEST

Indication For Use:

Betachek Blood Glucose (Sugar) is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

Any abnormal results should be verified by a medical professional, such as a physician, and confirmed with a quantitative, laboratory reference method. Only a trained medical professional can determine if an individual has diabetes. A test result within the normal range does not exclude the possibility that the individual has diabetes or pre-diabetes. Any individual who is concerned that he or she may have diabetes or pre-diabetes should seek the advice of a physician.

Betachek Blood Glucose Test is not intended to be used for children or by individuals who are diabetic or pregnant.

This test can not be used to screen or diagnose diabetes.

It should not be used for children or by individuals who are diabetic or pregnant.

This test is only intended for individual use at home.

It is not for use as part of a screening program in a healthcare setting or any other setting.

Prescription Use ____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ☑ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062187

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 04, 2008

NATIONAL DIAGNOSTIC PRODUCTS
(AUST) PTY LTD
7-9 MERRIWA ST.
GORDON
SYDNEY,
AUSTRALIA 2072
ATTN: BRANDON STEPHEN BRANSGROVE

510(k) Number: K062187
Device: BETACHEK GLUCOSE TEST

Extended Until: 23-JAN-2009

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Better life

NDP

Sydney, 31st July 2008

Document Mail Center (HFZ-401)
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850
USA

AUG 0 4 2008

Re: k062187
Request for 180 day extension

Dear Sir/Madam,

We have received a request for additional information dated July 28, 2008.

I write to seek a 180 day extension as offered by our examiner Vicki Moyer.

There is a need for us to redo studies, which will require us to seek ethics approval and recruit patients and this cannot be achieved in 30 days.

Thank you.

Regards,

Brandon Bransgrove
National Diagnostic Products
22/39 Herbert Street,
St.Leonards NSW 2065
Sydney Australia
www.betachek.com
Tel: 612 9432 8100
Fax 612 9436 1151

K14

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 29, 2008

NATIONAL DIAGNOSTIC PRODUCTS
(AUST) PTY LTD
7-9 MERRIWA ST.
GORDON
SYDNEY,
AUSTRALIA 2072
ATTN: BRANDON STEPHEN BRANSGROVE

510(k) Number: K062187
Product: BETACHEK GLUCOSE TEST

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.
Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 01, 2008

NATIONAL DIAGNOSTIC PRODUCTS
(AUST) PTY LTD
7-9 MERRIWA ST.
GORDON
SYDNEY,
AUSTRALIA 2072
ATTN: BRANDON STEPHEN BRANSGROVE

510(k) Number: K062187
Device: BETACHEK GLUCOSE TEST

Extended Until: 02-MAY-2008

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

16

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

National Diagnostic Products
22/39 Herbert Street,
St. Leonards NSW 2065
Sydney,
Australia

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850 USA
Attn.: Marjorie Schulman

510(k) Number : K062187
Product: BETACHEK GLUCOSE TEST

FDA CDRH DMC
MAR 31 2008
Received

Dear Madam,

I am writing to request an extension of time to submit additional information related to 510 (k) Number : K062187. We communicated this information by e-mail to our reviewer (Vicki Moyer) and more time would assist us to lodge the official response through the document mail center. Our submission was placed on hold on November 5, 2007 and if possible, we would like to have this date extended with 180 days.
Thank you very much for your assistance.

Best regards,

Brandon Bransgrove
National Diagnostic Products
22/39 Herbert Street,
St. Leonards NSW 2065
Sydney Australia
www.betachek.com
Tel: 612 94328100
Fax: 61294361151

K23

47

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

National Diagnostic Products
22/39 Herbert Street,
St. Leonards NSW 2065
Sydney,
Australia

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850 USA
Attn.: Marjorie Schulman

510(k) Number : K062187
Product: BETACHEK GLUCOSE TEST

FDA CDRH
Received
MAR 31 2008

Dear Madam,

I am writing to request an extension of time to submit additional information related to 510 (k) Number : K062187. We communicated this information by e-mail to our reviewer (Vicki Moyer) and more time would assist us to lodge the official response through the document mail center. Our submission was placed on hold on November 5, 2007 and if possible, we would like to have this date extended with 180 days.
Thank you very much for your assistance.

Best regards,

Brandon Bransgrove
National Diagnostic Products
22/39 Herbert Street,
St. Leonards NSW 2065
Sydney Australia
www.betachek.com
Tel: 612 94328100
Fax: 61294361151

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

National Diagnostic Products
22/39 Herbert Street,
St. Leonards NSW 2065
Sydney,
Australia

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850 USA
Attn.: Marjorie Schulman

510(k) Number : K062187
Product: BETACHEK GLUCOSE TEST

Dear Madam,

I am writing to request an extension of time to submit additional information related to 510 (k) Number : K062187. We communicated this information by e-mail to our reviewer (Vicki Moyer) and more time would assist us to lodge the official response through the document mail center. Our submission was placed on hold on November 5, 2007 and if possible, we would like to have this date extended with 180 days.
Thank you very much for your assistance.

Best regards,

Brandon Bransgrove
National Diagnostic Products
22/39 Herbert Street,
St. Leonards NSW 2065
Sydney Australia
www.betachek.com
Tel: 612 94328100
Fax: 61294361151

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40
9200 Corporate Blvd.
Rockville, Maryland 20850

November 05, 2007

NATIONAL DIAGNOSTIC PRODUCTS
(AUST) PTY LTD
7-9 MERRIWA ST.
GORDON
SYDNEY,
AUSTRALIA 2072
ATTN: BRANDON STEPHEN BRANSGROVE

510(k) Number: K062187
Product: BETACHEK GLUCOSE TEST

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may revi this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.
Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

National Diagnostic Products
22/39 Herbert Street
St.Leonards NSW 2065
Sydney Australia
Tel: +612 9432 8100
Fax: +612 9436 1151
Email: info@ndp.com.au

Dr. Jean Cooper
Division Director, Chemistry and Toxicology Devices
Document Mail Center (HFZ-401)
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850
USA

Appeal on a hold decision for K062187

Dear Dr Cooper,

I am seeking a review of an issue that lies at the very heart of our product and its effectiveness. The product is a fasting plasma glucose test named BETACHEK Glucose Test.

I am writing to you in accordance with the regulations in 21 CFR Part 10.75.

On the 29th of September 2006 we received a hold letter, point 1a of which is reproduced below;

1. (b)(4) [redacted]

(b)(4) [redacted]

K21

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

a) (b)(4)

b)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

We would like the following points to be considered:

1. (b)(4) [redacted]

2. (b)(4) [redacted]

3. (b)(4) [redacted]

4. (b)(4) [redacted]

5. (b)(4) [redacted]

(b)(4) [redacted]

Thank you for your time in attending to this matter, it is greatly appreciated.

Yours sincerely,

Brandon Bransgrove
Product Manager
Friday, March 23, 2007

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 11, 2006

NATIONAL DIAGNOSTIC PRODUCTS
(AUST) PTY LTD
7-9 MERRIWA ST.
GORDON
SYDNEY,
AUSTRALIA 2072
ATTN: BRANDON STEPHEN BRANSGROVE

510(k) Number: K062187
Product: BETACHEK GLUCOSE TEST

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Better life

NDP

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

November 28, 2006

Re: k062187
Trade Name: Betachek Blood Glucose Test

Dear Dr Gutierrez,

Thank you very much for your letter, dated September 29, 2006.

After receiving this, I sought clarification in a letter to Vicki Moyer dated October 3. A conference call was then arranged to discuss my queries on October 25. Unfortunately time only permitted us to touch on one or two of the issues. During this call it was agreed that your office would provide further information on what additional sensitivity studies you would like us to perform. On November 28, I received a suggested plan for sensitivity studies. I have since contacted Vicki Moyer and suggested we prepare a protocol for her approval.

There remain outstanding issues from my letter of October 3 which are incorporated in this response.

(b)(4)

[redacted]

(b)(4)

[redacted]

K2

1/14

230

National Diagnostic Products Pty Ltd ABN: 61 003 512 598 7-9 Merriwa Street Gordon Sydney 2072 AUSTRALIA
tel: +612 9418 1100 fax: +612 9418 1181 email: info@ndp.com.au www.betachek.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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b. (b)(4) [redacted]

Betachek Glucose Test uses the ADA guidelines adjusted for whole blood.

Please see our submission 'Determining the cut off'. Also see the Instructions for Use 'Expected Results' which are referenced to the ADA – see footnote 2.

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2. (b)(4) [redacted]

During our conference call I briefly raised this point and was relieved to hear that you may be flexible on this issue.

(b)(4) [redacted]

(b)(4) [redacted]

For your information I include below the predicates indications for use – which we have adopted almost word for word:

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

AND

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. *The results for several of your studies, such as precision and reportable range, were reported based on a*

(b)(4)

(b)(4)

(b)(4)

(b)(4)

a) (b)(4)

b)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

4. (b)(4) [redacted]:

(b)(4) [redacted]

Please see the above discussion on this issue.

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

4 b.

(b)(4) [redacted]

(b)(4) [redacted].

(b)(4) [redacted]

Please see the earlier discussion on this.

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

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(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4 b continued

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

5.

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

21 CFR 809.10 (a) (6)

(6) For a reagent, a means by which the user may be assured that the product meets appropriate standards of identity, strength, quality and purity at the time of use. This shall be provided, both for the product as provided and for any resultant reconstituted or mixed product, by including on the label one or more of the following:

(i) An expiration date based upon the stated storage instructions.

(ii) A statement of an observable indication of an alteration of the product, e.g., turbidity, color change, precipitate, beyond its appropriate standards.

(iii) Instructions for a simple method by which the user can reasonably determine that the product meets its appropriate standards.

21 CFR 809.10 (a) (6) doesn't require (iii) as it states 'one or more of the following'.

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

6.
(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Sensitivity will be covered by the new proposed study.

7. (b)(4) [redacted]

Please see separate attachments.

8. (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9.
(b)(4)

Storage Temperature:
(b)(4)

Operating Temperature:
(b)(4)

The operating range is the same as the predicate. Many enzyme based tests have similar temperature constraints.

10.
(b)(4)

We have reviewed this guidance and it is not applicable.

11.
(b)(4)

See above discussion.

b. (b)(4)

Should we recommend that the user see their doctor?

c. (b)(4)

Understood

d. *State that the test should not be used to monitor glucose levels or adjust any treatment.*

Understood

e. (b)(4)

We will appoint a US distributor with an assistance number once we have FDA approval. Is this acceptable?

f. (b)(4)

Understood

g. (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Could this please be explained?

Kind regards,

Brandon Bransgrove

National Diagnostic Products
7-9 Merriwa Street
Gordon NSW 2072
Sydney Australia
Tel: 612 9418 4777
Fax:612 9418 4747
Brandon@ndp.com.au

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK
Interference studies – ACETAMINOPHEN
Synopsis of the protocol

(b)(4)

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

7. Experimental procedure

(b)(4) [redacted]

8. [redacted] (b)(4) [redacted] ,
[redacted].

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7. [redacted]

reference method.

(b)(4) [redacted]

reference method.

8. [redacted] (b)(4) [redacted],

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK
Interference studies –Bilirubin
Synopsis of the protocol

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7. Experimental procedure

   (b)(4) [redacted]

method.

(b)(4) [redacted]

8. (b)(4) [redacted].

---

[1] (b)(4) [redacted].

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Interference studies –Cholesterol
Synopsis of the protocol

1. (b)(4) [redacted]

2. [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

(b)(4) [redacted].

3. Experimental procedure

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK

Interference studies –Creatinine

Synopsis of the protocol

(b)(4)

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

7. Experimental procedure

(b)(4)

[redacted]

8. [redacted] (b)(4) [redacted]

---

[1] (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK
Interference studies – DOPAMINE
Synopsis of the protocol

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

(b)(4) [redacted]

7. Experimental procedure

(b)(4) [redacted]

8. (b)(4) [redacted]

[1] (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK
Interference studies – EDTA
Synopsis of the protocol

1. (b)(4)
2.
3.
4.

(b)(4)

5. Experimental procedure

(b)(4)

6. (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK
Interference studies – EPHEDRINE
Synopsis of the protocol

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

(b)(4) [redacted]

7. Experimental procedure

(b)(4) [redacted]

8. [redacted] (b)(4)[1] [redacted] , [redacted].

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK

Interference studies –Gentisic acid

Synopsis of the protocol

(b)(4)

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

(b)(4)

[redacted]

7. Experimental procedure

(b)(4)

[redacted]

8. [redacted] (b)(4) [redacted].

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK
Interference studies –Ibuprofen
Synopsis of the protocol

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

(b)(4) [redacted]

7. Experimental procedure

(b)(4) [redacted]

8. (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Interference studies – L-DOPA
Synopsis of the protocol

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

8. (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK
Interference studies – Li Heparin
Synopsis of the protocol

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. Experimental procedure
   (b)(4) [redacted]
6. [redacted] (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK
Interference studies – Li Heparin
Synopsis of the protocol

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. Experimental procedure
   (b)(4) [redacted]
6. [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK
Interference studies – Methyl-DOPA
Synopsis of the protocol

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

8. (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Interference studies –NaCitrate
Synopsis of the protocol

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. (b)(4) [redacted]
6. [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK

Interference studies – Sodium Fluoride/ Oxalate

Synopsis of the protocol

1. (b)(4) [redacted]

2. [redacted]

3. [redacted]

4. [redacted]

5. (b)(4) [redacted]

6. [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Interference studies –Salicylic acid

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

8. (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK
Interference studies – Tetracycline
Synopsis of the protocol

1. (b)(4) [redacted]
2.
3.
4.
5.
6.

(b)(4) [redacted]

7. (b)(4) [redacted]
8.

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK
Interference studies –Tolazamide
Synopsis of the protocol

1. (b)(4) [redacted]
2.
3.
4.
5.
6.

(b)(4) [redacted]

7. (b)(4) [redacted]
8.

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Interference studies –Tolbutamide
Synopsis of the protocol

(b)(4)

1.

2.

3.

4.

5.

6.

(b)(4)

(b)(4)

8. (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK
Interference studies –Triglyceride
Synopsis of the protocol

1. (b)(4) [redacted]

2. [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) [redacted]

3. Experimental procedure

(b)(4) [redacted]

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BETACHEK

Interference studies –Uric acid

Synopsis of the protocol

(b)(4)

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

(b)(4)

[redacted]

7. Experimental procedure

(b)(4)

[redacted]

8. [redacted] (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Brandon Stephen Bransgrove
National Diagnostic Products
7-9 Merriwa Street
Sydney, NSW, 2072
Australia

SEP 29 2006

Re: k062187
Trade Name: Betacheck Blood Glucose Test
Dated: July 20, 2006
Received: August 1, 2006

Dear Mr. Bransgrove:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require your response to the following items:

1. [redacted] (b)(4) [redacted].
   a. (b)(4) [redacted]
   b. [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2. (b)(4) [redacted]

3. (b)(4) [redacted]

   a. (b)(4) [redacted]

   b. [redacted]

4. (b)(4) [redacted]:

   a. (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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b. (b)(4) [redacted]

5. (b)(4) [redacted]

6.

7.

8.

9.

10.

11.

a. (b)(4) [redacted]

b.

c.

d.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

e.
f.
g.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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http://www.fda.gov/cdrh/mdufma/guidance/1219.html.
The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Vicki Moyer at 240-276-0490 x157. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SEP 29 2006

Mr. Brandon Stephen Bransgrove
National Diagnostic Products
7-9 Merriwa Street
Sydney, NSW, 2072
Australia

Re: k062187
Trade Name: Betacheck Blood Glucose Test
Dated: July 20, 2006
Received: August 1, 2006

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1. (b)(4) [redacted].
   a. (b)(4) [redacted]
   b. [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

2. (b)(4) [redacted]

3. [redacted]

a. (b)(4) [redacted]

b. [redacted]

4. [redacted] (b)(4) [redacted]

a. (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

b. (b)(4) [redacted]

5. (b)(4) [redacted]

6.

7.

8.

9.

10.

11.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

(b)(4)

e. [redacted]

f. [redacted]

g. [redacted]

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.
The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Vicki Moyer at 240-276-0490 x157. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Prepared by Vicki Moyer: OIVD/DCTD:/HFZ-440: August 27, 2006
Final by Elmani: OIVD/DCTD:/HFZ-440: August 28, 2006

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
DIVD.	Hane	9/28/06						

*U.S. GPO: 1989-624-403

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 08, 2006

NATIONAL DIAGNOSTIC PRODUCTS
(AUST) PTY LTD
7-9 MERRIWA ST.
GORDON
SYDNEY,
AUSTRALIA 2072
ATTN: BRANDON STEPHEN BRANSGROVE

510(k) Number: K062187
Received: 07-AUG-2006
Product: BETACHEK GLUCOSE TEST

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRHs eCopy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 01, 2006

NATIONAL DIAGNOSTIC PRODUCTS
(AUST) PTY LTD
7-9 MERRIWA ST.
GORDON
SYDNEY,
AUSTRALIA 2072
ATTN: BRANDON STEPHEN BRANSGROVE

510(k) Number: K062187
Received: 01-AUG-2006
Product: BETACHEK GLUCOSE
User Fee ID Number: 6026378

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier(e.g.,Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-fee number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at 301-827-2860. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

K062187

National Diagnostic Products
7-9 Merriwa Street,
Gordon
Sydney, NSW, 2072, AS
Phone: (+61) 294-1847 Ext: 77
Fax: (+61) 294-3611 Ext: 51

July 20, 2006

RECEIVED
2006 JUL -1 A 11:16
FDA/CDRH/OCE/DID

Attn: CeSub Team
Center for Devices and Radiological Health
Document Mail Center
HFZ-401
9200 Corporate Blvd.
Rockville, MD 20850

Dear Sir or Madam:

This submission dated July 20, 2006, is filed pursuant to the In Vitro Diagnostic Device Evaluation and Safety program's Electronic Review (eReview).

The submission is a(n) 510(k), Original Submission, Traditional referring to the product, Glucose Test System also known as trade name(s): BETACHEK with model(s): GLUCOSE TEST. The classification panel for this submission is CLINICAL CHEMISTRY.

Summary or Statement
See Attached Pdf

Indications for Use
Betachek Glucose Test is intended as a screening test for the early identification of abnormal fasting blood glucose levels that can be a sign of diabetes or other health problems. The test uses a drop of capillary blood to provide a preliminary, semi-quantitative result. Any abnormal result should be confirmed using a quantitative method. The test is not intended for use by individuals who are pregnant.

The prior submissions that are related to this release are as follows: N/A

User Fee Payment ID: (b)(4) [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,

Brandon Stephen Bransgrove
Product Manager
National Diagnostic Products

CH

K26

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

National Diagnostic Products
7-9 Merriwa Street,
Gordon
Sydney, NSW, 2072, AS
Phone: (+61) 294-1847 Ext: 77
Fax: (+61) 294-3611 Ext: 51

July 20, 2006

Attn: CeSub Team
Center for Devices and Radiological Health
Document Mail Center
HFZ-401
9200 Corporate Blvd.
Rockville, MD 20850

Dear Sir or Madam:

This submission dated July 20, 2006, is filed pursuant to the In Vitro Diagnostic Device Evaluation and Safety program's Electronic Review (eReview).

The submission is a(n) 510(k), Original Submission, Traditional referring to the product, Glucose Test System also known as trade name(s): BETACHEK with model(s): GLUCOSE TEST. The classification panel for this submission is CLINICAL CHEMISTRY.

Summary or Statement
See Attached Pdf

Indications for Use
Betachek Glucose Test is intended as a screening test for the early identification of abnormal fasting blood glucose levels that can be a sign of diabetes or other health problems. The test uses a drop of capillary blood to provide a preliminary, semi-quantitative result. Any abnormal result should be confirmed using a quantitative method. The test is not intended for use by individuals who are pregnant.

The prior submissions that are related to this release are as follows: N/A

User Fee Payment ID: (b)(4) [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,

Brandon Stephen Bransgrove

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Product Manager
National Diagnostic Products

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Submission Report

Section: Main Menu

Welcome

Information:	*Updates to this software are automatic. These updates will occur, as available, if you are logged onto the Internet at the time that the application is launched.*

Welcome to the CDRH Electronic Submissions Software (CeSub)

This software application is intended to automate the current paper submission process. This software contains a number of data capturing tools and helpful dialog boxes to reduce redundant responses for you, and to allow us to capture data in a more useful, structured format. These benefits will enable CDRH to improve our review process and reduce lengthy review times.

For your convenience, an email account has been established to support any questions that you may have regarding the use of this software. Please email any questions or comments to the CeSub team at: **cdrhesub@cdrh.fda.gov.** Please be sure to include your name, company name and contact information in the email.

Thank you again for using our electronic product reporting software. We look forward to hearing from you soon.

What type of product is this submission referring to? *
In Vitro Diagnostic Device

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.*

Section A	**Type of Submission**

Submission Type	*	510(k)
. 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	*	MD6026378956733

MDUFMA Cover Sheet	
Please attach the completed MDUFMA Cover Sheet.	*
File Attachment	Medical Device User Fee Cover Sheet

1.1 Bundled Submission

Note:	*Bundling refers to the inclusion of multiple devices or multiple indications for use for a device in a single premarket submission, including products subject to the device and biologics license application (BLA) authorities, for purposes of review and user fee payment. Multiple devices may include different models within a generic type of device or devices that are of differing generic types.*

For more information please refer to the "Bundling Multiple Devices or Multiple Indications in a Single Submission" Guidance Document

Warning:	*It is important to specifically identify which assay is being referred to in the question response. If a question does not apply, simply type "N/A."*

2.0 Contact Information

Note:	*Contains Information on the Applicable Contacts*

Section B	**Primary Submitter, Applicant, or Sponsor**

Contact Information		*
Contact Information:		
Contact Name	Mr Brandon Stephen Bransgrove	
Occupation Title	Product Manager	
Email Address	brandon@ndp.com.au	

Establishment Information:	
Establishment Name	National Diagnostic Products
Division Name	Laboratories
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Physical Location:	
Address	7-9 Merriwa Street, Gordon Sydney, NSW, 2072, AS
Telephone Number	(+61) 294-1847 Ext: 77
Fax Number	(+61) 294-3611 Ext: 51

Section C	**Applicant Correspondent or Secondary Contact**

Note:	*For example, the application correspondent could be a consultant, if different than above.*
Contact information	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Physical Location:	
Address	
Telephone Number	
Fax Number	

3.0 Reason for Submission

Note:	*The following questions require information on the reasons for a submission, based on the submission type.*
Section D3	**Reason for Submission - 510(k)**

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

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	Chemcard Glucose Test K943503

For this submission, are you including a 510(k) Statement or Summary? *	510(k) Summary

Enter your 510(k) Summary or Statement. *
See Attached Pdf

File Attachment	510(k) Summary Betachek Glucose Test

4.0 Product Information

Section F	Product Information

Common or classification name *
Glucose Test System

FDA Document Numbers of all prior related submissions (regardless of outcome) *	
Item 1	N/A

4.1 Trade, Proprietary, or Model Names

Item: 1

Trade, proprietary, or model name for this device *	BETACHEK
Model number *	GLUCOSE TEST

5.0 Product Classification

Section G1	Product Classification

Choose the product code for this submission.	
Product Code	GLUCOSE OXIDASE, GLUCOSE (CGA)
Device Class	CLASS II
Classification Panel	CLINICAL CHEMISTRY
C.F.R. Section	862.1345 - GLUCOSE TEST SYSTEM.

Add any other product codes that are applicable to this submission.

Item	Product Code	Device Class	Classification Panel	C.F.R. Section
Item 1	GLUCOSE OXIDASE, GLUCOSE (CGA)	CLASS II	CLINICAL CHEMISTRY	862.1345 - GLUCOSE TEST SYSTEM.

If the product code(s) is/are unknown, please describe the classification of the product.
N/A

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).*

Enter the intended use of the product. *
Betachek Glucose Test is intended as a screening test for the early identification of abnormal fasting blood glucose levels that can be a sign of diabetes or other health problems. The test uses a drop of capillary blood to provide a preliminary, semi-quantitative result. Any abnormal result should be confirmed using a quantitative method. The test is not intended for use by individuals who are pregnant.

File Attachment		
.	Intended Use	Over the Counter

Information:	*An indication for use is "a general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended." [see 21 CFR 814.20(b)(3)(i)]. The indications include all the labeled patient uses of the device, for example: The condition(s) or disease(s) to be screened, monitored, treated, or diagnosed; Prescription versus over-the-counter use; Part of the body or type of tissue applied to or interacted with; Frequency of use; Physiological purpose (e.g., removes water from blood, transports blood, etc.),or; Patient population.*
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."

Enter the product's indications for use. *	
Betachek Glucose Test is intended as a screening test for the early identification of abnormal fasting blood glucose levels that can be a sign of diabetes or other health problems. The test uses a drop of capillary blood to provide a preliminary, semi-quantitative result. Any abnormal result should be confirmed using a quantitative method. The test is not intended for use by individuals who are pregnant.	
File Attachment	

Enter any special applications of the device or contraindications not addressed in the Intended Use Statement.	
N/A	
File Attachment	

Special instrument requirements: Enter a brief description of instrumentation required to perform testing. If instrumentation has been previously cleared for marketing, identify the 510(k) number. *	
N/A	
File Attachment	

Information:	*Note any changes that have been made to the instrument or software for use with this new analyte (or confirm that no changes have been made). Provide risk assessment and validation data for each of these changes and demonstrate compliance with FDA software policy.*

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	Mr Brandon Stephen Bransgrove
Occupation Title	Product Manager
Email Address	brandon@ndp.com.au
Establishment Information:	
Establishment Name	National Diagnostic Products
Division Name	Laboratories/Production
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Physical Location:	
Address	7-9 Merriwa Street, Gordon Sydney, NSW, 2072, AS
Telephone Number	(+61) 294-1847 Ext: 77
Fax Number	(+61) 294-3611 Ext: 51
Mailing Location:	
Address	Unit 22/39 Herbert Street St.Leonards Sydney, NSW, 2065, AS
Item: 2	

Status Change	*	No
Site Operation		
. Manufacturer	*	Yes

.	Contract Manufacturer *	No
.	Contract Sterilizer *	No
.	Repackager/Relabeler *	No

Contact Information	
Contact Information:	
Contact Name	Mr Brandon Stephen Bransgrove
Occupation Title	Product Manager
Email Address	brandon@ndp.com.au
Establishment Information:	
Establishment Name	National Diagnostic Products
Division Name	Head Office/Packaging/Warehouse
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Physical Location:	
Address	22/39 Herbert Street, St.Leonards Sydney, NSW, 2065, AS
Telephone Number	(+61) 294-3281 Ext: 00
Fax Number	(+61) 294-3611 Ext: 51
Mailing Location:	
Address	Unit 22/39 Herbert Street St.Leonards Sydney, NSW, 2065, AS

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
Item 1	In vitro diagnostic test systems - Requirements for in vitro whole blood glucose monitoring systems intended for use by patients for self testing in management of diabetes mellitus, First Edition 2003-05-01, Approved (15197)(15197)	InVitro	ISO
Item 2	Medical devices - Application of risk management to medical devices (14971:2000)(14971:2000)	General	ISO
Item 3	Interference Testing in Clinical Chemistry; Approved Guideline (EP 7-A)(EP 7-A)	InVitro	NCCLS
Item 4	Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (EP09-A2)(EP09-A2)	InVitro	NCCLS
Item 5	Stability Testing of In Vitro Diagnostic Reagents (13640)(13640)	InVitro	CEN

Did you reference any other standards?	Yes

7.1 Other Standards

Item: 1

Section I	**Utilization of Standards**

Standards Number	ISO 13485
Standards Organization	ISO
Standards Title	Medical Devices Quality M
Version	Edition 2
Date	01/01/2003

Please attach the standard. Before attaching, please verify any copyright restrictions.	
File Attachment	

Item: 2

Section I	**Utilization of Standards**

Standards Number	ISO 15197
Standards Organization	ISO
Standards Title	IVD blood glucose self te
Version	First edition
Date	05/01/2006

Please attach the standard. Before attaching, please verify any copyright restrictions.	
File Attachment	

8.0 Utilization of Guidance Documents

Please enter all referenced Guidance Documents.

Item	Document Title	Office	Division	Web Page
Item 1	Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology	OIVD	DCTD	http://www.fda.gov/cdrh/ode/gluc.html
Item 2	Guidance for Industry In Vitro Diagnostic Glucose Test System; Final	OIVD	DCTD	http://www.fda.gov/cdrh/ode/76.html
Item 3	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 4	Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management	OCER	DUPSA	http://www.fda.gov/cdrh/humfac/1497.html
Item 5	Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)	OCER		http://www.fda.gov/cdrh/dsma/470.pdf
Item 6	Assessing the Safety/Effectiveness of Home-use In Vitro Diagnostic Devices (IVDs): Draft Points to Consider Regarding Labeling and Premarket Submissions	OIVD		http://www.fda.gov/cdrh/ode/odecl272.html

Item 7	Guideline for the Manufacture of In Vitro Diagnostic Products	OIVD		http://www.fda.gov/cdrh/comp/918.pdf
Item 8	Regulating In Vitro Diagnostic Device (IVD) Studies	OIVD		http://www.fda.gov/cdrh/comp/ivdreg.html
Item 9	In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions	OCER		http://www.fda.gov/cdrh/manual/ivdmanul.html
Item 10	Points to Consider for Collection of Data in Support of In-Vitro Device Submissions for 510(k) Clearance	OIVD		http://www.fda.gov/cdrh/ode/95.pdf

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

1.0 Type of Product

Please select one:	*	Assay/Reagents Only

Select Device Type:	*	Quantitative and Semi-quantitative

Select device technology:	*	Colorometry

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). *	
See attached.	
File Attachment 1	Device Description

Is there an instrument associated with this assay? *	No
. Has this instrument previously been cleared?	
. Please enter the 510(k) number.	
Item	
. Have there been any modifications to the cleared instrument for this particular assay?	

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.)?	
File Attachment	

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?	
File Attachment	

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

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

Assay Types

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

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

Calibration	
Descr be the cal bration procedures for the system (i.e., use of whole blood and commercial calibration materials).	
File Attachment	

Quality Control	
Descr be 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).	
File Attachment	

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.).	
File Attachment	

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.	
File Attachment	

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	*
Chemcard Glucose Test K943503	
Descr be the item being compared	*

Detection Method
Similarities *
Enzyme linked colour change
Differences *
N/A
Item: 2

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device *	
Chemcard Glucose Test K943503	
Descr be the item being compared *	
Sample	
Similarities *	

Finger stick blood sample
Differences *
N/A
Item: 3

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device *	
Chemcard Glucose Test K943503	
Descr be the item being compared *	
Sample Volume	
Similarities *	
1 drop (no sample premeasurement)	
Differences *	

N/A

Item: 4

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

Predicate device *

Chemcard Glucose Test K943503

Descr be the item being compared *

Enzyme

Similarities *

Glucose oxidase

Differences *
N/A
Item: 5

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

Predicate device *
Chemcard Glucose Test K943503
Descr be the item being compared *
Dye
Similarities *

TMB
Differences *
N/A
Item: 6

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device *	
Chemcard Glucose Test K943503	
Descr be the item being compared *	
Instrument required	
Similarities *	
No	

Differences *
N/A
Item: 7

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device *	
Chemcard Glucose Test K943503	
Descr be the item being compared *	
Intended Use	
Similarities *	
For the early detection of abnormal glucose concentrations that can	

be a sign of diabetes or other health problems

Differences *

N/A

Item: 8

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

Predicate device *

Chemcard Glucose Test K943503

Descr be the item being compared *

Operating Temperature

Similarities *

18 – 35° C

Differences *

N/A

Item: 9

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

Predicate device *

Chemcard Glucose Test K943503

Descr be the item being compared *

Test Time

Similarities *

N/A

Differences *
60 seconds (Predicate 3 minutes)

Item: 10

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

Predicate device *
Chemcard Glucose Test K943503
Descr be the item being compared *
Test Range
Similarities *
N/A
Differences *

18-661mg/dL (Predicate 50-150 mg/dL)

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 ant bodies and epitopes).	*
The reaction is based on the well known glucose oxidase - peroxidase - TMB reaction. A drop of blood is applied to the reagent containing membrane and wiped after 30 seconds. A colour reaction occurs that is directly proportional to the concentration of glucose in the sample. See Attached.	
File Attachment 1	Test Principle

5.0 Performance Characteristics

Note:	*Provide the informationdescribed below as appropriate to support the substantial equivalence determination. The type of data to be provided in this section depends on the intended use, technological characteristics of the new device, and claims.*

Note:	*If you followed CLSI guidelines, which have specific instructions and calculations for determining performance, you may certify this instead of describing all the specifics of your protocol, statistical analyses, and line data. You should clarify which specific aspects of the protocol you followed, describe your deviations from the protocol, and describe any manufacturer-specific choices not specified in the guideline (e.g. number of lots or sites for precision or partitioning of sub-populations for reference range evaluation). You should also provide a summary of the results as listed below. CLSI guidelines relevant for the following sections include: EP5, Evaluation of Precision Performance of Clinical Chemistry Devices; EP12, User Protocol for Evaluation of Qualitative Test Performance; EP6, Evaluation of the Linearity of Quantitative Analytical Methods; EP7, Interference Testing in Clinical Chemistry; EP9, Method Comparison and Bias Estimation Using Patient Samples; EP14, Evaluation of Matrix Effects; GP10, Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; C28, How to Define and Determine Reference Intervals in the Clinical Laboratory; M2, Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard; M7 , Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard; M11, Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved*

	Standard; M23, Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters; Approved Guideline; M24, Susceptibility Testing of Mycobacteria, Nocardia, and Other Aerobic Actinomycetes; Approved Standard; M27, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard and M100, Performance Standards for Antimicrobial Susceptibility Testing; Fifteenth Informational Supplement.

5.1.1 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.	*
See Attached	
File Attachment 1	Description of studies

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.	*
See Attached	
File Attachment 1	Description of Specimens

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).	*
See Attached.	
File Attachment 1	Sources of variability

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

See Attached

File Attachment 1	Description of statistical methods

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. *

See Attached

File Attachment 1	Mean std deviation, CV%, number of tests etc

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.

File Attachment	

5.1.2 Linearity/Assay 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 descr be recovery of the assay in graphic and tabular form. *

See Attached

File Attachment 1	State the linear range and the measuring

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

(b)(4)

[redacted]

File Attachment	

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

File Attachment 1	Enter a description of how reportable range is determined

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

File Attachment 1	Enter a description of specimen type and preparation

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

See Attached

File Attachment 1	Number of samples replicates, statistical methods

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

See Attached

File Attachment 1	(b)(4) [redacted]

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

See Attached

File Attachment 1	(b)(4) [redacted]

Descr be how results outside the measuring (reportable) range are reported to the user. *

The Instructions for Use (IFU) advise that results darker than the 35mmol/L (631mg/dL) colour block should be interpreted as higher than 35mmol/L (631mg/dL). Results lighter than the 1 mmol/L (18mg/dL) colour block should be interpreted as being lower than 1mmol/L (18mg/dL).

File Attachment	

Descr be validation of instructions for out-of-range specimens, if applicable. *

N/A

File Attachment	

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

File Attachment	

5.1.3 Calibrators and Controls

Are calibrators or controls included in the submission? *	No
. If you answered "no" to the above questions explain why. *	Available commercially
. Enter the 510(k) number.	
. Provide information on the commercial source and control preparation methods. *	
N/A. Controls are not feasible for a test of this nature nor are they provided with the predicate.	

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).

File Attachment	

Enter the description of internal controls, the reaction, functions monitored, and frequency of controls needed, if applicable. *	
Each label has a zero colour block. This is the colour that an unreacted test strip in good condition should be. Instructions for Use warn that any blueing of the unreacted test strip is a sign of deterioration.	
File Attachment	

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

Where applicable, briefly summarize the following information 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. *	
N/A	
File Attachment	

5.1.5 Analytical Limits at Low Levels

Enter the description of specimen type and preparation including matrix, analyte levels, and how levels were established. *	
See Linearity Study	
File Attachment	

Enter the number of replicates (runs, days, instruments, and operators, as appropriate) included at each concentration. *

See Linearity Study

File Attachment	

Descr be the statistical method used. *

See Linearity Study

File Attachment	

Enter the results of analytical limits at low levels (e.g. limit of detection, functional sensitivity). *

(b)(4) [redacted]

File Attachment	

Enter the definition/calculation used to determine assay limits at low levels. For example: enter the number of standard deviations above the mean value of the sample without analyte. Include mean and standard deviation (limit of blank). The lowest concentration at which %CV and accuracy are within specified criteria and describe the evaluations to determine they were met. *

See Linearity Study (b)(4) [redacted]

File Attachment	

For qualitative assays, include the percent of replicates that test positive at each concentration and evaluate the 95% interval for cutoff and limit of detection.

File Attachment	

5.1.6 Analytical Specificity

Enter a description of study design and statistical methods. *
The list is referenced to CDRH Guidance Document: Review Criteria Assessment of Portable Blood Glucose Monitoring In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology. The high test level was referenced to NCCLS Document **EP7-A** Vol.22 No.27 Appendix C. Interferent Test Concentrations.
File Attachment

Enter the specimen description and preparation including matrix, analyte levels present in the sample, and how these levels were established. *
Study conducted in accordance with Interference Testing in Clinical Chemistry; Approved Guidline NCCLS EP7-A Vol.22 No.27
File Attachment

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. *	
See Attached.	
File Attachment 1	Interference testing table of results

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. *

Study conducted in accordance with Interference Testing in Clinical Chemistry; Approved Guidline NCCLS EP7-A Vol.22 No.27.

File Attachment	

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

No stipulated test substances were found to interefere with the results.

File Attachment	

5.1.7 Analytical Characterization of Cut-off

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

See Attached

File Attachment 1	Determination of the cut off

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

N/A

File Attachment	

Enter a definition of "equivocal zone," if applicable. *	
N/A	
File Attachment	

Enter the statistical method used (e.g., Receiver Operator Characteristic Analysis). *	
N/A - Cut off well recognised.	
File Attachment	

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.	
File Attachment	

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.	
File Attachment	

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

Carryover	
Provide studies to demonstrate lack of over estimation of results due to the carryover effect. The testing pool should consist of samples at clinically meaningful levels.	
File Attachment	

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

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. *	
An indirect comparison with the predicate was performed. The comparator used was the legally marketed Roche Accu-chek Active System K011738. This system determines glucose in a small capillary sample in approximately 5 seconds. The test procedure was as indicated by the manufacturer. The system is calibrated by means of the hexokinase method, which is traceable to an NIST standard. All reference method tests were performed with strips from the same lot. Accu-Chek Active system is indicated for blood glucose monitoring, e.g. in diabetic patients, persons suspected of having diabetes, emergency diagnosis, and self-testing by diabetics. Test may be performed with fresh capillary blood, with venous blood anticoagulated with lithium or ammonium heparin or EDTA. The Accu-Chek Active permissible hematocrit range is indicated to be between 25-55%.The performance characteristics stated by the manufacturer specify that the system has a mean systematic deviation from the hexokinase method with deproteinisation of max 4%, the coefficients of variation for repeatability and reproducibility, evaluated in a typical series of tests conducted in a hospital environment , were 1.7% and 1.4% respectively. The manufacturer specifies that the system is linear within the range 0.6mmol/L-33.3mmol/L.	
File Attachment	

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.

Inclusion Criteria

To be eligible for the study, all subjects must meet the following criteria:

- age 18+ years;

- no condition that in the opinion of the investigator would preclude participation in the study e.g. blindness

- subject understands the study protocol and agrees to comply with it;

- ability and willingness to provide informed consent.

A broad cross section of ages and backgrounds should be achieved in the sample population. Participant consent should be obtained in writing and witnessed through the use of a consent form.

Exclusion Criteria

Persons under the age of 18 and therefore unable to give consent should not be included.

File Attachment	

Enter the sample description (e.g., matrix). *
For both methods (Reference and Betachek Glucose Test), fresh capillary samples were used in method comparison studies performed. The samples were collected by skin puncture (finger-stick) and used immediately, in the vast majority of cases. In order to obtain sufficient samples in the lowest and highest concentration intervals, glucose concentrations were adjusted [1] as follows: (b)(4) [redacted] (b)(4) [redacted] 1. ISO 15197 *In vitro* diagnostic test systems- Requirements for blood-glucose monitoring systems for self- testing in managing diabetes mellitus
File Attachment

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. *	
See Attached. For the method comparison a trained technician performed both the reference and the Betachek Glucose Test. For studies where the intended user is represented see lay user studies under clinical studies section.	
File Attachment 1	Settings and Locations where data was collected

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

(b)(4) [redacted]

File Attachment	

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? *

(b)(4) [redacted]

Subjects included both males and females and an enrolment goal was to achieve an approximately equal sex distr bution.

File Attachment	

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) [redacted]

File Attachment	

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

The Betachek testing procedure was performed by a trained technician, without any specific information regarding the patient medical history (diet, type of medication, diabetes management, other investigations).

After recording the Betachek results the reference method testing was performed and recorded.

File Attachment	

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

For both methods (Reference and Betachek Glucose Test), fresh capillary samples were used in method comparison studies performed. The samples were collected by skin puncture (finger-stick) and used immediately, in the vast majority of cases.In order to obtain sufficient samples in the lowest and highest concentration intervals, glucose concentrations were adjusted [1] as follows:

(b)(4) [redacted]

(b)(4) [redacted]

1. ISO 15197 *In vitro* diagnostic test systems- Requirements for blood-glucose monitoring systems for self- testing in managing diabetes mellitus

File Attachment	

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

(b)(4)

- (b)(4)

- (b)(4)

Additional capillary blood specimens were collected from (subjects and preserved with Li Heparin. These specimens were adjusted in order to obtain sufficient samples in the lowest and highest concentration intervals as stipulated by ISO 15197. [1] The adjusted specimens were then used to conduct 2 tests on each of the methods.

1. ISO 15197 *In vitro* diagnostic test systems- Requirements for blood-glucose monitoring systems for self- testing in managing diabetes mellitus.

File Attachment	

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

See Attached

File Attachment 1	Control Testing

Attach or enter a table to descr be 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. *

See Attached

File Attachment 1	Clinical and demographic characteristics of the population

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 (b) subjects satisfied the inclusion elig bility criteria and all were tested.

File Attachment	

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. *

See Attached

File Attachment 1	Indeterminate results outliers invalid etc

Enter analyte level distribution among samples to demonstrate that the medical decision points were challenged and the proposed measuring range was covered. *
See Attached
File Attachment 1 — Analyte level distribution

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.
File Attachment

Do you have an equivocal zone with your assay? *	No

Attach or enter the appropriate table. *
See Attached
File Attachment 1 — FDA Positive Negative table for method comparison

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. *
See Attached

File Attachment 1	Description of statistical methods of analysisand results.

Include graphs of the new test results against the results of the comparator for each separate specimen type, sample subgroup or testing site (and combinedif justified). Other tabular orgraphical representations may also be appropriate, e.g., Bland-Altman plots. *
Se Attached
File Attachment 1 — Graphs and tables of results

Provide descriptive statistics where applicable: n, mean, standard deviation, minimum, median, maximum, and stratified results (e.g. by patient enrollment site, lab testing site). *
See Attached
File Attachment 1 — Descriptive Statistics

Descr be the adverse events from performing the new or comparator tests. *
N/A
File Attachment

5.2.2 Matrix Description and Comparison

Descr be, 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. *

N/A capillary finger tip sample only
File Attachment

5.3 Clinical Studies (where applicable)

Are there clinical studies included in this submission? *	Yes

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. *
A lay user study was undertaken and feedback from users was obtained. See Attached.

File Attachment 1	Protocol - Betachek Glucose Lay User Study
File Attachment 2	Lay User Study Percent Positive Negative Table
File Attachment 3	Betachek Glucose Test Consumer Feedback Summary

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.). *
N/A
File Attachment

5.4 Clinical Cut-off

Descr be the established cut-off and its validation for the new device. Define "equivocal zone" if applicable, and include a description of how results within this zone are reported to the user. *	
See Attached	
File Attachment 1	Determination of the cut off

5.5 Reference Interval (Expected Values)

Enter the reference interval for this measurand and the method used to determine it. *	
See Attached	
File Attachment 1	Determination of the cut off

Include the literature references establishing the reference intervals and justification for applying this range to the new device. *	
See Attached	
File Attachment 1	Determination of the cut off

Include a description of your methods for determining the reference intervals if they are not well established from the literature or if the range cannot be transferred to the new device. Also, descr be the population studied (demographics, inclusion/exclusion criteria, number of individuals). Indicate if separate reference intervals for subclasses where clinically justified. Determine the method of clinical diagnosis of the reference population(s). Finally, include the statistical method used to calculate ranges. *

Expected Values are well established.
File Attachment

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, cal bration, quality controls, results (calculations, formulas), results(interpretation), performance characteristics (summarize reproduc bility, etc.), and study design (population studied, N, type of sample, matrix, dilution, target concentrations, etc.).	*
See Atttached.	
File Attachment 1	Predicate - Chematics Chemcard, Instructions for use
File Attachment 2	Betachek Glucose Test Box
File Attachment 3	Betachek Glucose Test Label
File Attachment 4	Betachek Glucose Test Instructions for Use

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: Risk analysis [Special 510(k)s], manufacturing information for critical reagents, copies of bibliography references, financial disclosures, and software validation or certification statements, if necessary to support equivalence.	*
See Attached Risk Analysis	
File Attachment 1	Risk Analysis - Betachek Glucose Test

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510 (k) Summary

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1.	Submitter's Name:	National Diagnostic Products (Aust) Pty Ltd
	Address:	22/39 Herbert Street, St.Leonards NSW 2065, Australia
	Contact Person:	Brandon Bransgrove
	Date Prepared:	July 20 2006
2.	Device Name:	Betachek Glucose Test
	Proprietary/Trade name:	Betachek Glucose Test
	Common Name:	Glucose Test System
	Classification Name:	Glucose Test System
	Device Classification:	II
	Regulation Number:	21 CFR 862.1345
	Classification Panel:	Clinical Chemistry (75)
	Product Code:	CGA (Glucose Oxidase, Glucose)
3.	Predicate Device Name:	Chemcard Glucose Test
	Manufacturer:	CHEM-ELEC, INC
	510 (K) Number:	K943503

4. Description of the Device

Reagent test principle – glucose oxidase

5. Intended Use

Betachek Glucose Test is intended as a screening test for the early identification of abnormal fasting blood glucose levels that can be a sign of diabetes or other health problems. The test uses a drop of capillary blood to provide a preliminary, semi-quantitative result. Any abnormal result should be confirmed using a quantitative method. The test is not intended for use by individuals who are pregnant.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

6. Substantial Equivalence

Similarities		
Item	**Device**	**Predicate**
	Betachek Glucose Test	**Chemcard**
Detection Method	Enzyme linked colour change	Enzyme linked colour change
Sample	Finger stick blood sample	Finger stick blood sample
Sample Volume	1 drop (no sample premeasurement)	1 drop (no sample premeasurement)
Enzyme 1	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Enzyme 2	Peroxidase	Peroxidase
Dye	TMB	TMB
Instrument required	No	No
Intended use	For detecting abnormal glucose concentrations that can be a sign of diabetes or other health problems.	For detecting abnormal glucose concentrations that can be a sign of diabetes or other health problems
Operating Temperature	18 – 35° C	18 – 35° C

Differences		
Item	**Device**	**Predicate**
	Betachek Glucose Test	**Chemcard**
Test Range	9 mg/dL – 661 mg/dL	50 mg/dL – 150 mg/dL
Test Time	1 minute	3 minutes
Dimensions	5mm x 75mm x 0.175mm	Test Card
User steps	Blood wiped at 30 seconds and result read after 60 seconds.	Card Peeled at 3 mins and result must read within 30 seconds.
Hematocrit Range	35% - 55%	Unknown
Number of colour blocks	9	5

7. Data demonstrating substantial equivalence

Betachek Glucose Test has the same intended use and technological characteristics as the predicate device and clinical evaluations demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Therefore, Betachek Glucose Test is substantially equivalent to the predicate device.

For the total number of (b)(4) subjects participating in this study, the glucose level, as tested with the reference method (two measurements for each subject), had the following distribution:

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

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Could you have diabetes?

60 second Glucose Test

2 tests

BETACHEK
Better life

Glucose Test

BETACHEK
Better life

2 tests

BETACHEK
Better life

Glucose Test

CE 0197

Blood Glucose Test

Ingredients
Peroxidase 0.19%, Glucose Oxidase 0.09%, TMB 1.2%, DCP 0.35%, stabiliser 8.3%, Inert ingredients 89.87%.

REF: 0956800020

Made in Australia

In vitro diagnostic use
Store between 39-86°F

UPC-A Bar Code
009568 00020

LOT

EXP

NDP National Diagnostic Products
Sydney, Australia
www.betachek.com

BETACHEK
Better Life

www.betachek.com

Why do I need to do this test?

- A diabetes epidemic is underway (Source: World Health Organisation).
- Unhealthy diets, obesity and lack of exercise are the main causes of diabetes.
- High blood pressure, elevated cholesterol, being overweight or having a family history of diabetes increases your risk of developing diabetes.
- Approximately 30% of people with diabetes don't know they have it.

How does it work?

Betachek is an effective test for abnormal blood sugar (glucose) levels that can be a sign of diabetes or other medical problems.

Diabetes is a disorder that causes high blood sugar (glucose) levels. Untreated this can lead to heart disease, kidney failure, blindness and limb amputations. Early diagnosis and treatment will prevent this.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek Glucose Test - Summary of Feedback	**Yes**	**No**	**Unsure**	**Total**
Where you aware of the need to fast for 8 hours before testing?	(b)(4)	[redacted]	[redacted]	[redacted]
Did you fast prior to the test?	[redacted]	[redacted]	[redacted]	[redacted]
Did you wash your hands before lancing your finger?	[redacted]	[redacted]	[redacted]	[redacted]
Where the instructions for lancing easy to follow?	[redacted]	[redacted]	[redacted]	[redacted]
Did you start timing immediately after applying the blood?	[redacted]	[redacted]	[redacted]	[redacted]
Did you wipe the blood at exactly 30seconds?	[redacted]	[redacted]	[redacted]	[redacted]
Did you realise timing was important in this test procedure?	[redacted]	[redacted]	[redacted]	[redacted]
Did you check the result after 60 seconds?	[redacted]	[redacted]	[redacted]	[redacted]
Was the result clear?	[redacted]	[redacted]	[redacted]	[redacted]
Did you understand your result?	[redacted]	[redacted]	[redacted]	[redacted]
Did the result indicate you had a high glucose level?	[redacted]	[redacted]	[redacted]	[redacted]
Do you know what you must do if your result is higher than the cut off?	[redacted]	[redacted]	[redacted]	[redacted]
Can the test alone diagnose diabetes?	[redacted]	[redacted]	[redacted]	[redacted]
If a result is high should you consult your doctor?	[redacted]	[redacted]	[redacted]	[redacted]
Would you consider yourself in a group at high risk of diabetes?	[redacted]	[redacted]	[redacted]	[redacted]
Do you believe you carried out the test correctly?	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

BETACHEK

Better life

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Glucose Test

What is this Test for?

Betachek Glucose Test is intended as a screening test for the early identification of abnormal fasting blood glucose levels that can be a sign of diabetes or other health problems. The test uses a drop of capillary blood to provide a preliminary, semi-quantitative result. Any abnormal result should be confirmed using a quantitative method. The test is not intended for use by individuals who are pregnant.

Background – Type 2 Diabetes

It is estimated that 30% of people with diabetes in the US remain undiagnosed[1]. The initial stage of the disease is asymptomatic and characterised by abnormal blood glucose levels. Diagnosis often occurs only after the onset of symptoms, by which time preventable, severe and irreversible damage has already occurred. The early detection of abnormal blood glucose levels is therefore desirable. Betachek Glucose Test is a convenient and effective way to detect abnormal blood glucose levels in just 60 seconds. Individuals who obtain an abnormal result should see their doctor for further definitive testing.

How Does the Test Work?

On each test strip there is a test zone containing sensitive chemicals. When blood is applied to the zone, a chemical reaction takes place causing color to develop in direct proportion to the amount of glucose in the blood. The test employs the Glucose Oxidase/ Peroxidase reaction which along with chromogen indicators and non reactive agents is contained in the test zone.

Chemical Composition

Each Betachek test strip contains: Glucose Oxidase 0.09%, Peroxidase 0.19%, TMB 1.2%, DCP 0.35%, Stabilizer 8.30%, Inert Ingredients 89.87% (w/w).

Precautions and Limitations

For *in vitro* diagnostic use. Use the test strips only between 64 and 95°F (18 and 35°C).Use only fresh capillary whole blood from a finger stick. The test strips are for single use only. Incorrect timing - leaving the blood on too long will increase the result and wiping the blood too early will decrease the result. Failure to fast will produce invalid results.

Storage and Handling

Store Betachek Test Strips in their original container in a cool, dry place between 39-86°F (4-30°C) Do not freeze. Use the test strip immediately after it is removed from the container; replace the container cap immediately and close it tightly.

Quality Checks

The test strips can be checked against the '0' (unreacted) color block to see they are in good condition. If any sign of blue is visible, the strip should not be used. After performing a test a clear color change should occur that approximates a color standard on the label.

What is Included?

2 tests, 2 single use lancets, 1 label on container with color chart, 2 tissues, 2 alcohol swabs, 1 package insert.

What is not Included but Needed?

A watch with a second hand or a timer.

Measurement Range

The measurement range is 18-631mg/dl (1-35mmol/l). A test result lighter than the 18 mg/dl color standard is less than 18mg/dl (1 mmol/l). A test result darker than the 631 mg/dl color standard is greater than 631 mg/dl (35 mmol/l).

When Should I Test?

An ideal time to test is before breakfast. Ensure you do not eat or drink for 8 hours before testing (you may drink water only).

How do I Run a Test?

See the step by step color instructions numbered 1-7.

How do I Read the Result?

Results are obtained by matching the test zone to the nearest color on the label. Use natural light when color matching for best results. When matching colors always ask the question is the test zone lighter or darker than the color standard it is being compared to. After deciding move to the next color standard and repeat until you find the closest match. The test zone color will remain stable for 5 minutes.

Expected Results

Fasting blood glucose results ≥110 mg/dl (6.1 mmol/l) are considered abnormal[2].

Results	Glucose concentration (mg/dl) *Capillary whole blood*
Normal	Fasting > 50 and < 90
Impaired fasting Glucose (IFG)	Fasting ≥ 90 and < 110
Abnormal	Fasting ≥ 110

If the test zone is *darker than* the 108mg/dl (6 mmol/l) color standard on the label then your result is abnormal and you should see your doctor for further testing.

Do I Need to Test Again?

Testing should be conducted annually by individuals who are any of the following: obese; have a first-degree relative with diabetes; are members of a high-risk ethnic population (Indian, African, Hispanic, Native American, Aboriginal, Pacific-Islander, Asian); have delivered a baby weighing more than 9 pounds; have had gestational diabetes; have high blood pressure; have HDL cholesterol levels ≤35mg/dl or triglyceride levels ≥250mg/dl; or who, on previous testing had impaired glucose tolerance or impaired fasting glucose. All adults older than 45 years of age should test for diabetes every three years.

Performance Characteristics

Accuracy

In a study involving 120 patients attending a diabetes clinic, results obtained by a laboratory technician using Betachek Glucose Test produced the following least squares regression equation when compared to a reference method: $y=0.9752x + 0.3332$. $R^2=0.98$.

Results <75 mg/dl compared to the reference:

Within ± 5mg/dl	Within ± 10mg/dl	Within ± 15mg/dl
47.7%	84.1%	95.4%

Results ≥ 75mg/dl

Within ±5%	Within ±10%	Within ±15%	Within ±20%
43.9%	79.1%	94.9%	97.4%

Classification Accuracy

Studies were conducted at 3 sites with a total of 120 untrained subjects who performed the test unassisted and classified their results as either normal or abnormal. Of the 120 subjects, 119 correctly classified themselves. By computing the 95 percent confidence interval for the binomial distribution, Betachek Glucose Test exhibited a classification accuracy of greater than 95 percent.

Precision

The within-lot precision of Betachek strips was determined for three lots of strips, at five different glucose levels, covering a range between 36 mg/dl and 342 mg/dl. A reflectance meter programmed with a calibration curve was used to read the Betachek test strips. CV's for all lots ranged from 2.6 to a maximum of 4.86%.

References:

1.Catherine C. Cowie et al., Prevalence of Diabetes and Impaired Fasting Glucose in Adults in the U.S. Population *Diabetes Care* 29:1263-1268, 2006

2. American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus, *Diabetes Care* 29:S43-S48, 2006

[Plasma equivalent: ≥126mg/dl (7.0 mmol/l)]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Version DTUS001 July 2006

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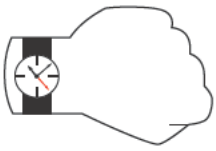
BETACHEK
Better life

Glucose Test



You need:
a timer or watch with a second hand

Do not eat or drink for 8 hours before testing. *(water allowed).*

Read steps 1-7 before starting. Pay close attention to steps 4,5 and 6. Wash hands in WARM water. Dry thoroughly.

Twist off blue plastic end piece.

Select your middle or ring finger and press the lancet firmly into the centre of the tip until you hear a *'click'*.

Gently squeeze your finger until you have a large hanging drop of blood. ***Get ready to start timing***.

Place a drop of blood onto the test pads and ***IMMEDIATELY START TIMING!***

Ensure both test pads are fully covered. Do not smear or dab blood thinly.

After ***EXACTLY*** 30 seconds, wipe the blood off using a tissue. Wipe again using a clean area of the tissue.

After a further 30 seconds read your result by matching the test zone against the color chart on the label.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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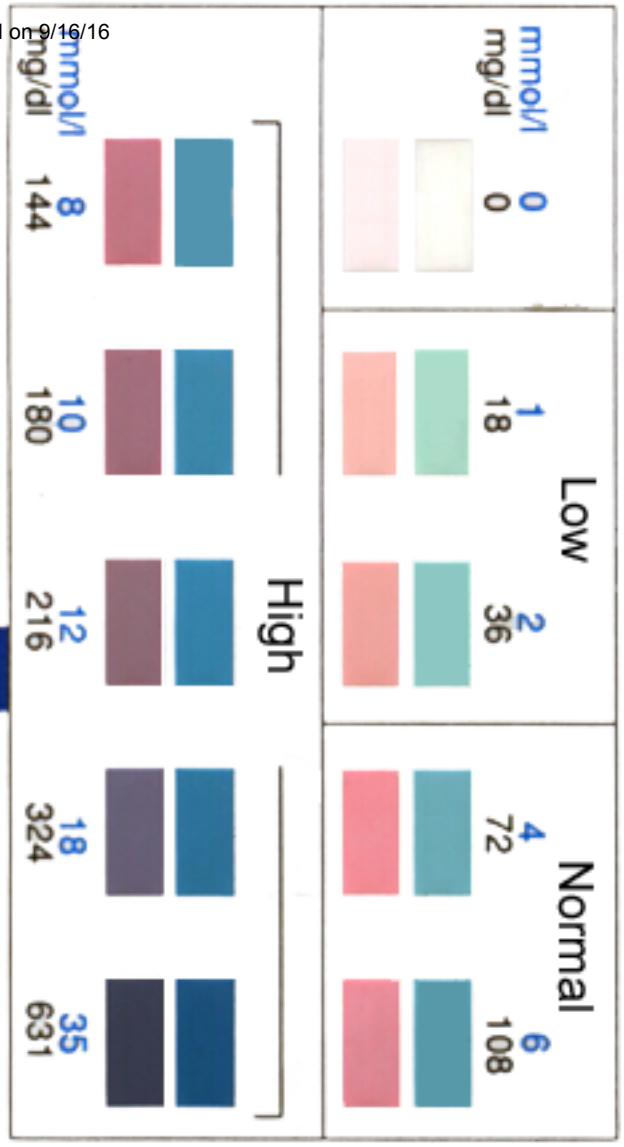
BETACHEK

Better Life

Glucose Test



Fasting blood glucose level

2 Tests + 2 Lancets

Distributor Name
Address xxx
xxxxx xxxxxxx

LOT **785790**

EXP **2007-06**

Store between 39 and 86 F

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

For in vitro diagnostic use

A summary of all subjects tested is presented in the following tables:

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

The age distribution of subjects is presented in the table below:

(b)(4) [redacted]

The glucose results obtained across age groups was as follows:

(b)(4) [redacted]

(b)(4)

[redacted]

Table 1 Reference system control testing

(b)(4)

[redacted]

Table 2 Betachek control testing

(b)(4)

[redacted]

Description of specimens

(b)(4)

[redacted]

Table 1. Glucose concentration intervals for repeatability and between-lot reproducibility evaluation

(b)(4)

[redacted]

(b)(4)

[redacted]

[1] ISO 15197:2003 In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.

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Description of statistical methods to analyse data, model assumptions.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Description of statistical methods of analysis and results.

(b)(4)

(b)(4)

Figure 1 gives a histogram of the Betachek strips differences compared with Accu-chek Active results for (b) samples subject of this study.

(b)(4)

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(b)(4)

[redacted]

Table 1 Regression statistics for Betachek

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Description of studies

(b)(4)

[redacted]

[1] ISO 15197 *In vitro* diagnostic test systems- Requirements for blood-glucose monitoring systems for self- testing in managing diabetes mellitus

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Descriptive statistics: n, media, sd, median, min, max etc

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Determination of the cut off

(b)(4)

[redacted]

WHO:

(b)(4)

[redacted]

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Abnormal = Fasting Blood Glucose ≥ 110mg/dL

(b)(4)

[redacted]

Normal Blood Glucose

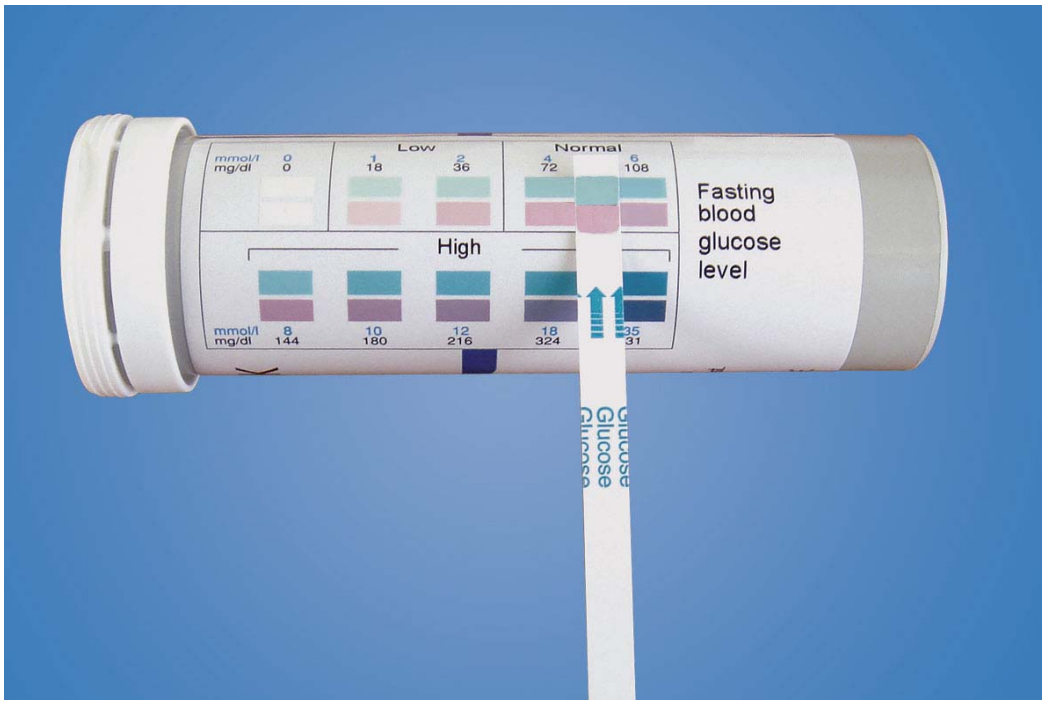
(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Device Description

Betachek Glucose Test is a two colour (pink/blue) visually read test strip for the semi-quantitative measurement of glucose in fresh capillary whole blood. Each test comprises two reagent zones attached to the end of a plastic strip. Each container label has a 9 increment colour chart for result interpretation.



Betachek Glucose Test is intended as a screening test for the early identification of abnormal fasting blood glucose levels that can be a sign of diabetes or other health problems. The test uses a drop of capillary blood to provide a preliminary, semi-quantitative result. Any abnormal result should be confirmed using a quantitative method. The test is not intended for use by individuals who are pregnant.

The reaction is based on the Glucose Oxidase/ Peroxidase reaction which along with chromogen indicators and non-reactive ingredients is contained in the reagent pads.

(b)(4)

[redacted]

Test Procedure

Step 1. A drop of blood is applied to the test zone.

Step 2. The blood is wiped from the test zone after 30 seconds.

Step 3. After waiting a further 30 seconds the result is read by matching the test zone with the appropriate colour standard on the label.

Physical Description

Item	Device
	Betachek Glucose Test
Detection Method	(b)(4) [redacted]
Sample	
Sample Volume	
Enzyme 1	
Enzyme 2	
Dye	
Instrument required	
Intended use	
Operating Temperature	
Test Range	
Test Time	
Dimensions of the Strips	
User steps	
Hematocrit Range	
Number of color blocks	

Single use lancets

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

The following aspects were considered for determination of Betachek Glucose Test reportable range:

- (b)(4) [redacted]
- [redacted]
- [redacted]

The acceptance criteria for Betachek Glucose Test results, within the reportable range, are the ones specified in International Standard ISO 15197:

- (b)(4) [redacted]
- [redacted]

Enter description of specimen type and preparation (matrix, analyte level, method used to determine the target levels).

(b)(4) [redacted]

According to the NCCLS EP6 protocol, (b)(4) [redacted] (Table 2.).

Table 1. : Levels of Dilution Schemes

(b)(4) [redacted]

The Low and High concentrations used were 0.5 mmol/L and 56.5 mmol/L, respectively.

(b)(4) [redacted]

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Estimate slope, intercept, 95% CI, R^2

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Graphs, bias plot, other tabular data

Linear regression studies (ordinary linear regression) for Betachek compared with Accu-chek Active are presented in Figure 1.

(b)(4) [redacted]

Figure 1 (b)(4) [redacted]

A bias plot is presented in Figure 2. (b)(4) [redacted].

(b)(4) [redacted]

The bold lines represent the ISO 15197 recommended acceptance criteria limits.

(b)(4) [redacted]

Tables 1 and 2 present the accuracy of Betachek visual strips segregated for (b)(4) [redacted]

Table 1 Betachek strips accuracy for glucose (b)(4) [redacted]

(b)(4) [redacted]

Table 2 Betachek (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 1 Reference method anomalous results

(b)(4)

[redacted]

Table 2 Betachek method anomalous results

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The study design specifies that the indeterminate, invalid, missing responses and outliers are treated as follows:

Table 3.

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Interferences from Exogenous Substances

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4) [redacted]

Studies were conducted at three separates sites to evaluate the ability of an untrained individual to perform the test and interpret their result as being either normal or abnormal. (b)(4) [redacted].

1. (b)(4) [redacted]

Within-lot precision results are shown in the table below (b)(4) [redacted]

Blood Glucose Level	Level 1	Level 2	Level 3	Level 4	Level 5
(b)(4) [redacted]					

2.
In order to evaluate the between-lot variation, 10 Betachek Glucose lots were [redacted]

[redacted]					
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]

3.

(b)(4)

[redacted]

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Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. 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) [redacted]
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

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

NATIONAL DIAGNOSTIC PRODUCTS
22/39 Herbert Street
St.Leonards NSW 2072
AU

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
NO DATA

2. CONTACT NAME
Brandon Bransgrove

2.1 E-MAIL ADDRESS
brandon@ndp.com.au

2.2 TELEPHONE NUMBER (include Area code)
612-9432 8100

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
612-9436 1151

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/dc/mdufma

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

3.1 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. 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, parents, and partner firms

[ ] This biologics application is submitted under secion 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

6. 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

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4) [redacted]

27-Jun-2006

Form FDA 3601 (08/2003)

Close Window

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Number of samples, replicates, statistical methods used.

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

CHEMCARD SYSTEMS

A Complete 3 Minute Whole Blood Screening Test for Identification of ABNORMAL PLASMA GLUCOSE LEVELS

INTENDED USE

The Chemcard™ Glucose Test is intended for use as a rapid, *in vitro* method for early identification of abnormal fasting plasma glucose concentration which can be a sign of diabetes or other medical problems. The Chemcard™ provides a preliminary, semi-quantitative result using fingerstick blood as the test specimen. Any abnormal result obtained using the Chemcard™ should be verified using a quantitative method.

The Chemcard™ Glucose Test is not intended for use with individuals who are known to be diabetic or pregnant.

SUMMARY

It is estimated that 3.2 percent of the adult population in the U.S., between the ages of 20 and 74, suffers from undiagnosed Diabetes Mellitus.[1] Diagnosis often occurs after the onset of severe and often irreversible complications. The Chemcard™ Glucose Test is a highly effective test for use in glycemic screening and early identification of generally asymptomatic individuals, for abnormal blood glucose levels often associated with diabetes or other carbohydrate metabolic disorders. These individuals can then be referred for more definitive diagnostic testing, often before the onset of complications.

Chemcard™ Glucose Test is a rapid, convenient, cost effective test system which is effective in screening for abnormal blood glucose concentrations. Each test card is a self contained assay that combines proven detection methods with a patented whole blood separator for unsurpassed convenience and simplicity.

PRINCIPLE

The Chemcard™ Glucose Test is a disposable device which uses a unique blood cell separator coupled with a dry phase enzymatic chemistry to provide a semi-quantitative measurement of fasting blood glucose concentration, from a single, unmeasured drop of fingerstick blood. The separator removes cellular constituents from the specimen and delivers a volumetric sample of plasma to the detection chemistry. Results are visually interpreted by comparing the color change in the reagent pad with an integral color standard. The glucose detection method is based on that described by Keston,[2] Comer[3] and Free[4] but uses tetramethylbenzidine (TMB) in the chromogenic complex as follows:

$$\text{d-glucose} + O_2 + H_2O \xrightarrow{\text{GLUCOSE OXIDASE}} \text{d-glucono-1,5 lactone} + H_2O_2$$

$$H_2O_2 + \text{chromogen} \xrightarrow{\text{PEROXIDASE}} \text{dye} + H_2O$$

COMPOSITION

Glucose Oxidase (1.1.3.4)	8.40% w/w
Peroxidase (1.11.1.7)	6.70% w/w
pH Buffers	34.30% w/w
Tetramethylbenzidine	47.50% w/w
Non-reactive ingredients	3.10% w/w

STORAGE AND STABILITY

Chemcard™ Glucose Tests should be stored at room temperature, not to exceed 86°F (30°C). Refrigeration is not required. Test cards may be used until the expiration date appearing on each package. Any packages that appear to have a broken seal should not be used for testing. Once the foil package is opened, the test should be used immediately.

MATERIALS PROVIDED

Each individual test package contains a single test card along with a sterile lancet.

MATERIALS NEEDED BUT NOT PROVIDED

Clean Dry Tissue
Timing Device (3 minute)

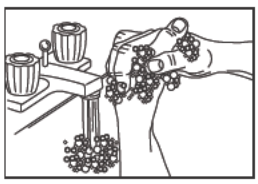
PRECAUTIONS

- For *in vitro* diagnostic use only.
- Never use a test beyond the expiration date specified on the test package.
- The individual to be tested should fast for 6 to 12 hours before specimen collection.
- The Chemcard™ Glucose Test is intended for use with fresh, capillary blood only.
- The Chemcard™ Glucose Test is not intended for use to monitor diabetic patients.
- Not recommended for use in children under the age of 2 years old.
- Not recommended for use with patients known to be pregnant.

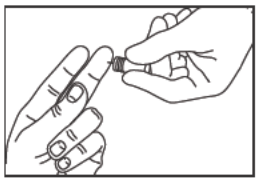
PROCEDURE

1 The individual to be tested must FAST for 6 to 12 hours before testing. No food or drink (other than water) should be consumed during the fasting period.

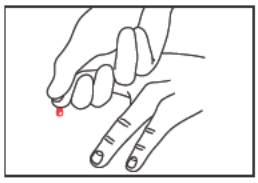
2 CLEAN FINGERTIP area thoroughly using soap and warm water. Dry thoroughly.



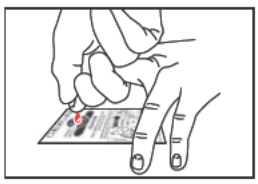
3 PRICK FINGER with lancet. Discard the first drop of blood by wiping on clean dry tissue.



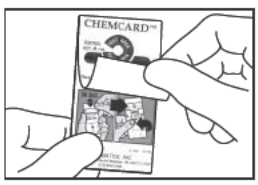
4 Squeeze finger to obtain a LARGE DROP of blood, enough to hang down from the fingertip.



5 PLACE BLOOD ON TEST AREA: Gently bring the lower part of the blood drop into contact with the test area. Verify that "Control Dot A" changes color (if not, add another drop of blood). START TIMER.

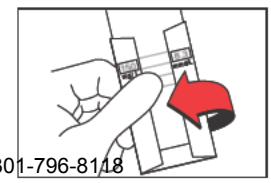


6 After 3 MINUTES, PEEL OFF THE "TAB" to remove the top layer of the test card and discard.



7 COMPARE COLOR of the "Test Area" with the color in the adjacent windows by sliding inner card up and down. Find the closest matching color within 30 seconds. Note: The "Test Area" will begin to fade within 3–5 minutes.

8 TURN THE TEST CARD OVER. The plasma glucose concentration appears in the windows on the back side in both mg/dl and mmol/l.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297, Released by CDRH on 9/16/16

RESULTS

Semi-quantitative plasma glucose concentration values are obtained by visual comparison of the reagent pad with the sliding color chart, then turning the test card over and reading the glucose level from the windows on the back. A reagent pad which appears lighter than the 50 mg/dl color block should be interpreted as being less than 50 mg/dl (2.8 mmol/l). A reagent pad which appears darker than the 150+ color block should be interpreted as being higher than 150 mg/dl (8.3 mmol/l).

Chemcard results of 50 mg/dl (2.8 mmol/l) or less are considered abnormally low. Chemcard results of 125 mg/dl (6.9 mmol/l) or higher are considered abnormally high for a fasting individual. Any abnormal result obtained using the Chemcard™ should be verified using a quantitative method.

LIMITATIONS OF PROCEDURE

- Failure to fast prior to testing may affect results.
- Not for use to test patients under the age of two years.
- Not for use with patients who are known to be pregnant.
- Since the effective range of the Chemcard™ is 50 to 150 mg/dl, this test should not be used for monitoring of known diabetics or for instituting or modifying drug therapy.
- All abnormal results obtained using this test should be verified using quantitative diagnostic methods.
- The Chemcard™ is designed for use with free flowing, capillary blood, usually obtained from a fingerstick. Other specimens should not be used with this test.

EXPECTED RESULTS

Normal values for fasting blood glucose concentration are widely reported to be in the 60 to 100 mg/dl range.[1, 5] The American Diabetes Association[7] defines normoglycemia as fasting plasma glucose levels <110 mg/dl (6.1 mmol/l) and states that fasting plasma glucose levels ≥126 mg/dl (7.0 mmol/l) are indications for retesting.

The Chemcard™ Glucose Test is designed to implement the American Diabetes Association's decision level strategy[7] for screening. Semi-quantitative interpretation is visually accomplished by matching colors with any of five color blocks, each representing a range of values with medians at 50, 75, 100, 125 and 150+ mg/dl. Chemcard™ results of 125 or 150+ are considered abnormally high and are recommended for follow-up diagnostic testing. Readings of 50 mg/dl or lower are considered abnormally low and should also be followed with additional testing.

CALIBRATION AND QUALITY CONTROL

The Chemcard™ Glucose Test is calibrated at the time of manufacture and requires no calibration by the user. The Chemcard™ Glucose Test has been categorized, by level of complexity, as a WAIVED TEST in accordance with regulations codified in 42 CFR 493.17, implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88). Each site should establish standards of performance in accordance with good laboratory practice.

Each test card employs two design features which allow the user to verify that the test has worked properly. "Control Dot A" changes color allowing the user to verify a sufficient blood volume (>20 µL) has been applied to the test area. The presence of a green or blue color in the reagent pad indicates that the detection chemistry is working properly. A reagent pad that is white or cream colored indicates an invalid test result.

PERFORMANCE CHARACTERISTICS

Measuring Range

The Chemcard™ Glucose Test has an effective measurement range of 50 to 150 mg/dl.

Correlation

The accuracy of the Chemcard™ Glucose Test has been demonstrated by determining correlation with a Kodak Ektachem 700® clinical analyzer. Chemcard™ results, obtained by a nurse, were paired with results obtained for each of 197* patients, whose glucose levels were within the measuring range of the Chemcard,™ using the Ektachem® 700. The following least-squares regression equation was obtained:

$y = 1.02x - 2.11$ (Chemcard on y axis)

correlation coefficient $r = 0.94$

*An additional 33 patients had plasma glucose levels outside the measuring range of the Chemcard™ (30 above, 3 below). All 33 were correctly read on the Chemcard™ as being below 50 mg/dl or above 150 mg/dl.

Classification Accuracy

Studies were conducted at five separate sites to evaluate the ability of an untrained individual to perform the test and interpret their result as being either normal or abnormal. In this study, 90 of 91 subjects correctly classified blood glucose level as normal or abnormally high. By computing the 95 percent confidence interval for the binomial distribution,[6] we find that the Chemcard™ exhibited a classification accuracy of greater than 94 percent in this study.

Precision

Within-lot precision of two different lots of Chemcard™ tests was determined by running 20 tests with whole blood at each of three different glucose levels across the measuring range of the Chemcard.™ Color development on the Chemcard™ was quantitated using colorimetric densitometry and optical densities converted to glucose concentration using a standard curve. Average, standard deviation, percent coefficient of variation and 95 percent confidence intervals were computed as follows:

Lot 1

57 mg/dl	76 mg/dl	125 mg/dl
Avg.: 54.9 mg/dl	Avg.: 78.9 mg/dl	Avg.: 124.0 mg/dl
s.d.: 1.9 mg/dl	s.d.: 2.4 mg/dl	s.d.: 4.8 mg/dl
CV: 3.5%	CV: 3.0%	CV: 3.9%
95% CI: 50.5–59.3 mg/dl	95% CI: 73.5–84.4 mg/dl	95% CI: 113.1–135.3 mg/dl

Lot 2

58 mg/dl	79 mg/dl	120 mg/dl
Avg.: 56.5 mg/dl	Avg.: 81.3 mg/dl	Avg.: 119.2 mg/dl
s.d.: 2.4 mg/dl	s.d.: 1.8 mg/dl	s.d.: 2.1 mg/dl
CV: 4.2%	CV: 2.2%	CV: 1.8%
95% CI: 51.1–61.9 mg/dl	95% CI: 77.1–85.5 mg/dl	95% CI: 114.1–124.0 mg/dl

REFERENCES

1. Harris, M.; Hadden, W. C.; Knowler, W. C.; Bennett P. H.: Prevalence of Diabetes and Impaired Glucose Tolerance and Plasma Glucose Levels in U.S. Population aged 20–74 years. Diabetes, 36:523–534, 1987.
2. Keston, A., in Abstracts of Papers, 129th Meeting, American Chemical Society, Dallas, Texas; p.31c (April 1956).
3. Corner, J., Analytical Chemistry, 28:1748 (1956).
4. Free, A., et al., Clinical Chemistry, 3:163 (1957).
5. Teitz, N. W., Fundamentals of Clinical Chemistry, Second edition, Philadelphia, W. B. Saunders Company, 1976, p. 242.
6. Lentner, C., in Geigy Scientific Tables, Vol. 2, Introduction to Statistics, Statistical Tables, Mathematical Formulae, 8th Edition, CIBA-Geigy Corp., West Caldwell, NJ, 198.
7. American Diabetes Association: Clinical Practice Recommendations 1998; Screening for Type 2 Diabetes, Diabetes Care, Volume 21 Supplement 1.

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TM P.O. Box 293 • North Webster, IN 46555
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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47610

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Evaluation of Betachek® Glucose Test

A home test for the detection of abnormal glucose levels

Protocol

Aim

The study aims to compare Betachek Glucose Test results obtained by a lay user with those obtained by a healthcare professional, using paired samples.

Study Population

A minimum of (b) [redacted] participants should be recruited.

Inclusion Criteria

(b)(4) [redacted]

Exclusion Criteria

(b)(4) [redacted]

Procedure

(b)(4) [redacted]

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Proposed– Feedback Form

Betachek Glucose Test - Feedback *Please place a tick in the appropriate box*	**Yes**	**No**	**Unsure**
Where you aware of the need to fast for 8 hours before testing?			
Did you fast prior to the test?			
Did you wash your hands before lancing your finger?			
Where the instructions for lancing easy to follow?			
Did you start timing immediately after applying the blood?			
Did you wipe the blood at exactly 30seconds?			
Did you realise timing was important in this test procedure?			
Did you check the result after 60 seconds?			
Was the result clear?			
Did you understand your result?			
Did the result indicate you had a high glucose level?			
Do you know what you must do if your result is higher than the cut off?			
Can the test alone diagnose diabetes?			
If a result is high should you consult your doctor?			
Would you consider yourself in a group at high risk of diabetes?			
Do you believe you carried out the test correctly?			

Comparison to Predicate Device
The comparison with the predicate device will be indirect with the two devices compared to a reference method.

Reference Method
The reference is the legally marketed Accu-chek blood glucose meter.

The results for the predicate device (Chemcard Glucose Test) are as follows;

Performance
Classification Accuracy
Studies were conducted at five separate sites to evaluate the ability of an untrained individual to perform the test and interpret their result as being either normal or abnormal. In this study, subjects correctly classified blood glucose level as normal or abnormally high. By computing the 95% confidence interval for the binomial distribution, we find that the Chemcard exhibited a classification accuracy of greater than 94% in this study.
(Source: Chematics, Chemcard instructions for use)

Copyrig

Similar statistical analysis will be performed with the results obtained using Betachek Glucose Test.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Risk Analysis
BETACHEK® Glucose Test

(b)(4)

[redacted]

Potential Hazards

(b)(4)

[redacted]

Analysis of each risk and steps taken to reduce the risk.

(b)(4)

[redacted]

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(b)(4)

[redacted]

(b)(4)

[redacted]ATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Description of sources of variability

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Figure 1. presents the plot of data against the target concentrations.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Test Principle and chemical composition

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

The range of % recovery at each concentration (observed value/target value)

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Vicki Moyer

Subject: 510(k) Number K062187/S3

To: The Record

Please list CTS decision code CS V Moyer 3/23/09

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓ OTC
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)		✓	
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓

Rev. 7/2/07

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*	✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*	✓

Regulation Number	Class*	Product Code
21CFR862.1345	II	NBW, CGA

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: [signature] (Branch Chief) DCTD (Branch Code) 3/24/09 (Date)

Final Review: Carol C Benson (Division Director) March 24, 2009 (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) draft document

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Memo

To: Memo to File

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297: Released by CDRH on 9/16/16

(b)(4)

[redacted]

The intended use is:

Betachek Blood Glucose is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

Any abnormal results should be verified by a medical professional, such as a physician, and confirmed with a quantitative, laboratory reference method. Only a trained medical professional can determine if an individual has diabetes. A test result within the normal range does not exclude the possibility that the individual has diabetes or pre-diabetes. Any individual who is concerned that he or she may have diabetes or pre-diabetes should seek the advice of a physician.

Betachek Blood Glucose is not intended to be used for children or by individuals who are diabetic or pregnant.

This test can not be used to screen or diagnose diabetes.

It should not be used for children or by individuals who are diabetic or pregnant.

This test is only intended for individual use at home.

It is not for use as part of a screening program in a healthcare setting or any other setting.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

This test can not be used to screen or diagnose diabetes.

It should not be used for children or by individuals who are diabetic or pregnant.

This test is only intended for individual use at home.

It is not for use as part of a screening program in a healthcare setting or any other setting.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Vicki Moyer esubmission

Subject: 510(k) Number K062182/S2

To: The Record

Vicki Moyer 7/25/08

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold). 21CFR 862.1345

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*	
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*	

Regulation Number	Class*	Product Code
21 CFR 862.1345	II.	Chem 75 CGA

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Jean Cooper, D.V.M. DCTD 7-28-08
(Branch Chief) (Branch Code) (Date)

Final Review:
(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Moyer, Vicki

From: Moyer, Vicki
Sent: Monday, July 28, 2008 2:58 PM
To: 'Brandon Bransgrove'
Cc: Cooper, Jean M
Subject: Request for Information k062187

JC 7/28/08

Attachments: FDA Additional Information request for k062187 _07.28.08_.pdf

Dear Brandon-

We reviewed your response to our November 5, 2007 request for additional information. In order to complete our review we need you to respond to the items listed in the attachment to this e-mail. To allow you time to complete your response, the submission will be placed on hold. As with previous occasions where your submission was placed on hold, you have 30 days to respond to the items identified or you may make a written request for an extension up 180 days from the date of the hold. The administrative details are specified in the letter you will be receiving from FDA shortly.

FDA Additional Information req...

While an official regulatory decision can not be made until we review the information in your response and determine it to be adequate, one option we are considering is a Substantial Equivalence with Limitations decision. FDA may make such a recommendation in cases where we believe there is a reasonable likelihood that a device could be used for an intended use not identified in the proposed labeling and that such use could cause harm. For example, we may recommend a precaution such "The safety and effectiveness of this device for use in screening the general population or asymptomatic individuals for diabetes" be included. Furthermore, such information use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If you have any questions or I can be of further assistance please do not hesitate to contact me by phone or e-mail. Once you are ready to send in your complete official response using the eSubmitter program, you should follow the instructions found at our website (http://www.fda.gov/cdrh/cesub/).

Best regards,
Vicki

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration
Phone (240) 276-0698
vicki.moyer@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Additional Information
National Diagnostic Products Betachek Glucose test, k062187
July 28, 2008

1. (b)(4) [redacted]

2. (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

3. (b)(4)

4. (b)(4)

5.

(b)(4)

6.

7.

8.

[redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Vicki Mayer

Subject: 510(k) Number K062187/S1

To: The Record

Hold 7 Mar 11/2/07

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Carol C Benson (Branch Chief) DCTD (Branch Code) November 2, 2007 (Date)

Final Review: _____ (Division Director) _____ (Date)

Rev. 5/30/07

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Memo

To: Memo to File

From: Vicki Moyer, Scientific Reviewer, CDRH/OIVD/DCTD

Date: November 2, 2007

Re: k062187-S1 hold

Vicki A Moyer 11/2/07

The S1 response to our request for additional information was received by DMC September 25, 2007 and by the reviewer on Sept. 27. Note that this response was received approximately 1 year from the date of our AI letter (9/26/07). The device was completely redesigned taking into consideration some of FDA's suggestions.

(b)(4) [redacted]

1. Method Comparison:
   a. (b)(4) [redacted]
   b. [redacted]
2. Lay user study:
   a. (b)(4) [redacted]
3. (b)(4) [redacted]
4. Reproducibility, Between Lot Precision
   a. (b)(4) [redacted]
   b. [redacted]
   c. [redacted]

53

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

5. Day to Day Precision
   a. (b)(4) [redacted]
   b. [redacted]

6. Repeatability
   a. (b)(4) [redacted]
   b. [redacted]

7. Sensitivity
   (b)(4) [redacted]

8. (b)(4) [redacted]

9. (b)(4) [redacted]

10. (b)(4) [redacted]

11. T(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Moyer, Vicki To be sent 11/2/07

To: Brandon Bransgrove
Subject: k062187-FDA Review of S1

Dear Brandon,
We have reviewed the information provided in your response and determined that we need additional information and clarification on the studies performed. This is described in detail in the attachment. To allow you ample time to respond to the questions, the submission will be placed on hold.

Please do not hesitate to contact me to discuss any of the questions. We are also available to work with you on specific labeling recommendations, packaging, and the intended use. I also recommend that you send me your response by e-mail so that I may review it prior to sending it to the Document Mail Center. This will help ensure that any question or concerns can be addressed before the submission is taken off of hold.

Best regards,
Vicki

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration
Phone (240) 276-0698
vicki.moyer@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

k062187-NDP Betachek Glucose Test: Review of S1 response

1. Method Comparison:
   (b)(4) [redacted]

2. Lay user study:
   a. (b)(4) [redacted]

3. (b)(4) [redacted]

4. Reproducibility, Between Lot Precision
   a. (b)(4) [redacted]
   b.
   c.

5. Day to Day Precision
   a. (b)(4) [redacted]
   b.

6. (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

7. Sensitivity
(b)(4)

8.

9.

10.

11.

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

e. (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Response to Hold K062187 July 20.2006

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Moyer, Vicki

From: Brandon Bransgrove [BrandonBransgrove@ndp.com.au]
Sent: Sunday, October 28, 2007 8:19 PM
To: Moyer, Vicki
Subject: FW: lay user data

Hi Vicki,

Please find attached the requested information.

Regards,

Brandon Bransgrove
National Diagnostic Products
22/39 Herbert Street,
St.Leonards NSW 2065
Sydney Australia
www.betachek.com
Tel: 612 9432 8100
Fax 612 9436 1151

-----Original Message-----
From: Delfina Mihaila
Sent: Monday, 29 October 2007 11:15 AM
To: Brandon Bransgrove
Subject: FW:

Hi Brandon,

The annexes are not included in the report. Attached is a file with all annexes from the Lay-user Study Protocol.
Also, I send you the results of Lay-user Study in excel format.
The Table of Contents comprises the list of pdf. documents sent to FDA in our last response.

Regards,
Delfina

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Annex 1.

Patient Information Letter

Dear Sir/Madam,

You are invited to take part in a study to assess the Performance of the Betachek Glucose Test in the hands of untrained users. The results will be supplied to the regulatory body in the United States, to help gain permission for the product to be marketed in the USA.

If you agree to participate in the study, you will be given a Betachek Glucose Test Kit and asked to perform a test unassisted. A trained technician will then perform a second finger-prick and will repeat the test.

All aspects of the study, including results, will be strictly confidential and only the study coordinators and investigators will have access to participant information. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Participation in this study is entirely voluntary. You are not obliged to participate and you can withdraw at any time.

When you have read this information, the study investigator will discuss with you further and answer any questions you may have.
This information is for you to keep.

Yours sincerely,

Study Coordinator

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Annex 2.

PARTICIPANT INFORMED CONSENT

A Clinical Trial to Assess the Effectiveness of
Betachek Glucose Test

I,
have read and understood the information for participants and have discussed it with the investigator.

I am aware of the procedures involved in the study, including any inconvenience, risk, discomfort or side effect, and their implications.

I freely choose to participate in this study and understand that I can withdraw without compromise at any time.

I also understand that the study is strictly confidential.

I hereby agree to participate in this study.

Signature……

Date……

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Annex 3.

Quality Check Form

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Annex 4: Betachek GLUCOSE TEST Feedback Questionnaire

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Annex 5. Patient Record Form

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Annex 6. Technician Record Form

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Moyer, Vicki

From: Moyer, Vicki
Sent: Tuesday, October 23, 2007 7:30 AM
To: 'Brandon Bransgrove'
Subject: k062187-S1 contents

Dear Brandon-
Can you provide a table of contents for the S1 response? I can not locate Annex 4, 5, and 6 that are referred to on page 4 of the Lay User performance evaluation report. Please direct me to where these forms are located in the submission. Also, please send the raw data from the lay user study for analysis by our statistician.

Best regards,
Vicki

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration
Phone (240) 276-0698
vicki.moyer@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Moyer, Vicki

From: Brandon Bransgrove [BrandonBransgrove@ndp.com.au]
Sent: Wednesday, October 03, 2007 10:13 PM
To: Moyer, Vicki
Subject: RE: k062187-S1 response
Attachments: Data.xls

Hi Vicki,

That's good news. Here is the data in excel. I hope your statistician enjoys it.

Regards,

Placed in Image 2000 (eSub).

Brandon Bransgrove
National Diagnostic Products
22/39 Herbert Street,
St.Leonards NSW 2065
Sydney Australia
www.betachek.com
Tel: 612 9432 8100
Fax 612 9436 1151

From: Moyer, Vicki [mailto:vicki.moyer@fda.hhs.gov]
Sent: Wednesday, 3 October 2007 5:50 AM
To: Brandon Bransgrove
Subject: k062187-S1 response

Hello Brandon-
We received you response and will begin our review. Can you please provide the raw data for the method comparison study in MS Excel format (via email)? This will be sent to our statistician for analysis.

Best regards,
Vicki

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration
Phone (240) 276-0698
vicki.moyer@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Vicki Mayer

Subject: 510(k) Number K062187/S'

To: The Record - It is my recommendation that the subject 510(k) Notification:

VMayer 12/15/04

- ☒ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☐ NO
Is this device subject to the Tracking Regulation?	☐ YES	☐ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☐ NO
Is this a prescription device?	☐ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☐ NO
Special 510(k)?	☐ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☐ NO

Truthful and Accurate Statement ☐ Requested ☐ Enclosed

☐ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☐ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) _____

Animal Tissue Source ☐ YES ☐ NO Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: _____

Additional Product Code(s) with panel (optional): _____

Review: _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Revised:4/2/03

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Memo

To: Memo to File

From: Vicki Moyer, Scientific Reviewer, CDRH/OIVD/DCTD Vicki Moyer 12/15/06

Date: December 15, 2006

Re: National Diagnostic Products Betachek Blood Glucose test, k062187

The sponsor sent in a response to our request for additional information that is not complete. Specifically, the sponsor provided a test plan but did not perform studies to support the deficiencies listed below.

The sponsor initially sent in the response by e-mail 11/30/06 and confirmed on 12/6/06 that the same document was sent in hardcopy to the DMC. The sponsor (Mr. Brandon Bransgrove) contacted me by phone on 12/7/06. I explained that sending the response would take the submission off of hold and that it he has not provided the data to support some of our concerns. The response was incomplete. The sponsor has never submitted a device for FDA clearance or approval so I explained some basic principles about US regulations, the 510(k) process and the timeclock. In an earlier e-mail I suggested he review some of our guidance documents.

The decision was made to refuse the response once it is received and put the submission back on hold. I explained that sponsors have a total of 180 days to respond and address any deficiencies identified in our request for additional information.

1. (b)(4) [redacted]

   a. (b)(4) [redacted]

   b. [redacted]

This concern has not been sufficiently addressed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

2. (b)(4) [redacted]

3. (b)(4) [redacted]

4. (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) [redacted]

5. (b)(4) [redacted]

6. (b)(4) [redacted]

7. (b)(4) [redacted]

8. (b)(4) [redacted]

9. (b)(4) [redacted]

10. (b)(4) [redacted]

11. (b)(4) [redacted]

    a. (b)(4) [redacted]
    b.
    c.
    d.
    e.
    f.
    g.

The labeling has not been revised.

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Moyer, Vicki

From: Brandon Bransgrove [BrandonBransgrove@ndp.com.au]
Sent: Monday, December 11, 2006 5:47 PM
To: Moyer, Vicki
Subject: RE: 12/7/06 phone discussion

Hello Vicki,

We have decided to take the 100 day option. Please do what you need to at your end.

We have a lot of work to do.

Thanks!

Kind Regards,

Refuse to accept - once supplement is received.

Brandon Bransgrove
National Diagnostic Products
7- 9 Merriwa Street,
Gordon NSW 2072
Sydney Australia
www.betachek.com
Tel: 612 9418 4777
Fax 612 9418 4747

From: Moyer, Vicki [mailto:vicki.moyer@fda.hhs.gov]
Sent: Friday, 8 December 2006 11:13 PM
To: Brandon Bransgrove
Subject: RE: 12/7/06 phone discussion

Hi Brandon,
I think a response by Tuesday should be fine since we haven't gotten your response yet via mail.

Enjoy your weekend,
Vicki

From: Brandon Bransgrove [mailto:BrandonBransgrove@ndp.com.au]
Sent: Friday, December 08, 2006 1:40 AM
To: Moyer, Vicki
Subject: RE: 12/7/06 phone discussion

Hi Vicki,

Thank you for your help on the phone this morning (12/7), I now understand the FDA's concerns more clearly and it means we need more time to reply. Whether we need more than 100 days will be decided after a few meetings which we will have early next week.

I will let you know which option we will take, by Tuesday. It would be nice to take the 100 day option so the response is totally updated (and the current one refused).

In the mean time, have a good weekend.

Kind Regards,

Brandon Bransgrove

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

National Diagnostic Products
7- 9 Merriwa Street,
Gordon NSW 2072
Sydney Australia
www.betachek.com
Tel: 612 9418 4777
Fax 612 9418 4747

From: Moyer, Vicki [mailto:vicki.moyer@fda.hhs.gov]
Sent: Friday, 8 December 2006 8:25 AM
To: Brandon Bransgrove
Subject: 12/7/06 phone discussion

Hello Brandon,

(b)(4)

[redacted]

I hope our discussion was helpful to you. I look forward to your reply.

Regards,
Vicki

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration
Ph. (240) 276-0490 x157
vicki.moyer@fda.hhs.gov

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Vicki Moyer

Subject: 510(k) Number K062187

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

VMoyer 9/27/06
21 CFR 862.1345

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☐ NO
Is this device subject to the Tracking Regulation?	☐ YES	☐ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☐ NO
Is this a prescription device?	☐ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☐ NO
Special 510(k)?	☐ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☐ NO

Truthful and Accurate Statement ☐ Requested ☐ Enclosed

☐ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☐ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) _____

Animal Tissue Source ☐ YES ☐ NO Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 da

Predicate Product Code with class: CGA Class II, Chem 75

Additional Product Code(s) with panel (optional): _____

Review: _____ (Branch Code) 9/28/06 (Date)
(Branch Chief)

Final Review: _____ (Date)
(Division Director)

280

Revised:4/2/03

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?	—	—
3. Have you verified that the Document is labeled Class III for GMP purposes? N/A		
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	—	—
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

September 26, 2007

NATIONAL DIAGNOSTIC PRODUCTS
(AUST) PTY LTD
7-9 MERRIWA ST.
GORDON
SYDNEY,
AUSTRALIA 2072
ATTN: BRANDON STEPHEN BRANSGROVE

510(k) Number: K062187
Product: BETACHEK GLUCOSE TEST

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

K062187/S1

Dr Alberto Gutierrez
Director Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration

Re: k062187

Dear Dr Gutierrez,

Please find below our response to your review of our 510(k) premarket notification for the Betachek Glucose Test device.

1. Reportable range

(b)(4)

[redacted]

2. This point refers to several issues that are addressed separately below.

(b)(4)

[redacted]

1/7

71

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Issue 2: (b)(4)

(b)(4)

Issue 3: (b)(4)

a. (b)(4)
b.
c.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3. Visual Approximations between color blocks

(b)(4)

your

a. (b) (4)

b. (b)(4)

4. Performance Studies

a. (b)(4)

b. (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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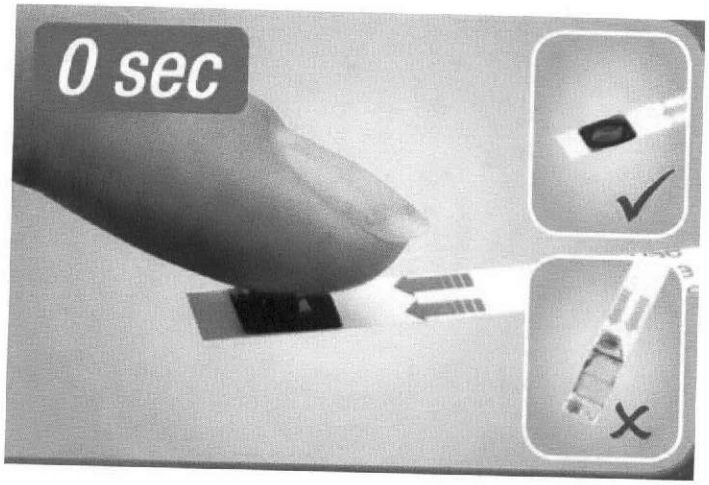
5. Procedural Controls

The device has three procedural controls that allow the user to verify the test has worked correctly.

1. A color block representing a fresh unused strip is included on the label.

2. The device is a test strip which has no inbuilt window to show whether sufficient blood has been applied. As is the case with a urine test strip there is no need for a window in order to know if sample has covered the reaction zone. As a procedural control there are provided images of a correctly covered test zone and an insufficiently covered test zone. The instructions state that the reaction zone should be completely covered with blood – the image of a correctly covered test zone can be checked against the actual test zone.



3. The presence of a green and pink color in the test zone indicates that the detection chemistry is working properly. A reagent pad that is white or cream colored indicates an invalid test result.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. 6. Value assignment process and Sensitivity testing

Value Assignment

Color standards are prepared for each lot of tests as follows:

(b)(4)

4.

5.

6.

7.

8.

9.

10.

11.

12.

13.

14.

15.

16.

17.

Sensitivity

Please see the sensitivity study.

7. Interference Study
– please see attached

8. Effect of Ketoacidosis
- please see interference study.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9. How were the limitations for storage (39 – 86 F) and Operating temperature (64-95°F) defined.

Storage

[redacted] (b)(4)

Operating temperature

[redacted] (b)(4)

10. N/A

11. Product Labelling

a. (b)(4) [redacted]
b.
c.
d.
e.
f.
g.

Glucose Test.

(b)(4) [redacted]

(Extract)

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

(b)(4)

[redacted]

We would appreciate it if this issue could be reconsidered.

Yours Sincerely,

Brandon Bransgrove
National Diagnostic Products
16 September 2007

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1/2 (Front)

BETACHEK GLUCOSE TEST

What is this Test for?
Betachek Glucose Test is intended as a screening test for the early detection of abnormal fasting plasma glucose levels. Abnormal fasting glucose levels can be a sign of diabetes or other health problems. The test uses a drop of capillary blood to provide a preliminary semi-quantitative result. Any abnormal result should be confirmed by a doctor using a quantitative laboratory based method. The test is not intended to provide a formal diagnosis of diabetes. A formal diagnosis can only be made by a doctor. The test is for over-the-counter use.

Background – Type 2 Diabetes
It is estimated that 30% of Diabetics in the US remain undiagnosed[1]. This is because when a person first develops diabetes it is common for them to have no signs of sickness. They do however have high levels of glucose in their blood which over time badly damages many parts of the body. Often Diabetes is only discovered many years later when the damage has occurred. This damage can be prevented if high glucose levels are reduced by early treatment. It is therefore important to check your blood glucose level regularly and if it is high, to seek treatment before it causes serious health problems that cannot be reversed. Betachek® Diabetes Test is a convenient and effective way to measure glucose levels in just 3 minutes. Individuals who obtain an abnormal result should see their doctor for further testing.

How Does the Test Work?
The test zone consists of two test pads containing sensitive chemicals. When blood is applied to this zone, the chemicals react with the glucose in the blood. The reaction produces a colour change that varies with the amount of glucose in the blood. The test uses the enzymes Glucose Oxidase and Peroxidase which along with color forming chemicals and non-reactive ingredients is contained in the test zone.

Chemical Composition
Each Betachek® test strip contains (Quantity/cm²): Glucose Oxidase 0.08 U, Peroxidase 9.4 µg, TMB 77 µg, DCP 20 µg, Stabiliser 0.12 mg, APAC 15 µg, Inert ingredients 2.20 mg (w/w).

Precautions and Limitations of the Test
Failure to fast will produce invalid results. For *in vitro* diagnostic use only. Use the test strips only between 64 and 95°F (18 and 35°C). Use only fresh capillary whole blood from a finger stick. The test strips are for single use only. *Incorrect timing* – leaving the blood on too long will increase the result and wiping the blood too early will decrease the result. The test is not intended for use by individuals who are pregnant. As the reading range is 50 - 150 mg/dl, the test should not be used by people with diabetes to monitor their glucose levels or adjust any treatment.

Storage and Handling
Store Betachek® Test Strips in their original container in a cool, dry place between 39-86°F (4-30°C). Do not freeze. Use the test strip immediately after it is removed from the container. Always replace the cap quickly.

Quality Checks
The test strips can be checked against the '0' (unreacted) color block to see they are in good condition. If there is any sign of blue, the strip should not be used.

What is Included?
2 tests, 2 single use lancets, 1 label on container with color chart, tissue, alcohol swab, 1 package insert.

What is not Included but Needed?
A watch with a second hand or a timer.

Measurement Range
The measurement range is 50 – 150 mg/dl (2.8 – 8.3 mmol/l).

When Should I Test?
An ideal time to test is before breakfast. Do not eat or drink for 8 hours before testing (you may drink water only).

How do I Run a Test?
Have a timer ready. See the step by step color instructions numbered 1-7.

How do I Read the Result?
Results are obtained by comparing the test zone to the color chart on the label. Use natural light for best results. If the test zone color lies between two color blocks on the chart then calculate the average of the two values;

no

e.g. (for a result that appears to be between the 125 and the 150mg/dl color blocks)

$$\frac{125 + 150}{2} = 137.5 \text{ mg/dl}$$

A test zone lighter than 50mg/dl, is less than 50mg/dl (2.8mmol/l). A test zone darker than 150 mg/dl is greater than 150mg/dl (8.3mmol/l).

Expected Results
Fasting blood glucose results ≥126 mg/dl (7.0 mmol/l) are considered abnormal

Results[2]	Glucose concentration (mg/dl)
Normal	Fasting <100
Pre-diabetes	Fasting ≥100 and <126 remove
Abnormal	Fasting ≥ 126

If the test zone color is *darker* than the 125 mg/dl (6.9 mmol/l) color block then your result is abnormal and you should see your doctor for further testing. Results less than 50 mg/dl (3.3 mmol/l) are considered abnormally low and should also be followed up with additional testing by your doctor.

Do I Need to Test Again?
Blood glucose should be checked annually by individuals who are any of the following: obese; have a first-degree relative with diabetes; are members of a high-risk ethnic population (Indian, African, Hispanic, Native American, Aboriginal, Pacific-Islander, Asian). Also those who have delivered a baby weighing more than 9 pounds; have had gestational diabetes; have high blood pressure; have HDL cholesterol levels ≤ 35mg/dl or triglyceride levels ≥ 250mg/dl; or who, on previous testing had impaired glucose tolerance or impaired fasting glucose. All adults older than 45 years of age should test every three years.

Performance Characteristics
Accuracy
The accuracy of Betachek® Glucose Test was confirmed in a study involving 108 patients attending a clinic. Results obtained by a laboratory technician using Betachek® Glucose Test were compared to results obtained using a YSI 2300 STAT Plus laboratory analyzer. Results obtained using Betachek® Glucose Test produced the following least squares regression equation when compared to the YSI 2300 STAT Plus: $y = 1.12x - 7.01$. $r = 0.95$ indicating good agreement with the laboratory method.

Results < 75 mg/dl compared to the reference:

Within ± 5mg/dl	Within ± 10mg/dl	Within ± 15mg/dl
64%	86%	100%

Results ≥ 75 mg/dl

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
40%	79%	88%	96%

Classification Accuracy
Studies were conducted at 3 sites with a total of 156 untrained subjects. Subjects performed the test unassisted and classified their results as either normal or abnormal. In this study, 154 of 156 subjects correctly classified their blood glucose level as normal or abnormally high. By computing the 95 percent confidence interval for the binomial distribution, we found that the Betachek Glucose Test exhibited a classification accuracy of greater than 95 percent in this study.

Precision
The within –lot precision of Betachek GT strips was determined for three lots of strips. Three different glucose levels were used, covering a range 50-150mg/dL. CV's for lots ranged from 0 to 4.8%.

More information on diabetes can be found at:
www.diabetes.org
Betachek Helpline: xxxx xxxxxxxxx

Version BGT-US-002 SEPT 2007

[1] Catherine C. Cowie et al., Prevalence of Diabetes and Impaired Fasting Glucose in Adults in the U.S. Population *Diabetes Care* 29:1263-1268, 2006

[2] American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus, *Diabetes Care* 29:S43-S48, 2006

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

2/2
(Back)
Not to scale
(80%)

BETACHEK®

Glucose Test

Instructions for use

77 Released by CDRH on 9/16/16

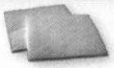
⚠ IMPORTANT!
Read instructions carefully. You need a timer or watch with second hand ready. This test has an important timing step that must be followed exactly to ensure accurate results.

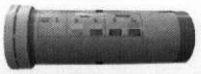
Before you perform the test:

Ensure you have ***not eaten*** for at least 8 hours.
(You may drink water only)

Sterile Lancing Devices & Betachek Tests

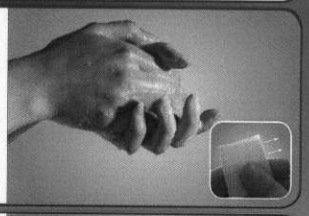
Sterile Alcohol Swabs


Tissues

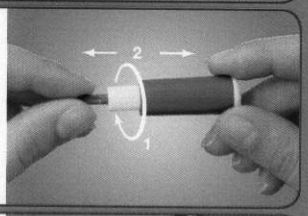

Results Chart on label

1. Wash hands and dry thoroughly.

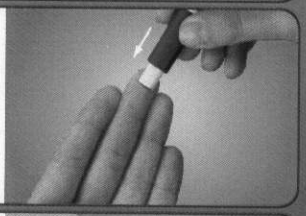
Use the alcohol swab provided to wipe the fingertip. Allow to dry before testing.



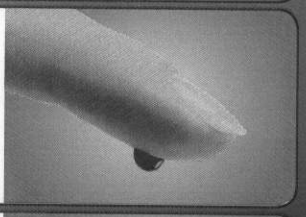
2. Twist off protective lancet cap.



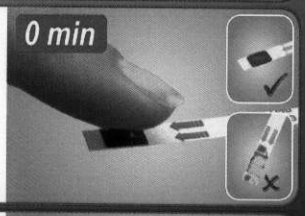
3. Push the lancet firmly into the finger until you hear a 'click'.



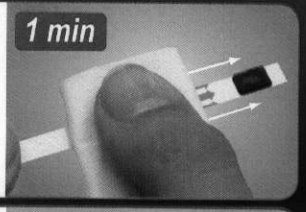
4. Gently squeeze your finger until you have a large hanging drop of blood. ***Get ready to start timing.***



5. Have your timer ready
Place a drop of blood onto the test zone and immediately start timing.
Check - see pictures in boxes
Ensure both test pads are fully covered. Do not smear or dab blood thinly.

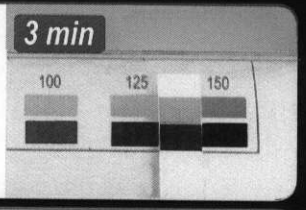


6. **After exactly 1 minute wipe the blood off the test zone, using the tissue provided.**



7. **Wait 2 minutes after wiping and then match the test zone against the label color chart for the result.**
See section: How do I read the result?

The test area will start to fade after 5 minutes.



What does my result mean?

If the test zone color is *darker* than the 125mg/dl (6.9mmol/l) color block on the label then your result is abnormal and you should see your doctor for a laboratory based test. See section: Expected Results

Questions? Contact FDA/CDRH/OCE/DID at CDRH-ECISTATUS@fda.hhs.gov or 301-796-5118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GLUCOSE TEST SENSITIVITY TESTING STUDY DESIGN

1. Purpose

The purpose of this document is to assist the Production Laboratory in characterizing the sensitivity of the colour blocks on the Betachek Glucose Test colour chart. The study is designed after a suggestion made by FDA.

2. Scope

Betachek Glucose Test

3. Standards applied

ISO 15197:2003 *In vitro* diagnostic tests system- Requirements for self-testing in managing diabetes mellitus.

4. Terms and definitions

(b)(4)

[redacted]

6. Reference Measurement Procedure

The reference method used in the study will be the YSI 2300 Stat Plus Analyser. (b)(4) [redacted].

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

(b)(4) [redacted]

7. Quality assurance and safety requirements

(b)(4) [redacted]

7.2. Safety precautions

(b)(4) [redacted]

7.3. Quality control

7.3.1.YSI 2300 Stat Plus :

- Daily Operational Checks must be performed. Refer to section 4.4 of the instruction manual

7.3.2. Betachek GT strips:

- (b)(4) [redacted]

8. Sensitivity evaluation

8.1 General requirements

Sensitivity should be evaluated for each of the five glucose concentrations (b)(4) [redacted]

8.2. Samples requirements

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

In order to study the sensitivity of the five colour blocks (50,75,100,125 and 150mg/dL), the following glucose concentrations will be prepared:

Table 1 (b)(4) [redacted]

(b)(4) [redacted]

Table 2 (b)(4) [redacted]

(b)(4) [redacted]

Table 3 (b)(4) [redacted]

(b)(4) [redacted]

Table 4 (b)(4) [redacted]

(b)(4) [redacted]

Table 5 (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The samples should be equilibrated to a temperature of 23ºC±5 ºC

8.3. Environment requirements

(b)(4) [redacted]

8.4 Reagent system

(b)(4) [redacted]

8.5 Evaluation procedure

8.5.1 Subjects information

(b)(4) [redacted]

8.5.2 Strips preparation

(b)(4) [redacted]

8.5.3 Samples preparation

a) (b)(4) [redacted]

b)

c)

d)

e)

f)

8.5.4 Quality control

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

8.5.5 Measurement procedure

(b)(4) [redacted]

9. Data analysis and presentation

9.1 Drift analysis

(b)(4) [redacted]

9.2 Outliers

(b)(4) [redacted]

9.3 Sensitivity analysis

(b)(4) [redacted]

9.4 Data presentation

The following information shall be reported:

a) (b)(4) [redacted]
b)
c)
d)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

e)
f)
g)

10. Decision criteria

(b)(4)

Table 2

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Annex 1

Information Letter

Dear Participant,

You have been invited to take part in a study to assess the Performance of Betachek GT Glucose Test.

If you agree to participate in the study, you will be asked interpret visual test strips used for blood glucose testing.
All aspects of this study, will be strictly confidential and only the study coordinator and investigators will have access to subject information. A report of the study may be submitted for publication; however, no subject identifiers will be listed in such a report.

While we intend that this study further medical knowledge and may improve treatment of diabetes in the future, it may not be of direct benefit to you.

Participation in this study is entirely voluntary: you are not obliged to participate and you can withdraw at any time.

When you have read this information, the study investigator will discuss the study with you further and answer any questions you may have.
This information is for you to keep.

Yours sincerely,

Study Coordinator

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Annex 2

PARTICIPANT INFORMED CONSENT

A Trial to Assess the Performance of
Betachek Glucose Test

I, ...
have read and understood the information for participants on the named study and have discussed it with the investigator.

I am aware of the procedures involved in the study, including any inconvenience, risk, discomfort or side effect, and their implications.

I freely choose to participate in this study and understand that I can withdraw without compromise at any time.

I also understand that the study is strictly confidential.

I hereby agree to participate in this study.

Signature.....

Date.....

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Annex 3

Quality Check Form

Betachek GT

Lot				
Date				
Technician				
	Range	**Test 1** (before)	**Test 2** (after)	**Accept/Reject**
Control 1 Lot				
Control 2 Lot				

Betachek GT

Lot				
Date				
Technician				
	Range	**Test 1** (before)	**Test 2** (after)	**Accept/Reject**
Control 1 Lot				
Control 2 Lot				

Betachek GT

Lot				
Date				
Technician				
	Range	**Test 1** (before)	**Test 2** (after)	**Accept/Reject**
Control 1 Lot				
Control 2 Lot				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Annex 3

Quality Check Form

YSI 2300 Stat Plus

Initial & Date					
Empty Waste Bottle					
Check Calibrator Bottle					
Check Buffer Bottle					
Check Printer Paper					
Check Leaks / Spills					
Calibration solution Lot					
	Range mmol/L	**Range mg/dL**	Result (before)	Result (after)	**Accept / Reject**
Membrane integrity Test Lot	(b)(4) [redacted]				
Control 1 Lot					
Control 2 Lot					
Ambient temperature					

YSI 2300 Stat Plus

Initial & Date					
Empty Waste Bottle					
Check Calibrator Bottle					
Check Buffer Bottle					
Check Printer Paper					
Check Leaks / Spills					
Calibration solution Lot					
	Range mmol/L	**Range mg/dL**	Result (before)	Result (after)	**Accept / Reject**
Membrane integrity Test Lot	(b)(4) [redacted]				
Control 1 Lot					
Control 2 Lot					
Ambient temperature					
Ambient temperature					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Annex 4

Reference Method Record
Colour block challenged:.....

Sample no.	Target concentration mg/dL	Reference results (before)		Reference results (after)		Hematocrit	Initials/date
1							
2							
3							
4							
5							

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Annex 5 - **Participant Record Form**

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

(b)(4) [redacted]

A. STUDY DESIGN

(b)(4) [redacted]

1. Purpose

The purpose o this document is to assist the Production Laboratory in evaluation of Betachek GT between-lot precision (reproducibility) by offering scientifically valid experiment designs and by clarifying appropriate data analysis and interpretation, so that meaningful reproducibility claims may be provided to the users.
This document will define a systematic investigation strategy and will specify data collection and analysis requirements.

2. Scope

Betachek GT strips

3. Standards applied

The evaluation of Betachek GT reproducibility is performed in accordance with ISO 15197:2003 *In vitro* diagnostic tests system- Requirements for self-testing in managing diabetes mellitus.

4. Terms and definitions

The terms and definitions specified in ISO 15197 apply.

5. Equipment and materials

(b)(4) [redacted]

(b) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

6. Reference Measurement Procedure

(b)(4)

[redacted]

7. Quality assurance and safety requirements

7.1. Requirements for operators

(b)(4)

[redacted]

7.2. Safety precautions

(b)(4)

[redacted]

7.3. Quality control

7.3.1.YSI 2300 Stat Plus :

(b)(4)

[redacted]

8. Between-lot precision (reproducibility) evaluation

8.1 General requirements

(b)(4)

[redacted]

8.2. Samples requirements

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

(b)(4)

Table 1 Glucose concentrations intervals for reproducibility evaluation

(b)(4)

8.3. Environment requirements

(b)(4)

8.4 Reagent system

(b)(4)

8.5 Evaluation procedure

8.5.1 Strips preparation

(b)(4)

8.5.2 Samples preparation

a) (b)(4)

b)

c)

8.5.3 Quality Control

(b)(4)

8.5.4 Measurement procedure

(b)(4)

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

All results should be recorded (Annex 1,2).

a) (b)(4)
b)
c)
d)
e)

(b)(4)

9. Data analysis and presentation

9.1 Drift analysis

(b)(4)

9.2 Outliers

(b)(4)

9.3 Reproducibility analysis

(b)(4)

9.4 Data presentation

The following information shall be reported:

a) (b)(4)
b)
c)
d)
e)
f)
g)
h)

10. Acceptability criteria

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

B. RESULTS

Betachek GT Between-lot Precision Studies- Reproducibility

(b)(4)

[redacted]

All levels performed at one

71-150 72-85 86-120

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

C. CONCLUSION

(b)(4)

[redacted]

Table 1 Glucose concentrations intervals for reproducibility evaluation

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Between-Lot Precision Test Report

The between-lot reproducibility for the Betachek GT lots tested is shown in Table 2. The table gives the mean, standard deviation (total, within-lot and between-lot) (b)(4) [redacted]

Table 2
Betachek GT Between lot Reproducibility results

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

(b)(4) [redacted]

A. STUDY DESIGN

(b)(4) [redacted]

1. Purpose

The purpose o this document is to assist the Production Laboratory in evaluation of Betachek GT day-to-day precision (reproducibility) by offering scientifically valid experiment designs and by clarifying appropriate data analysis and interpretation, so that meaningful reproducibility claims may be provided to the users.
This document will define a systematic investigation strategy and will specify data collection and analysis requirements.

2. Scope

Betachek GT strips

3. Standards applied

The evaluation of Betachek GT reproducibility is performed in accordance with ISO 15197:2003 *In vitro* diagnostic tests system- Requirements for self-testing in managing diabetes mellitus.

4. Terms and definitions

The terms and definitions specified in ISO 15197 apply.

5. Equipment and materials

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

6. Reference Measurement Procedure

(b)(4) [redacted]

7. Quality assurance and safety requirements

7.1. Requirements for operators

(b)(4) [redacted]

7.2. Safety precautions

(b)(4) [redacted]

7.3. Quality control

(b)(4) [redacted]

8. Day-to-day precision (reproducibility) evaluation

8.1 General requirements

(b)(4) [redacted]

8.2. Samples requirements

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

(b)(4) [redacted]

Table 1
Glucose concentrations intervals for day-to-day reproducibility evaluation

(b)(4) [redacted]

(b)(4) [redacted]

8.3. Environment requirements

The evaluation should be performed at a temperature of (b)(4) [redacted]

8.4 Reagent system

(b)(4) [redacted]

8.5 Evaluation procedure

8.5.1 Strips preparation

(b)(4) [redacted]

8.5.2 Samples preparation

(b)(4) [redacted]

8.5.3 Quality Control

(b)(4) [redacted]

8.5.4 Measurement procedure

All results should be recorded (Annex 1,2).

a) (b)(4) [redacted]
b)
c)
d)

The results will be recorded on separate forms for each operator to prevent results being disclosed between operators.

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

9. Data analysis and presentation

9.1 Drift analysis

(b)(4) [redacted]

9.2 Outliers

(b)(4) [redacted]

9.3 Reproducibility analysis

(b)(4) [redacted]

9.4 Data presentation

The following information shall be reported:

a) (b)(4) [redacted]
b)
c)
d)
e)
f)
g)
h)
i)

10. Acceptability criteria

The acceptability criteria for reproducibility of Betachek GT strips are as follows:

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

B. RESULTS

Betachek GT Day-to-day Precision Studies- Reproducibility

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

C. CONCLUSION

(b)(4)

[redacted]

Table 1
Glucose concentrations intervals for day-to-day reproducibility evaluation

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Day-to-day Precision Test Report

Table 2
Betachek GT Day-to-day Reproducibility results

(b)(4)

[redacted]

The day-to-day precision of Betachek GT was very good, (b)(4) [redacted].

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Repeatability Test Report

(b)(4) [redacted]

A. STUDY DESIGN

(b)(4) [redacted]

1. Purpose

The purpose o this document is to assist the Production Laboratory in evaluation of Betachek GT within-lot precision (repeatability) by offering scientifically valid experiment designs and by clarifying appropriate data analysis and interpretation, so that meaningful repeatability claims may be provided to the users.
This document will define a systematic investigation strategy and will specify data collection and analysis requirements.

2. Scope

Betachek GT strips

3. Standards applied

The evaluation of Betachek GT repeatability is performed in accordance with ISO 15197:2003 *In vitro* diagnostic tests system- Requirements for self-testing in managing diabetes mellitus.

4. Terms and definitions

The terms and definitions specified in ISO 15197 apply.

5. Equipment and materials

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

6. Reference Measurement Procedure

(b)(4)

[redacted]

7. Quality assurance and safety requirements

7.1. Requirements for operators

(b)(4)

[redacted]

7.2. Safety precautions

(b)(4)

[redacted]

7.3. Quality control

(b)(4)

[redacted]

8. Within-lot precision (repeatability) evaluation

The within-lot precision (repeatability) for Betachek GT system is evaluated in accordance with ISO 15197:2003 , part 7.2.2

8.1 General requirements

(b)(4)

[redacted]

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Repeatability Test Report

8.2. Samples requirements

ISO 15157:2003 specifies the following requirements for samples preparation:

(b)(4) [redacted]

(b)(4) [redacted]

Table 1 Glucose concentrations intervals for repeatability evaluation

(b)(4) [redacted]

8.3. Environment requirements

(b)(4) [redacted]

8.4 Reagent system

(b)(4) [redacted]

8.5 Evaluation procedure

8.5.1 Strips preparation

(b)(4) [redacted].

8.5.2 Samples preparation

a) (b)(4) [redacted]

b)

c)

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.5.3 Quality Control

(b)(4) [redacted]

8.5.4 Measurement procedure

All results should be recorded (Annex 1.2).

a) (b)(4) [redacted]
b)
c)
d)
e)

The reference method results and the Betachek GT results will be recorded on separate forms to prevent results being disclosed between technicians.

9. Data analysis and presentation

9.1 Drift analysis

(b)(4) [redacted]

9.2 Outliers

(b)(4) [redacted]

9.3 Repeatability analysis

(b)(4) [redacted]

9.4 Data presentation

The following information shall be reported:

a) (b)(4) [redacted]
b)
c)
d)
e)
f)

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10. Acceptability criteria

The acceptability criteria for repeatability of Betachek GT strips are as follows:

(b)(4)

[redacted]

B. RESULTS

Betachek GT Within-lot Precision Studies- Repeatability

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Repeatability Test Report

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Repeatability Test Report

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Repeatability Test Report

C. CONCLUSION

(b)(4)

(b)(4)

The method used to evaluate the drift in blood samples was the YSI 2300 Stat Plus Analyser. (b)(4)

turn

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Repeatability Test Report

(b)(4)

Table 2
Repeatability : Betachek GT Lot 445285

(b)(4)

Table 3
Repeatability : Betachek GT Lot 446385

(b)(4)

Table 4
Repeatability : Betachek GT Lot 447185

(b)(4)

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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updated 32

Betachek GT Method Comparison Test Report

Method comparison studies for Betachek GT were conducted following the ISO 15197:2003 *In vitro* diagnostic tests system- Requirements for self-testing in managing diabetes mellitus.
The study design, the measurements results and the conclusions of evaluation are presented bellow.

A. STUDY DESIGN

Betachek GT Method comparison- Accuracy

1. Introduction

(b)(4)

[redacted]

2. Purpose

This document is intended to assist investigators in the evaluation of Betachek GT accuracy. Scientifically valid experiment designs and appropriate data analysis and interpretation, are to be used so that meaningful accuracy claims may be provided to users and regulatory bodies. This document defines a systematic investigation strategy and specifies data collection and analysis requirements.

3. Scope

Betachek GT strips.

4. Standards applied

The evaluation of Betachek GT accuracy is to be performed in accordance with: ISO 15197:2003 *In vitro* diagnostic tests system- Requirements for self-testing in managing diabetes mellitus.
CLSI/NCCLS EP9 Method comparison and Bias Estimation using Patient Samples, approved guidelines Clinical and Laboratory Standards institute, 2005.

5. Terms and definitions

The terms and definitions specified in ISO 15197 apply.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

6. Equipment and materials

(b)(4)

[redacted]

7. Reference Measurement Procedure

(b)(4)

[redacted]

8. Quality assurance and safety requirements

8.1. Requirements for operators

(b)(4)

[redacted]

8.2. Safety precautions

(b)(4)

[redacted]

8.3. Quality control

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9. Subject Eligibility

9.1. Study population

(b)(4)

9.2. Eligibility and exclusion criteria

9.2.1. Eligibility

(b)(4)

- ;
- .

9.2.2. Exclusion criteria

(b)(4)

- ;
- ;

10.0 System accuracy evaluation (method comparison)

The accuracy of the Betachek GT system will be evaluated in accordance with ISO 15197:2003 , part 7.3

10.1 General requirements

(b)(4)

.

10.2. Samples requirements

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Table 1. Glucose concentrations of samples for system accuracy evaluation

(b)(4) [redacted]

(b)(4) [redacted]

10.3. Environment requirements

(b)(4) [redacted]

10.4 Reagent system

(b)(4) [redacted]

10.5 Evaluation procedure

The requirements specified in ISO 15197: 2003, part 7.3 apply.

10.5.1 Subject's information

(b)(4) [redacted]

10.5.2 Strips preparation

(b)(4) [redacted]

10.5.3 Quality Control

(b)(4) [redacted]

10.5.4 Measurement procedure

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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c) (b)(4) [redacted]

d)

e)

(b)(4) [redacted]

10.5.5 Instructions for blood collection for later testing

(b)(4) [redacted]

Procedure:

(b)(4) [redacted]

(b)(4) [redacted]

11. Data analysis and presentation

11.1 Drift analysis

(b)(4) [redacted]

11.2 Outliers

11.2.1 Within-method outliers

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Method Comparison Test Report

The samples that are flagged by both the absolute and relative tests are within-method outliers.

11.2.2 The test for between-method outliers is based on the procedure described in NCCLS EP9. [redacted] (b)(4) [redacted] (b)(4) [redacted].

11.3 Anomalous results

Should any anomalous results arise, they will be deal with as follows:

(b)(4) [redacted]

11.4 Data analysis

11.4.1 System accuracy analysis

a) (b)(4) [redacted]

b)

c)

11.4.2 Regression analysis

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

(b)(4) [redacted]

11.5 Data presentation

The following information shall be reported:

a) (b)(4) [redacted]
b)
c)
d)
e)
f)
g)
h)
i)
j)
k)
l)

12. Acceptability criteria

(b)(4) [redacted]

13. Miscellaneous

13.1 Investigation centres

(b)(4) [redacted]

[redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

13.2 Study coordinators and investigators

Study Coordinator:
(b)(4) [redacted]

Study Investigators:
(b)(4) [redacted]

Contact details:
(b)(4) [redacted]

13.3 Training and Competences

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

B. RESULTS

Betachek GT Method comparison

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Method Comparison Test Report

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

C. CONCLUSION

(b)(4)

[redacted]

Table 2
Glucose concentrations of samples for system accuracy evaluation

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

(b)(4)

[redacted]

Linear regression (ordinary linear regression) for Betachek GT compared with YSI 2300 is presented in Figure 2.

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Method Comparison Test Report

Figure 2:

(b)(4)

Table 3

Regression statistics of Betachek GT against YSI 2300

(b)(4)

Tables 4 and 5 present the accuracy of Betachek GT segregated for glucose levels

(b)(4)

Table 5. Betachek GT accuracy for glucose concentrations ≥75mg/dL

(b) samples were tested in this range)

(b)(4)

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Method Comparison Test Report

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK GT

Linearity/ assay reportable range

(b)(4)

A. STUDY DESIGN

(b)(4)

1. Scope

Betachek GT strips

2. Standards applied

The evaluation of Betachek GT linearity/ assay reportable range is performed in accordance with the NCCLS EP6-P2 protocol.

3. Terms and definitions

The terms and definitions specified in ISO 15197 apply.

4. Equipment and materials

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5. Reference Measurement Procedure

(b)(4) [redacted]

6. Quality assurance and safety requirements

7.1. Requirements for operators

(b)(4) [redacted]

7.2. Safety precautions

(b)(4) [redacted]

7.3. Quality control

(b)(4) [redacted]

8. Linearity/assay reportable range evaluation

(b)(4) [redacted]

8.1 General requirements

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Linearity/ assay reportable range

(b)(4) [redacted]

(b)(4) [redacted]

8.2. Samples requirements

ISO 15157:2003 specifies the following requirements for samples preparation:

(b)(4) [redacted]

Table 1 Glucose concentrations intervals for linearity evaluation

(b)(4) [redacted]

8.3. Environment requirements

(b)(4) [redacted]

8.4 Reagent system

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

BETACHEK GT

Linearity/ assay reportable range

8.5. Evaluation procedure

[redacted] (b)(4)

8.5.1 Strips preparation

a) (b)(4) [redacted]

8.5.2 Samples preparation

a) (b)(4) [redacted]

b)

c)

8.6.3 Measurement procedure

All results should be recorded (Annex 1).

a) (b)(4) [redacted]

b)

c)

d)

e)

f)

g)

h)

sa

i)

j)

k)

samples.

9. Data analysis and presentation

9.1 Drift analysis

(b)(4) [redacted]

9.2 Outliers

(b)(4) [redacted]

9.3 Linearity analysis

a) (b)(4) [redacted]

b)

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT

Linearity/ assay reportable range

9.4 Data presentation

The following information shall be reported:

a) (b)(4) [redacted]
b)
c)
d)
e)
f)
g)

10. Acceptability criteria

The acceptability criteria for linearity of Betachek GT strips are as follows:

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

B. RESULTS

Betachek GT Linearity/ assay reportable range

Data

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT

Linearity/ assay reportable range

Calculation

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK GT

Linearity/ assay reportable range

Graph

(b)(4)

[redacted]

C. CONCLUSION

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT

Linearity/ assay reportable range

Table 1 Glucose concentration intervals for linearity evaluation

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Lay-user Performance Evaluation Report

(b)(4)

[redacted]

A. STUDY DESIGN

Betachek GT Lay-user Performance Evaluation

1. Introduction

We are conducting a study to assess the performance of the Betachek Glucose Test in the hands of lay-users. The study will compare results obtained by Lay-users to results obtained by trained technicians using the Betachek Glucose Test.

2. Purpose

To validate the performance of the product in the hands of untrained users.

3. Scope

Betachek GT strips.

4. Standards applied

The evaluation of Betachek GT accuracy is performed in accordance with: ISO 15197:2003 *In vitro* diagnostic tests system- Requirements for self-testing in managing diabetes mellitus.
CLSI/NCCLS EP9 Method comparison and Bias Estimation using Patient Samples, approved guidelines Clinical and Laboratory Standards institute, 2005.

5. Terms and definitions

The terms and definitions specified in ISO 15197 apply.

6. Study objectives

The specific objectives are as follows:

(b)(4)

- [redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7. Equipment and materials

(b)(4)

[redacted]

8. Quality assurance and safety requirements

8.1. Requirements for operators

(b)(4)

[redacted]

8.2. Safety precautions

(b)(4)

[redacted]

8.3. Quality control

(b)(4)

[redacted]

9. Subject Eligibility

9.1. Study population

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9.2. Eligibility and exclusion criteria

9.2.1. Eligibility

(b)(4)

[redacted]

9.2.2. Exclusion criteria

Subjects who meet any of the following criteria are not eligible for the study:

- Age <18 years
- Unable to provide informed consent
- Blind (or without reading glasses), illiterate.

10.Lay-user performance evaluation

The lay-user performance for Betachek GT system is evaluated in accordance with ISO 15197:2003 , part 8.

10.1 General requirements

(b)(4)

[redacted]

10.2. Samples requirements

ISO 15157:2003 specifies the following requirements for samples to be used for lay-user performance evaluation:

The evaluation should be performed with capillary blood samples, obtained by skin puncture.
In some cases, a second skin puncture may be necessary to obtain sufficient sample volume to complete the protocol.

10.3. Environment requirements

[redacted] (b)(4) [redacted].

10.4 Reagent system

[redacted] (b)) (4

10.5 Evaluation procedure

The procedure is performed according to the requirements specified in ISO 15197: 2003, part 8.

10.5.1 Strips preparation

[redacted] (b) (4)

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10.5.2 Subjects information

(b)(4) [redacted]

10.5.3 Quality Control

(b)(4) [redacted]

10.5.4 Instructions for investigators

a) (b)(4) [redacted]

b)

c)

d)

[redacted] (b)(4) [redacted]

[redacted] (b)(4) [redacted]

11. Data analysis and presentation

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

11.2 Anomalous results

Should any anomalous results arise, they will be deal with as follows:

(b)(4)

[redacted]

11.3 Data analysis

11.3.1 Lay-user performance analysis

a) (b)(4)

b)

c)

[redacted]

11.3.2 Regression analysis

(b)(4)

[redacted]

11.4 Data presentation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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i) (b)(4) [redacted]

j)

k)

l)

m)

n)

12. Acceptability criteria

(b)(4) [redacted]

13. Miscellaneous

13.1 Investigation centres

The collection of specimens and testing will take place at:

(b)(4) [redacted]

13.2 Study coordinators and investigators

Study Coordinator:

(b)(4) [redacted]

Study Investigators:

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Contact details:

(b)(4)

[redacted]

13.3 Training and Competences

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Lay-user Performance Evaluation Report

B. RESULTS

Betachek GT Method comparison

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Lay-user Performance Evaluation Report

(b)(4)

[redacted]

2150
known?
dark gum

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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C. CONCLUSION

(b)(4)

[redacted]

Table 1
Characteristics of lay-user population for lay-user performance evaluation

	(b)(4)
Sex distribution	[redacted]
Disease status	
Native language	
Education	

(b)(4)

[redacted]

(b)(4)

[redacted]

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(b)(4)

Table 2
Betachek GT lay-user classification accuracy

(b)(4)

The plot of bias is presented in Figure 1. The graph shows the differences between Betachek GT Lay-user result and Betachek GT technician result plotted against the Betachek GT technician results.

Figure 1

(b)(4)

(b)(4)

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Betachek GT Lay-user Performance Evaluation Report

Linear regression (ordinary linear regression) for Betachek GT lay-user compared with Betachek GT technician is presented in Figure 2.

Figure 2

(b)(4) [redacted]

(b)(4) [redacted]

Table 3
Regression statistics of Betachek GT lay-user results against technician results

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Table 4 presents the accuracy of Betachek GT lay-user results. The number of samples tested, and the percentage results in specified ranges are shown.

Table 4
Betachek GT lay-user results compared with technician results

(b)(4)

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK GT INTERFERENCE TESTING STUDY DESIGN

1. Purpose

(b)(4) [redacted]

2. Scope

2.1. Products: Betachek GT

2.2. Interfering Substances

(b)(4) [redacted]

Table 1
Interferences from Exogenous Substances:

Interfering compound	Units	Therapeutic Levels	Test (High) Concentration
Acetaminophen	(b)(4) [redacted]		
Ascorbic Acid			
Dopamine			
Gentisic acid			
Ibuprofen			
Levo-Dopa			
Methyl-Dopa			
Salicylic acid			
Tetracycline			
Tolazamide			
Tolbutamide			

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 2
Interferences from Endogenous Substances:

Interfering compound	(b)(4)
Bilirubin	
Cholesterol	
Creatinine	
β-Hydroxy-butyric acid	
Triglyceride	

3. Decision criteria

3.1. Clinical Acceptability Criteria

(b)(4)

3.2. Statistical Significance and Power

(b)(4)

3.3. Glucose Test Concentrations

(b)(4)

3.4. Interferent Test Concentration

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

4. Quality assurance and safety

(b)(4)

[redacted]

5. Reference Measurement Procedure

(b)(4)

[redacted]

(b)(4)

[redacted]

6. Determination of interference characteristics

6.1.Interference screen

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.1.1. Samples preparation

Follow the specific protocols for each interferent substance.

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

6.1.4. Experimental procedure

1. (b)(4) [redacted]
2.
3.
4.
5.
6.
7.

6.1.5. Data analysis

(b)(4) [redacted]

6.2. Characterization of Interference Effects

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

6.2.1. Experimental design

(b)(4)

6.2.2. Samples preparation

(b)(4)

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.2.3. Interferent Stock solution preparation –see 6.1.2.

6.2.4. Replication requirements

(b)(4) [redacted]

6.2.5. Experimental procedure

1. (b)(4) [redacted]
2.
3.
4.
5.
6.
7.

6.2.6. Data analysis

(b)(4) [redacted]

6.2.7. Interpretation of results

Conclude that:

(b)(4) [redacted]

7. Evaluating Interference Using Patients Specimens

7.1. (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

7.2. Comparative method

(b)(4) [redacted]

7.3. Test specimens

(b)(4) [redacted]

7.4. Control specimens

(b)(4) [redacted]

7.5. Experimental procedure

1. (b)(4) [redacted]
2.
3.
4.

7.6. Data analysis

(b)(4) [redacted]

7.6.1. Plotting bias versus the comparative method value

The following steps are followed when plotting bias versus the comparative method value:

1. (b)(4) [redacted]
2.

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3. (b)(4) [redacted]

4. [redacted]

7.6.2. Plotting bias versus potential interferent

(b)(4) [redacted]

1. (b)(4) [redacted]

2. [redacted]

(b)(4) [redacted]

7.7. Interpretation of results

The following limitation shall be considered in interpretation of results:

- (b)(4) [redacted]
- [redacted]
- [redacted]
- [redacted]

7.8. Simplified procedure with patients samples

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8. RESULTS
BETACHEK GT Interference studies

(b)(4)

(b)(4)

tested: approx. 75mg/dL (4.2mmol/L) and 125mg/dL (6.9mmol/L).

No interference was detected[6] for the substances tested in these experiments.

A summary of tested interferences is provided in the table below. The list is referenced to CDRH Guidance Document: Review Criteria Assessment of portable Blood Glucose Monitoring In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology. The high test is referenced to NCCLS document EP7-A Vol.22 No.27, Appendix C. Interferent Test Concentrations.

(b)(4)

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Figure 1 Bias Plot for Control and Test groups

(b)(4)

[redacted]

YSI 2300Stat (mg/dL)

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

A summary of tested interferences is provided in the table below. The list is referenced to CDRH Guidance Document: Review Criteria Assessment of portable Blood Glucose Monitoring In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology. The hightest is referenced to NCCLS document EP7-A Vol.22 No.27, Appendix C. Interferent Test Concentrations.

Interferences from Exogenous Substances:

Interfering compound	Units	Therapeutic Levels	Test (High) Concentration	Result
Acetaminophen	(b)(4) [redacted]			
Ascorbic Acid				
Dopamine				
Gentisic acid				
Ibuprofen				
Levo-Dopa				
Methyl-Dopa				
Salicylic acid				
Tetracycline				
Tolazamide				
Tolbutamide				

Interferences from Endogenous Substances:

Interfering compound	(b)(4) [redacted]
Bilirubin	
Cholesterol	
Creatinine	
β-Hydroxy-butyric acid	
Triglyceride	

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Sensitivity studies

The purpose of this study was to assist the Production Laboratory in characterizing the sensitivity of the colour blocks on the Betachek Glucose Test colour chart.

(b)(4)

[redacted]

(b)(4)

[redacted]

Betachek GT reagent system

(b)(4)

[redacted]

Lay user

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

(b)(4) [redacted]

Table 1 Glucose concentrations for sensitivity evaluation of colour block 50mg/dL

(b)(4) [redacted]

Table 2 Glucose concentrations for sensitivity evaluation of colour block (b)(4) [redacted]

(b)(4) [redacted]

Table 3 Glucose concentrations for sensitivity evaluation of colour block 100mg/dL

(b)(4) [redacted]

Table 4 Glucose concentrations for sensitivity evaluation of colour block 125mg/dL

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 5 Glucose concentrations for sensitivity evaluation of colour block 150mg/dL

(b)(4)

[redacted]

Samples preparation

a) (b)(4)

b)

c)

d)

e)

f)

[redacted]

Drift analysis

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Results

(b)(4)

[redacted]

Order

Table 6

Sensitivity of colour block 50 mg/dl

(b)(4)

(b)(4)

[redacted]

Table 7

Sensitivity of colour block 75 mg/dl

(b)(4)

(b)(4)

[redacted]

Are these results acceptable? Do we need more samples

Table 8

Sensitivity of colour block 100 mg/dL

(b)(4)

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 9

Sensitivity of colour block 125 mg/dL

(b)(4) [redacted]

(b)(4) [redacted]

Table 10

Sensitivity of colour block 150 mg/dL

(b)(4) [redacted]

(b)(4) [redacted]

The Sensitivity of the challenged colour blocks was found to be as summarized in Table 11

(b)(4) [redacted]

According to the predetermined clinical acceptability criteria:

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Interference studies – ACETAMINOPHEN
Synopsis of the protocol

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

Control and test samples are prepared as follows:

(b)(4) [redacted]

7. (b)(4) [redacted]
8. [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Record processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK

Interference studies – ASCORBIC ACID

Synopsis of the protocol

(b)(4)

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

Control and test samples are prepared as follows:

(b)(4)

[redacted]

7. Experimental procedure

Record results on Interference Testing Form

(b)(4)

8. [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK

Interference studies –Bilirubin

Synopsis of the protocol

(b)(4)

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

Control and test samples are prepared as follows:

(b)(4)

[redacted]

7. Experimental procedure

(b)(4)

8. [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK

Interference studies –Creatinine

Synopsis of the protocol

(b)(4)

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

Control and test samples are prepared as follows:

(b)(4)

[redacted]

7. Experimental procedure
   Record results on Interference Testing Form

(b)(4)

8. [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT
Interference studies –Cholesterol
Synopsis of the protocol

1. (b)(4) [redacted]

2. [redacted]

(b)(4) [redacted]

3. Experimental procedure

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK

Interference studies –Creatinine

Synopsis of the protocol

(b)(4)

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

Control and test samples are prepared as follows:

(b)(4)

[redacted]

7. Experimental procedure
   Record results on Interference Testing Form

(b)(4)

8. [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK

Interference studies – L-DOPA

Synopsis of the protocol

(b)(4)

1. [redacted]

2. [redacted]

3. [redacted]

4. [redacted]

5. [redacted]

6. [redacted]

Control and test samples are prepared as follows

(b)(4)

[redacted]

7. Experimental procedure

Record results on Interference Testing Form

(b)(4)

8. [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK

Interference studies –β-Hydroxy butyric acid

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

Control and test samples are prepared as follows:

(b)(4) [redacted]

7. (b)(4) [redacted]
8. [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK

Interference studies –Gentisic acid

Synopsis of the protocol

(b)(4)

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

(b)(4)

[redacted]

7. Experimental procedure
   Record results on Interference Testing Form

(b)(4)

8. [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Interference studies – DOPAMINE
Synopsis of the protocol

(b)(4)

1.

2.

3.

4.

5.

6.

Control and test samples are prepared as follows:

(b)(4)

7.

8.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

BETACHEK
Interference studies –Tolazamide
Synopsis of the protocol

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

Control and test samples are prepared as follows:

(b)(4) [redacted]

7. Experimental procedure
   Record results on Interference Testing Form
8. (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT
Interference studies –Triglyceride
Synopsis of the protocol

1. (b)(4) [redacted]

2. [redacted]

used as a guide.

(b)(4) [redacted]

(b)(4) [redacted]

3. Experimental procedure

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Interference studies –Tetracycline
Synopsis of the protocol

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

	Venous blood	*Stock solution*	*Diluent*
Control sample	(b)(4) [redacted]		
Test sample			

(b)(4) [redacted]

(b)(4) [redacted]

7. Experimental procedure
(b)(4) [redacted]
8. [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK

Interference studies –Tolbutamide

Synopsis of the protocol

(b)(4)

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

	Venous blood	*Stock solution*	*Diluent*
Control sample	(b)(4) [redacted]		
Test sample			

Tolbutamide
Tolbutamide concentration: (b)(4) [redacted]

7. Experimental procedure
   Record results on Interference Testing Form

(b)(4)

8. [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Interference studies –Salicylic acid

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

	Venous blood	Stock solution	Diluent
Control sample	(b)(4) [redacted]		
Test sample			

(b)(4) [redacted]

(b)(4) [redacted]

7. Experimental procedure

(b)(4) [redacted]

8. [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Interference studies – Methyl-DOPA
Synopsis of the protocol

1. (b)(4) [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

	Venous blood	*Stock solution*	*Diluent*
Control sample	(b)(4) [redacted]		
Test sample			

(b)(4) [redacted]

(b)(4) [redacted]

7. Experimental procedure

(b)(4) [redacted]

8. [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK
Interference studies –Ibuprofen
Synopsis of the protocol

1. (b)(4)
2.
3.
4.
5.
6.

Control and test samples are prepared as follows:

	Venous blood	*Stock solution*	*Diluent*
Control sample	(b)(4)		
Test sample			

(b)(4)

(b)(4)

7. Experimental procedure
(b)(4)

8.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: L-DOPA

(b)(4)

[redacted]

Betachek GT reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

Sample preparation

Samples were prepared from human venous blood collected on Li Heparin as anticoagulant.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

	Venous blood	Stock solution	Diluent
Control sample	(b)(4) [redacted]		
Test sample			

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

L-DOPA Concentration	Glucose conc. (Betachek)	Difference (Test mean-Control mean)	95% CI for difference	Maximum allowable difference
(b)(4) [redacted]				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: Triglycerides

(b)(4)

[redacted]

(b)(4)

[redacted]

Betachek GT reagent system

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

(b)(4) [redacted]

Sample preparation

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Statistical considerations, data analysis

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Results

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Figure 1 Bias plot for Control and Test groups

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound : Cholesterol

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Betachek GT reagent system

(b)(4)

[redacted]

Reference reagent system

(b)(4)

[redacted]

Sample preparation

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

(b)(4) [redacted]

(b)(4) [redacted]

Statistical considerations, data analysis

(b)(4) [redacted]

Results

(b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Figure 1 Bias plot for Control and Test groups

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: Ascorbic acid

(b)(4)

[redacted]

Betachek reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

For each glucose concentration, the control and test samples were prepared as follows:

	Venous blood	Stock solution	Diluent
(b)(4) [redacted]			

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

Conclusion:
ASCORBIC ACID , at a concentration of 227µmol/L, does not interfere in Betachek testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: Gentisic acid

(b)(4)

[redacted]

Betachek reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

Sample preparation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

For each glucose concentration, the control and test samples were prepared as follows:

	Venous blood	Stock solution	Diluent
(b)(4) [redacted]			

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: Tolbutamide

(b)(4)

[redacted]

Betachek GT reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

Sample preparation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

	Venous blood	Stock solution	Diluent
(b)(4) [redacted]			

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

Conclusion:
Tolbutamide, at a concentration of 2.37mmol/L, does not interfere in Betachek GT testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: Tolazamide

(b)(4)

[redacted]

Betachek GT reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

Sample preparation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

	Venous blood	Stock solution	Diluent
Control sample	(b)(4) [redacted]		
Test sample			

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

Tolazamide Concentration	Glucose conc. (Betachek)	Difference (Test mean-Control mean)	95% CI for difference	Maximum allowable difference
(b)(4) [redacted]				

Conclusion:
Tolazamide, at a concentration of 5mg/dL, does not interfere in Betachek GT testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: Tetracycline

(b)(4)

[redacted]

Betachek GT reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

Sample preparation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

	Venous blood	Stock solution	Diluent
Control sample	(b)(4) [redacted]		
Test sample			

(b)(4) [redacted].

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

Tetracycline Concentration	Glucose conc. (Betachek)	Difference (Test mean-Control mean)	95% CI for difference	Maximum allowable difference
(b)(4) [redacted]				

Conclusion:
Tetracycline, at a concentration of 34.1mmol/L, does not interfere in Betachek GT testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: Methyl-DOPA

(b)(4)

[redacted]

Betachek GT reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

Sample preparation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

	Venous blood	Stock solution	Diluent
Control sample	(b)(4) [redacted]		
Test sample			

(b)(4) [redacted]

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

Methyl-DOPA Concentration	Glucose conc. (Betachek)	Difference (Test mean-Control mean)	95% CI for difference	Maximum allowable difference
(b)(4) [redacted]				

Conclusion:
Methyl-DOPA, at a concentration of 71.4µmol/L, does not interfere in Betachek GT testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: Ibuprofen

(b)(4)

[redacted]

Betachek GT reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

Sample preparation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

	Venous blood	Stock solution	Diluent
Control sample	(b)(4) [redacted]		
Test sample			

(b)(4) [redacted].

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

Ibuprophen Concentration	Glucose conc. (Betachek)	Difference (Test mean-Control mean)	95% CI for difference	Maximum allowable difference
(b)(4) [redacted]				

Conclusion:
Ibuprophen, at a concentration of 2425µmol/L, does not interfere in Betachek GT testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound : Dopamine

(b)(4)

[redacted]

Betachek reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

Sample preparation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) [redacted]:

	Venous blood	Stock solution	Diluent
(b)(4) [redacted]			

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

Dopamine Concentration	Glucose conc. (Betachek)	Difference (Test mean-Control mean)	95% CI for difference	Maximum allowable difference
(b)(4) [redacted]				

Conclusion:
Dopamine, at a concentration of 5.98μmol/L, does not interfere in Betachek testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: Acetaminophen

(b)(4)

[redacted]

Betachek GT reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

Sample preparation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

	Venous blood	Stock solution	Diluent
(b)(4) [redacted]			

(b)(4) [redacted]

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

Acetaminophen Concentration	Glucose conc. (Betachek)	Difference (Test mean-Control mean)	95% CI for difference	Maximum allowable difference
(b)(4) [redacted]				

Conclusion:
Acetaminophen, at a concentration of 1.66µmol/L, does not interfere in Betachek GT testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: Bilirubin

(b)(4)

[redacted]

Betachek GT reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

Sample preparation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

	Venous blood	Stock solution	Diluent
(b)(4) [redacted]			

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

Conclusion:
Bilirubin, at a concentration of 20mg/dL, does not interfere in Betachek GT testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: Salicylic acid

(b)(4)

[redacted]

Betachek reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

Sample preparation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

For each glucose concentration, the control and test samples were prepared as follows:

	Venous blood	***Stock solution***	***Diluent***
(b)(4) [redacted]			

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

Conclusion:
SALICYLIC ACID, at a concentration of 4.37mmol/L, does not interfere in Betachek testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: β-Hydroxy butyric acid

(b)(4)

[redacted]

Betachek GT reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

Sample preparation

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

	Venous blood	Stock solution	Diluent
(b)(4) [redacted]			

(b)(4) [redacted].

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

Na-β-Hydroxybutyrate Concentration	Glucose conc. (Betachek)	Difference (Test mean-Control mean)	95% CI for difference	Maximum allowable difference
(b)(4) [redacted]				

Conclusion:
Na-β-Hydroxybutyrate at a concentration of 3.0mmol/L, does not interfere in Betachek GT testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

Interfering compound: Creatinine

(b)(4)

[redacted]

Betachek GT reagent system

(b)(4)

[redacted]

Reference measurement procedure

(b)(4)

[redacted]

Sample preparation

(b)(4)

[redacted]

For each glucose concentration, the control and test samples were prepared as follows:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

	Venous blood	Stock solution	Diluent
(b)(4) [redacted]			

(b)(4) [redacted].

(b)(4) [redacted]

Statistical considerations

(b)(4) [redacted]

Results

(b)(4) [redacted]

Creatinine Concentration	Glucose conc. (Betachek)	Difference (Test mean-Control mean)	95% CI for difference	Maximum allowable difference
(b)(4) [redacted]				

Conclusion:
Creatinine, at a concentration of 30mg/dL, does not interfere in Betachek GT testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40
9200 Corporate Blvd.
Rockville, Maryland 20850

May 01, 2008

NATIONAL DIAGNOSTIC PRODUCTS
(AUST) PTY LTD
7-9 MERRIWA ST.
GORDON
SYDNEY,
AUSTRALIA 2072
ATTN: BRANDON STEPHEN BRANSGROVE

510(k) Number: K062187
Product: BETACHEK GLUCOSE TEST

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

K062187/S2

Submitter:
Brandon Stephen Bransgrove
Product Manager
National Diagnostic Products
laboratories
7-9 Merriwa Street
Gordon
Sydney, NSW, 2072, AS
Phone: +61 294 184777
Fax: +61 294 184747

FDA CDRH DMC

APR 30 2008

Received

April 28, 2008

Attn: CeSub Team
Center for Devices and Radiological Health
Document Mail Center
HFZ-401
9200 Corporate Blvd.
Rockville, MD 20850

Dear Sir or Madam:

This submission dated April 28, 2008, is filed pursuant to the In Vitro Diagnostic Device Evaluation and Safety program's Electronic Review (eReview).

The submission is a(n) **510(k), Original Submission, Traditional** referring to the product, Glucose Test System also known as trade name (s): BETACHEK with model(s): GLUCOSE TEST. The classification panel for this submission is CLINICAL CHEMISTRY.

Indications for Use
See attached

The prior submissions that are related to this release are as follows: K062187.
The devices to which substantial equivalence is claimed are as follows: Chemcard Glucose Test K 943503.

User Fee Payment ID: (b)(4) [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,

Brandon Stephen Bransgrove
Product Manager
National Diagnostic Products

FDA CDRH DMC

MAY 1 2008

Received

45 47

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Submitter:
Brandon Stephen Bransgrove
Product Manager
National Diagnostic Products
laboratories
7-9 Merriwa Street
Gordon
Sydney, NSW, 2072, AS
Phone: +61 294 184777
Fax: +61 294 184747

April 28, 2008

Attn: CeSub Team
Center for Devices and Radiological Health
Document Mail Center
HFZ-401
9200 Corporate Blvd.
Rockville, MD 20850

Dear Sir or Madam:

This submission dated April 28, 2008, is filed pursuant to the In Vitro Diagnostic Device Evaluation and Safety program's Electronic Review (eReview).

The submission is a(n) **510(k)**, **Original Submission**, **Traditional** referring to the product, Glucose Test System also known as trade name(s): BETACHEK with model(s): GLUCOSE TEST. The classification panel for this submission is CLINICAL CHEMISTRY.

Indications for Use
See attached

The prior submissions that are related to this release are as follows: K062187.
The devices to which substantial equivalence is claimed are as follows: Chemcard Glucose Test K 943503.

User Fee Payment ID: (b)(4) [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,

Brandon Stephen Bransgrove
Product Manager
National Diagnostic Products

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Submission Report

Section: Main Menu

Welcome

Welcome to the CDRH Electronic Submissions Software (CeSub)

This software application is intended to automate the current paper submission process. This software contains a number of data capturing tools and helpful dialog boxes to reduce redundant responses for you, and to allow us to capture data in a more useful, structured format. These benefits will enable CDRH to improve our review process and reduce lengthy review times.

For your convenience, an email account has been established to support any questions that you may have regarding the use of this software. Please email any questions or comments to the CeSub team at: **cdrhesub@cdrh.fda.gov.** Please be sure to include your name, company name and contact information in the email.

Thank you again for using our electronic product reporting software. We look forward to hearing from you soon.

What type of product is this submission referring to? *
In Vitro Diagnostic Device

Welcome (Cont.)

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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)
. 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) [redacted]

MDUFMA Cover Sheet

Please attach the completed MDUFMA Cover Sheet.	*
File Attachment	Medical Device User Fee Cover Sheet

2.0 Contact Information

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

Primary Contact Information		*
Contact Information:		
Contact Name	Mr Brandon Stephen Bransgrove	
Occupation Title	Product Manager	
Email Address	brandon@ndp.com.au	
Address		
Establishment Name	National Diagnostic Products	
Division Name	laboratories	
Address	7-9 Merriwa Street Gordon Sydney, NSW, 2072, AS	
Telephone Number	+61 294 184777	
Fax Number	+61 294 184747	

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	National Diagnostic Products
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Physical Location:	
Address	7-9 Merriwa Street Gordon Sydney, NSW, 2072, AS
Telephone Number	(+61) 294-1847 Ext: 77
Fax Number	(+61) 294-1847 Ext: 47

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.		
File Attachment		

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	Chemcard Glucose Test K 943503	

For this submission, are you including a 510(k) Statement or Summary?	*	510(k) Summary

Enter your 510(k) Summary or Statement.	*
See Attached	
File Attachment 1	Summary

4.0 Product Information

Section F	Product Information

Common or classification name	*
Glucose Test System	

FDA Document Numbers of all prior related submissions (regardless of outcome)	*
Item 1	K062187

4.1 Trade, Proprietary, or Model Names

Item: 1

Trade, proprietary, or model name for this device	*	BETACHEK
Model number	*	GLUCOSE TEST

5.0 Product Classification

Section G1	Product Classification

Choose the product code for this submission.	
Product Code	GLUCOSE OXIDASE, GLUCOSE (CGA)
Device Class	CLASS II
Classification Panel	CLINICAL CHEMISTRY
C.F.R. Section	862.1345 - GLUCOSE TEST SYSTEM.

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 descr be the classification of the product.

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).*

Enter the intended use of the product. *		
Betachek Glucose Test is a semi-quantitative glucose test intended to be used by a person who has not been diagnosed as diabetic to measure his or her fasting glucose level in order to determine whether the fasting glucose level is abnormal. This device can not be used to diagnose or monitor diabetes, or other medical problems. Abnormal results should be verified by a physician. The test is not intended for use by individuals who are pregnant.		
File Attachment		
.	Intended Use	Over the Counter

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."*

Enter the product's indications for use. *	
See attached	
File Attachment 1	Indications for use

Enter any special applications of the device or contraindications not addressed in the Intended Use Statement.	
Failure to fast will produce invalid results. For *in vitro* diagnostic use only. Use the test strips only between 64 and 95˚F (18 and 35˚C). Use only fresh capillary whole blood from a finger stick. The test strips are for single use only.	
File Attachment	

Special instrument requirements: Enter a brief description of instrumentation required to perform testing. If instrumentation has been previously cleared for marketing, identify the 510(k) number. *	
N/A	
File Attachment	

Enter a brief description of the test system, including the instrument required to perform the testing.	
File Attachment	

Information:	*Note any changes that have been made to the instrument or software for use with this new analyte (or confirm that no changes have been made). Provide risk assessment and validation data for each of these changes and demonstrate compliance with FDA software policy.*

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	Mr Brandon Stephen Bransgrove
Occupation Title	Product Manager
Email Address	brandon@ndp.com.au
Establishment Information:	
Establishment Name	National Diagnostic Products
Division Name	Laboratories/ Production
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Physical Location:	
Address	7-9 Merriwa Street, Gordon Sydney, NSW, 2072, AS
Telephone Number	(+61) 294-1847 Ext: 77
Fax Number	(+61) 294-1847 Ext: 47
Mailing Location:	
Address	Unit 22/39 Herbert Street St.Leonards Sydney, NSW, 2065, AS

Item: 2

Status Change	*	No

Site Operation

.	Manufacturer	*	Yes
.	Contract Manufacturer	*	No
.	Contract Sterilizer	*	No
.	Repackager/Relabeler	*	No

Contact Information	
Contact Information:	
Contact Name	Brandon Stephen Bransgrove
Occupation Title	Product Manager

Email Address	brandon@ndp.com.au
Establishment Information:	
Establishment Name	National Diagnostic Products
Division Name	Head office/ Packaging/ Warehouse
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	
Owner/Operator Number	
Physical Location:	
Address	22/39 Herbert Street, St. Leonards Sydney, NSW, 2065, AS
Telephone Number	(+61) 294-3281 Ext: 00
Fax Number	(+61) 294-3611 Ext: 51
Mailing Location:	
Address	22/39 Herbert Street, St. Leonards Sydney, NSW, 2065 AS, AS

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
Item 1	In vitro diagnostic test systems - Requirements for in vitro whole blood glucose monitoring systems intended for use by patients for self testing in management of diabetes mellitus, First Edition 2003-05-01, Approved (15197)(15197)	InVitro	ISO
Item 2	Medical devices - Application of risk management to medical devices (14971:2000)(14971:2000)	General	ISO
Item 3	Interference Testing in Clinical Chemistry; Approved Guideline (EP 7-A)(EP 7-A)	InVitro	NCCLS
Item 4	Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (EP09-A2)(EP09-A2)	InVitro	NCCLS
Item 5	Stability Testing of In Vitro Diagnostic Reagents (13640)(13640)	InVitro	CEN
Item 6	Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline (EP5-A)(EP5-A)	InVitro	NCCLS

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.

File Attachment	
Details	

Did you reference any other standards?	Yes

7.1 Other Standards

Item: 1

Section I	**Utilization of Standards**

Standards Number	ISO 13485
Standards Organization	ISO
Standards Title	Medical Devices Quality M
Version	Edition 2
Date	01/01/2003

Please attach the standard. Before attaching, please verify any copyright restrictions.	
File Attachment	

Item: 2

Section I	**Utilization of Standards**

Standards Number	
Standards Organization	
Standards Title	
Version	
Date	

Please attach the standard. Before attaching, please verify any copyright restrictions.	
File Attachment	

8.0 Utilization of Guidance Documents

Please enter all referenced Guidance Documents.

Item	Document Title	Office	Division	Web Page
Item 1	Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology	OIVD	DCTD	http://www.fda.gov/cdrh/ode/gluc.html
Item 2	Guidance for Industry In Vitro Diagnostic Glucose Test System; Final	OIVD	DCTD	http://www.fda.gov/cdrh/ode/76.html
Item 3	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 4	Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management	OCER	DUPSA	http://www.fda.gov/cdrh/humfac/1497.html
Item 5	Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)	OCER		http://www.fda.gov/cdrh/dsma/470.pdf
Item 6	Assessing the Safety/Effectiveness of Home-use In Vitro Diagnostic Devices (IVDs): Draft Points to Consider Regarding Labeling and Premarket Submissions	OIVD		http://www.fda.gov/cdrh/ode/odecl272.html
Item 7	Guideline for the Manufacture of In Vitro Diagnostic Products	OIVD		http://www.fda.gov/cdrh/comp/918.pdf
Item 8	Regulating In Vitro Diagnostic Device (IVD) Studies	OIVD		http://www.fda.gov/cdrh/comp/ivdreg.html

Item 9	In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions	OCER		http://www.fda.gov/cdrh/manual/ivdmanul.html
Item 10	Points to Consider for Collection of Data in Support of In-Vitro Device Submissions for 510(k) Clearance	OIVD		http://www.fda.gov/cdrh/ode/95.pdf

9.0 Certification of Compliance with Clinical Trials

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.	
File Attachment 1	FDA-3674
Details	N/A

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 Suscept bility Testing 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 I ke to complete the OIVD 510(k) Short Form?	*	No

1.0 Type of Product

Please select one:	*	Assay/Reagents Including Controls

Select Device Type:	*	Quantitative and Semi-quantitative

Select device technology: *	Colorometry
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). *	
See attached	
File Attachment 1	Device Description

Is there an instrument associated with this assay? *		No
.	Has this instrument previously been cleared?	
.	Please enter the 510(k) number.	
	Item	
.	Have there been any modifications to the cleared instrument for this particular assay?	

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.)?	
N/A	
File Attachment	

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?	
N/A	
File Attachment	

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

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.).	
N/A	
File Attachment	

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

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

Calibration	
Describe the calibration procedures for the system (i.e., use of whole blood and commercial cal bration materials).	
N/A	
File Attachment	

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).	
N/A	
File Attachment	

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.).	
N/A	
File Attachment	

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.	
N/A	
File Attachment	

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	*
Chemcard Glucose Test K 943503	
Describe the item being compared	*
Detection Method	

Similarities	*
Enzyme linked color change	
Differences	*
N/A	

Item: 2

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device	*
Chemcard Glucose Test K 943503	
Describe the item being compared	*
Sample	
Similarities	*
Finger stick blood sample	
Differences	*
N/A	

Item: 3

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device	*
Chemcard Glucose Test K 943503	
Describe the item being compared	*
Sample volume	
Similarities	*
1 drop (no sample premeasurement)	
Differences	*
N/A	

Item: 4

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device	*
Chemcard Glucose Test K 943503	
Describe the item being compared	*
Enzyme 1	
Similarities	*
Glucose Oxidase	
Differences	*

N/A

Item: 5

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device	*
Chemcard Glucose Test K 943503	
Describe the item being compared	*
Enzyme 2	
Similarities	*
Peroxidase	
Differences	*
N/A	

Item: 6

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device	*
Chemcard Glucose Test K 943503	
Describe the item being compared	*
Dye	
Similarities	*
TMB	
Differences	*
o-Tolidine, DCP	

Item: 7

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device	*
Chemcard Glucose Test K 943503	
Describe the item being compared	*
Instrument Required	
Similarities	*
No	
Differences	*
N/A	

Item: 8

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device	*
Chemcard Glucose Test K 943503	
Describe the item being compared	*
Operating Temperature	
Similarities	*
64 - 95°F (18 - 35°C)	
Differences	*
N/A	

Item: 9

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device	*
Chemcard Glucose Test K 943503	
Describe the item being compared	*
Intended Use	
Similarities	*
a semi-quantitative glucose test intended to be used by a person who has not been diagnosed as diabetic to measure his or her fasting glucose level in order to determine whether the fasting glucose level is abnormal	
Differences	*
N/A	

Item: 10

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device	*
Chemcard Glucose Test K 943503	
Describe the item being compared	*
Detection range	
Similarities	*
50-150mg/dL	
Differences	*
N/A	

Item: 11

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device	*
Chemcard Glucose Test K 943503	

Describe the item being compared	*
Test Time	
Similarities	*
3 minutes	
Differences	*
N/A	

Item: 12

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device	*
Chemcard Glucose Test K 943503	
Describe the item being compared	*
Format	
Similarities	*
N/A	
Differences	*
Test Strip (Predicate: Test card)	

Item: 13

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device	*
Chemcard Glucose Test K 943503	
Describe the item being compared	*
User Steps	
Similarities	*
Both have a timing step	
Differences	*
Blood wiped at 1minute and result read at 3 minutes. (Predicate: Card peeled at 3 minutes and result read within 30 seconds)	

Item: 14

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device	*
Chemcard Glucose Test K 943503	
Describe the item being compared	*
Hematocrit range	
Similarities	*

N/A
Differences *
35% - 55% (Predicate: Unknown)

Item: 15

Note:	*The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*
Predicate device *	
Chemcard Glucose Test K 943503	
Describe the item being compared *	
Number of graduations in result chart.	
Similarities *	
5 color blocks	
Differences *	
N/A	

4.0 Test Principle

Enter a brief description of the technology/methodology utilized in the device (i.e., descr be 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 ant bodies and epitopes). *	
See attached	
File Attachment 1	Test Principle

5.0 Performance Characteristics

Note:	*Provide the information described below as appropriate to support the substantial equivalence determination. The type of data to be provided in this section depends on the intended use, technological characteristics of the new device, and claims.*

Note:	*If you followed CLSI guidelines, which have specific instructions and calculations for determining performance, you may certify this instead of describing all the specifics of your protocol, statistical analyses, and line data. You should clarify which specific aspects of the protocol you followed, describe your deviations from the protocol, and describe any manufacturer-specific choices not specified in the guideline (e.g. number of lots or sites for precision or partitioning of sub-populations for reference range evaluation). You should also provide a summary of the results as listed below. CLSI guidelines relevant for the following sections include: EP5, Evaluation of Precision Performance of Clinical Chemistry Devices; EP12, User Protocol for Evaluation of Qualitative Test Performance; EP6, Evaluation of the Linearity of Quantitative Analytical Methods; EP7, Interference Testing in Clinical Chemistry; EP9, Method Comparison and Bias Estimation Using Patient Samples; EP14, Evaluation of Matrix Effects; GP10, Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; C28, How to Define and Determine Reference Intervals in the Clinical Laboratory; M2, Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard; M7 , Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard; M11, Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard; M23, Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters; Approved Guideline; M24, Susceptibility Testing of Mycobacteria, Nocardia, and Other Aerobic Actinomycetes; Approved Standard; M27, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard and M100, Performance Standards for Antimicrobial Susceptibility Testing; Fifteenth Informational Supplement.*

5.1.1 Analytical Limits at Low Levels

Enter the description of specimen type and preparation including matrix, analyte levels, and how levels were established. *

Blood specimens were used for evaluation of sensitivity of Betachek Glucose Test Strips at different glucose concentrations. Samples were prepared from freshly obtained human venous blood collected in Li Heparin blood tubes. (b)(4) [redacted]

The sensitivity of the five colour blocks (50,75,100,125 and 150mg/dL) was studied and the following glucose concentrations were prepared:

Table 38: Glucose concentration in samples for sensitivity evaluation (Reference method, mean of four replicates)

Colour block 50mg/dL	Colour block 75mg/dL	Colour block 100mg/dL	Colour block 125mg/dL	Colour block 150mg/dL

(b)(4) [redacted]

The reference method used to determine the glucose level in blood samples was the YSI 2300 Stat Plus Analyser. This system determines the glucose concentration in a (b)(4) [redacted].

The device has a broad measurement range of up to (b)(4) [redacted]. The system is traceable to an NIST standard.

File Attachment	

Enter the number of replicates (runs, days, instruments, and operators, as appropriate) included at each concentration. *

(b)(4) [redacted]

Colour block 50mg/dL	Colour block 75mg/dL	Colour block 100mg/dL	Colour block 125mg/dL	Colour block 150mg/dL

(b)(4) [redacted]

(b)(4)

(b)(4)

File Attachment	

Describe the statistical method used. *

(b)(4)

Table 39

Colour block 50mg/dL	Colour block 75mg/dL	Colour block 100mg/dL	Colour block 125mg/dL	Colour block 150mg/dL
Glucose level in blood samples (mg/dL)				

(b)(4)

(b)(4)

(b)(4)

File Attachment	

Enter the results of analytical limits at low levels (e.g. limit of detection, functional sensitivity). *

See attached

File Attachment 1	Sensitivity results

(b)(4) [redacted]

[redacted]

File Attachment	

For qualitative assays, include the percent of replicates that test positive at each concentration and evaluate the 95% interval for cutoff and limit of detection.

N/A

File Attachment	

5.1.2 Precision (Repeatability/Reproducibility)

(b)(4) [redacted]

[redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

File Attachment 1	Between-lot Precision
File Attachment 2	Day-to-day Precision
File Attachment 3	Within-lot Precision

(b)(4) [redacted] *

See attached

File Attachment 1	Description of specimens-Precision

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). *

Description of sources of variability

1. (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

All studies were performed in a laboratory environment, at the manufacturer's site.

2. Variability between strips from different Betachek Glucose Test lots

(b)(4) [redacted]

(b)(4) [redacted]

The studies determined the imprecision within-lot, between-lot and total (due to combined effects within and between lot).

All studies were performed in a laboratory environment, at the manufacturer's site.

3. Variability due to day-to-day environmental changes

(b)(4) [redacted]

All studies were performed in a laboratory environment, at the manufacturer's site.

File Attachment	

Enter a description of statistical methods used to analyze data; include any model assumptions. *	
(b)(4) [redacted]	
(b)(4) [redacted]	
File Attachment	

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. *	
See attached	
File Attachment 1	Results-Precision

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.	
File Attachment	

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 descr be recovery of the assay in graphic and tabular form. *	
See attached	
File Attachment 1	linear range, supportive data

Enter the linear range and measuring (reportable) range. Include the measure of deviation from linearity, if applicable. *	
Linear range: (b)(4) [redacted]	
Measuring range (b)(4) [redacted]	
File Attachment	

Enter a description of how reportable range is determined including acceptance criteria or results for accuracy, precision, or other characteristics within this range. *	
See attached	
File Attachment 1	reportable range criteria

Enter a description of specimen type and preparation including information on matrix, analyte levels, and the methods used to determine the target levels. *
Samples were prepared from human venous blood collected on Li Heparin as anticoagulant. (b)(4) [redacted]
(b)(4) [redacted]
[redacted]

(b)(4) [redacted].

Table 14 Glucose concentration intervals for linearity evaluation

(b)(4) [redacted]

The reference method used was (b)(4) [redacted]. The system is traceable to an NIST standard.

The analyte levels, as measured with the YSI 2300 Stat Plus Analyzer are presented in Table 16.

Table 16 YSI 2300Stat Plus Linearity assessment test results

(b)(4) [redacted]

File Attachment	

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

(b)(4) [redacted]

(b)(4) [redacted]

[redacted].

(b)(4) [redacted].

(b)(4) [redacted]

File Attachment	

Enter results such as: estimates of slope, intercept with confidence intervals, and R2 value of regression. *	
See attached	
File Attachment 1	Results Linearity

Enter the range of percent recovery at each concentration (observed value/target value). *	
The table below shows the range of percentage recovery across the nine levels of glucose measured:	

Table 18 Betachek GT Percent Recovery- Linearity study

(b)(4) [redacted]

File Attachment	

Describe how results outside the measuring (reportable) range are reported to the user. *	
The Instructions for Use (IFU) advise that results lighter than the 50mg/dl color block should be interpreted as lower than (b)(4) [redacted].	
File Attachment	

Describe validation of instructions for out-of-range specimens, if applicable. *	
N/A	
File Attachment	

Enter discussion of possible high-dose hook effect, if applicable. *	
N/A	
File Attachment	

5.1.4 Calibrators and Controls

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

Procedural Controls

The device has three procedural controls that allow the user to verify the test has worked correctly.

1. (b)(4) [redacted].

2. (b)(4) [redacted]

3. (b)(4) [redacted]

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 cal brator 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).	
File Attachment	

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

File Attachment	

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

Where applicable, briefly summarize the following information about cal brators 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.	
File Attachment	

5.1.6 Analytical Specificity

Enter a description of study design and statistical methods. *	
(b)(4) [redacted].	
File Attachment 1	Interference Study Design

Enter the specimen description and preparation including matrix, analyte levels present in the sample, and how these levels were established. *	
(b)(4) [redacted]. The system is traceable to an NIST standard.	
File Attachment 1	Report Acetaminophen
File Attachment 2	Report Ascorbica acid
File Attachment 3	Report Bilirubin
File Attachment 4	Report Cholesterol
File Attachment 5	Report Creatinine
File Attachment 6	Report Dopamine
File Attachment 7	Report Gentisic acid
File Attachment 8	Report Hydroxybutyrate
File Attachment 9	Report Ibuprophen
File Attachment 10	Report L-DOPA
File Attachment 11	Report Methyl-DOPA
File Attachment 12	Report Salicylic acid
File Attachment 13	Report Tetracycline
File Attachment 14	Report Tolazamide
File Attachment 15	Report To butamide
File Attachment 16	Report Triglyceride

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. *
A summary of interfering substances is provided in the tables below. The list is referenced to CDRH Guidance Document: Review Criteria Assessment of Portable Blood Glucose Monitoring In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology. The high test is

referenced to NCCLS Document EP7-A Vol.22 No.27 (which replaces EP7-P).

Table 21

Interferences from Exogenous Substances:

(b)(4)

[redacted]

Table 22

Interferences from Endogenous Substances:

(b)(4)

[redacted]

(b)(4)

(b)(4)

(b)(4)

No difference attributable to interference was indicated.

(b)(4)

File Attachment	

Enter a description of the positive and negative control samples that served as a reference to identify any interference or cross reactivity. Descr be how interference and cross reactivity were defined in relation to the results obtained for the control samples. *

(b)(4)

(b)(4)

(b)(4) [redacted]

(b)(4) [redacted]

[redacted]

File Attachment	

Enter a description of the degree of interference or cross-reactivity observed. *
See attached
File Attachment 1 — Report Interference Studies

5.1.7 Analytical Characterization of Cut-off

Enter the rationale for the units, cut-off and/or categories of the results. *
See attached
File Attachment 1 — Determination of the cut-off

Enter a description of specimen preparation including analyte levels, matrix, and how level was established. *
N/A
File Attachment

Enter a definition of "equivocal zone," if applicable. *
N/A
File Attachment

Enter the statistical method used (e.g., Receiver Operator Characteristic Analysis). *
N/A Cut-off well recognised
File Attachment

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.
File Attachment

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.	
File Attachment	

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

Carryover	
Provide studies to demonstrate lack of over estimation of results due to the carryover effect. The testing pool should consist of samples at clinically meaningful levels.	
File Attachment	

Interfering Substances	
Provide studies to show poss ble interference of substances such as lipids, hemoglobin, bilirubin, etc.	
File Attachment	

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 thereof, 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) [redacted]. The system is traceable to an NIST standard.	
File Attachment	

(b)(4) [redacted] *
Eligibility

(b)(4) [redacted]

File Attachment	

Enter the sample description (e.g., matrix). *
For both methods (Reference and Betachek Glucose Test), fresh capillary blood samples were used in method comparison studies performed. (b)(4) [redacted]
(b)(4) [redacted]
File Attachment

(b)(4) [redacted] *
For the method comparison, trained technicians performed both the reference and the Betachek Glucose Test. For studies where the intended user is represented, see lay user studies under clinical studies section.
File Attachment 1 — Locations, Investigators

Enter when the study was done, including beginning and ending dates of recruitment/testing. *
[redacted] (b)
File Attachment

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? *
(b)(4) [redacted]
File Attachment

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) [redacted]
(b)(4) [redacted]
File Attachment

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

The testing was performed by trained technicians, without any specific information regarding the patient medical history (diet, type of medication, diabetes management, other investigations).

The results were recorded on separate forms to prevent results being disclosed between technicians.

File Attachment	

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) [redacted] (b)(4)

(b)(4) [redacted].

File Attachment	

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

See attached

File Attachment 1	No of patients, specimens

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

Quality control tests were performed each day of testing on both reference and Betachek Glucose Test systems.

Daily maintenance check and tests were performed for YSI 2300 Stat Plus Analyzer, according to the instruction manual.

Betachek Glucose Test strips were tested with two Betachek control solutions.

Attached are the results of quality control tests.

File Attachment 1	Quality Control Testing

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. *

The system accuracy evaluation for Betachek GT was conducted with (b)(4) [redacted].

(b)(4) [redacted]

[redacted]

The age distribution for the 124 subjects included in the study is presented in table below:

(b)(4) [redacted]

(b)(4)

File Attachment	

Enter the number of specimens satisfying the criteria for inclusion that did or did not undergo the new device and/or comparator test. Also enter why the specimens failed to be tested.	*
See attached	
File Attachment 1	Specimens not tested

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.	*
The study design specifies the criteria and the action to be taken should any anomalous results arise, as follows:	

(b)(4)

	(b)(4) [redacted]
6	
7	
8	
34	
67	
73	
78	
90	
94	
100	

(b)(4) [redacted].

The excluded results are explained in tables below:

(b)(4) [redacted]	

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

File Attachment 1	Data analysis with outliers
File Attachment 2	Data analysis without outliers

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

The glucose concentrations, as measured with the Betachek GT system, (b)(4) [redacted]

Table 24

Samples distribution for system accuracy evaluation

(b)(4) [redacted]

File Attachment	

5.2.1.2 Results

(b)(4) [redacted]

File Attachment	

Do you have an equivocal zone with your assay? *	No

Attach or enter the appropriate table. *

(b)(4) [redacted]. The results are presented in table below:

(b)(4) [redacted]

(b)(4) [redacted]

File Attachment 1	Betachek Glucose Test Accuracy

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, and 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. *	
See attached	
File Attachment 1	Report Betachek GT Method Comparison

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 orgraphical representations may also be appropriate, e.g., Bland-Altman plots. *	
See attached	
File Attachment 1	Graphs Method Comparison

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

Descriptive statistics

(b)(4) [redacted].

(b)(4) [redacted]

Table 32

(b)(4) [redacted]

The method comparison studies were performed by testing (b)(4) [redacted]

Table 33 Descriptive statistics –Betachek Glucose Test

(b)(4)

File Attachment	

Describe the adverse events from performing the new or comparator tests. *
No adverse event was reported by participants or investigators.

(b)(4)

(b)(4)

(b)(4)

[redacted]

File Attachment	

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. *
N/A Capillary finger tip sample only.
File Attachment

5.3 Clinical Studies (where applicable)

Are there clinical studies included in this submission? *	Yes

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. *	
A lay user study was undertaken and feedback from users was obtained. See attached.	
File Attachment 1	Report Betachek GT Lay-user study

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.). *	
N/A	
File Attachment	

5.4 Clinical Cut-off

Describe the established cut-off and its validation for the new device. Define "equivocal zone" if applicable, and include a description of how results within this zone are reported to the user. *	
See attached	
File Attachment 1	Determination of the cut-off

5.5 Reference Interval (Expected Values)

Enter the reference interval for this measurand and the method used to determine it. *	
See attached	
File Attachment 1	Determination of the cut-off

Include the literature references establishing the reference intervals and justification for applying this range to the new device. *	
ADA. The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus Follow-up Report on the Diagnosis of Diabetes Mellitus. *Diabetes Care* 26:3160-3167, 2003	
File Attachment	

Include a description of your methods for determining the reference intervals if they are not well established from the literature or if the range cannot be transferred to the new device. Also, descr be the population studied (demographics, inclusion/exclusion criteria, number of individuals). Indicate if separate reference intervals for subclasses were clinically justified. Determine the method of clinical diagnosis of the reference population(s). Finally, include the statistical method used to calculate ranges. *	
Expected values are well established.	
File Attachment	

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, cal bration, 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.). *	
See attached	
File Attachment 1	Predicate-Chematics Chemcard, Instructions for use
File Attachment 2	Betachek GT Instructions for Use Page 1
File Attachment 3	Betachek GT Instructions for Use Page 2
File Attachment 4	Betachek GT Label
File Attachment 5	Predicate Package
File Attachment 6	Betachek Glucose Test Box

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: Risk analysis [Special 510(k)s], manufacturing information for critical reagents, copies of bibliography references, financial disclosures, and software validation or certification statements, if necessary to support equivalence. *	
See attached.	
File Attachment 1	Risk Analysis-Betachek Glucose Test

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File Attachment 2	Hematocrit Study-Betachek Glucose Test

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

BETACHEK GLUCOSE TEST

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

What is this Test for?
Betachek Glucose Test is intended as a screening test for the early detection of abnormal fasting plasma glucose (FPG) levels. Abnormal fasting glucose levels can be a sign of diabetes or other health problems. The test uses a drop of capillary blood to provide a preliminary semi-quantitative result. Any abnormal result should be confirmed by a doctor using a quantitative laboratory based method. The test is not intended to provide a formal diagnosis of diabetes. A formal diagnosis can only be made by a doctor. The test is for over-the-counter use.

Background
Type 2 Diabetes: It is estimated that 30% of people with diabetes in the US remain undiagnosed[1]. This is because when a person first develops diabetes it is common for them to have no signs of sickness. They do however have high levels of glucose in their blood which over time badly damages many parts of the body. Often Diabetes is only discovered many years later when the damage has occurred. This damage can be prevented if high glucose levels are reduced by early treatment. It is therefore important to check your blood glucose level regularly and if it is high, to seek treatment before it causes serious health problems that cannot be reversed.
Pre-Diabetes: In addition to undiagnosed diabetes, the American Diabetes Association (ADA) estimates that 54 million people in the US (18%) have pre-diabetes (glucose levels 100-125 mg/dl). The ADA and National Institute of Diabetes and Digestive and Kidney Diseases believe that people with pre-diabetes can delay or *prevent* diabetes if they begin treatment early[2]. Treatment can often involve simple measures such as diet and exercise.

Betachek® Diabetes Test is a convenient and effective way to measure glucose levels in just 3 minutes. Individuals who obtain an abnormal result should see their doctor for further testing.

How Does the Test Work?
The test zone consists of two test pads containing sensitive chemicals. When blood is applied to this zone, the chemicals react with the glucose in the blood. The reaction produces a colour change that varies with the amount of glucose in the blood. The test uses the enzymes Glucose Oxidase and Peroxidase which along with color forming chemicals and non-reactive ingredients is contained in the test zone.

Chemical Composition
Each Betachek® GT test strip contains (Quantity/cm²): Glucose Oxidase 0.08 U, Peroxidase 9.4 µg, TMB 77 µg, o-Tolidine 81µg, DCP 20 µg, Stabiliser 0.12 mg, APAC 15 µg, Inert ingredients 2.20 mg (w/w).

Precautions and Limitations of the Test
Failure to fast will produce invalid high results. For *in vitro* diagnostic use only. Use the test strips only between 64 and 95˚F (18 and 35˚C). Running a test below 64˚F will give low results and running a test above 95˚F will produce high results. There is no need to refrigerate this product, however if refrigerated, do not use the test until it has warmed to room temperature. Failure to do so could lead to low results. Use only fresh capillary whole blood from a finger stick. The test strips are for single use only. *Incorrect timing* – leaving the blood on too long will increase the result and wiping the blood too early will decrease the result. Blood drop must cover the test zone – see inset picture with tick. Smearing too little blood will lead to uneven color development that will not be readable. Blood cannot be added after timing has started – repeat with new test. The test is not intended for use by individuals who are pregnant. As the reading range is 50 - 150 mg/dl, the test should not be used by people with diabetes to monitor their glucose levels or adjust any treatment.

Storage and Handling
Store Betachek® GT Test Strips in their original container in a cool, dry place between 39-86˚F (4-30˚C). Do not freeze. Use the test strip immediately after it is removed from the container. Always replace the cap quickly.

Quality Checks
The test strips can be checked against the '0' (unreacted) color block to see they are in good condition. If there is any sign of blue, the strip should not be used.

What is Included?
2 tests, 2 single use lancets, 1 label on container with color chart, tissue, alcohol swab, 1 package insert.

What is not Included but Needed?
A watch with a second hand or a timer.

Measurement Range
The measurement range is 50 – 150 mg/dl (2.8 – 8.3 mmol/l).

When Should I Test?
An ideal time to test is before breakfast. Do not eat or drink for 8 hours before testing (you may drink water only).

How do I Run a Test?
Have a timer ready.
See the step by step color instructions numbered 1-7.

How do I Read the Result?
Results are obtained by comparing the test zone to the color chart on the label. Use natural light for best results. If the test zone color lies between two color blocks on the chart e.g. a color that appears to be between the 75 and the 100 mg/dl color blocks, then your result is in the range 75-100 mg/dl.
A test zone lighter than 50mg/dl, is less than 50mg/dl. A test zone darker than 150 mg/dl is greater than 150mg/dl.

Expected Results

Results[3]	**Fasting Plasma Glucose (FPG) (mg/dl)**
Abnormally Low	<75
Normal	75 - 100
Abnormal	> 100

If the test zone color is *darker* than the 100 mg/dl color block then your result is abnormal. Results less than 75 mg/dl are considered abnormally low. Abnormal results should be confirmed by re-testing – seek advice from a physician or medical professional.

Do I Need to Test Again?
Blood glucose should be checked annually by individuals who are any of the following: obese; have a first-degree relative with diabetes; are members of a high-risk ethnic population (Indian, African, Hispanic, Native American, Aboriginal, Pacific-Islander, Asian). Also those who have delivered a baby weighing more than 9 pounds; have had gestational diabetes; have high blood pressure; have HDL cholesterol levels ≤ 35mg/dl or triglyceride levels ≥ 250mg/dl; or who, on previous testing had impaired glucose tolerance or impaired fasting glucose. All adults older than 45 years of age should test every three years.

Performance Characteristics
Accuracy
Diabetes experts have suggested that glucose devices should agree within 15 mg/dL of a laboratory method when the glucose concentration is lower than 75 mg/dL, and within 20% of a laboratory method when the glucose concentration is 75 mg/dL or higher. The chart below displays how often the Betachek Glucose Test achieves this goal. The chart is based on a study done on 108 patients to see how well Betachek Glucose Test compared to laboratory results.

For glucose results lower than 75 mg/dL, the percentage (and number) of Betachek Glucose Test results that matched the laboratory method within 15 mg/dL :	(22/22) 100%
For glucose results at 75 mg/dL or higher, the percent (and number) of meter results that match the laboratory method within 20%:	(214/225) 95%

Note: When Betachek Glucose Test results are compared to the laboratory results, results below 75 mg/dL are compared in mg/dL.

Precision
The within – lot precision of Betachek GT strips was determined for three lots of strips. Three different glucose levels were used, covering a range 50-150mg/dL. CV's for lots ranged from 0 to 4.8%.

More information on diabetes and pre diabetes can be found at:
www.diabetes.org and www.diabetes.org/pre-diabetes.jsp
Betachek Helpline: xxxx xxxxxxxxx

Version BGT-US-003 NOV 2007

[1] Catherine C. Cowie et al., Prevalence of Diabetes and Impaired Fasting Glucose in Adults in the U.S. Population *Diabetes Care* 29:1263-1268, 2006
[2] American Diabetes Association, The Prevention or Delay of Type 2 Diabetes. Diabetes Care 25:742-749, 2002

[3] American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus, *Diabetes Care* 29:S43-S48, 2006

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK®
Glucose Test

Instructions for use

⚠ IMPORTANT!
Read instructions carefully. You need a timer or watch with second hand ready. This test has an important timing step that must be followed exactly to ensure accurate results.

Before you perform the test:

Ensure you have ***not eaten*** for at least 8 hours.
(You may drink water only)

1. Wash hands and dry thoroughly.

Use the alcohol swab provided to wipe the fingertip. Allow to dry before testing.

2. Twist off protective lancet cap.

3. Push the lancet firmly into the finger until you hear a 'click'.

4. Gently squeeze your finger until you have a large hanging drop of blood. ***Get ready to start timing.***

5. Have your timer ready
Place a drop of blood onto the test zone and immediately start timing.
Check - see pictures in boxes
Ensure both test pads are fully covered. Do not smear or dab blood thinly.

6. After exactly 1 minute wipe the blood off the test zone, using the tissue provided.

7. Wait 2 minutes after wiping and then match the test zone against the label color chart for the result.
See section: How do I read the result?

You have 5 minutes to read the result.
Do not read the result after 5 minutes as the test zone will start to fade.

What does my result mean?

If the test zone color is *darker* than the 100 mg/dl color block on the label then your result is abnormal and you should see your doctor for a laboratory based test. See section: Expected Results

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Tables 26 and 27 present the accuracy of Betachek GT segregated for glucose levels <75mg/dL and for glucose levels ≥75mg/dL. The number of samples tested, and the percentage results in specified ranges are shown.

Table26 Betachek GT accuracy for glucose concentrations <75 mg/dL

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Table 27 Betachek GT accuracy for glucose concentrations ≥75mg/dL

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Table 32

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Could you have diabetes?

2 tests

Glucose Test

BETACHEK
Better life

Glucose Test

BETACHEK
Better life

2 tests

Blood Glucose Test

BETACHEK
Better life

Glucose Test

CE 0197

Ingredients/test
Peroxidase 9.4ug, Glucose Oxidase 0.08U,
TMB 77ug, DCP 20ug, stabiliser 0.12mg
o-tolidine 81ug, APAC 15ug, inert ingredients 2.20 mg.

REF: 0956800020

Made in Australia

NDP National Diagnostic Products
Sydney, Australia
www.betachek.com

In vitro diagnostic use
Store between 39-86°F

UPC-A Bar Code
009568 00020

LOT

EXP

Why do I need to do this test?

- A diabetes epidemic is underway *(Source:World Health Organisation).*
- Unhealthy diets, obesity and lack of exercise are the main causes of diabetes.
- High blood pressure, elevated cholesterol, being overweight or having a family history of diabetes increases your risk of developing diabetes.
- Approximately 30% of people with diabetes don't know they have it.

How does it work?

Betachek is an effective test for abnormal blood sugar (glucose) levels that can be a sign of diabetes or other medical problems.

Diabetes is a disorder that causes high blood sugar (glucose) levels. Untreated this can lead to heart disease, kidney failure, blindness and limb amputations. Early diagnosis and treatment will prevent this.

BETACHEK
Better Life

www.betachek.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Between-Lot Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

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Betachek GT Between-Lot Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Between-Lot Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2397; Released by CDRH on 9/16/16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

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Questions? Contact FDA/CDRH/OSE/DIB at CDRH-FOISTATUS@ida.hhs.gov or 301-796-9115

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

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Table 7

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Day-to-day Precision Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Determination of the cut off

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Determination of the cut off

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Determination of the cut off

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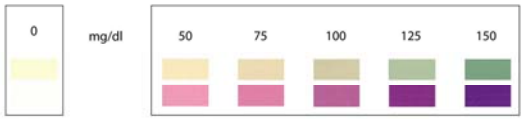
Device Description

Betachek Glucose Test is a two color (pink/green) visually read test strip for the semi-quantitative measurement of glucose in fresh capillary whole blood. Each Betachek Glucose test strip comprises two reagent zones attached to the end of a plastic strip.



The test uses a drop of capillary blood to provide a semi-quantitative result. The result is based on the Glucose Oxidase/ Peroxidase reaction which along with chromogen indicators and non-reactive ingredients is contained in the reagent pads. The test strips are packed in a plastic container with desiccant closure. Each container label has a 5-increment colour chart for result interpretation.

O_2 + Glucose ⇨ GLUCOSE OXIDASE ⇨ D-glucono-1,5 lactone +H_2O_2

H_2O_2 + reduced TMB ⇨ PEROXIDASE ⇨ oxidised TMB + H_2O

Each Betachek test strip contains:

Each Betachek® GT test strip contains (Quantity/cm²): Glucose Oxidase 0.08 U, Peroxidase 9.4 µg, TMB 77 µg, o-Tolidine 81µg, DCP 20 µg, Stabiliser 0.12 mg, APAC 15 µg, Inert ingredients 2.20 mg (w/w).

Test Procedure

Step 1. A drop of blood is applied to the test zone.

Step 2. The blood is wiped from the test zone after 1minute.

Step 3. After waiting a further 2 minutes the result is read by matching the test zone with the appropriate color standard on the label.

Physical Description

Item	Device
	Betachek Visual
Detection Method	Enzyme linked color change
Sample	Finger stick blood sample
Sample Volume	1 drop - approx 20 microlitres (no sample premeasurement)
Enzyme 1	Glucose Oxidase (Aspergillus niger)
Enzyme 2	Peroxidase (horseradish)
Dyes	TMB, o-Tolidine, DCP
Instrument required	No
Intended use	Betachek Glucose Test is a semi-quantitative glucose test intended to be used by a person who has not been diagnosed as diabetic to measure his or her fasting glucose level in order to determine whether the fasting glucose level is abnormal.
Operating Temperature	18 – 35° C
Test Range	50mg/dl – 150mg/dl
Test Time	3 minute
Dimensions of the Strips	5mm x 75mm x 0.175mm
User steps	Blood wiped at 1 minute and result read after 3 minutes.
Hematocrit Range	35% - 55%
Number of graduations in the results chart	5

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

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
National Diagnostic Products

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
20 July 2006

3. ADDRESS *(Number, Street, State, and ZIP Code)*
22/39 Herbert Street, St. Leonard's 2065, Sydney, NSW

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) +61 294 328100
(Fax) +61 294 361151

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)
(Attach extra pages as necessary)

Betachek Glucose Test

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)*
K062187

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, enacted by 121 Stat. 823, Public Law 110-85, 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, enacted by 121 Stat. 823, Public Law 110-85, 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, enacted by 121 Stat. 823, Public Law 110-85, 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.

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 *(Attach extra pages as necessary)*

NCT Number(s):

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. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) Brandon Bransgrove
(Title) Product Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
22/39 Herbert Street, St. Leonard's 2065, Sydney, NSW

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) +61 294 328100
(Fax) +61 294 361151

15. DATE OF CERTIFICATION
24 April 2008

FDA-3674 (1/08) (FRONT)

PSC Graphics: (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The plot of bias is presented in Figure 3. The graph shows the differences between Betachek GT individual results and YSI 2300 duplicates mean plotted against the mean of YSI 2300 duplicates.
The between methods outliers are plotted with a red symbol.
Figure 3

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[redacted]

Linear regression (ordinary linear regression) for Betachek GT compared with YSI 2300 is presented in Figure 4.

Figure 4

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Table 25
Regression statistics of Betachek GT against YSI 2300

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Betachek GT Hematocrit Studies Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Hematocrit Studies Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Hematocrit Studies Report

(b)(4)

[redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Hematocrit Studies Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Hematocrit Studies Report

B. RESULTS

Betachek GT - Effect of Hematocrit

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Hematocrit Studies Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Hematocrit Studies Report

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[redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Indication for Use

510(k) Number: k062187

Device Name: Betachek Glucose Test

Indication For Use:

Betachek Glucose Test is intended as a screening test for the early detection of abnormal fasting plasma glucose (FPG) levels. Abnormal fasting glucose levels can be a sign of diabetes or other health problems. The test uses a drop of capillary blood to provide a preliminary semi-quantitative result. Any abnormal result should be confirmed by a doctor using a quantitative laboratory based method. The test is not intended to provide a formal diagnosis of diabetes

Prescription Use _____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

_____
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)_____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK GT INTERFERENCE TESTING STUDY DESIGN

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Table 20
Interferences from Endogenous Substances:

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Annex 1

Interference screen – Betachek GT record form

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Annex 2

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Annex 3

(b)(4)

[redacted]

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Annex 4

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Annex 5

Interference dose-response- Betachek GT record form

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[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Annex 6

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[redacted]

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Annex 7

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Annex 8

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The collection of specimens and testing occurred at (b)(4) [redacted].

Location:

(b)(4) [redacted]

(b)(4) [redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. 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) [redacted]
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

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

NATIONAL DIAGNOSTIC PRODUCTS
22/39 Herbert Street
St.Leonards NSW 2072
AU

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
NO DATA

2. CONTACT NAME
Brandon Bransgrove

2.1 E-MAIL ADDRESS
brandon@ndp.com.au

2.2 TELEPHONE NUMBER (include Area code)
612-9432 8100

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
612-9436 1151

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/dc/mdufma

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

3.1 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. 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, parents, and partner firms
[ ] This biologics application is submitted under secion 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

6. 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

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4) [redacted]

27-Jun-2006

Form FDA 3601 (08/2003)

Close Window

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

Subject No.	Explanation
(b)(4) [redacted]	

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

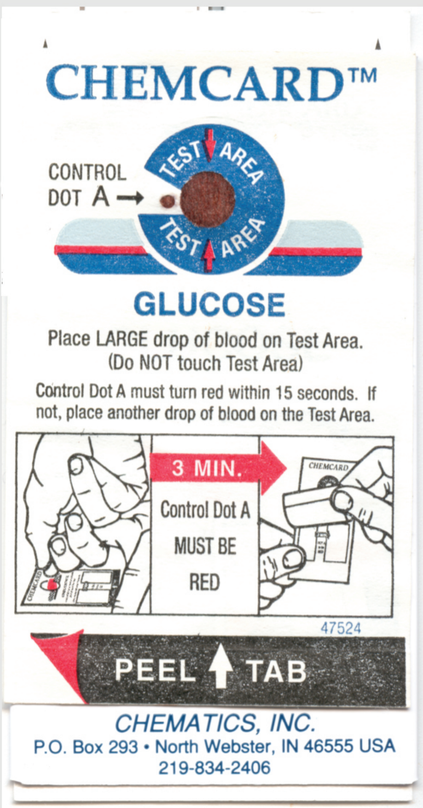
(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

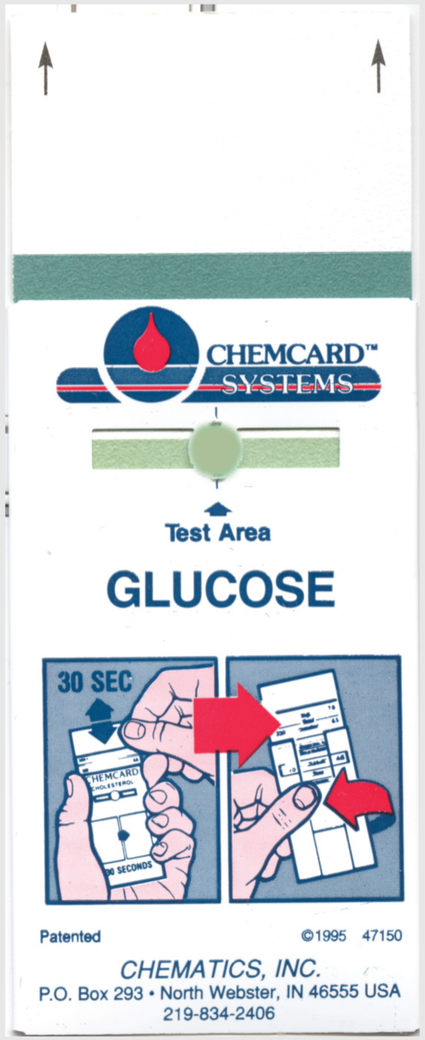
Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Image 1



Blood Applied

Image 2



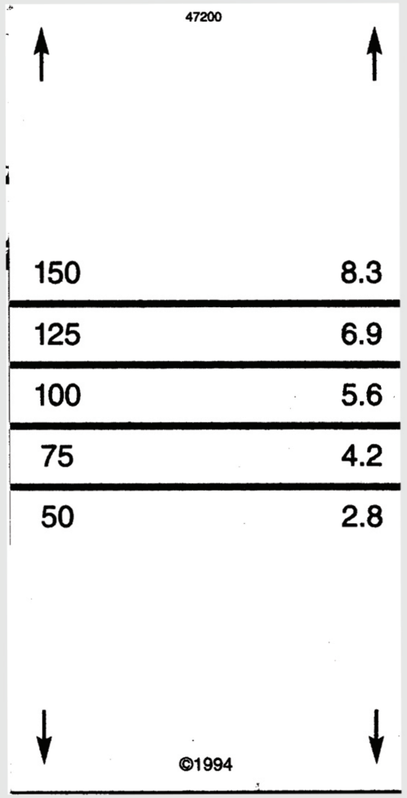
Tab removed

Color card behind front face slide upwards to match test zone

Image 3

A view of full color chart

Image 4



A view of the back of the color chart showing the values assigned to the colors

Image 5

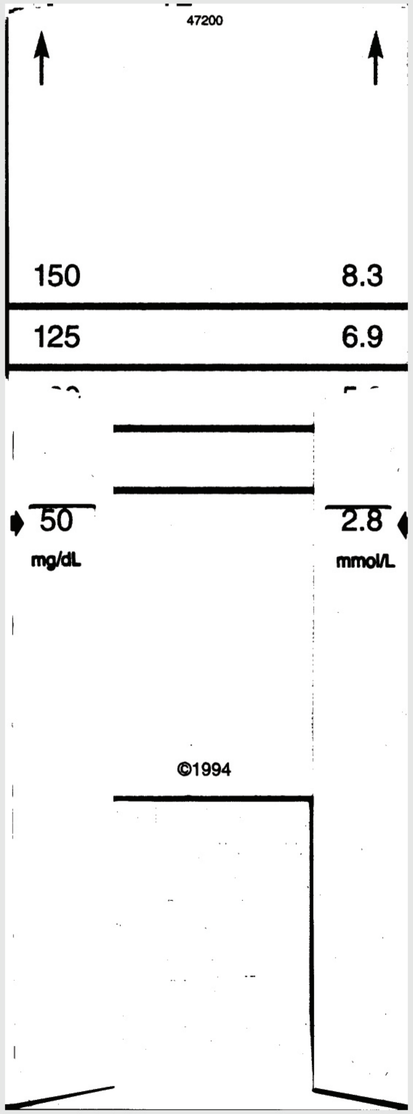


Image two seen from behind

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

CHEMCARD SYSTEMS

A Complete 3 Minute Whole Blood Screening Test for Identification of ABNORMAL PLASMA GLUCOSE LEVELS

INTENDED USE

The Chemcard™ Glucose Test is intended for use as a rapid, *in vitro* method for early identification of abnormal fasting plasma glucose concentration which can be a sign of diabetes or other medical problems. The Chemcard™ provides a preliminary, semi-quantitative result using fingerstick blood as the test specimen. Any abnormal result obtained using the Chemcard™ should be verified using a quantitative method.

The Chemcard™ Glucose Test is not intended for use with individuals who are known to be diabetic or pregnant.

SUMMARY

It is estimated that 3.2 percent of the adult population in the U.S., between the ages of 20 and 74, suffers from undiagnosed Diabetes Mellitus.[1] Diagnosis often occurs after the onset of severe and often irreversible complications. The Chemcard™ Glucose Test is a highly effective test for use in glycemic screening and early identification of generally asymptomatic individuals, for abnormal blood glucose levels often associated with diabetes or other carbohydrate metabolic disorders. These individuals can then be referred for more definitive diagnostic testing, often before the onset of complications.

Chemcard™ Glucose Test is a rapid, convenient, cost effective test system which is effective in screening for abnormal blood glucose concentrations. Each test card is a self contained assay that combines proven detection methods with a patented whole blood separator for unsurpassed convenience and simplicity.

PRINCIPLE

The Chemcard™ Glucose Test is a disposable device which uses a unique blood cell separator coupled with a dry phase enzymatic chemistry to provide a semi-quantitative measurement of fasting blood glucose concentration, from a single, unmeasured drop of fingerstick blood. The separator removes cellular constituents from the specimen and delivers a volumetric sample of plasma to the detection chemistry. Results are visually interpreted by comparing the color change in the reagent pad with an integral color standard. The glucose detection method is based on that described by Keston,[2] Comer[3] and Free[4] but uses tetramethylbenzidine (TMB) in the chromogenic complex as follows:

$$\text{d-glucose} + O_2 + H_2O \xrightarrow{\text{GLUCOSE OXIDASE}} \text{d-glucono-1,5 lactone} + H_2O_2$$

$$H_2O_2 + \text{chromogen} \xrightarrow{\text{PEROXIDASE}} \text{dye} + H_2O$$

COMPOSITION

Glucose Oxidase (1.1.3.4)	8.40% w/w
Peroxidase (1.11.1.7)	6.70% w/w
pH Buffers	34.30% w/w
Tetramethylbenzidine	47.50% w/w
Non-reactive ingredients	3.10% w/w

STORAGE AND STABILITY

Chemcard™ Glucose Tests should be stored at room temperature, not to exceed 86°F (30°C). Refrigeration is not required. Test cards may be used until the expiration date appearing on each package. Any packages that appear to have a broken seal should not be used for testing. Once the foil package is opened, the test should be used immediately.

MATERIALS PROVIDED

Each individual test package contains a single test card along with a sterile lancet.

MATERIALS NEEDED BUT NOT PROVIDED

Clean Dry Tissue
Timing Device (3 minute)

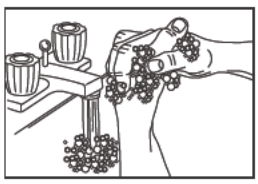
PRECAUTIONS

- For *in vitro* diagnostic use only.
- Never use a test beyond the expiration date specified on the test package.
- The individual to be tested should fast for 6 to 12 hours before specimen collection.
- The Chemcard™ Glucose Test is intended for use with fresh, capillary blood only.
- The Chemcard™ Glucose Test is not intended for use to monitor diabetic patients.
- Not recommended for use in children under the age of 2 years old.
- Not recommended for use with patients known to be pregnant.

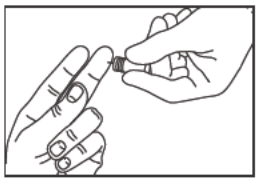
PROCEDURE

1 The individual to be tested must FAST for 6 to 12 hours before testing. No food or drink (other than water) should be consumed during the fasting period.

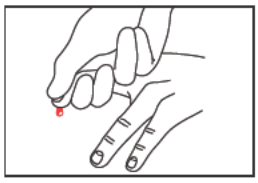
2 CLEAN FINGERTIP area thoroughly using soap and warm water. Dry thoroughly.



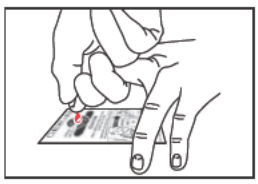
3 PRICK FINGER with lancet. Discard the first drop of blood by wiping on clean dry tissue.



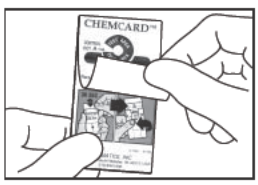
4 Squeeze finger to obtain a LARGE DROP of blood, enough to hang down from the fingertip.



5 PLACE BLOOD ON TEST AREA: Gently bring the lower part of the blood drop into contact with the test area. Verify that "Control Dot A" changes color (if not, add another drop of blood). START TIMER.

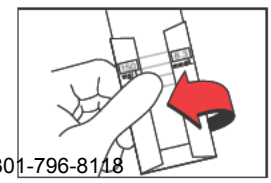


6 After 3 MINUTES, PEEL OFF THE "TAB" to remove the top layer of the test card and discard.



7 COMPARE COLOR of the "Test Area" with the color in the adjacent windows by sliding inner card up and down. Find the closest matching color within 30 seconds. Note: The "Test Area" will begin to fade within 3–5 minutes.

8 TURN THE TEST CARD OVER. The plasma glucose concentration appears in the windows on the back side in both mg/dl and mmol/l.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RESULTS

Semi-quantitative plasma glucose concentration values are obtained by visual comparison of the reagent pad with the sliding color chart, then turning the test card over and reading the glucose level from the windows on the back. A reagent pad which appears lighter than the 50 mg/dl color block should be interpreted as being less than 50 mg/dl (2.8 mmol/l). A reagent pad which appears darker than the 150+ color block should be interpreted as being higher than 150 mg/dl (8.3 mmol/l).

Chemcard results of 50 mg/dl (2.8 mmol/l) or less are considered abnormally low. Chemcard results of 125 mg/dl (6.9 mmol/l) or higher are considered abnormally high for a fasting individual. Any abnormal result obtained using the Chemcard™ should be verified using a quantitative method.

LIMITATIONS OF PROCEDURE

- Failure to fast prior to testing may affect results.
- Not for use to test patients under the age of two years.
- Not for use with patients who are known to be pregnant.
- Since the effective range of the Chemcard™ is 50 to 150 mg/dl, this test should not be used for monitoring of known diabetics or for instituting or modifying drug therapy.
- All abnormal results obtained using this test should be verified using quantitative diagnostic methods.
- The Chemcard™ is designed for use with free flowing, capillary blood, usually obtained from a fingerstick. Other specimens should not be used with this test.

EXPECTED RESULTS

Normal values for fasting blood glucose concentration are widely reported to be in the 60 to 100 mg/dl range.[1, 5] The American Diabetes Association[7] defines normoglycemia as fasting plasma glucose levels <110 mg/dl (6.1 mmol/l) and states that fasting plasma glucose levels ≥126 mg/dl (7.0 mmol/l) are indications for retesting.

The Chemcard™ Glucose Test is designed to implement the American Diabetes Association's decision level strategy[7] for screening. Semi-quantitative interpretation is visually accomplished by matching colors with any of five color blocks, each representing a range of values with medians at 50, 75, 100, 125 and 150+ mg/dl. Chemcard™ results of 125 or 150+ are considered abnormally high and are recommended for follow-up diagnostic testing. Readings of 50 mg/dl or lower are considered abnormally low and should also be followed with additional testing.

CALIBRATION AND QUALITY CONTROL

The Chemcard™ Glucose Test is calibrated at the time of manufacture and requires no calibration by the user. The Chemcard™ Glucose Test has been categorized, by level of complexity, as a WAIVED TEST in accordance with regulations codified in 42 CFR 493.17, implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88). Each site should establish standards of performance in accordance with good laboratory practice.

Each test card employs two design features which allow the user to verify that the test has worked properly. "Control Dot A" changes color allowing the user to verify a sufficient blood volume (>20 µL) has been applied to the test area. The presence of a green or blue color in the reagent pad indicates that the detection chemistry is working properly. A reagent pad that is white or cream colored indicates an invalid test result.

PERFORMANCE CHARACTERISTICS

Measuring Range

The Chemcard™ Glucose Test has an effective measurement range of 50 to 150 mg/dl.

Correlation

The accuracy of the Chemcard™ Glucose Test has been demonstrated by determining correlation with a Kodak Ektachem 700® clinical analyzer. Chemcard™ results, obtained by a nurse, were paired with results obtained for each of 197* patients, whose glucose levels were within the measuring range of the Chemcard,™ using the Ektachem® 700. The following least-squares regression equation was obtained:

$y = 1.02x - 2.11$ (Chemcard on y axis)

correlation coefficient $r = 0.94$

*An additional 33 patients had plasma glucose levels outside the measuring range of the Chemcard™ (30 above, 3 below). All 33 were correctly read on the Chemcard™ as being below 50 mg/dl or above 150 mg/dl.

Classification Accuracy

Studies were conducted at five separate sites to evaluate the ability of an untrained individual to perform the test and interpret their result as being either normal or abnormal. In this study, 90 of 91 subjects correctly classified blood glucose level as normal or abnormally high. By computing the 95 percent confidence interval for the binomial distribution,[6] we find that the Chemcard™ exhibited a classification accuracy of greater than 94 percent in this study.

Precision

Within-lot precision of two different lots of Chemcard™ tests was determined by running 20 tests with whole blood at each of three different glucose levels across the measuring range of the Chemcard.™ Color development on the Chemcard™ was quantitated using colorimetric densitometry and optical densities converted to glucose concentration using a standard curve. Average, standard deviation, percent coefficient of variation and 95 percent confidence intervals were computed as follows:

Lot 1

57 mg/dl	76 mg/dl	125 mg/dl
Avg.: 54.9 mg/dl	Avg.: 78.9 mg/dl	Avg.: 124.0 mg/dl
s.d.: 1.9 mg/dl	s.d.: 2.4 mg/dl	s.d.: 4.8 mg/dl
CV: 3.5%	CV: 3.0%	CV: 3.9%
95% CI: 50.5–59.3 mg/dl	95% CI: 73.5–84.4 mg/dl	95% CI: 113.1–135.3 mg/dl

Lot 2

58 mg/dl	79 mg/dl	120 mg/dl
Avg.: 56.5 mg/dl	Avg.: 81.3 mg/dl	Avg.: 119.2 mg/dl
s.d.: 2.4 mg/dl	s.d.: 1.8 mg/dl	s.d.: 2.1 mg/dl
CV: 4.2%	CV: 2.2%	CV: 1.8%
95% CI: 51.1–61.9 mg/dl	95% CI: 77.1–85.5 mg/dl	95% CI: 114.1–124.0 mg/dl

REFERENCES

1. Harris, M.; Hadden, W. C.; Knowler, W. C.; Bennett P. H.: Prevalence of Diabetes and Impaired Glucose Tolerance and Plasma Glucose Levels in U.S. Population aged 20–74 years. Diabetes, 36:523–534, 1987.
2. Keston, A., in Abstracts of Papers, 129th Meeting, American Chemical Society, Dallas, Texas; p.31c (April 1956).
3. Corner, J., Analytical Chemistry, 28:1748 (1956).
4. Free, A., et al., Clinical Chemistry, 3:163 (1957).
5. Teitz, N. W., Fundamentals of Clinical Chemistry, Second edition, Philadelphia, W. B. Saunders Company, 1976, p. 242.
6. Lentner, C., in Geigy Scientific Tables, Vol. 2, Introduction to Statistics, Statistical Tables, Mathematical Formulae, 8th Edition, CIBA-Geigy Corp., West Caldwell, NJ, 198.
7. American Diabetes Association: Clinical Practice Recommendations 1998; Screening for Type 2 Diabetes, Diabetes Care, Volume 21 Supplement 1.

CHEMATICS INC.
TM P.O. Box 293 • North Webster, IN 46555
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Betachek Glucose Test

(b)(4)

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YSI 2300 Stat Plus Analyser

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[redacted]

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BETACHEK GT Interference studies

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Lay-user Performance Evaluation Report

(b)(4)

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Lay-user Performance Evaluation Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Lay-user Performance Evaluation Report

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Betachek GT Lay-user Performance Evaluation Report

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Betachek GT Lay-user Performance Evaluation Report

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Betachek GT Lay-user Performance Evaluation Report

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Betachek GT Lay-user Performance Evaluation Report

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Betachek GT Lay-user Performance Evaluation Report

Annex 2.

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Betachek GT Lay-user Performance Evaluation Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Lay-user Performance Evaluation Report

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[redacted]

Other Comments:

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Questions? Contact FDA/CDRH/OSE/DID at CDRHFOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Lay-user Performance Evaluation Report

(b)(4)

[redacted]

.....

Record your result here .....mg/dl

Where you : NORMAL☐ OR ABNORMAL☐

COMMENTS : .....

.....

.....

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Betachek GT Lay-user Performance Evaluation Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Lay-user Performance Evaluation Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Lay-user Performance Evaluation Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Lay-user Performance Evaluation Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Lay-user Performance Evaluation Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Lay-user Performance Evaluation Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Lay-user Performance Evaluation Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Lay-user Performance Evaluation Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Lay-user Performance Evaluation Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Repor

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

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Betachek GT Method Comparison Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

Information Letter

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Betachek GT Method Comparison Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

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C. CONCLUSION

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Questions? Contact FDA/CDRH/OSEL/DID at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8116

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Betachek GT Method Comparison Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

The between methods outliers are plotted with a red symbol.

Figure 1

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[redacted]

Linear regression (ordinary linear regression) for Betachek GT compared with YSI 2300 is presented in Figure 2.

Figure 2

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Method Comparison Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Method Comparison Test Report

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

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[redacted]

	Venous blood	Stock solution	Diluent
(b)(4) [redacted]			

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Conclusion:
Bilirubin, at a concentration of 20mg/dL, does not interfere in Betachek GT testing.

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BETACHEK GT Interference studies

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Betachek GT reagent system

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Figure 1 Bias plot for Control and Test groups

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETACHEK GT Interference studies

Interfering compound: Creatinine

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

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(b)(4) [redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

For each glucose concentration, the control and test samples were prepared as follows:

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[redacted]

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[redacted]

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BETACHEK GT Interference studies

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

For each glucose concentration, the control and test samples were prepared as

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[redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Figure 2 Bias Plot for Control and Test groups

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) [redacted]

(b)(4) [redacted].

(b)(4) [redacted]

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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BETACHEK GT Interference studies

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

BETACHEK GT Interference studies

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Results

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

(b)(4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Risk Analysis
BETACHEK® Glucose Test

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Potential Hazards

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

510 (k) Summary

a) According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1.	Submitter's Name:	National Diagnostic Products (Aust) Pty Ltd
	Address:	22/39 Herbert Street, St.Leonards NSW 2065, Australia
	Phone:	+61 2 94328108
	Fax:	+61 2 94361151
	Contact Person:	Brandon Bransgrove
	Date Prepared:	April 21 2008
2.	Device Name:	Betachek Glucose Test
	Proprietary/Trade name:	Betachek Glucose Test
	Common Name:	Glucose Test System
	Classification Name:	Glucose Test System
	Device Classification:	II
	Regulation Number:	21 CFR 862.1345
	Classification Panel:	Clinical Chemistry (75)
	Product Code:	CGA (Glucose Oxidase, Glucose)
3.	Predicate Device Name:	Chemcard Glucose Test
	Manufacturer:	CHEM-ELEC, INC
	510 (K) Number:	K943503

4. Description of the Device
Reagent test principle – glucose oxidase

5. Intended Use

Betachek Glucose Test is a semi-quantitative glucose test intended to be used by a person who has not been diagnosed as diabetic to measure his or her fasting glucose level in order to determine whether the fasting glucose level is abnormal. This device cannot be used to diagnose or monitor diabetes, or other medical problems. Abnormal results should be verified by a physician.
The test is not intended for use by individuals who are pregnant.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6. Substantial Equivalence

Similarities		
Item	**Device**	**Predicate**
	Betachek Glucose Test	**Chemcard Glucose Test**
Detection Method	Enzyme linked colour change	Enzyme linked colour change
Sample	Finger stick blood sample	Finger stick blood sample
Sample Volume	1 drop (no sample premeasurement)	1 drop (no sample premeasurement)
Enzyme 1	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Enzyme 2	Peroxidase	Peroxidase
Dye	TMB, o-Tolidine, DCP	TMB
Instrument required	No	No
Intended use	a semi-quantitative glucose test intended to be used by a person who has not been diagnosed as diabetic to measure his or her fasting glucose level in order to determine whether the fasting glucose level is abnormal	a semi-quantitative glucose test intended to be used by a person who has not been diagnosed as diabetic to measure his or her fasting glucose level in order to determine whether the fasting glucose level is abnormal
Operating Temperature	18 – 35° C	18 – 35° C
Test Range	50 mg/dL – 150 mg/dL	50 mg/dL – 150 mg/dL
Test Time	3 minute	3 minutes
Number of colour blocks	5	5

Differences		
Item	**Device**	**Predicate**
	Betachek Glucose Test	**Chemcard Glucose Test**
Format	Test strip	Test Card
User steps	Blood wiped at 1 minute and result read after 3minutes.	Blood pre-filter peeled at exactly 3 minutes and result must read within 30 seconds.
Hematocrit Range	35% - 55%	Unknown

7. Performance Characteristics

Betachek Glucose Test has the same intended use and technological characteristics as the predicate device and clinical evaluations demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Therefore, Betachek Glucose Test is substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Each Betachek Glucose test strip comprises two reagent zones attached to the end of a plastic strip.

O_2 + Glucose ⇨ GLUCOSE OXIDASE ⇨ D-glucono-1,5 lactone +H_2O_2

H_2O_2 + reduced TMB ⇨ PEROXIDASE ⇨ oxidised TMB + H_2O

Each Betachek test strip contains:

Each Betachek® GT test strip contains (Quantity/cm²): Glucose Oxidase, 0.08 U, Peroxidase 9.4 µg, TMB 77 µg, o-Tolidine 81µg, DCP 20 µg, Stabiliser 0.12 mg, APAC 15 µg, Inert ingredients 2.20 mg (w/w).

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Betachek GT Repeatability Test Report

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Betachek GT Repeatability Test Report

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Betachek GT Repeatability Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Repeatability Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Repeatability Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Repeatability Test Report

Annex 2

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Betachek GT Repeatability Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Repeatability Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Repeatability Test Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Betachek GT Repeatability Test Report

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 16 YSI 2300Stat Plus Linearity assessment test results

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Figure 1 Betachek GT regression plot -Linearity study

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The table below shows the range of percentage recovery across the nine levels of glucose measured:

(b)(4)

[redacted]

The following aspects were considered for determination of Betachek Glucose Test reportable range:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

December 29, 2008

NATIONAL DIAGNOSTIC PRODUCTS
(AUST) PTY LTD
7-9 MERRIWA ST. GORDON
SYDNEY
AUSTRALIA 2072
ATTN: BRANDON STEPHEN BRANSGROVE

510k Number: K062187

Product: BETACHEK GLUCOSE TEST

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Indication for Use

510(k) Number: K062187

Device Name: BETACHEK BLOOD GLUCOSE (SUGAR) TEST

Indication For Use:

Betachek Blood Glucose (Sugar) is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

Any abnormal results should be verified by a medical professional, such as a physician, and confirmed with a quantitative, laboratory reference method. Only a trained medical professional can determine if an individual has diabetes. A test result within the normal range does not exclude the possibility that the individual has diabetes or pre-diabetes. Any individual who is concerned that he or she may have diabetes or pre-diabetes should seek the advice of a physician.

Betachek Blood Glucose Test is not intended to be used for children or by individuals who are diabetic or pregnant.

This test can not be used to screen or diagnose diabetes.

It should not be used for children or by individuals who are diabetic or pregnant.

This test is only intended for individual use at home.

It is not for use as part of a screening program in a healthcare setting or any other setting.

Prescription Use ____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ☑ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062187

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

510 (k) Summary k062187

a) According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1.	Submitter's Name:	National Diagnostic Products (Aust) Pty Ltd
	Address:	22/39 Herbert Street, St.Leonards NSW 2065, Australia
	Phone:	+61 2 94328100
	Fax:	+61 2 94361151
	Contact Person:	Brandon Bransgrove
	Date Prepared:	March 24, 2009
2.	Device Name:	Betachek Blood Glucose Test
	Proprietary/Trade name:	Betachek Blood Glucose Test
	Common Name:	Glucose Test System
	Classification Name:	Glucose Test System
	Device Classification:	II
	Regulation Number:	21 CFR 862.1345
	Classification Panel:	Clinical Chemistry (75)
	Product Code:	CGA (Glucose Oxidase, Glucose)
3.	Predicate Device Name:	Chemcard Glucose Test
	Manufacturer:	CHEM-ELEC, INC
	510 (K) Number:	K943503

4. Description of the Device
Reagent test principle – glucose oxidase

5. Intended Use

Betachek Blood Glucose Test is a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

Any abnormal results should be verified by a medical professional, such as a physician, and confirmed with a quantitative, laboratory reference method. Only a trained medical professional can determine if an individual has diabetes. A test result within the normal range does not exclude the possibility that the individual has diabetes or pre-diabetes. Any individual who is concerned that he or she may have diabetes or pre-diabetes should seek the advice of a physician.
Betachek Blood Glucose Test is not intended to be used for children or by individuals who are diabetic or pregnant.

This test can not be used to screen or diagnose diabetes.
It should not be used for children or by individuals who are diabetic or pregnant.
This test is only intended for individual use at home.
It is not for use as part of a screening program in a healthcare setting or any other setting.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6. Substantial Equivalence

Similarities		
Item	**Device**	**Predicate**
	Betachek Blood Glucose Test	**Chemcard Glucose Test**
Detection Method	Enzyme linked colour change	Enzyme linked colour change
Sample	Finger stick blood sample	Finger stick blood sample
Sample Volume	1 drop (no sample premeasurement)	1 drop (no sample premeasurement)
Enzyme 1	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Enzyme 2	Peroxidase	Peroxidase
Dye	TMB, APAC, DCP	TMB
Instrument required	No	No
Intended use	a test intended to be used by non-diabetic individuals at home to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.	a semi-quantitative glucose test intended to be used by a person who has not been diagnosed as diabetic to measure his or her fasting glucose level in order to determine whether the fasting glucose level is abnormal
Operating Temperature	18 – 35° C	18 – 35° C
Test Range	50 mg/dL – 150 mg/dL	50 mg/dL – 150 mg/dL
Test Time	3 minute	3 minutes
Number of colour blocks	5	5

Differences		
Item	**Device**	**Predicate**
	Betachek Blood Glucose Test	**Chemcard Glucose Test**
Format	Test strip	Test Card
User steps	Blood wiped at 1 minute and result read after 3minutes.	Card Peeled at 3 minutes and result must read within 30 seconds.
Hematocrit Range	35% - 55%	Unknown

7. Performance Characteristics

Betachek Blood Glucose Test has the same intended use and technological characteristics as the predicate device and clinical evaluations demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Therefore, Betachek Blood Glucose Test is substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K062187/53

Submitter:
Brandon Stephen Bransgrove
Product Manager
National Diagnostic Products
laboratories
7-9 Merriwa Street
Gordon
Sydney, NSW, 2072, AS
Phone: +61 294 184777
Fax: +61 294 184747

DEC 24 2008

December 22, 2008

Attn: CeSub Team
Center for Devices and Radiological Health
Document Mail Center
HFZ-401
9200 Corporate Blvd.
Rockville, MD 20850

Dear Sir or Madam:

This submission dated December 22, 2008, is filed pursuant to the In Vitro Diagnostic Device Evaluation and Safety program's Electronic Review (eReview).

The submission is a Supplement to K062187.

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,

Brandon Stephen Bransgrove
Product Manager
National Diagnostic Products

K46

32

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Product Manager
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Submission Report

Section: Main Menu

Welcome

Welcome to the CDRH Electronic Submissions Software (CeSub)

This software application is intended to automate the current paper submission process. This software contains a number of data capturing tools and helpful dialog boxes to reduce redundant responses for you, and to allow us to capture data in a more useful, structured format. These benefits will enable CDRH to improve our review process and reduce lengthy review times.

For your convenience, an email account has been established to support any questions that you may have regarding the use of this software. Please email any questions or comments to the CeSub team at: **cdrhesub@cdrh.fda.gov.** Please be sure to include your name, company name and contact information in the email.

Thank you again for using our electronic product reporting software. We look forward to hearing from you soon.

What type of product is this submission referring to? *
In Vitro Diagnostic Device

Welcome (Cont.)

Section: Admin

1.0 Type of Submission

Introduction

Department of Health and Human Services
Food and Drug Administration

CDRH PreMarket Review Submission Cover Sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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)
. Submission Sub-Type	*	Supplement
- Submission Sub-Sub-Type		
Enter the original submission number.	*	K062187
Is this a bundled submission?		

User Fee Payment ID Number	

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

2.0 Contact Information

Note:	*Contains Information on the Applicable Contacts*

Section B	**Primary Submitter, Applicant, or Sponsor**

Contact Information		*
Contact Information:		
Contact Name	Mr. Brandon Stephen Bransgrove	
Occupation Title	Product Manager	
Email Address	brandon@ndp.com.au	
Establishment Information:		
Establishment Name	National Diagnostic Products	
Division Name	laboratories	
FDA Establishment Identifier (FEI)		
Central File Number (CFN)		
Registration Number		
Owner/Operator Number		
Physical Location:		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Address	7-9 Merriwa Street Gordon Sydney, NSW, 2072, AS
Telephone Number	(+61) 294-1847 Ext: 77
Fax Number	(+61) 294-1847 Ext: 47
Mailing Location:	
Address	7-9 Merriwa Street Gordon Sydney, NSW, 2072, AS

Section C	**Applicant Correspondent or Secondary Contact**

Note:	*For example, the application correspondent could be a consultant, if different than above.*
Contact information	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Physical Location:	
Address	
Telephone Number	
Fax Number	

7.1 Other Standards

Section: Supplement

1.0 Deficiencies and Responses

Item: 1

Enter the deficiency that you are responding to. *

1. (b)(4) [redacted]

(b)(4) [redacted]

Enter or attach the response to the deficiency. *	
Please see attached.	
File Attachment 1	Indications for use form

Item: 2

Enter the deficiency that you are responding to. *
2. (b)(4) [redacted]:
(b)(4) [redacted]

(b)(4)

Enter or attach the response to the deficiency. *	
Please see attached.	
File Attachment 1	Betachek GT Sensitivity Study Report

Item: 3

Enter the deficiency that you are responding to. *
3. (b)(4)

of the test protocol and study results for our review.

Enter or attach the response to the deficiency. *	
Please see attached.	
File Attachment 1	Betachek GT Precision Study Report

Item: 4

Enter the deficiency that you are responding to. *

4. (b)(4) [redacted] this study and provide a summary of the test protocol and study results for our review.

Enter or attach the response to the deficiency. *	
Please see Betachek GT Precision Study Report.	
File Attachment 1	Betachek GT Precision Study Report

Item: 5

Enter the deficiency that you are responding to. *

5. (b)(4) [redacted]

(b)(4) [redacted].

Enter or attach the response to the deficiency. *	
Please see attached.	
File Attachment 1	Betachek GT Shelf-life Stability Study Report
File Attachment 2	Betachek GT Operating temperature Study Report
File Attachment 3	Betachek GT Transport Simulation Study Report

Item: 6

Enter the deficiency that you are responding to. *

6. (b)(4) [redacted].

Enter or attach the response to the deficiency. *	
Please see attached.	
File Attachment 1	Interference additional information

Item: 7

Enter the deficiency that you are responding to. *

7. (b)(4) [redacted]

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Enter or attach the response to the deficiency.	*
Please see attached.	
File Attachment 1	Method Comparison additional information

Item: 8

Enter the deficiency that you are responding to.	*
8. (b)(4)	

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Betachek GT Operating Temperature Study

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Questions? Contact FDA/CDRH/OSE/DID at CDRHFOISTATUS@fda.hhs.gov or 301-796-8110

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CONCLUSION

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Betachek GT Precision Study Report

Precision studies for Betachek GT were conducted in accordance with applicable standards. The study design (A), results (B) and the conclusions (C) of the evaluation are presented below.

A. STUDY DESIGN: BETACHEK GLUCOSE TEST PRECISION EVALUATION

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Betachek GT Sensitivity Study Report

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6. Reference Measurement Procedure

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Annex 1

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B. RESULTS

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[redacted]

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[redacted]

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Betachek GT Stability Report

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B. RESULTS

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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C. CONCLUSION

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Betachek GT Transport Simulation Stability Report

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

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Records processed under FOIA Request #2016-2297; Released by CDRH on 9/16/16

Table 5

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Figure 2

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[redacted]

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BETACHEK®
Glucose Test

NDP

2 tests

Contents:
2 Betachek Tests, 2 [illegible] Lancets
2 Alcohol Swabs, 2 Medical Wipes & Result Chart

In vitro diagnostic use
Store between 39-86°F

BETACHEK®
Glucose Test

30% of people with Type 2 Diabetes don't know they have it!

Diabetes:
It is estimated that 30% of people with diabetes in the US remain undiagnosed. This is because when a person first develops diabetes it is common for them to have no signs of sickness. They do however have high levels of glucose (sugar) in their blood, which over time badly damages many parts of the body. Often Diabetes is only discovered many years later when the damage has occurred. This damage can be prevented if high glucose (sugar) levels are reduced by early treatment. It is therefore important to check your blood glucose (sugar) regularly and if it is high, to seek treatment before it causes serious health problems that cannot be reversed.

Made in Australia
NDP
Betachek Tests:
Nationa Diagnostic Products
Sydney, 2065 Australia
www.betachek.com

BDT2US1208

Insert UPC Barcode
932405300017

LOT
EXP

www.betachek.com

BETACHEK®
Glucose Test

The Betachek Glucose Test is a semi-quantitative test intended to be used by non-diabetic individuals to determine a fasting blood glucose level. The test is for over-the-counter use.

Betachek Glucose Test is not intended to be used for children or by individuals who are diabetic or pregnant. Any abnormal results should be verified by a medical professional and confirmed with a quantitative, laboratory reference method. Results within the normal range do not exclude the possibility of diabetes or pre-diabetes. Individuals who are concerned that they may have diabetes or pre-diabetes should seek the advice of a physician. This device is only intended for individual use and not as part of a screening program in a healthcare or other setting.

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BETACHEK®
Glucose Test

www.betachek.com

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BETACHEK®
Glucose Test
Instructions for use

Have a watch or timer ready.

⚠ IMPORTANT!
Read instructions carefully. You need a timer or watch with second hand ready. This test has an important timing step that must be followed exactly to ensure best results

(Backside of booklet)

BETACHEK® GLUCOSE TEST

What is this Test for?

Betachek® Glucose test is a semi-quantitative test intended to be used by non-diabetic individuals to determine a fasting blood glucose level. The test is for over-the-counter use.
Betachek Glucose is not intended to be used for children or by individuals who are diabetic or pregnant.
Any abnormal results should be verified by a medical professional and confirmed with a quantitative, laboratory reference method.
Results within the normal range do not exclude the possibility of diabetes or pre-diabetes. Individuals who are concerned that they may have diabetes or pre-diabetes should seek the advice of a physician.

Before you perform the test:

You should perform the test before breakfast and after you have not eaten for at least 8 hours.

Contents:

This device is only intended for individual use and not as part of a screening program in a healthcare or other setting.

Background

Type 2 Diabetes: It is estimated that 30% of people with diabetes in the US remain undiagnosed[i]. This is because when a person first develops diabetes it is common for them to have no signs of sickness. They do however have high levels of glucose in their blood which over time badly damages many parts of the body. Often Diabetes is only discovered many years later when the damage has occurred. This damage can be prevented if high glucose levels are reduced by early treatment. It is therefore important to check your blood glucose level regularly and if it is high, to seek treatment before it causes serious health problems that cannot be reversed.

Pre-Diabetes: In addition to undiagnosed diabetes, the American Diabetes Association (ADA) estimates that 54 million people in the US (18%) have pre-diabetes (glucose levels 100-125 mg/dl). The ADA and National Institute of Diabetes and Digestive and Kidney Diseases believe that people with pre-diabetes can delay or *prevent* diabetes if they begin treatment early [ii]. Treatment can often involve simple measures such as diet and exercise.

Betachek® Glucose Test is a convenient way to estimate your fasting glucose (blood sugar) in just 3 minutes. People with concerns about their health should consult with a healthcare provider.

Do I Need to Test Again?

Blood glucose should be checked annually by individuals who are any of the following: obese; have a first-degree relative with diabetes; are members of a high-risk ethnic population (Indian, African, Hispanic, Native American, Aboriginal, Pacific-Islander and Asian). Also those who have delivered a baby weighing more than 9 pounds; have had gestational diabetes; have high blood pressure; have HDL cholesterol levels ≤ 35mg/dl or triglyceride levels ≥ 250mg/dl; or who, on previous testing had impaired glucose tolerance or impaired fasting glucose. All adults older than 45 years of age should test every three years.

How Does the Test Work?

The test zone consists of two test pads containing sensitive chemicals. When blood is applied to this zone, the chemicals react with the glucose in the blood. The reaction produces a colour change that varies with the amount of glucose in the blood.

Precautions and Limitations of the Test

- You must not eat for 8 hours before testing
- If you eat before the test the result will be incorrect.
- Use the test strips only between 64 and 95°F (18 and 35°C).
- Running a test below 64°F will give low results and running a test above 95°F will produce high results.
- There is no need to refrigerate this product, however if refrigerated, do not use the test until it has warmed to room temperature.
- Failure to do so could lead to low results.
- Only use blood from your finger
- Each test can only be used once.
- *Incorrect timing* – leaving the blood on too long will increase the result and wiping the blood too early will decrease the result.
- Blood drop must cover the test zone – see picture with tick. Smearing too little blood will lead to uneven color development that will not be readable.
- Blood cannot be added after timing has started – repeat with new test.
- As the reading range is 50 - 150 mg/dl, the test should not be used by people with diabetes to monitor their glucose levels or adjust any treatment.

Storage and Handling

Store Betachek® GT Test Strips in their original container in a cool, dry place between 39-86°F (4-30°C). Do not freeze. Use the test strip immediately after it is removed from the container. Always replace the cap quickly.

Before performing a test

Before performing a test check the color of the test zone matches the color of the '0' on the color chart. If the test zone is blue, the strip is damaged and should not be used. Call customer service.

What is Included?

2 tests, 2 single use lancets, 1 label on container with color chart, tissue, alcohol swab, 1 package insert.

What is not Included but Needed?

A watch with a second hand or a timer.

When Should I Test?

The test should be performed before breakfast.
Do not eat or drink for 8 hours before testing (you may drink water only).

How do I Run a Test?

Follow the step by step instructions, using the quick guide.

How do I Read the Result?

- Compare the 2 colors on your test strip to the color chart on the package. Use both colors to help you read your results.
- Use natural light for best results.
- If the test zone color lies between two color blocks on the chart e.g. a color that appears to be between the 75 and the 100 mg/dl color blocks, then your result is in the range 75-100 mg/dl.
- A test zone lighter than 50mg/dl is less than 50mg/dl.
- A test zone darker than 150 mg/dl is greater than 150mg/dl.

Expected Results

Results[iii]	Fasting Plasma Glucose (FPG) (mg/dl)
Abnormally Low	Less than 75
Normal	75 - 100
Abnormal	Greater than 100

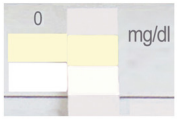
- If your results match the colors in the 50-75 mg/dL range, your fasting blood glucose today is abnormally low. You should have something to eat. You should consider seeking the advice of a medical professional.
- If your results match the colors in the 75-100 mg/dL range, your fasting blood glucose today is in the normal range. You should seek the advice of a medical professional if you still have concerns about your health.
- If your results match the colors in the 100-125 mg/dL range, your blood glucose today is in the pre-diabetes range. You should seek the advice of a medical professional for further evaluation.

If you results match the colors in the 125-150 mg/dL range or appear to be darker in color than the 150 mg/dL color block, your blood glucose today is in the diabetes range. You should seek the advice of a medical professional for further evaluation and treatment.

Performance Characteristics

Step 1:

Compare the test strip in the package to the color chart on the outside of the package. The test zone should match the label color for 0. It should not be blue. If you are unsure if the test strip is in good condition, you should call the toll-free phone number for technical assistance.



Step 2:

Wash hands with warm water and dry thoroughly. Place the contents of the test kit on a flat, clean surface. Use the alcohol swab provided to wipe the tip of your middle finger.

Step 3:

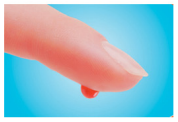
Hold the lancet as shown and twist off the protective cap.

Step 4:

Use the photo as a guide to help you position the lancet on your finger tip. Push the lancet firmly against your finger until you hear a click.

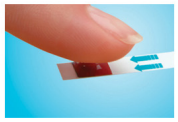
Step 5:

Hold your finger down and allow the blood to flow until you have a large hanging drop. Do not SQUEEZE your finger. Get ready to start timing.



Step 6:

With the test strip on a firm surface, place the drop of blood on the test zone of the test strip. Start the timing.



Check

Do not smear or dab blood

Ensure both test pads are fully covered.

Step 7:

After exactly 1 minute wipe the blood off the test zone using the tissue provided.

More information on diabetes and pre diabetes can be found at:
www.diabetes.org
www.diabetes.org/pre-diabetes.isp

Betachek Helpline: 1-888-XXX-XXXX (9:00 AM to 5 PM PST).

Version BGT-US-004 DEC 2008

Step 8:

Wait 2 minutes after wiping and then match the test zone against the label color chart for the result.

See section: How do I read my result?

Do not read the result after 5 minutes as the test zone will start to fade.

[i] Catherine C. Cowie et al., Prevalence of Diabetes and Impaired Fasting Glucose in Adults in the U.S. Population *Diabetes Care* 29:1263-1268, 2006
[ii] American Diabetes Association, The Prevention or Delay of Type 2 Diabetes. Diabetes Care 25:742-749, 2002

[iii] American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus, *Diabetes Care* 29:S43-S48, 2006

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2 Tests PLUS 2 lancets

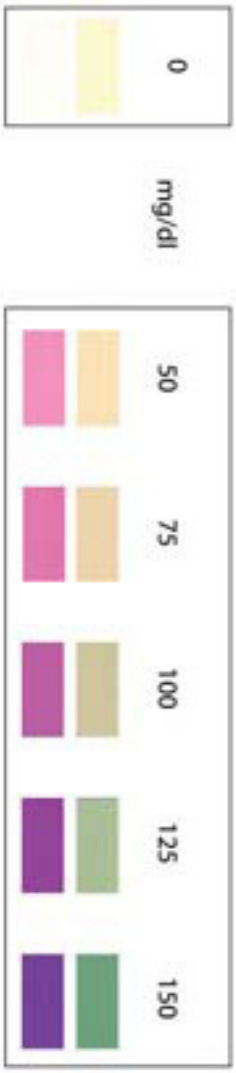
BETACHEK® Glucose

Distributor Name
Address
xxx xxxxxx xxxx
xxxxxxxxx xxxxxxx

Expiry

LOT

Store between 39 and 96 F
In Vitro Diagnostic Use Only



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Indication for Use

510(k) Number (if known): K062187

Device Name: BETACHEK GLUCOSE TEST

Indication For Use:

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Prescription Use NO (21 CFR Part 801 Subpart D) And/Or Over the Counter Use YES . (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

_____
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)_____

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The tables below summarize the results of tested interferences for Betachek GT and for the reference method (YSI 2300), together with the percent difference observed between the control and test samples (blood samples without and with interfering compound, respectively).

Interferences from Exogenous Substances:

(b)(4)

[redacted]

Interferences from Endogenous Substances:

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

Subject No.	Reason for exclusion
(b)(4)	

(b)(4)

The Betachek GT lot of strips used for the (b)(4) subjects of this study were as follows:

(b)(4)

The table below demonstrates the number of results obtained (n), the regression equations, the correlation coefficients (R) and the glucose ranges for each lot and for all results combined.

(b)(4)

[redacted]