Records processed under FOIA Request 2014-5422; Released 10/29/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

HemoCue, Incorporated
c/o R.J. Slomoff
9229 Cranford Drive
Potomac, Maryland 20854

AUG 2 5 2003

Re: k032203
Trade/Device Name: HemoCue® Hb 201+ System
Regulation Number: 21 CFR § 864.5620
Regulation Name: Automated Hemoglobin System
Regulatory Class: II
Product Code: GKR
Dated: July 14, 2003
Received: July 31, 2003

Dear Mr. Slomoff:

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). 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.

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

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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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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

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510(k) Number: K032203

Device Name: **HemoCue® Hb 201+ System**

Indications For Use:

Quantitative determination of hemoglobin in capillary, venous and arterial whole blood.

The HemoCue® Hb 201 Microcuvettes are intended for use in the HemoCue® Hb 201$^+$ analyzer. The HemoCue 201 system is used for the quantitative determination of hemoglobin in blood using a specially designed analyzer, the HemoCue Hb 201$^+$ analyzer, and specially designed microcuvettes the HemoCue Hb 201 Microcuvettes. The HemoCue Hb 201$^+$ analyzer is only to be used with HemoCue Hb 201 Microcuvettes.

The reagents/microcuvettes and the analyzer form an analytical system. The HemoCue Hb 201$^+$ analyzer is only to be used together with HemoCue Hb 201 microcuvettes. The use of any other device in the HemoCue Hb 201$^+$ analyzer except the HemoCue Hb 201 microcuvettes is neither supported nor recommended by HemoCue, and could give erroneous results with serious clinical consequences.

The HemoCue Hb 201 microcuvettes are for in vitro diagnostic use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

(Optional Format 3-10-98)

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032203

000

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

Records processed under FOIA Request 2014-5422; Released 10/29/14

DCC Coversheet for Documents Deleted or Withdrawn from eCopy Hold

Today's Date: 3/26/14

Complete Document Numbers:

K041234/A001
K041230/A002
K032203/A002
K020935/A003
K962415/A004
K961312/A006
K961311/A002
K943432/A003
K911141/A003

These specific documents were not entered into the review queue because:

X they were deleted based on lack of response to the eCopy hold letter(s).

☐ they were withdrawn based on request from the applicant.

Records processed under FOIA Request 2014-5422; Released 10/29/14

DCC Coversheet for Documents Deleted or Withdrawn from eCopy Hold

Today's Date: 3/26/14

Complete Document Numbers:

K041234/A001
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K961311/A002
K943432/A003
K911141/A003

These specific documents were not entered into the review queue because:

X they were deleted based on lack of response to the eCopy hold letter(s).

☐ they were withdrawn based on request from the applicant.

Records processed under FOIA Request 2014-5422; Released 10/29/14

Allen, Samie Niver

From: Allen, Samie Niver
Sent: Wednesday, March 26, 2014 4:51 PM
To: 'rcastillo@focusdx.com'
Cc: DCCLetters
Subject: See attached list of 9 510(k) amendments
Attachments: Focus list.pdf

Roderick,

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) previously informed you that the document referenced above was on eCopy hold.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an eCopy for certain types of submissions. You received at least one letter stating that your document above was on eCopy hold because either you did not provide an eCopy or you provided an eCopy that did not meet the technical standards described in the eCopy guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.

Over 180 days has elapsed, and CDRH has not received an eCopy that meets the technical standards. Accordingly, we are withdrawing the document specified above and closing it in our database without it being put into the queue for review by FDA staff. If you choose to resubmit, a new number will be assigned, and your new submission will be subject to eCopy processing. Furthermore, your new document may be subject to a user fee.

If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Thanks,
Samie Allen, CAPT, USPHS
Policy Analyst
FDA/CDRH/ODE
samie.allen@fda.hhs.gov
301-796-6055

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

Records processed under FOIA Request 2014-5422; Released 10/29/14

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

eCopy Hold Letter

May 23, 2013

R.J. Slomoff
Hemocue, Inc.
C/O Robert Joel Slomof, 9229 Cranford Drive
Potomac, MD 20854

Dear R.J. Slomoff:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the following unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

510(k) Number: K961311/A002
Device: Hemocue B-Glucose System
Dated: 20-MAY-2013
Received: 23-MAY-2013

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or flash drive, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

You have received this letter because you have either not provided an eCopy or you provided an eCopy that failed the loading process because it did not conform to the technical specifications. If you provided an eCopy that failed the loading process, then please see the attached document that identifies all reasons for the failure that need to be addressed.

Please write the specific submission number identified above AND "Replacement eCopy" directly on the CD (or other media) and send that with a paper copy of your cover letter (revised if applicable) to the CDRH Document Control Center (DCC) at the address below.

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

When your Replacement eCopy has been received and been verified as a valid eCopy, review of this submission will start as of that date.

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

For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf. In addition, we strongly encourage you to visit FDA's eSubmitter website at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,
Samie Allen
Policy Analyst
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request 2014-5422; Released 10/29/14

Pugh, Dominique *

From: Pugh, Dominique *
Sent: Thursday, May 23, 2013 4:16 PM
To: RCASTILLO@FOCUSDX.COM
Cc: DCCLetters
Subject: K961311/A002 ECOPY HOLD LETTER - NO ECOPY PROVIDED
Attachments: K961311-A002.pdf

Tracking:

Recipient	Delivery
RCASTILLO@FOCUSDX.COM	
DCCLetters	Delivered: 5/23/2013 4:16 PM

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

Records processed under FOIA Request 2014-5422; Released 10/29/14

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

eCopy Hold Letter

May 23, 2013

Clas Runnberg, Business Director
Hemocue, Inc.
23263 Madero, Suite A
Mission Viejo, CA 92691

Dear Clas Runnberg:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the following unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

510(k) Number: K962415/A004
Device: Hemocue B-Glcose System
Dated: 20-MAY-2013
Received: 23-MAY-2013

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or flash drive, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

You have received this letter because you have either not provided an eCopy or you provided an eCopy that failed the loading process because it did not conform to the technical specifications. If you provided an eCopy that failed the loading process, then please see the attached document that identifies all reasons for the failure that need to be addressed.

Please write the specific submission number identified above AND "Replacement eCopy" directly on the CD (or other media) and send that with a paper copy of your cover letter (revised if applicable) to the CDRH Document Control Center (DCC) at the address below.

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Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

When your Replacement eCopy has been received and been verified as a valid eCopy, review of this submission will start as of that date.

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

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If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Samie Allen
Policy Analyst
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

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Pugh, Dominique *

From: Pugh, Dominique *
Sent: Thursday, May 23, 2013 4:07 PM
To: RCASTILLO@FOCUSDX.COM
Cc: DCCLetters
Subject: K962415/A004 ECOPY HOLD LETTER - NO ECOPY PROVIDED
Attachments: K962415-A004.pdf

Tracking:

Recipient	Delivery
RCASTILLO@FOCUSDX.COM	
DCCLetters	Delivered: 5/23/2013 4:07 PM

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

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

eCopy Hold Letter

May 23, 2013

R.J. Slomoff
Hemocue, Inc.
23263 Madero, Suite A
Mission Viejo, CA 92691

Dear R.J. Slomoff:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the following unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

510(k) Number: K943432/A003
Device: Hemocue B-Glucose System
Dated: 20-MAY-2013
Received: 23-MAY-2013

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or flash drive, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

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Please write the specific submission number identified above AND "Replacement eCopy" directly on the CD (or other media) and send that with a paper copy of your cover letter (revised if applicable) to the CDRH Document Control Center (DCC) at the address below.

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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

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If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Samie Allen
Policy Analyst
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 2014-5422; Released 10/29/14

Pugh, Dominique *

From: Pugh, Dominique *
Sent: Thursday, May 23, 2013 4:04 PM
To: RCASTILLO@FOCUSDX.COM
Cc: DCCLetters
Subject: K943432/A003 ECOPY HOLD LETTER - NO ECOPY PROVIDED
Attachments: K943432-A003.pdf

Tracking:

Recipient	Delivery
RCASTILLO@FOCUSDX.COM	
DCCLetters	Delivered: 5/23/2013 4:04 PM

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
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

eCopy Hold Letter

May 23, 2013

R. Slomoff, Consultant To Hemocue, Inc.
Hemocue, Inc.
C/O R.J. Slomoff
9229 Cranford Dr.
Potomac, MD 20854

Dear R. Slomoff:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the following unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

510(k) Number: K032203/A002
Device: Hemocue Hemoglobin 201 + System Article 121704
Dated: 20-MAY-2013
Received: 23-MAY-2013

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Silver Spring, MD 20993-0002

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

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If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Samie Allen
Policy Analyst
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 2014-5422; Released 10/29/14

Pugh, Dominique *

From: Pugh, Dominique *
Sent: Thursday, May 23, 2013 4:15 PM
To: RCASTILLO@FOCUSDX.COM
Cc: DCCLetters
Subject: K032203/A002 ECOPY HOLD LETTER - NO ECOPY PROVIDED
Attachments: K032203-A002.pdf

Tracking:

Recipient	Delivery
RCASTILLO@FOCUSDX.COM	
DCCLetters	Delivered: 5/23/2013 4:15 PM

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
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

eCopy Hold Letter

May 23, 2013

Robert Slomof
Hemocue, Inc.
C/O Robert Joel Slomof, 9229 Cranford Drive
Potomac, MD 20854

Dear Robert Slomof:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the following unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

510(k) Number: K961312/A006
Device: Hemocue B-Hemoglobin System
Dated: 20-MAY-2013
Received: 23-MAY-2013

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or flash drive, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

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Please write the specific submission number identified above AND "Replacement eCopy" directly on the CD (or other media) and send that with a paper copy of your cover letter (revised if applicable) to the CDRH Document Control Center (DCC) at the address below.

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

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

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If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Samie Allen
Policy Analyst
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 2014-5422; Released 10/29/14

Pugh, Dominique *

From: Pugh, Dominique *
Sent: Thursday, May 23, 2013 3:56 PM
To: RCASTILLO@FOCUSDX.COM
Cc: DCCLetters
Subject: K961312/A006 ECOPY HOLD LETTER - NO ECOPY PROVIDED
Attachments: K961312-A006.pdf

Tracking:

Recipient	Delivery
RCASTILLO@FOCUSDX.COM	
DCCLetters	Delivered: 5/23/2013 3:56 PM

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

Records processed under FOIA Request 2014-5422; Released 10/29/14

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

eCopy Hold Letter

May 23, 2013

R.J. Slomoff, Consultant
Hemocue, Inc.
C/O R.J. Slomoff
9229 Cranford Dr.
Potomac, MD 20854

Dear R.J. Slomoff:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the following unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

510(k) Number: K020935/A003
Device: Hemocue Glucose 201 System, Article Number 120706
Dated: 20-MAY-2013
Received: 23-MAY-2013

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or flash drive, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

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Center for Devices and Radiological Health
Document Control Center WO66-G609
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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 2014-5422; Released 10/29/14

For more information about FDA's new eCopy program, including the new technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf. In addition, we strongly encourage you to visit FDA's eSubmitter website at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm221506.htm in order to develop an eCopy in accordance with the new technical standards prior to sending it to FDA.

If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,
Samie Allen
Policy Analyst
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 2014-5422; Released 10/29/14

Pugh, Dominique *

From: Pugh, Dominique *
Sent: Thursday, May 23, 2013 4:13 PM
To: RCASTILLO@FOCUSDX.COM
Cc: DCCLetters
Subject: K020935/A003 ECOPY HOLD LETTER - NO ECOPY PROVIDED
Attachments: K020935-A003.pdf

Tracking:

Recipient	Delivery
RCASTILLO@FOCUSDX.COM	
DCCLetters	Delivered: 5/23/2013 4:13 PM

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

eCopy Hold Letter

May 23, 2013

R.J. Slomoff, Consultant To Hemocue Inc
Hemocue, Inc.
C/O R.J. Slomoff
9229 Cranford Dr.
Potomac, MD 20854

Dear R.J. Slomoff:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the following unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

510(k) Number: K041230/A002
Device: Clinical Laboratory Analyzing System
Dated: 20-MAY-2013
Received: 23-MAY-2013

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or flash drive, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

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Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,
Samie Allen
Policy Analyst
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 2014-5422; Released 10/29/14

Pugh, Dominique *

From: Pugh, Dominique *
Sent: Thursday, May 23, 2013 4:18 PM
To: RCASTILLO@FOCUSDX.COM
Cc: DCCLetters
Subject: K041230/A002 ECOPY HOLD LETTER - NO ECOPY PROVIDED
Attachments: K041230-A002.pdf

Tracking:

Recipient	Delivery
RCASTILLO@FOCUSDX.COM	
DCCLetters	Delivered: 5/23/2013 4:18 PM

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

Records processed under FOIA Request 2014-5422; Released 10/29/14

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

eCopy Hold Letter

May 23, 2013

R.J. Slomoff, Consultant To Hemocue Inc.
Hemocue, Inc.
C/O R.J. Slomoff
9229 Cranford Dr.
Potomac, MD 20854

Dear R.J. Slomoff:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the following unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

510(k) Number: K041234/A001
Device: Hemocue Hemoglobin 201dm Analyzing System
Dated: 20-MAY-2013
Received: 23-MAY-2013

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or flash drive, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

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Please write the specific submission number identified above AND "Replacement eCopy" directly on the CD (or other media) and send that with a paper copy of your cover letter (revised if applicable) to the CDRH Document Control Center (DCC) at the address below.

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

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If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Samie Allen
Policy Analyst
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request 2014-5422; Released 10/29/14

Pugh, Dominique *

From: Pugh, Dominique *
Sent: Thursday, May 23, 2013 3:53 PM
To: 'RCASTILLO@FOCUSDX.COM'
Cc: DCCLetters
Subject: K041234/A001 ECOPY HOLD LETTER- NO ECOPY PROVIDED
Attachments: K041234-A001.pdf

Tracking:

Recipient	Delivery
'RCASTILLO@FOCUSDX.COM'	
DCCLetters	Delivered: 5/23/2013 3:53 PM

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
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

eCopy Hold Letter

May 23, 2013

R. Slomoff
Hemocue, Inc.
C/O Robert Joel Slomof, 9229 Cranford Drive
Potomac, MD 20854

Dear R. Slomoff:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the following unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

510(k) Number: K911141/A003
Device: Hemocue(R) B-Glucose Microcuvette/Photometer
Dated: 20-MAY-2013
Received: 23-MAY-2013

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or flash drive, accompanied by a signed cover letter and the complete original paper submission. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

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10903 New Hampshire Avenue
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Samie Allen
Policy Analyst
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 2014-5422; Released 10/29/14

Pugh, Dominique *

From: Pugh, Dominique *
Sent: Thursday, May 23, 2013 4:02 PM
To: RCASTILLO@FOCUSDX.COM
Cc: DCCLetters
Subject: K911141/A003 ECOPY HOLD LETTER - NO ECOPY PROVIDED
Attachments: K911141-A003.pdf

Tracking:

Recipient	Delivery
RCASTILLO@FOCUSDX.COM	
DCCLetters	Delivered: 5/23/2013 4:02 PM

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FOCUS Diagnostics

K041234/A001
K041230/A2

FDA CDRH DMC
MAY 23 2013
Received

K032203/A2
K020935/A3
K962415/A4
K961312/A6
K961311/A2
K943432/A3
K911141/A3

May 20, 2013

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring MD 20993

Subject: Transfer of HemoCue, Inc. 510(k)s to HemoCue AB.

Attention: Document Control Clerk,

HemoCue, Inc. has transferred title of HemoCue, Inc.'s pre-market notifications to HemoCue AB.

The pre-market notifications transferred to HemoCue AB are listed below.

HemoCue, Inc.'s registration number is 2027756.

HemoCue AB's registration number is 3003044483.

HemoCue, Inc.'s Pre-market Notifications Transferred to HemoCue AB

emoCue Donor Hemoglobin Checker System	HemoCue, Inc	BK030020	4/17/2003
HemoCue Low Hemoglobin Analyzing System	HemoCue, Inc	BK000043	4/9/2001
Hemocue Hemoglobin 201DM Analyzing System	HemoCue, Inc	K041234 A1	06/10/2004
HemoCue Glucose 201DM Analyzing System	HemoCue, Inc	K041230 A2	05/20/2004
Hemocue Hemoglobin 201 + System	HemoCue, Inc	K032203 A2	08/25/2003
Hemocue Glucose 201 System	HemoCue, Inc	K020935 A3	04/03/2002
Hemocue B-Glucose System	HemoCue, Inc	K962415 A4	10/15/1996
Hemocue B-Hemoglobin System	HemoCue, Inc	K961312 A6	09/24/1996
Hemocue B-Glucose System	HemoCue, Inc	K961311 A2	08/23/1996
Hemocue B-Glucose System	HemoCue, Inc	K943432 A3	01/17/1995
Hemocue B-Glucose Microcuvette and Photometer	HemoCue, Inc	K911141 A3	05/08/1991

Focus Diagnostics, Inc. 11331 Valley View, Cypress, California 90630 Tel 562-240-6500 Fax 562-240-6510 www.focusdx.com

60

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

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To the best of my knowledge, all information submitted herein is truthful and accurate and no material fact has been omitted.

hank you for your handling the notification. If you have any questions or comments, or if we can be of any further assistance, please contact me by phone 562.240.6500 or rcastillo@focusdx.com.

Sincerely,

Roderick Castillo
Official Correspondent
HemoCue, Inc.
11331 Valley View street
Cypress, CA 90630
562.240.6234
rcastillo@focusdx.com

cc

Donald J. St. Pierre
Deputy Director for New Product Evaluation
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
10903 New Hampshire Avenue
White Oak 66, Rm 5682
Silver Spring, MD 20993
tel 301.796.5454
don.st.pierre@fda.hhs.gov

eresita C. Mercado, MS, MT(ASCP)
Chief, Devices Review Branch
FDA/CBER/OBRR/DBA
tel 301.827.6139
teresita.mercado@fda.hhs.gov

HemoCue AB US Agent
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Radiometer America Inc.
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mackerman@radiometeramerica.com

HemoCue AB Official Correspondent
Eva Steinick
HemoCue AB
Kuvettgatan 1
Angelholm, SWEDEN SE-262 71
tel 46.431.481.387
eva.steinick@hemocue.se

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

Records processed under FOIA Request 2014-5422; Released 10/29/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

MAY 28 2004

R. J SLOMOFF
CONSULTANT TO HEMOCUE, INC.
HEMOCUE, INC.
9229 CRANFORD DR.
POTOMAC MD 20854

Re: K032203

Test System: HEMOCUE HEMOGLOBIN 201 + / HEMOCUE HEMOGLOBIN MICROCUVETTE SYSTEM
Analyte : HGB, SINGLE ANALYTE INST. W/SELF-CONT...
Complexity : Waived
510K or PMA Number : K032203

This letter corrects our complexity categorization letter of 04-MAY-2004
The letter which was stated as moderate has been changed to waived.

Sincerely yours,

Steven Gutman, M.D.
Steven I. Gutman, M.D., M.B.A.
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

(b) (4)

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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 2014-5422 Released 10/29/14

510(k) Number: 032203

Device Name: **HemoCue® Hb 201+ System**

Indications For Use:

Quantitative determination of hemoglobin in capillary, venous and arterial whole blood.

The HemoCue® Hb 201 Microcuvettes are intended for use in the HemoCue® Hb 201$^+$ analyzer. The HemoCue 201 system is used for the quantitative determination of hemoglobin in blood using a specially designed analyzer, the HemoCue Hb 201$^+$ analyzer, and specially designed microcuvettes the HemoCue Hb 201 Microcuvettes. The HemoCue Hb 201$^+$ analyzer is only to be used with HemoCue Hb 201 Microcuvettes.

The reagents/microcuvettes and the analyzer form an analytical system. The HemoCue Hb 201$^+$ analyzer is only to be used together with HemoCue Hb 201 microcuvettes. The use of any other device in the HemoCue Hb 201$^+$ analyzer except the HemoCue Hb 201 microcuvettes is neither supported nor recommended by HemoCue, and could give erroneous results with serious clinical consequences.

The HemoCue Hb 201 microcuvettes are for in vitro diagnostic use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

7

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

b) (4)

Records processed under FOIA Request 2014-5422; Released 10/29/14

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b) (4)

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(b) (4)

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b) (4)

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Records processed under FOIA Request 2014-5422; Released 10/29/14

Art.nr 151705 030610 g/dL (g/L, mmol/L)

151705030610

HemoCue® Hb 201 Microcuvettes and HemoCue® Hb 201+ analyzer

HemoCue Hb 201 Microcuvettes are available in individual packages or in vials.
Please read the relevant Operating Manual[14] for the analyzer for proper use of the system.

Intended Use

Quantitative determination of hemoglobin in capillary, venous and arterial whole blood
The HemoCue® Hb 201 Microcuvettes are intended for use in the HemoCue® Hb 201+ analyzer. The HemoCue 201 system is used for the quantitative determination of hemoglobin in blood using a specially designed analyzer, the HemoCue Hb 201+ analyzer, and specially designed microcuvettes, the HemoCue Hb 201 Microcuvettes. The HemoCue Hb 201+ analyzer is only to be used with HemoCue Hb 201 Microcuvettes.
The reagents/microcuvettes and the analyzer form an analytical system. The HemoCue® Hb 201+ analyzer is only to be used together with HemoCue Hb 201 Microcuvettes. The use of any other device in the HemoCue® Hb 201+ analyzer except the HemoCue® Hb 201 Microcuvettes is neither supported nor recommended by HemoCue, and could give erroneous results with serious clinical consequences.
The HemoCue Hb 201 Microcuvettes are for in vitro diagnostic use only.

Summary and explanation of the test

The quantitative hemoglobin determination is indicated as a general fundamental test in acute as well as elective care. The test may be used for assessing the status of a patient in such clinical situations as hemorrhage, hemolysis, dehydration and other shifts in plasma volume - and for verifying the results of transfusion or treatment of other deficiency states such as malnutrition. The assay of hemoglobin is also used as a part of a general health screen e.g., for prospective blood donors and in the assessment of women's and children's health.
The determination of hemoglobin by a simplified photometric approach was first proposed by Stadie[1]. He showed that hemoglobin, released from lysed erythrocytes, was converted to methemoglobin by using potassium ferricyanide and that potassium cyanide would then convert the methemoglobin to cyanmethemoglobin, which could be easily measured in a colorimeter. Drabkin[2,3] confirmed Stadie's work and showed that several other oxidants, including sodium nitrite, would convert hemoglobin to methemoglobin. Van Kampen and Zijlstra[4] employed a non-ionic surfactant, which decreased the reaction time to four minutes. Vanzetti[5] exchanged potassium cyanide for sodium azide, which converted methemoglobin to azidemethemoglobin within one minute.
The disposable HemoCue Hb 201 Microcuvette is made of plastic and comprises a body having a cavity with a volume of about 10 µL. The microcuvette contains dry reagents deposited uniformly within the cavity. The blood sample is drawn into the cavity by capillary action and is spontaneously mixed with the reagents. When used with the HemoCue Hb 201+ analyzer, the system provides a direct reading of the concentration of hemoglobin in whole blood.
The chemistry method utilized by the HemoCue Hb 201 Microcuvette is a modification of Vanzetti's reagents and yields an azidemethemoglobin reaction in 15-60 seconds. The HemoCue Hb 201 Microcuvettes are ready for use upon removal from the package. To make a determination, the filling end of the microcuvette is brought in contact with a drop of capillary, venous or arterial whole blood. By capillary action 10 µL of the sample is drawn into the cavity where the blood reacts with the reagents. The microcuvette is placed in the HemoCue Hb 201+ analyzer and the chemical reaction is followed photometrically by the instrument to a steady-state condition. The HemoCue Hb 201+ analyzer uses a dual wavelength measuring method, 570 nm and 880 nm, for turbidity compensation. The HemoCue Hb 201 Microcuvette is discarded once the test has been completed.

Principles of the procedure

The Technique

The HemoCue technique is based on an optical measuring microcuvette of a small volume and a short light path. The microcuvette cavity contains reagents deposited on its inner walls. The blood sample is drawn into the cavity by capillary action and is mixed spontaneously with the reagents. The microcuvette is then placed in a HemoCue Hb 201+ analyzer in which the transmittance is measured and the hemoglobin level calculated. Thus the technique makes it possible to sample the blood, mix and chemically react it with the reagents in the same microcuvette as is used for measurement.

The Microcuvette

The microcuvette is made of polystyrene plastic and comprises a body having a cavity with a volume of about 10 µL. The distance between the walls of the optical window is 0.130 mm, which permits photometric determination of hemoglobin in undiluted blood.

The Chemistry Principle

The reaction in the microcuvette is a modified azidemethemoglobin reaction. The erythrocyte membranes are disintegrated by sodium deoxycholate, releasing the hemoglobin. Sodium nitrite converts the hemoglobin iron from the ferrous to the ferric state to form methemoglobin, which then combines with azide to form azidemethemoglobin.

Reagents

40 % w/w Sodium Deoxycholate, 18 % w/w Sodium Azide, 20 % w/w Sodium Nitrite, 22 % w/w Nonreactive Ingredients.

Warning and precautions

The HemoCue Hb 201 Microcuvettes are for in vitro diagnostic use only. The chemicals deposited in the cavity of the microcuvette are harmful if swallowed. Although the reagents in the microcuvette are present in extremely low quantities, consult local environmental authorities for proper disposal. Always handle blood specimens with care, as they may be infectious.

Storage and handling of the HemoCue Hb 201 Microcuvettes

The reagents contained within HemoCue Hb 201 Microcuvettes are moisture sensitive. As this test method relies on photometric measurement, care should be taken not to hold the microcuvette by the filling end. Also take care to wipe away all contaminating substances from the outer surface of the microcuvette. All unused microcuvettes must remain in the original package. Use the HemoCue Hb 201 Microcuvettes prior to their expiration date. The expiration date is printed on each package.

Storage of microcuvettes kept in a vial

Store HemoCue Hb 201 Microcuvettes at a temperature of 59-86 °F (15-30 °C). Do not refrigerate. As the microcuvettes are moisture sensitive, it is important that the cap of the vial is closed properly between use. Unused microcuvettes must be kept in the vial. The expiration date of HemoCue Hb 201 Microcuvettes in a sealed vial is 2 years from the date of manufacture. Once the seal is broken, the microcuvettes are stable for 3 months.

Storage of individually packed microcuvettes

Store HemoCue Hb 201 Microcuvettes at a temperature of 59-86 °F (15-30 °C). Do not refrigerate. The expiration date of each single packed HemoCue Hb 201 Microcuvette is 15 months from the date of manufacture.

Instrument

The HemoCue Hb 201 Microcuvette is specifically designed for use with the HemoCue Hb 201+ analyzer. The HemoCue Hb 201+ analyzer is factory calibrated against the international reference method for hemoglobin determination, ICSH[1].

Specimen collection and preparation

Capillary, venous or arterial blood may be used. Appropriate anticoagulants in solid form (eg EDTA, heparin or heparin/fluoride) may be used. Mix all samples thoroughly on a mechanical mixer for at least 2 minutes or invert the tube 8-10 times by hand. Alternatively, follow the local recommendations. Hemoglobin remains unchanged for days, provided that the blood does not become infected. If the specimen has been stored in a refrigerator, it will be viscid and the blood should be allowed to warm up to room temperature before mixing[6].

Procedure

Read the relevant Operating Manual[14] for the HemoCue Hb 201+ analyzer for proper use of the system.

Materials provided

HemoCue Hb 201 Microcuvettes

Materials required but not provided

HemoCue Hb 201+ analyzer
Gauze or lint free tissue
If quality control is performed with a commercial blood control, use controls recommended by HemoCue.

Proper temperatures

The HemoCue Hb 201 system is designed for use at room temperature 59-86 °F (15-30 °C).

Directions for use

1 Read the relevant Operating Manual for the analyzer for proper use of the system. Pull the cuvette holder out to its loading position. Press and hold the on/off button until the display is activated.
2 Use of the HemoCue Hb 201 Microcuvettes.
a) Take the microcuvette out of the package. Follow the instructions given under "Storage and handling of HemoCue Hb 201 Microcuvettes". **If microcuvettes from a vial are used, replace the cap immediately after the microcuvette has been removed.**
b) The shape of the microcuvette and the names of the different parts of the microcuvette can be seen in Fig. 1.
c) Hold the microcuvette opposite the filling end and bring into contact with the capillary specimen, see Fig. 2. When test tubes are used, such as vacuum tubes, we recommend that an aliquot of the well-mixed specimen is pipetted from the test tube onto a hydrophobic plastic or glass slide, where direct sampling of the specimen may occur, see Fig. 3. Always avoid contamination of the optical eye.
d) Allow the cavity of the microcuvette to fill completely by capillary action. **Do not refill the cavity of the microcuvette!**
e) When completely filled, wipe off the outside of the microcuvette with a clean lint-free tissue, being careful not to touch the open end of the microcuvette, see Fig. 4. If air bubbles are seen in the optical eye, the microcuvette should be discarded and a new sample be taken for analysis. Small air bubbles around the edge do not influence the result.
f) Place the filled HemoCue Hb 201 Microcuvette in the cuvette holder of the analyzer, see Fig. 5
g) Push the cuvette holder to its measuring position.
h) After 15-60 seconds the HemoCue Hb 201+ analyzer will find the steady-state of the chemical reaction and the result will appear in the display.
i) Pull the cuvette holder out to its loading position and discard the used microcuvette.
j) If the display shows an error code, see the trouble shooting guide in the Operating Manual for further information. If "HIGH" is displayed, the result is greater than 25.6 g/dL (256 g/L, 15.9 mmol/L), consult the Operating Manual for the analyzer.

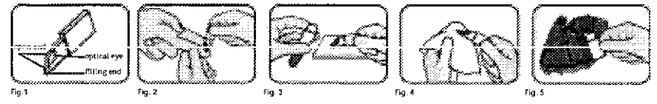

Fig. 1 Fig. 2 Fig. 3 Fig. 4 Fig. 5

Stability of the final reaction

Measurement of a HemoCue Hb 201 Microcuvette in a HemoCue Hb 201+ analyzer must be performed immediately or at the latest 10 minutes after the microcuvette has been filled with blood.

Quality control

The HemoCue Hb 201+ analyzer has an internal electronic "SELFTEST". Every time the analyzer is turned on, it will automatically verify the performance of the optronic unit of the analyzer. This test is performed at regular intervals if the analyzer is on. The HemoCue Hb 201 system can also be verified on the days of testing using commercially available hematology controls, recommended by HemoCue.
Do not use cyanmethemoglobin standards with this test.

Results

The measured hemoglobin value is read directly from the HemoCue Hb 201+ analyzer in g/dL, g/L or mmol/L.
No calculations are necessary. Results above 25.6 g/dL (256 g/L, 15.9 mmol/L) are displayed as "HIGH". The test is linear up to 23.5 g/dL (235 g/L, 14.6 mmol/L).

Limitations of the procedure

a) Measurement of hemoglobin must be made as soon as possible after the blood has been drawn into the microcuvette. If the readings are made after 10 minutes of filling the microcuvette, false results may be obtained.
b) Mixing blood for too long a period can produce increased oxygen pressure and viscosity that may give falsely high results
c) If air bubbles are seen in the optical eye of the microcuvette, the microcuvette should be discarded and a new sample taken for analysis. Small air bubbles around the edge do not influence the result.
d) Caution should be taken not to hold the microcuvette by the filling end, which may stain the optical eye. Care should also be taken in wiping off excess specimen from the outer surface of the optical eye.
e) Acetaminophen (20 mg/dL), ascorbic acid (3 mg/dL), conjugated bilirubin (40 mg/dL), unconjugated bilirubin (20 mg/dL), ibuprofen (40 mg/dL), creatinine (30 mg/dL), salicylic acid (50 mg/dL), tetracycline (20 mg/dL), urea (500 mg/dL), uric acid (20 mg/dL), lipaemia (Intralipid 4000 mg/L, approx Triglycerides 1200 mg/dL) have not been found to interfere. The highest concentration tested is referred to in brackets.
f) Turbidity due to leukocytes does not interfere (tested up to 550 x 10^9/L).
g) Carboxyhemoglobin levels up to 10% do not interfere (reference values for nonsmokers: 1-2 %, smokers: 5-6 %)[7]
h) pH values between 6.7-8.5 do not interfere with the system.
i) Sulfhemoglobin is not measured with this method.
j) Values above 23.5 g/dL (235 g/L, 14.6 mmol/L) must be confirmed using a suitable laboratory method.

Interference studies have been performed according to NCCLS Document EP7-P Vol 6 No 13[12]

Expected values[8]

Adult males	13.0 - 17.0 g/dL (130 - 170 g/L, 8.1 - 10.5 mmol/L)
Adult females	12.0 - 15.0 g/dL (120 - 150 g/L, 7.4 - 9.3 mmol/L)
Infants after neonatal period	11.0 - 14.0 g/dL (110 - 140 g/L, 6.8 - 8.7 mmol/L)

Children, 2 years to teenage, gradually increase to adult normals.
Due to the wide range of conditions (dietary, geographical, etc) which affect normal values, it is recommended that each laboratory establish its own normal range.

Specific performance characteristics

The results given below in "Within-run precision" and "Total precision" come from one batch of HemoCue Hb 201 Microcuvettes and five HemoCue Hb 201+ analyzers. No restandardization was done during the analyzing period. The results given in the "Correlation Study" came from one HemoCue Hb 201+ analyzer which had not been restandardized during the study period. ICSH is the international reference method for hemoglobin determination(HiCN).

Within-run and Total precision *

Within-run precision was determined according to the NCCLS Document EP5-A Vol 19 No 2[11]. Commercially available controls at two different levels were used. The hemoglobin concentration was measured in duplicate twice a day, morning and afternoon, during twenty consecutive days on five analyzers. A new vial of each control level was used every day.

Control level	N	x g/dL	Within-run Precision SD g/dL	Within-run Precision CV %	Total Precision SD g/dL	Total Precision CV %
1	400	7.70	0.057	0.74	0.100	1.30
2	400	15.36	0.078	0.51	0.109	0.71

$SD = \sqrt{\frac{\sum d^2}{2n}}$ where d is the difference between two microcuvettes and n is the number of blood samples in the study.

Correlations Studies

A number of correlation studies of the HemoCue Hb 201 system have been performed.
The results of the comparison studies between the HemoCue Hb 201 system and other hemoglobin methods are summarized in the table below.

Study	N	Min g/dL	Max g/dL	Regression line	Correlation coeffecient (r)
1	138	4.6	19.9	Y = 1.045X – 0.126	0.999
2	120	7.4	18.7	Y = 1.015X + 0.100	0.999
3	120	4.4	20.1	Y = 1.012X – 0.219	0.999
4	120	4.2	20.6	Y = 0.995X + 0.275	0.998
5	498	4.3	20.5	Y = 1.017X – 0.276	0.994
6	53	7.8	16.3	Y = 1.032X – 0.122	0.997
7	498	4.1	21.0	Y = 0.981X + 0.139	0.998

1 = Beckman Coulter GEN-S, venous EDTA blood
2 = Advia 120, venous EDTA blood
3 = Coll-Dyn 4000, venous EDTA blood
4 = Sysmex XE2100, venous EDTA blood
5 = ICSH (Cyanmethemoglobin method), venous EDTA blood, multicenter study
6 = Beckman Coulter GEN-S, venous EDTA blood
7 = B-Hemoglobin, venous EDTA blood, multicenter study

[1]International Council for Standardization in Haematology

Patent

The HemoCue Hb 201+ Microcuvette is covered by United States Patent 5,674,457.

Bibliography

1. Stadie, W.C., J. Biol. Chem. 41, 237 (1920)
2. Drabkin, D.L. and Austin J.H., J. Biol. Chem. 98, 719 (1932)
3. Austin, J.H. and Drabkin, D.L., J. Biol. Chem. 112, 67 (1935-36)
4. Van Kampen, E.J. and Zijlstra, W.G., Clin. Chem. Acta 6, 538 (1961)
5. Vanzetti, G., Am. J. Lab. & Clin. Med. 67, 116 (1966)
6. Dacie and Lewis, Practical Haemotology, Ninth Edition, 2001.
7. G.Kwatt et al. Clin. Lab. Haemat, Calibration of a practical hemoglobinometer, 1987,9 387-393.
Gradwohl's Clinical Laboratory Methods and Diagnosis, Frankel, S., Reitman, S. and Sonnenwith, A.C., Editors, C.V. Mosby Co., St. Louis, 7th Edition, 1970 Vol, 1, p. 405
8. ICSH Standard EP 6/2: 1977, Standard EP 6/3: 1977, V. Clin. Path. 3/1 139-143 (1978)
9. Makarem, A. , Henry R.J., Cannon, D.C., and Winkelman, J.W., Eds., Harper and Row, Hagerstown, MD, In Clin. Chem. Principles and Technics, 2nd ed., 1974, pp. 1127-1147
10. Wallach, J. Interpretation of Diagnostic Tests, 1st ed., Little, Brown and Company, Boston, MA, 1970, pp. 6-7
11. Evaluation of precision performance of clinical chemistry devices; approved Guideline NCCLS Document EP5-A Vol 19 No 2 Feb 1999
12. Interference testing in clinical chemistry NCCLS proposed guideline; NCCLS Document EP7-P Vol 6 No 13
13. Burtis,Carl A., Ashwood Edward R.,Tietz Fundamentals of Clinical Chemistry, Fifth edition
14. HemoCue® Hb 201+ Operating Manual.

Manufacturer

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E-mail: info@hemocue.se
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HemoCue Distributor USA:

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Orders 800-323-1674
Technical support 800-426-7256
Fax 949-859-3066

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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

HemoCue, Incorporated
c/o R.J. Slomoff
9229 Cranford Drive
Potomac, Maryland 20854

AUG 2 5 2003

Re: k032203
Trade/Device Name: HemoCue® Hb 201+ System
Regulation Number: 21 CFR § 864.5620
Regulation Name: Automated Hemoglobin System
Regulatory Class: II
Product Code: GKR
Dated: July 14, 2003
Received: July 31, 2003

Dear Mr. Slomoff:

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). 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.

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

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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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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

Records processed under FOIA Request 2014-5422; Released 10/29/14

510(k) Number: K032203

Device Name: **HemoCue® Hb 201+ System**

Indications For Use:

Quantitative determination of hemoglobin in capillary, venous and arterial whole blood.

The HemoCue® Hb 201 Microcuvettes are intended for use in the HemoCue® Hb 201$^+$ analyzer. The HemoCue 201 system is used for the quantitative determination of hemoglobin in blood using a specially designed analyzer, the HemoCue Hb 201$^+$ analyzer, and specially designed microcuvettes the HemoCue Hb 201 Microcuvettes. The HemoCue Hb 201$^+$ analyzer is only to be used with HemoCue Hb 201 Microcuvettes.

The reagents/microcuvettes and the analyzer form an analytical system. The HemoCue Hb 201$^+$ analyzer is only to be used together with HemoCue Hb 201 microcuvettes. The use of any other device in the HemoCue Hb 201$^+$ analyzer except the HemoCue Hb 201 microcuvettes is neither supported nor recommended by HemoCue, and could give erroneous results with serious clinical consequences.

The HemoCue Hb 201 microcuvettes are for in vitro diagnostic use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

(Optional Format 3-10-98)

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032203

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

August 01, 2003

HEMOCUE, INC.
C/O R.J. SLOMOFF
9229 CRANFORD DR.
POTOMAC, MD 20854
ATTN: R. J. SLOMOFF

510(k) Number: K032203
Received: 31-JUL-2003
Product: HEMOCUE HEMOGLOBIN
201 + SYSTEM ARTICLE
121704

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. We will notify you when the processing of your premarket notification 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.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

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 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.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

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

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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 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 18, 2003

HEMOCUE, INC.
C/O R.J. SLOMOFF
9229 CRANFORD DR.
POTOMAC, MD 20854
ATTN: R. J. SLOMOFF

510(k) Number: K032203
Received: 18-JUL-2003
Product: HEMOCUE HEMOGLOBIN
User Fee ID Number: SYSTEM ARTICLE 121704

The Food and Drug Administration (FDA) Center for Devices and Radiological Heath (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. The payment information we need in order to begin the review of your 510(k) includes, the user fees cover sheet with the payment ID faxed to the Office of Financial Management at (301) 827-9213 and a check mailed to:

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 also 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 http://www.fda.gov/oc/mdufma.

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

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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 an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/cdrh/dsmamain.html, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

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

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K032203

ROBERT JOEL SLOMOFF

9229 CRANFORD DRIVE
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TELEPHONE: 301/983-1707 TELEFAX: 301/983-2746

July 14, 2003

FDA/CDRH/OCE/DID
2003 JUL 18 P 12:49

Food & Drug Administration
Center for Devices & Radiological Health
Division of Clinical Laboratory Devices
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Special 510(k) Submission: **Device Modification**
HemoCue. Incorporated
Blood Glucose Analyzing System

Dear Sir:

HemoCue, Incorporated respectfully requests permission to market its Whole Blood Hemoglobin 201 Analyzing System. The system is manufactured and packaged by HemoCue AB in Sweden. This device is a modification of the HemoCue Hemoglobin Analyzing System (K961312). Under the New Paradigm Guidance document, a thirty day review is respectfully requested. See discussion in Attachment to this cover letter.

The Premarket Notification information required by 21 CFR 807.87 is as follows:

a. Classification Name: Clinical Laboratory Device
Common/Usual Name: Clinical Laboratory Analyzing System
Proprietary Name: HemoCue Hemoglobin 201 Analyzing System

b. Establishment Registration Number: 2027756
c. Classification Pursuant to *Section* 513 of the Federal Food, Drug & Cosmetic Act, as amended. Analyzing systems are classified as Class II Medical Devices.

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

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d. Performance Standards: No performance have been established for these devices.

e. A CDRH Cover Sheet is provided. See Section 1.

f. A separate Indication Form is provided as required. See Section 2.

g. A Truthful and Accuracy Statement is provided. See Section 3

h. A 510(k) Statement is provided. See Section 4.

i. A Financial Statement Certificate is provided. See Section 5.

j. Design Control Activity including Risk Analysis is provided. See Section 6.

k. Comparison Studies including clinical comparison with the unmodified device, imprecision, and interferences studies are provided. See Section 7.

l. Studies with the Device are provided. See Section 8.

m. Instructions for Use and Labeling information are provided. Sec; Section 9

n. Expiration and Storage Date is provided. See Section 10.

o. Predicate Devices information is provided. See Section 11.

p. Cited literature is provided. See Section 12.

q. Design Specifications and Risk Analysis are provided. See Section13.

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

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HemoCue, Inc. considers its intention to market this device in the United States to be confidential commercial information and, therefore, exempt from public disclosure.

We would appreciate your earliest consideration of this Special 510(k) submission. The product will not, of course, be offered for sale until we receive clearance of this submission. Should you have any questions, please contact me at the address and telephone number provided.

With sincere regards,

R. J. Slomoff
Consultant to HemoCue, Inc.

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

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Elements of the Special 510k: Device Modification Guidance Paradigm

A. **Intended** Use

The Intended Use of the HemoCue Hemoglobin 201 and the Labeling are identical to the Intended Use and Labeling for the HemoCue B-Hemoglobin System K961312.

B. Fundamental Scientific Technology

The principal modification, which has allowed the Analyzer to be reduced in size and weight, is the use of a plastic bridge to reflect the light instead of a mirror. The measuring wavelengths, sample source and size, chemistry and calculation algorithms remain the same.

It should be disclosed that the next generation processor with its associated software is now being used in the HemoCue 201. All design elements of design controls including input, output, specifications, validation, verification, and complete risk analysis were performed. In addition, extensive laboratory evaluation including accuracy and precision tests were conducted. Comparative clinical testing was also done. Summaries and data of the foregoing are included in the submission for your review.

C. Clinical Considerations

Collection of the clinical data was done in Sweden. No Investigational Device Exemption was necessary, however, all appropriate elements of. the Helsinki accords were observed. No safety or effectiveness issues required investigation.

In sum, we respectfully believe that the modified HemoCue B-Hemoglobin system meets the requirements set out in, the Guidance Paradigm for a Special 510(k).

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

Records processed under FOIA Request 2014-5422; Released 10/29/14

Special 510(k): Device Modification Qualification

HemoCue Hemoglobin 201 Analyzer and Microcuvette System

Dear Reviewer:

Please find enclosed a Premarket Notification for the new HemoCue Hemoglobin 201 Analyzer and Microcuvette system. This notification is being submitted as a Special 510(k): Device Modification, under the CDRH Alternate Approaches Paradigms Guidance Document.

The Guidance Document sets out the facts and information which must be present to qualify for this accelerated review. HemoCue believes the modification of its existing 510(k) Hemoglobin System (K961312) meets therequirements, and explains its thinking as follows.

The classic HemoCue' B-Hemoglobin, K961312, is a dual wavelength spectrophotometer and disposable microcuvette system for the whole blood determination of hemoglobin. As a point of care analyzer, size and weight were elements important to the clinical community. A design program, Project Viking, to reduce the analyzer dimensions has resulted in the HemoCue Hemoglobin 201. This design modification was achieved primarily by conveying the light over a plastic bridge, instead of reflecting it off a beam splitting mirror. The light itself has not been changed.

The body of the microcuvette was slightly changed to prevent inadvertent use in the Classic analyzer. The sample collection end of the microcuvette was not changed in any respect. The container for the new microcuvettes is also identical to the presently marketed microcuvettes, except of course for the labels.

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

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HemoCue, Inc.
Special 510(k) Device Modification
HemoCue® Hb 201+ System
June 30, 2003

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

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HemoCue, Inc.
Special 510(k) Device Modification
HemoCue® Hb 201+ System
June 30, 2003

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VOLUME II OF II

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

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CDRH SUBMISSION COVER SHEET

Date of Submission: **FDA Document Number:**

Section A **Type of Submission**

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission Summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	XX Original Submission: ☐ Traditional ☒ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg. ☐ Pre-PMA mtg. ☐ Pre-PDP mtg. ☐ 180-Day mtg. ☐ Other (specify):
IDE	**Humanitarian Device Exemption**	**Class II Exemption**	**Evaluation of Automatic Class III Designation**	**Other Submission**
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	Describe Submission:

Section B **Applicant or Sponsor**

Company/Institution Name: HEMOCUE, INC.	Establishment registration number: 2027756
Division Name (if applicable): N/A	Phone number (include area code): 949/859-2630
Street Address: 40 Empire Drive	Fax number (include area code): 949/859-3080

City:	State/Province:	Zip code:	Country:
LAKE FOREST	CA	92630	USA

Contact Name: SERINA TAUB

Contact Title: NATIONAL OPERATIONS MANAGER	Contact e-mail address: SERINA@HEMOCUE.COM

Section C **Submission Correspondent (if different from above)**

Company/Institution Name: R. J. SLOMOFF	Establishment registration number: N/A
Division name (if applicable)	Phone number (include area code): 301/983-1707
Street Address: 9229 CRANFORD DRIVE	Fax number (include area code): 301/983-2746

City:	State/Province:	Zip Code:	Country
POTOMAC	MD	20854	USA

Contact Name: CONSULTANT TO HEMOCUE, INC.

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Section D1 — Reason for Submission – PMA,PDP, or HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Licensing Agreement

- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other (specify below)

- ☐ Location Change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor

- ☐ Processing Change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)

- ☐ Labeling Change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other (specify below)_

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post Approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site

- ☐ Change in Ownership
- ☐ Change in correspondent

- ☐ Other Reason (specify):

Section D2 — Reason for Submission - IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion/extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request

Change in:
- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing process
- ☐ Protocol – feasibility
- ☐ Protocol – other
- ☐ Sponsor

- ☐ Report Submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final

- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approval
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension for time to respond to FDA
  - ☐ Request meeting

- ☐ Other reason (specify):

Section D3 — Reason for Submission – 510(k)

- ☐ New Device
- ☐ Additional or expanded indications
- ☐ Other reason (specify):

- ☐ Change in technology
- ☒ Change in design

- ☐ Change in materials
- ☐ Change in manufacturing process

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Section E **Additional Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data: ☐ 510(k) summary attached ☒ 510(k) statement
1 GKR	2 GKR	3	4	
5	6	7	8	

510(k) Number	Trade of Proprietary or model name	Manufacturer
1 K832020	1 HemoCue B-Hemoglobin System	1 HemoCue AB
2 K961312	2 HemoCue B-Hemoglobin System Data Management	2 HemoCue AB
3	3	3
4	4	4
5	5	5
6	6	6

Section F **Product Information – Applicable to All Applications**

Common or usual name or classification name:

HEMOCUE HEMOGLOBIN 201+ SYSTEM

Trade or proprietary or model name	Model Number
1 HEMOCUE HEMOGLOBIN 201+ SYSTEM	1 Article Number: 121704
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome): NONE

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

Section G **Product Classification – Applicable to All Applicants**

Product code: GKR	C.F.R. Section 864.5620	Device Class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification Panel: Hemotology		

Indications (from labeling): Quantitative determination of hemoglobin in blood using a specially designed analyzer, the HemoCue Hb 201+ analyzer, and specially designed microcuvettes, the HemoCue Hb 201 microcuvettes.

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H **Manufacturing/Packaging/Sterilization Sites Relating to a Submission**

☒ Original ☐ Add ☐ Delete	FDA establishment registration number:	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler
Company/Institution name: HEMOCUE AB		Establishment registration number: 3003044483
Division name (if applicable): N/A		Phone number (include area code): 46-431-45-8200
Street address: KUVETTGATEN 1		FAX number (include area code): 46-431-45-8225

City	State/Province	Zip code:	Country
ANGELHOLM			SWEDEN

Contact name: STEFAN JOHANSSON

Contact title: QUALITY ASSURANCE MANAGER

☐ Original ☒ Add ☐ Delete	FDA Establishment registration number: 2027756	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☒ Repackager/relabeler
Company/Institution Name: HEMOCUE, INC.		Establishment registration number:
Division name (if applicable): N/A		Phone number (include area code): 949/859-2630
Street address: 40 EMPIRE DRIVE		FAX number (include area code): 949/859-3080

City:	State/Province:	Zip code:	Country:
LAKE FOREST	CA	92630	USA

Contact name: SERINA TAUB

Contact title NATIONAL OPERATIONS MANAGER	Contact e-mail address: SERINA@HEMOCUE.COM

☐ Original ☐ Add ☐ Delete	FDA Establishment registration number:	☐ Manufacturer ☐ Contract sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler
Company/Institution name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code):
Street address:		FAX number (include area code):

City:	State/Province:	Zip code:	Country:

Contact name:

Contact title	Contact e-mail address:

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510(k) Number: K032203

Device Name: **HemoCue® Hb 201+ System**

Indications For Use:

Quantitative determination of hemoglobin in capillary, venous and arterial whole blood.

The HemoCue® Hb 201 Microcuvettes are intended for use in the HemoCue® Hb 201$^+$ analyzer. The HemoCue 201 system is used for the quantitative determination of hemoglobin in blood using a specially designed analyzer, the HemoCue Hb 201$^+$ analyzer, and specially designed microcuvettes the HemoCue Hb 201 Microcuvettes. The HemoCue Hb 201$^+$ analyzer is only to be used with HemoCue Hb 201 Microcuvettes.

The reagents/microcuvettes and the analyzer form an analytical system. The HemoCue Hb 201$^+$ analyzer is only to be used together with HemoCue Hb 201 microcuvettes. The use of any other device in the HemoCue Hb 201$^+$ analyzer except the HemoCue Hb 201 microcuvettes is neither supported nor recommended by HemoCue, and could give erroneous results with serious clinical consequences.

The HemoCue Hb 201 microcuvettes are for in vitro diagnostic use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyshree Bantwal

Division Sign-Off

(Optional Format 3-10-98)

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032203

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

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HemoCue, Inc.
Special 510(k) Device Modification
HemoCue® Hb 201+ System
June 30, 2003

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT*

(As Required by 21 CFR 807.87(k))

I certify that, in my capacity as President of HemoCue, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Bruce M. Burgess
(Typed Name)

30 JUNE 2003
(Dated)

510(k) Premarket Notification: K032203

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HemoCue, Inc.
Special 510(k) Device Modification
HemoCue® Hb 201+ System
June 30, 2003

510(k) STATEMENT
(As required by 21 CFR 807.93)

I certify that, in my capacity as President of HemoCue, Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification is determined to be substantially equivalent.

The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(Signature)

Bruce M. Burgess
(Typed Name)

30 JUNE 2003
(Dated)

510(k) Premarket Notification: K: 032203

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: 3/31/02

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

(b) (6)

[redacted]

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Bruce Burgess	General Manager
FIRM/ORGANIZATION: HemoCue Inc.	
SIGNATURE: B. M. B.	DATE: 8 JULY 2003

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

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HemoCue® AB
510(k) Premarket Notification
HemoCue® Hb 201+ System
June 14, 2003

Declaration of Conformity with Design Controls

1) Per requirements, all risk analysis, verification and validation activities were performed by the designated individuals and the predetermined acceptance criteria were met, and

2) The manufacturing facility is in conformance with the design control procedure requirements specified in 21 CFR 820.30 and the records are available for review.

Stefan Johansson June 14, 2003

Stefan Johansson Date

Title: Quality Assurance Manager

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HemoCue, Inc.
Special 510(k) Device Modification
HemoCue® Hb 201+ System
June 30, 2003

PREMARKET NOTIFICATION

STATEMENT OF CONFORMITY WITH INDICATIONS AND INTENDED USES

I certify as President of HemoCue, Inc., that the intended use and indications of the modified device, as described in the attached labeling, are the same as the intended use and indications for the sponsor's unmodified predicate device (K832020).

(Signature)

Bruce M. Burgess
(Typed Name)

30 JUNE 2003
(Dated)

510(k) Premarket Notification: K _ _ _ _ _ _

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HemoCue, Inc.
Special 510(k) Device Modification
HemoCue® Hb 201+ System
June 30, 2003

PREMARKET NOTIFICATION

STATEMENT THAT MODIFICATION HAS NOT ALTERED THE FUNDAMENTAL TECHNOLOGY

I certify as President of HemoCue, Inc., that the modification has not altered the fundamental technology of the sponsor's predicate device (K832020).

(Signature)

Bruce M. Burgess
(Typed Name)

30 JUNE 2003
(Dated)

510(k) Premarket Notification: K _ _ _ _ _ _

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Comparison to Marketed Predicate Device

Analyzer

The classic HemoCue® B-Hemoglobin System comprises a dual wavelength photometer and disposable Microcuvette for the whole blood determination of hemoglobin. As a point of care analyzer, size and weight were elements important to the clinical community.

A design program, Project Viking, to reduce the analyzer dimensions has resulted in the HemoCue Hb 201$^+$ System. This design modification was achieved primarily by conveying the light over a plastic bridge, instead of reflecting it off a beam splitting mirror. The light itself has not been changed.

Microcuvette

The optical sample area, volume, and reagents in the HemoCue Hb 201 Microcuvette are identical to the marketed HemoCue B-Hemoglobin Microcuvette. However, the shape of the HemoCue Hb 201microcuvette is "keyed" such that it will only fit in the Hb 201$^+$ photometer. Similarly, the B-Hemoglobin Microcuvette will only fit in the B-Hemoglobin photometer. In all other respects the Hb 201 Microcuvette is identical to the existing B-Hemoglobin Microcuvette.

The packaging vial for the HemoCue Hb 201 Microcuvettes is the one used for our marketed B-Hemoglobin Microcuvettes. Labeling, of course, is updated to show the HemoCue Hb 201$^+$ System name and Article Number.

The HemoCue Hb 201 Microcuvettes are packaged with the same Storage, Handling and Expiration Date specifications as the existing B-Hemoglobin Microcuvettes.

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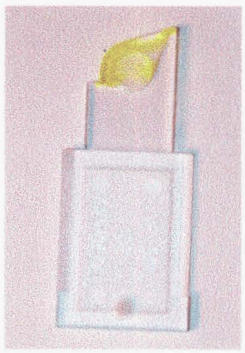
Comparison to Marketed Predicate Device

Existing B-Hemoglobin

New Hb 201+



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SUMMARY OF CLINICAL PERFORMANCE STUDIES

A number of correlation studies with the HemoCue Hb201$^+$ system have been performed.

The studies have been performed with human venous whole blood and the results are summarized in the table 1.

The table shows high precision of the HemoCue Hb201$^+$ system and excellent correlation with the comparative methods.

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Table 1. Summary of correlation studies with the HemoCue Hb201^{+} system

Study	Comparative Method/Instrument	N	Reg. line	S_{xy} (g/dL)	Corr. Coeff. (r)	Corr. Coeff. (R^2)
(b)(4) [redacted]						

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Art nr 151705 030610 g/dL (g/L, mmol/L)

151705030610

HemoCue® Hb 201 Microcuvettes and HemoCue® Hb 201+ analyzer

HemoCue Hb 201 Microcuvettes are available in individual packages or in vials.
Please read the relevant Operating Manual[14] for the analyzer for proper use of the system.

Intended Use

Quantitative determination of hemoglobin in capillary, venous and arterial whole blood
The HemoCue® Hb 201 Microcuvettes are intended for use in the HemoCue® Hb 201+ analyzer. The HemoCue 201 system is used for the quantitative determination of hemoglobin in blood using a specially designed analyzer, the HemoCue Hb 201+ analyzer, and specially designed microcuvettes, the HemoCue Hb 201 Microcuvettes. The HemoCue Hb 201+ analyzer is only to be used with HemoCue Hb 201 Microcuvettes.
The reagents/microcuvettes and the analyzer form an analytical system.The HemoCue® Hb 201+ analyzer is only to be used together with HemoCue Hb 201 Microcuvettes. The use of any other device in the HemoCue® Hb 201+ analyzer except the HemoCue® Hb 201 Microcuvettes is neither supported nor recommended by HemoCue, and could give erroneous results with serious clinical consequences.
The HemoCue Hb 201 Microcuvettes are for in vitro diagnostic use only.

Summary and explanation of the test

The quantitative hemoglobin determination is indicated as a general fundamental test in acute as well as elective care. The test may be used for assessing the status of a patient in such clinical situations as hemorrhage, hemolysis, dehydration and other shifts in plasma volume - and for verifying the results of transfusion or treatment of other deficiency states such as malnutrition. The assay of hemoglobin is also used as a part of a general health screen e.g., for prospective blood donors and in the assessment of women's and children's health.
The determination of hemoglobin by a simplified photometric approach was first proposed by Stadie[1]. He showed that hemoglobin, released from lysed erythrocytes, was converted to methemoglobin by using potassium ferricyanide and that potassium cyanide would then convert the methemoglobin to cyanmethemoglobin, which could be easily measured in a colorimeter. Drabkin[2,3] confirmed Stadie's work and showed that several other oxidants, including sodium nitrite, would convert hemoglobin to methemoglobin. Van Kampen and Zijlstra[4] employed a non-ionic surfactant, which decreased the reaction time to four minutes. Vanzetti[5] exchanged potassium cyanide for sodium azide, which converted methemoglobin to azidemethemoglobin within one minute.
The disposable HemoCue Hb 201 Microcuvette is made of plastic and comprises a body having a cavity with a volume of about 10 µL. The microcuvette contains dry reagents deposited uniformly within the cavity. The blood sample is drawn into the cavity by capillary action and is spontaneously mixed with the reagents. When used with the HemoCue Hb 201+ analyzer, the system provides a direct reading of the concentration of hemoglobin in whole blood.
The chemistry method utilized by the HemoCue Hb 201 Microcuvette is a modification of Vanzetti's reagents and yields an azidemethemoglobin reaction in 15-60 seconds. The HemoCue Hb 201 Microcuvettes are ready for use upon removal from the package. To make a determination, the filling end of the microcuvette is brought in contact with a drop of capillary, venous or arterial whole blood. By capillary action 10 µL of the sample is drawn into the cavity where the blood reacts with the reagents. The microcuvette is placed in the HemoCue Hb 201+ analyzer and the chemical reaction is followed photometrically by the instrument to a steady-state condition. The HemoCue Hb 201+ analyzer uses a dual wavelength measuring method, 570 nm and 880 nm, for turbidity compensation. The HemoCue Hb 201 Microcuvette is discarded once the test has been completed.

Principles of the procedure

The Technique
The HemoCue technique is based on an optical measuring microcuvette of a small volume and a short light path. The microcuvette cavity contains reagents deposited on its inner walls. The blood sample is drawn into the cavity by capillary action and is mixed spontaneously with the reagents. The microcuvette is then placed in a HemoCue Hb 201+ analyzer in which the transmittance is measured and the hemoglobin level calculated. Thus the technique makes it possible to sample the blood, mix and chemically react it with the reagents in the same microcuvette as is used for measurement.

The Microcuvette
The microcuvette is made of polystyrene plastic and comprises a body having a cavity with a volume of about 10 µL. The distance between the walls of the optical window is 0.130 mm, which permits photometric determination of hemoglobin in undiluted blood.

The Chemistry Principle
The reaction in the microcuvette is a modified azidemethemoglobin reaction. The erythrocyte membranes are disintegrated by sodium deoxycholate, releasing the hemoglobin. Sodium nitrite converts the hemoglobin iron from the ferrous to the ferric state to form methemoglobin, which then combines with azide to form azidemethemoglobin.

Reagents

40 % w/w Sodium Deoxycholate, 18 % w/w Sodium Azide, 20 % w/w Sodium Nitrite, 22 % w/w Nonreactive Ingredients.

Warning and precautions

The HemoCue Hb 201 Microcuvettes are for in vitro diagnostic use only. The chemicals deposited in the cavity of the microcuvette are harmful if swallowed. Although the reagents in the microcuvette are present in extremely low quantities, consult local environmental authorities for proper disposal. Always handle blood specimens with care, as they may be infectious.

Storage and handling of the HemoCue Hb 201 Microcuvettes

The reagents contained within HemoCue Hb 201 Microcuvettes are moisture sensitive. As this test method relies on photometric measurement, care should be taken not to hold the microcuvette by the filling end. Also take care to wipe away all contaminating substances from the outer surface of the microcuvette. All unused microcuvettes must remain in the original package. Use the HemoCue Hb 201 Microcuvettes prior to their expiration date. The expiration date is printed on each package.

Storage of microcuvettes kept in a vial
Store HemoCue Hb 201 Microcuvettes at a temperature of 59-86 °F (15-30 °C). Do not refrigerate. As the microcuvettes are moisture sensitive, it is important that the cap of the vial is closed properly between use. Unused microcuvettes must be kept in the vial. The expiration date of HemoCue Hb 201 Microcuvettes in a sealed vial is 2 years from the date of manufacture. Once the seal is broken, the microcuvettes are stable for 3 months.

Storage of individually packed microcuvettes
Store HemoCue Hb 201 Microcuvettes at a temperature of 59-86 °F (15-30 °C). Do not refrigerate. The expiration date of each single packed HemoCue Hb 201 Microcuvette is 15 months from the date of manufacture.

Instrument

The HemoCue Hb 201 Microcuvette is specifically designed for use with the HemoCue Hb 201+ analyzer. The HemoCue Hb 201+ analyzer is factory calibrated against the international reference method for hemoglobin determination, ICSH[8].

Specimen collection and preparation

Capillary, venous or arterial blood may be used. Appropriate anticoagulants in solid form (eg EDTA, heparin or heparin/fluoride) may be used. Mix all samples thoroughly on a mechanical mixer for at least 2 minutes or invert the tube 8-10 times by hand. Alternatively, follow the local recommendations. Hemoglobin remains unchanged for days, provided that the blood does not become infected. If the specimen has been stored in a refrigerator, it will be viscid and the blood should be allowed to warm up to room temperature before mixing[6].

Procedure

Read the relevant Operating Manual[14] for the HemoCue Hb 201+ analyzer for proper use of the system.

Materials provided

HemoCue Hb 201 Microcuvettes

Materials required but not provided

HemoCue Hb 201+ analyzer
Gauze or lint free tissue
If quality control is performed with a commercial blood control, use controls recommended by HemoCue.

Proper temperatures

The HemoCue Hb 201 system is designed for use at room temperature 59-86 °F (15-30 °C).

Directions for use

1 Read the relevant Operating Manual for the analyzer for proper use of the system. Pull the cuvette holder out to its loading position. Press and hold the on/off button until the display is activated.
2 Use of the HemoCue Hb 201 Microcuvettes.
a) Take the microcuvette out of the package. Follow the instructions given under "Storage and handling of HemoCue Hb 201 Microcuvettes". **If microcuvettes from a vial are used, replace the cap immediately after the microcuvette has been removed.**
b) The shape of the microcuvette and the names of the different parts of the microcuvette can be seen in Fig. 1.
c) Hold the microcuvette opposite the filling end and bring into contact with the capillary specimen, see Fig. 2. When test tubes are used, such as vacuum tubes, we recommend that an aliquot of the well-mixed specimen is pipetted from the test tube onto a hydrophobic plastic or glass slide, where direct sampling of the specimen may occur, see Fig. 3. Always avoid contamination of the optical eye.
d) Allow the cavity of the microcuvette to fill completely by capillary action. **Do not refill the cavity of the microcuvette!**
e) When completely filled, wipe off the outside of the microcuvette with a clean lint-free tissue, being careful not to touch the open end of the microcuvette, see Fig. 4. If air bubbles are seen in the optical eye, the microcuvette should be discarded and a new sample be taken for analysis. Small air bubbles around the edge do not influence the result.
f) Place the filled HemoCue Hb 201 Microcuvette in the cuvette holder of the analyzer, see Fig. 5.
g) Push the cuvette holder to its measuring position.
h) After 15-60 seconds the HemoCue Hb 201+ analyzer will find the steady-state of the chemical reaction and the result will appear in the display.
i) Pull the cuvette holder out to its loading position and discard the used microcuvette.
j) If the display shows an error code, see the trouble shooting guide in the Operating Manual for further information. If "HHH" is displayed, the result is greater than 25.6 g/dL (256 g/L, 15.9 mmol/L), consult the Operating Manual for the analyzer.

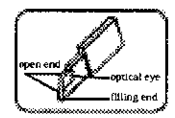

Fig. 1

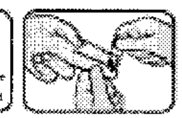
Fig. 2

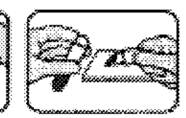
Fig. 3

Fig. 4

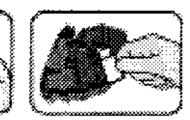
Fig. 5

Stability of the final reaction

Measurement of a HemoCue Hb 201 Microcuvette in a HemoCue Hb 201+ analyzer must be performed immediately or at the latest 10 minutes after the microcuvette has been filled with blood.

Quality control

The HemoCue Hb 201+ analyzer has an internal electronic "SELFTEST". Every time the analyzer is turned on, it will automatically verify the performance of the optronic unit of the analyzer. This test is performed at regular intervals if the analyzer is on. The HemoCue Hb 201 system can also be verified on the days of testing using commercially available hematology controls, recommended by HemoCue.
Do not use cyanmethemoglobin standards with this test.

Results

The measured hemoglobin value is read directly from the HemoCue Hb 201+ analyzer in g/dL, g/L or mmol/L.
No calculations are necessary. Results above 25.6 g/dL (256 g/L, 15.9 mmol/L) are displayed as "HHH". The test is linear up to 23.5 g/dL (235 g/L, 14.6 mmol/L).

Limitations of the procedure

a) Measurement of hemoglobin must be made as soon as possible after the blood has been drawn into the microcuvette. If the readings are made after 10 minutes of filling the microcuvette, false results may be obtained.
b) Mixing blood for too long a period can produce increased oxygen pressure and viscosity that may give falsely high results
c) If air bubbles are seen in the optical eye of the microcuvette, the microcuvette should be discarded and a new sample taken for analysis. Small air bubbles around the edge do not influence the result.
d) Caution should be taken not to hold the microcuvette by the filling end, which may stain the optical eye. Care should also be taken in wiping off excess specimen from the outer surface of the optical eye.
e) Acetaminophen (20 mg/dL), ascorbic acid (3 mg/dL), conjugated bilirubin (40 mg/dL), unconjugated bilirubin (20 mg/dL), ibuprofen (40 mg/dL), creatinine (30 mg/dL), salicylic acid (50 mg/dL), tetracycline (20 mg/dL), urea (500 mg/dL), uric acid (20 mg/dL), lipaemia (Intralipid 4000 mg/L, approx Triglycerides 1200 mg/dL) have not been found to interfere. The highest concentration tested is referred to in brackets.
f) Turbidity due to leukocytes does not interfere (tested up to 550×10^9/L).
g) Carboxyhemoglobin levels up to 10% do not interfere (reference values for nonsmokers: 1-2 %, smokers: 5-6 %)[13]
h) pH values between 6.7-8.5 do not interfere with the system.
i) Sulfhemoglobin is not measured with this method.
j) Values above 23.5 g/dL (235 g/L, 14.6 mmol/L) must be confirmed using a suitable laboratory method.

Interference studies have been performed according to NCCLS Document EP7-P Vol 6 No 13[12]

Expected values[9]

Adult males	13.0 - 17.0 g/dL (130 - 170 g/L, 8.1 - 10.5 mmol/L)
Adult females	12.0 - 15.0 g/dL (120 - 150 g/L, 7.4 - 9.3 mmol/L)
Infants after neonatal period	11.0 - 14.0 g/dL (110 - 140 g/L, 6.8 - 8.7 mmol/L)

Children, 2 years to teenage, gradually increase to adult normals.
Due to the wide range of conditions (dietary, geographical, etc) which affect normal values, it is recommended that each laboratory establish its own normal range.

Specific performance characteristics

The results given below in "Within-run precision" and "Total precision" come from one batch of HemoCue Hb 201 Microcuvettes and five HemoCue Hb 201+ analyzers. No restandardization was done during the analyzing period. The results given in the "Correlation Study" came from one HemoCue Hb 201+ analyzer which had not been restandardized during the study period. ICSH is the international reference method for hemoglobin determination(HiCN).

Within-run and Total precision
Within-run precision was determined according to the NCCLS Document EP5-A Vol 19 No 2[11]. Commercially available controls at two different levels were used. The hemoglobin concentration was measured in duplicate twice a day, morning and afternoon, during twenty consecutive days on five analyzers. A new vial of each control level was used every day.

Control level	N	x g/dL	Within-run Precision		Total Precision	
			SD g/dL	CV %	SD g/dL	CV %
1	400	7.70	0.057	0.74	0.100	1.30
2	400	15.36	0.078	0.51	0.109	0.71

$$SD = \sqrt{\frac{\sum d^2}{2n}}$$ where d is the difference between two microcuvettes and n is the number of blood samples in the study.

Correlations Studies
A number of correlation studies of the HemoCue Hb 201 system have been performed.
The results of the comparison studies between the HemoCue Hb 201 system and other hemoglobin methods are summarized in the table below.

Study	N	Min g/dL	Max g/dL	Regression line	Correlation coeffecient (r)
1	138	4.6	19.9	Y = 1.045X – 0.126	0.999
2	120	7.4	18.7	Y = 1.015X + 0.100	0.999
3	120	4.4	20.1	Y = 1.012X – 0.219	0.999
4	120	4.2	20.6	Y = 0.995X + 0.275	0.998
5	498	4.3	20.5	Y = 1.017X – 0.276	0.994
6	53	7.8	16.3	Y = 1.032X – 0.122	0.997
7	498	4.1	21.0	Y = 0.981X + 0.139	0.998

1 = Beckman Coulter GEN-S, venous EDTA blood
2 = Advia 120, venous EDTA blood
3 = Cell-Dyn 4000, venous EDTA blood
4 = Sysmex XE2100, venous EDTA blood
5 = ICSH[1] (Cyanmethemoglobin method), venous EDTA blood, multicenter study
6 = Beckman Coulter GEN-S, venous EDTA blood
7 = B-Hemoglobin, venous EDTA blood, multicenter study

[1]International Council for Standardization in Haematology

Patent

The HemoCue Hb 201+ Microcuvette is covered by United States Patent 5,674,457.

Bibliography

1. Stadie, W.C., J. Biol. Chem. 41, 237 (1920)
2. Drabkin, D.L. and Austin J.H., J. Biol. Chem. 98, 719 (1932)
3. Austin, J.H. and Drabkin, D.L., J. Biol. Chem. 112, 67 (1935-36)
4. Van Kampen, E.J. and Zijlstra, W.G., Clin. Chem. Acta 6, 538 (1961)
5. Vanzetti, G., Am. J. Lab. & Clin. Med. 67. 116 (1966)
6. Dacie and Lewis. Practical Haemotology, Ninth Edition, 2001.
7. G.Kwant et al. Clin. Lab. Haaemat. Calibration of a practical hemoglobinometer, 1987,9 387-393.
   Gradwohl's Clinical Laboratory Methods and Diagnosis, Frankel, S., Reitman, S. and Sonnenwith, A.C., Editors, C.V. Mosby Co., St. Louis, 7th Edition, 1970 Vol, 1, p. 405
8. ICSH Standard EP 6/2: 1977, Standard EP 6/3: 1977, V. Clin. Path. 3/1 139-143 (1978)
9. Makarem, A., Henry R.J., Cannon, D.C., and Winkelman, J.W., Eds., Harper and Row, Hagerstown, MD, In Clin. Chem. Principles and Technics, 2nd ed., 1974, pp. 1127-1147
10. Wallach, J. Interpretation of Diagnostic Tests, 1st ed., Little, Brown and Company, Boston, MA, 1970, pp. 6-7
11. Evaluation of precision performance of clinical chemistry devices; approved Guideline NCCLS Document EP5-A Vol 19 No 2 Feb 1999
12. Interference testing in clinical chemistry NCCLS proposed guideline; NCCLS Document EP7-P Vol 6 No 13
13. Burtis, Carl A.; Ashwood Edward R., Tietz Fundamentals of Clincal Chemistry, Fifth edition
14. HemoCue® Hb 201+ Operating Manual.

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HemoCue Hb 201+

Operating Manual
Manual de Operación
Manuel d'utilisation
Manual de operações

HEMOCUE®

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HemoCue Hb 201+ *Operating Manual*
HemoCue Hb 201+ *Manual de operações*
HemoCue Hb 201+ *Manuel d'utilisation*
HemoCue Hb 201+ *Manual de operações*

US

The HemoCue Hb 201+ analyzer provides determination of hemoglobin quickly, easily and with lab quality results. Capillary, venous or arterial whole blood may be used. The analyzer is shipped either in the "enhanced" mode, which stores test results, date and time for up to 600 measurements, or in the "standard" mode, which lacks these features. If the analyzer is in the standard mode, sections titled Setup do not apply. To change the current mode or for further information, contact your HemoCue distributor or HemoCue Inc.

ES

HemoCue 201+ es un analizador para la determinación de hemoglobina de forma rápida y sencilla, con calidad de laboratorio. Puede usarse sangre completa capilar, venosa o arterial. El sistema HemoCue 201+, ligero, portátil y con opción de corriente de red, es adecuado como unidad de uso estacionario y móvil. El analizador tiene memoria para guardar resultados de prueba con fecha y hora para 600 mediciones. Este manual de operación contiene las instrucciones básicas para el empleo rutinario y especificaciones técnicas del aparato. Para más información, consulte con su distribuidor local de HemoCue o póngase en contacto directamente con HemoCue.

CFR

L'analyseur HemoCue Hb 201+ permet la détermination simple et rapide du taux d'hémoglobine. Les résultats obtenus sont d'une qualité équivalente à ceux d'un laboratoire. Les mesures peuvent être réalisées sur du sang artériel, veineux ou capillaire. Cet appareil peut mémoriser 600 résultats reportant date heure de chaque mesure, en mode "développé". Il peut aussi être vendu en mode "standard", lequel ne dispose pas de ces fonctions. Les sections intitulées "Configurer" vous seront alors inutiles. Pour changer le mode d'utilisation ou pour d'obtenir des informations supplémentaires, vous pouvez contacter votre distributeur HemoCue ou la société HemoCue AB.

PT

O analisador HemoCue 201+ proporciona a determinação da hemoglobina com rapidez, facilidade e com resultados de qualidade laboratorial. Pode ser usado sangue completo capilar, venoso ou arterial. Sendo leve e portátil, e tendo ainda uma opção de alimentação por corrente, o sistema HemoCue 201+ está igualmente adaptado tanto a uso estacionário como móvel. O analisador guarda resultados de testes, com data e hora até um máximo de 600 medições. Este manual fornece as instruções básicas de rotina bem como as especificações técnicas. Mais informações podem ser obtidas do seu concessionário HemoCue ou directamente da HemoCue.

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Components
Componentes
Composants
Componentes

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US

1. The HemoCue Hb 201+ analyzer
2. AC adaptor
3. 4 type AA batteries*
4. A vial of HemoCue Hb 201 Microcuvettes*
5. Individually packaged HemoCue Hb 201 Microcuvettes*

The HemoCue Hb 201+ and its adaptor are delivered in a carton. Open the carton on a stable surface and lift out the instrument and accessories. On the bottom of the analyzer there is a lid covering the battery compartment. Press the flap to remove the lid. Place 4 type AA batteries in the battery compartment, observing the indication of polarity in the battery holders. Replace the lid. Consult local environmental authorities for proper disposal of batteries.

* Not included.

ES

1. Analizador HemoCue Hb 201+
2. Adaptador de red
3. 4 pilas AA o R6 de 1.5 V.*
4. Un contenedor de microcubetas HemoCue Hb 201.*
5. Microcubetas HemoCue Hb 201 en envases individuales.*

El aparato HemoCue Hb 201+ y su adaptador de red se entregan en una caja.
Abrir la caja sobre una superficie estable y sacar el analizador y los accesorios.
Desechar las pilas gastadas observando la normativa medioambiental vigente.

* No incluidos.

CFR

1. L'analyseur HemoCue Hb 201+.
2. Un adaptateur secteur.
3. 4 piles de type R6 ou AA, 1.5 V.*
4. Un flacon de microcuvettes HemoCue Hb 201.*
5. Des microcuvettes HemoCue Hb 201 en emballage individuel.*

L'analyseur HemoCue Hb 201+ et son adaptateur sont livrés dans une boîte en carton. Ouvrir le carton sur une surface stable et sortir l'instrument et ses accessoires en les soulevant. En bas de l'analyseur se trouve un couvercle de protection du logement pour piles. Appuyer sur la languette pour ôter le couvercle. Placer les piles dans leur logement, en respectant les indications de polarité indiquées dans le compartiment. Refermer le couvercle Pour l'élimination des piles usagées, consulter les autorités compétentes locales.

* Non fournis.

PT

1. Analisador HemoCue Hb 201+.
2. Transformador de corrente.
3. 4 pilhas de tipo AA ou R6, 1.5 V.*
4. Um frasco de Microcuvettes HemoCue Hb 201*
5. Microcuvetes HemoCue Hb 201 de embalagens unitárias*

O HemoCue Hb 201+ e o seu transformador de corrente são entregues numa caixa de cartão. Abra a caixa sobre uma superfície estável e levante o analisador e acessórios. Consulte as autoridades ambientais locais para um descarte legal das pilhas.

* Não incluído.

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US

1a. If AC power is available, plug the supplied power adapter into the power inlet at the back of the analyzer.
1b. If no power is available, insert the 4 type AA batteries, 1.5 V, into the battery compartment.
1c. If a battery symbol appears on the display, the batteries are running low on power. The analyzer will continue to give accurate results, but the batteries should be replaced as soon as possible.
2. Connection ports for printer and PC *(only applicable for the enhanced* mode)
3. Pull the cuvette holder out to the loading position.
4. Press and hold the left button until the display is activated (all symbols appear on the display).
5. The display shows the version number of the program, after which it will show "⧗" and "Hb". During this time the analyzer will automatically verify the performance of the optronic unit.
6. After 10 seconds, the display will show three flashing dashes and the HemoCue symbol. This indicates that the HemoCue *Hb 201+ is ready for use.*

To turn the analyzer off, press and hold the left button until the display reads OFF and then goes blank. Disconnect the equipment from the power source by removing the AC adaptor from the outlet.

ES

1a. Si se dispone de corriente de red, conectar el adaptador en la toma de la parte posterior.
1b. Si no se dispone de corriente de red, poner 4 pilas tipo AA o R6 de 1.5 V en el compartimento de pilas.
1c. Si se visualiza un símbolo de pila en la pantalla, es señal de que la carga de las pilas es baja. El analizador seguirá presentando resultados precisos, pero es necesario cambiar las pilas cuanto antes.
2. El analizador se puede conectar a un PC *(para más información, consultar la* página 9 o el manual de la conexión del PC) o directamente a una impresora (ver la página 26).
3. Poner el soporte de cubeta en la posición de carga.
4. Mantener presionado el botón izquierdo hasta que se active la pantalla (se visualizan todos los símbolos en la pantalla).
5. La pantalla muestra el número de versión del programa y, a continuación, "⧗" y "Hb". Durante este tiempo el analizador verifica automáticamente el funcionamento de la unidad óptica.
6. Después de 10 segundos, la pantalla *mostrará tres rayas parpadeantes y el* símbolo de HemoCue. Esto indica que el HemoCue Hb 201+ está preparado para funcionar.

Para apagar el analizador, pulsar y mantener presionado el botón izquierdo hasta que la pantalla muestre OFF y se apague.

CFR

1a. Pour l'alimentation secteur, connecter l'adaptateur à la prise située à l'arrière de l'analyseur.
1b. Si l'alimentation secteur n'est pas disponible, *mettre 4 piles 1.5 V de type AA ou* R6 dans le compartiment piles.
1c. Si un symbole de pile s'affiche à l'écran, cela indique que les piles sont faibles. L'analyseur continue à donner des résultats précis, mais les piles doivent être remplacées au plus tôt.
2. L'analyseur peut être connecté à un PC (applicable uniquement pour le mode développé).
3. Extraire le support de cuvette dans sa position de charge.
4. Appuyer sur la touche de gauche et la maintenir enfoncée jusqu'à activation de l'écran (tous les symboles s'affichent).
5. L'écran affiche le numéro de version du programme, puis le symbole "6" et "Hb". Entre temps, l'analyseur exécute automatiquement un vérification du bon fonctionnement de la cellule optique.
6. Au bout de 10 secondes, trois tirets clignotants apparaissent à l'écran sous le symbole HemoCue, indiquant que l'HemoCue Hb 201+ est prêt à fonctionner.

Pour éteindre l'analyseur, appuyer sur la touche de gauche et maintenir la pression jusqu'à ce que ce que l'écran indique OFF puis s'éteigne. Débrancher l'appareil en ôtant l'adaptateur de la prise.

PT

1a. Se tiver transformador, conecte-o à tomada situada por trás.
1b. Se não tiver transformador, insira as 4 pilhas de tipo AA ou R6, 1.5 V, no *compartimento das mesmas.*
1c. Se o símbolo de pilha aparecer no écran, é porque as pilhas estão gastas. O analisador continuará a fornecer resultados precisos, mas as pilhas têm de ser substituídas o mais depressa possível.
2. O analisador pode ser conectado a um PC (para mais informações, ver página 9 ou manual separado para conexão com PC) ou directamente a uma impressora (ver página 26).
3. Puxe o porta-cuvetes para a sua posição de carga.
4. Prima e segure a tecla esquerda até que seja activado o écran (todos os símbolos *aparecem no écran).*
4. O écran exibe o número de versão do programa, depois do que apresentará "⧗" e "Hb". Depois deste tempo o analisador verificará automaticamente o funcionamento da unidade optrónica.
6. Ao fim de 10 segundos o écran exibirá três traços a piscar e o símbolo HemoCue. Isto indica que o HemoCue Hb 201+ está pronto a ser usado.

Para desligar o analisador, prima e segure a tecla esquerda até que o écran mostre OFF e fique vazio.

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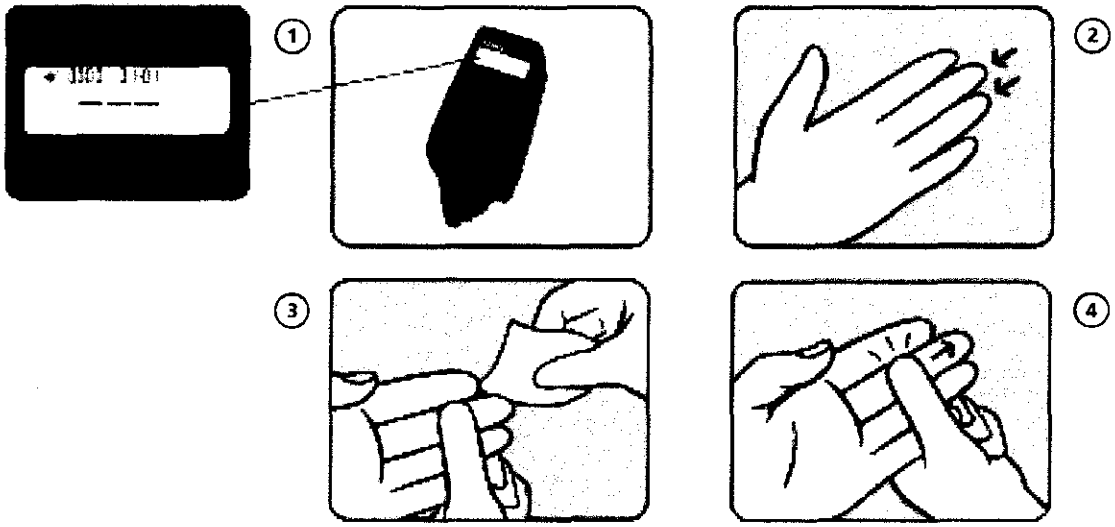
Measuring Capillary blood

Medição Sangue capilar

Mesure Sang capillaire

Meting Capillair bloed



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US

1. To perform a test using capillary blood, the cuvette holder should be in its loading position. The display will show three flashing dashes and the HemoCue symbol.
2. Make sure the patient's hand is warm and relaxed. Use only the middle or ring finger for sampling. Avoid fingers with rings on.
3. Clean with disinfectant and allow to dry or wipe off with a dry, lint-free wipe.
4. Using your thumb, lightly press the finger from the top of the knuckle towards the tip. This stimulates the blood flow towards the sampling point.

ES

1. Después de la activación, el soporte de cubeta debe estar en su posición de carga. La pantalla mostrará tres rayas parpadeantes y el símbolo de HemoCue.
2. Comprobar que la mano del paciente esté caliente y relajada. Usar solamente el dedo medio o el dedo anular para sacar muestras. No usar dedos con anillos puestos.
3. Limpiar con desinfectante y dejar que éste se seque.
4. Presionar suavemente el dedo desde la parte superior del nudillo hasta la punta, con el pulgar. Así se estimula el flujo sanguíneo hacia el punto de toma de la muestra.

CFR

1. Après le démarrage de l'appareil, le support de cuvette doit se trouver en position de charge. Trois tirets clignotants et le symbole HemoCue apparaissent à l'écran.
2. S'assurer que la main du patient est chaude et détendue. Le prélèvement devra être effectué sur le majeur ou l'annulaire. Éviter de porter des bagues pendant la manipulation.
3. Nettoyer avec un désinfectant le bout du doigt à piquer et laisser sécher ou essuyer avec une serviette sèche et non pelucheuse.
4. Avec le pouce, presser doucement le doigt, de l'articulation vers l'extrémité, pour stimuler la circulation du sang vers la zone de prélèvement.

PT

1. Depois do início, o porta-cuvete deve estar na sua posição de carga. O écran mostra três traços a piscar e o símbolo HemoCue.
2. Assegure-se de que a mão do doente está quente e relaxada. Use apenas o dedo médio ou anelar para tirar provas. Evite dedos com anéis.
3. Limpe com desinfectante e deixe secar.
4. Com o seu polegar, massage levemente o dedo do nó para a ponta. Isto estimula o fluxo de sangue para o ponto de colheita da prova.

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US

5. For best blood flow and least pain, sample at the side of the fingertip, not in the center.
6. While applying light pressure towards the fingertip, puncture the finger using a lancet.
7. Wipe away the first 2 or 3 drops of blood.
8. Re-apply light pressure towards the fingertip until another drop of blood appears.

ES

5. Para obtener un flujo sanguíneo óptimo y reducir al mínimo el dolor, tomar la muestra en un lado de la punta del dedo, y no en el centro.
6. Pinchar el dedo con una lanceta, presionando al mismo tiempo con suavidad hacia la punta del dedo.
7. Limpiar las 2 ó 3 primeras gotas de sangre.
8. Aplicar de nuevo una suave presión hacia la punta del dedo hasta que salga otra gota de sangre.

CFR

5. Pour une meilleure circulation du sang et pour occasionner moins de douleur, prélever l'échantillon sur la face latérale du doigt, pas en pleine pulpe.
6. En pressant délicatement vers le bout du doigt, piquer le point de prélèvement avec une lancette.
7. Essuyer les 2 ou 3 premières gouttes de sang.
8. Exercer à nouveau une légère pression vers le bout du doigt jusqu'à ce qu'apparaisse une nouvelle goutte de sang.

PT

5. Para melhor fluxo de sangue e menos dôr, colha a prova do lado e não do centro da ponta do dedo.
6. Pressionando levemente contra a ponta do dedo, dê um golpe no dedo com uma lanceta.
7. Limpe as 2 ou 3 primeiras gotas de sangue.
8. Torne a fazer pressão contra a ponta do dedo até vir mais uma gota de sangue.

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US

9. When the blood drop is large enough, fill the microcuvette in one continuous process. Do NOT refill!
10. Wipe off excess blood from the outside of the microcuvette with a clean, lint-free tissue, being careful not to touch the open end of the microcuvette, which could result in blood being drawn out of the microcuvette.
11. Look for air bubbles in the filled microcuvette. If present, discard the microcuvette and fill a new microcuvette. Small bubbles around the edge can be ignored.

ES

9. Cuando la gota de sangre sea suficientemente grande, llenar la cubeta en un proceso continuo. ¡NO rellenar!
10. Limpiar la sangre sobrante en la parte exterior de la punta de la cubeta. Al hacerlo, procurar no sacar sangre de la cubeta.
11. Ver si hay burbujas de aire en la cubeta llena. De haberlas, tomar una nueva muestra. Puede hacerse caso omiso de las burbujas pequeñas alrededor del borde.

CFR

9. Quand la goutte de sang est assez grande, appliquer la microcuvette et la laisser se remplir d'une seule traite. Ne jamais remplir une seconde fois.
10. Nettoyer la surface externe de la cuvette de toute trace de sang avec un tissu propre et non pelucheux en prenant bien soin de ne pas toucher l'ouverture de la microcuvette, ce qui risquerait de laisser s'échapper du sang de l'intérieur.
11. Vérifier que la cuvette remplie ne contienne pas de bulles d'air. Dans le cas contraire, jeter la microcuvette et prélever un autre échantillon. Ne pas tenir compte d'éventuelles petites bulles d'air autour du bord de la cuvette.

PT

9. Quando a gota de sangue for suficientemente grande, encha a cuvete num processo contínuo. NÃO tornar a encher!
10. Limpe o sangue em excesso fora da ponta da cuvete. Assegure-se de que não saiu nenhum sangue da cuvete durante este procedimento.
11. Veja se há bolhas de ar na cuvete cheia. Se houver, tire outra prova. Bolhinhas à volta da ponta podem ser ignoradas.

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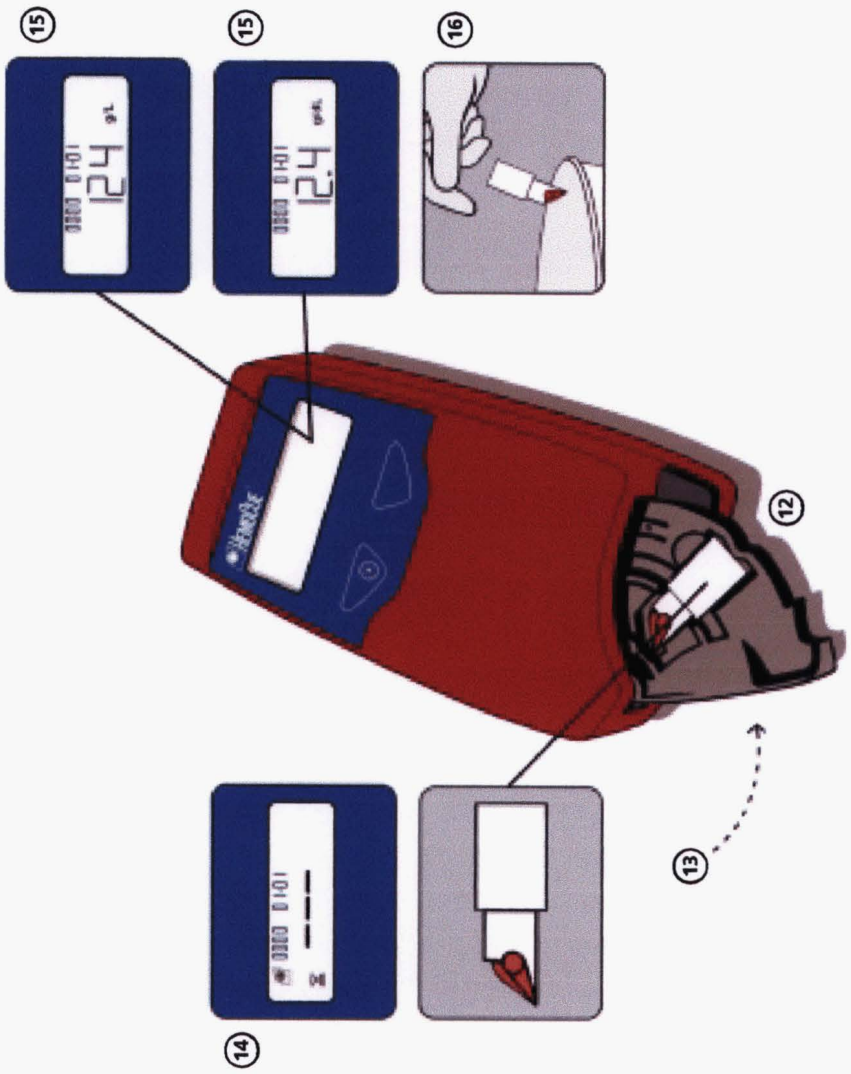

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US

12. Place the filled microcuvette in the cuvette holder. This must be performed within ten minutes after filling the microcuvette!
13. Push the cuvette holder to the measuring position.
14. During the measurement "⌛" will be shown on the display.
15. After 15–60 seconds, the hemoglobin value of the sample is displayed. The result will remain on the display as long as the cuvette holder is in the measuring position. When operating on battery power, the analyzer will automatically turn off after approximately 5 minutes.
16. Although the reagents are present in the microcuvette in extremely low quantities, consult local environmental authorities for proper disposal. Always handle blood specimens with care, as they might be infectious.

ES

12. Colocar la cubeta llena en el soporte de cubeta. ¡Esta operación debe hacerse dentro de un lapso de 10 minutos después de llenar la cubeta!
13. Poner el soporte de cubeta en la posición de medición.
14. Durante la medición se visualiza "⌛" en la pantalla.
15. Después de un lapso de 15–60 segundos se visualiza en la pantalla el valor de glucosa de la muestra. El resultado permanecerá en la pantalla mien tras el soporte de cubeta esté en la posición de medición. En el funcionamiento con pilas, el analizador se des activa automáticamente después de aproximadamente 5 minutos si no es utilizado.*
16. Aunque la cubeta contiene cantidades extremadamente bajas de reactivos, consultar con la autoridad ambiental en cuanto a la forma de desecharlas. Manipular siempre las muestras de sangre con cuidado porque pueden ser infecciosas.

CFR

12. Placer la cuvette remplie dans le support de cuvette. Cette opération doit être réalisé dans les dix minutes qui suivent le remplissage de la microcuvette.
13. Pousser le support dans sa position de mesure.
14. Pendant la mesure, le symbole "⌛" s'affiche à l'écran.
15. 15 à 60 secondes après, la valeur du taux d'hémoglobine de l'échantillon s'affichera et le restera aussi longtemps que le support de cuvette est maintenu en position de mesure. Si l'analyseur fonctionne à piles, il s'éteindra automatiquement après 5 minutes environ s'il n'est pas utilisé.
16. Bien que les réactifs ne soient présents dans les microcuvettes qu'en quantités infinitésimales, consulter les autorités locales compétentes en matière d'environnement pour leur élimination. Pour éviter tout risque de contamination, il faudra toujours manipuler les échantillons de sang avec la plus grande précaution.

PT

12. Coloque a cuvete cheia no porta-cuvetes. Isto deve ser realizado dentro de 10 minutos depois de encher a cuvete!
13. Empurre o porta-cuvete para a sua posição de medição.
14. Durante a medição aparecerá "⌛" no écran.
15. Ao fim de 15–60 segundos o valor da glicose da prova será exibido no écran. O resultado permanecerá no écran enquanto o porta-cuvetes estiver na posição de medição. Se estiver a trabalhar a pilhas, o analisador desliga-se automaticamente depois de uns 5 minutos de inactividade.*
16. Embora os reagentes se encontrem na cuvete em quantidades extremamente pequenas, consulte as autoridades ambientais para descarte adequado. Manuseie sempre provas de sangue com cuidado, pois podem estar infectadas.

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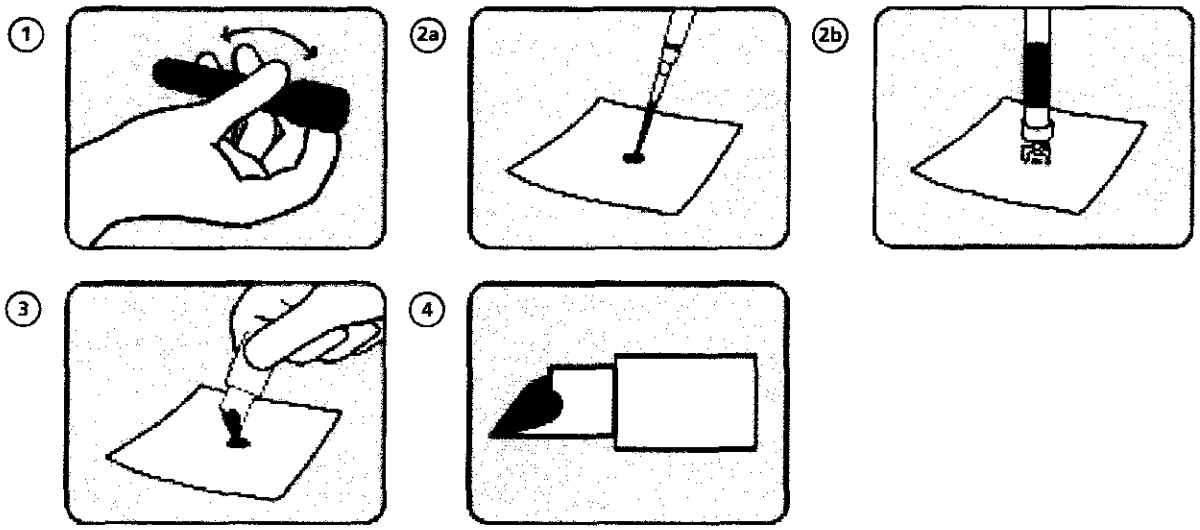
Measuring Control material, venous or arterial blood

Medición de sangre venosa o arterial

Mesure Echantillon de contrôle, Sang veineux et artériel

Medição Sangue venoso ou arterial



0119
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US

The HemoCue Hb 201 system can be verified on the days of testing through the use of commercially available hemotology controls recommended by HemoCue.

1. The blood or control material should be well mixed prior to performing a measurement.

2ab. Place a drop of blood or control material onto a hydrophobic surface, e.g., a plastic film, using a pipette or a DIFF-Safe™.

3. Fill the microcuvette in one continuous process. Do NOT refill! Wipe off excess blood from the outside of the microcuvette with a clean, lint-free tissue, being careful not to touch the open end of the microcuvette, which could result in blood being drawn out of the microcuvette.

4. Look for air bubbles in the filled microcuvette. If present, discard the microcuvette and fill a new microcuvette. Small bubbles around the edge can be ignored.

Perform the analysis as per steps 12–16 on page 15.

ES

1. Mezclar bien la sangre antes de hacer la medición.

2ab. Poner una gota de sangre en una superficie hidrofóbica, como una película de plástico, utilizando una pipeta o un DIFF-Safe™.

3. Llenar la cubeta en un proceso continuo. ¡NO rellenar! Limpiar la sangre sobrante en la parte exterior de la punta de la cubeta. Al hacerlo, procurar no sacar sangre de la cubeta.

4. Ver si hay burbujas de aire en la cubeta llena. De haberlas, tomar una nueva muestra. Puede hacerse caso omiso de las burbujas pequeñas alrededor del borde.

Hacer el análisis siguiendo los pasos 12–16 de la página 17.

CFR

On peut vérifier le bon fonctionnement du système Hemocue Hb 201 lors des jours de test, grâce à des échantillons de contrôle vendus dans le commerce et recommandés par HemoCue.

1. Bien mélanger l'échantillon de sang ou l'échantillon de contrôle avant d'effectuer la mesure.

2ab. Placer une goutte de sang ou de l'échantillon de contrôle sur une surface hydrophobe, par exemple un film plastique, en utilisant une pipette ou un DIFF-Safe™.

3. Laisser la cuvette se remplir d'une seule traite. Ne jamais s'y reprendre à deux fois. Nettoyer la surface externe de la cuvette de toute trace de sang avec un tissu propre et non pelucheux en prenant bien soin de ne pas toucher l'ouverture de la microcuvette, ce qui risquerait de laisser s'échapper du sang de l'intérieur.

4. Vérifier qu'il n'y ait pas de bulles d'air dans la cuvette remplie. Dans le cas contraire, prélever un autre échantillon. Ne pas tenir compte d'éventuelles petites bulles sur le bord de la cuvette. Effectuer l'analyse en exécutant les opérations.

De 12 à 16 décrites à la page15.

PT

1. Misture bem o sangue antes de fazer a medição.

2ab. Coloque uma gota de sangue sobre uma superfície hidrófoba, por exemplo uma película de plástico, usando uma pipeta ou DIFF-Safe™.

3. Encha a cuvete de uma só vez. NÃO tornar a encher! Limpe o excesso de sangue no exterior da ponta da cuvete. Assegure-se de que não saiu nenhum sangue da cuvete durante este procedimento.

4. Veja se há bolhas de ar na cuvete cheia. Se houver, tire outra prova. Bolhinhas à volta da ponta podem ser ignoradas.

Faça os passos da análise 12–16 na página 17.

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US

The cuvette holder should be cleaned after each day of use.

1. Check that the analyzer is turned off. The display should be blank.
2. Pull the cuvette holder out to its loading position. Carefully press the small catch positioned in the upper right corner of the cuvette holder.
3. While pressing the catch, carefully rotate the cuvette holder towards the left as far as possible. Carefully pull the cuvette holder away from the analyzer.
4. Clean the cuvette holder with alcohol or mild detergent. It is important that the cuvette holder is completely dry before being replaced.

A dirty optronic unit may cause the analyzer to display an error code. To clean the optronic unit, proceed as follows.

5. Push the HemoCue Cleaner* swab into the opening of the cuvette holder. Move from side to side 5 –10 times. If the swab is stained, repeat with a new swab. No further cleaning is required if the swab remains clean.
6. Wait 15 minutes before replacing the cuvette holder and using the analyzer.

The cover may be cleaned with alcohol or a mild soap solution.

*Not included. As an alternative to the HemoCue Cleaner, a cotton tip swab moistened with a alcohol (without additive) or water may also be used for cleaning.

ES

1. Comprobar que el analizador esté desconectado. La pantalla debe estar en blanco.
2. Poner el soporte de cubeta en la posición de carga. Con un objeto puntiagudo, presionar con cuidado el enganche pequeño situado en la parte superior derecha del soporte de cubeta.
3. Con el enganche presionado, tirar del soporte de cubeta hacia el lado izquierdo tanto como se pueda. Sacar con cuidado el soporte de cubeta en la dirección de la empuñadura del mismo.
4. Limpiar el soporte de cubeta con alcohol o un detergente suave.
5. Insertar un paño HemoCue Cleaner* en la abertura del soporte de cubeta. Introducirlo y sacarlo de 5 a 10 veces. Si el paño se mancha, repetir el procedimiento con un paño nuevo. Interrumpir la limpieza cuando el paño salga limpio.
6. Esperar 15 minutos antes de volver a utilizar el analizador. Colocar el soporte de cubeta.

La tapa se puede limpiar con alcohol o con una solución jabonosa suave.

* No incluido.

CFR

Le support de cuvette doit être systématiquement nettoyé à la fin de la journée, après usage.

1. Vérifier que l'analyseur est éteint et l'écran vide.
2. Extraire le support de cuvette pour le mettre en position de charge. Utiliser un objet pointu pour abaisser avec précaution le petit fermoir situé dans le coin supérieur droit du support.
3. En gardant le fermoir abaissé, tirer le support aussi loin que possible vers la gauche. Sortir le support de cuvette avec précaution en l'écartant de l'analyseur.
4. Nettoyer le support de la cuvette avec de l'alcool ou un détergent doux. Il est important que le support de cuvette soit parfaitement sec avant d'être remis en place.

Quand la cellule optique est sale, l'analyseur risque d'afficher un message d'erreur. Pour nettoyer cette cellule optique, procéder ainsi:

5. Introduire le tampon HemoCue Cleaner* dans le logement vide du support de cuvette. Le faire glisser de gauche à droite 5 à 10 fois. Si le tampon est taché, recommencer avec un autre tampon, et ainsi de suite jusqu'à ce que le tampon reste propre.
6. Attendre 15 minutes avant de remettre en place le support de cuvette, pour pouvoir utiliser à nouveau l'analyseur.

La coque de l'analyseur peut être nettoyée avec de l'alcool ou une solution de savon doux.

* Non fourni. Si l'on ne dispose pas de HemoCue Cleaner, on peut nettoyer l'appareil avec l'extrémité d'un coton tige imbibé d'alcool (sans additif) ou d'eau.

PT

1. Verifique se o analisador está desligado. O écran deve estar vazio.
2. Puxe o porta-cuvete para a sua posição de carga. Use um objecto afilado para baixar cuidadosamente o fecho situado no canto superior direito do porta-cuvete.
3. Mantendo o fecho despressionado, puxe cuidadosamente o porta-cuvete o mais possível para o lado esquerdo. Puxe cuidadosamente o porta-cuvete para o lado apontado pelo manípulo.
4. Limpe o porta-cuvete com álcool ou detergente suave.
5. Empurre a esponja do HemoCue Cleaner* na abertura do porta-cuvete. Puxe para fora e empurre para dentro 5 –10 vezes. Se a esponja estiver corada repita com uma nova. Páre quando a esponja sair sem estar corada.
6. Aguarde 15 minutos antes de tornar a usar o analisador. Colocar o portacuvete.

A cobertura pode ser limpa com álcool ou com detergente líquido suave.

* Não incluído.

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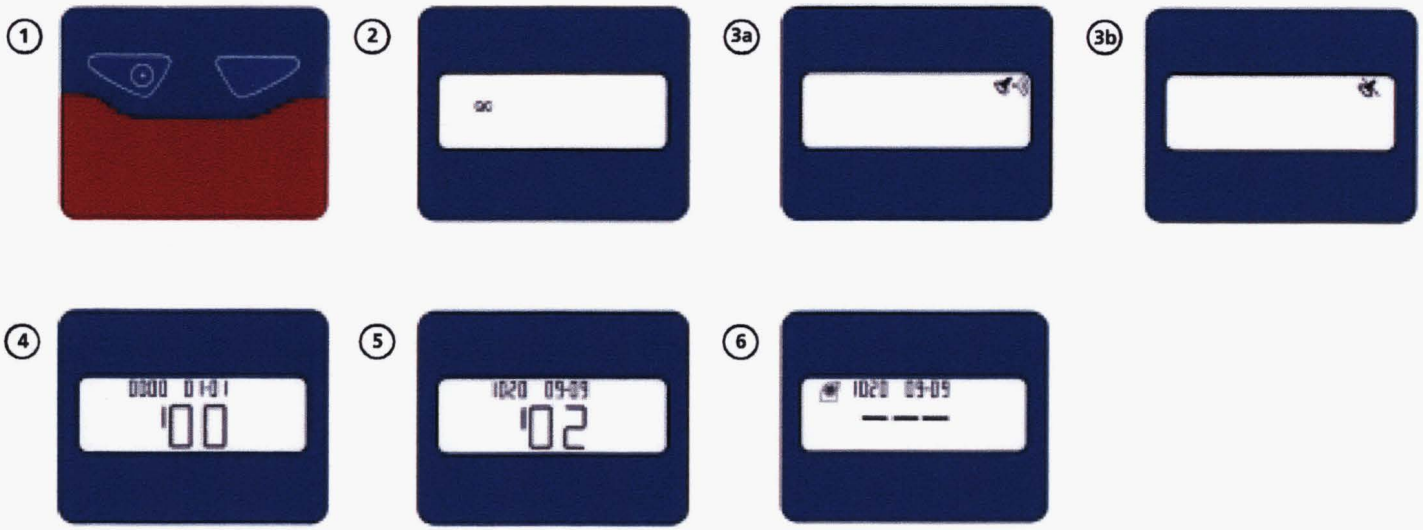
Set-up Audio signal, time and date

Configuración Señal acústica, hora y fecha

Configurer Signal sonore, heure et date

Configuração Sinal sonoro, hora e data



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US

The time and date function within the set-up menu must be activated before data can be transferred to a PC.

1. Press both buttons at the same time.
2. The display now shows a flashing QC-symbol.

3ab. Use the right button to scroll until the display shows an audio symbol in the upper right corner. The signal can be activated or deactivated by pressing the left button.

4. Continue to scroll using the right button until the display shows characters for time, date and year. The hour figure will be flashing.
5. To change the hour, either hold the left button down for faster advancement or press and release the left button to advance slowly. When the desired hour is displayed, press and release the right button. The minute figure will then be flashing. Proceed as above until desired time, year and date are obtained.
6. When all the settings are completed, hold the right button down for approximately 5 seconds. The analyzer will then automatically return to the measuring position.

The analyzer is supplied with default time and date settings. These settings can only be changed by using the PC program (for further information, see separate manual for PC connection).

ES

Las funciones de hora y fecha del menú de configuración deben ser activadas antes de poder transferir datos a un PC.

1. Presionar ambos botones simultáneaente.
2. La pantalla visualiza un símbolo de QC parpadeante.

3ab. Desplazar con el botón derecho hasta que la pantalla muestre un símbolo de audio en la parte superior derecha. La señal se puede activar o desactivar presionando el botón izquierdo.

4. Seguir desplazando con el botón derecho hasta que la pantalla muestre los caracteres de hora, fecha y año. La cifra de la hora parpadea.
5. Usar el botón derecho para cambiar entre horas, minutos, año, día y mes. Para cambiar una cifra parpadeante, mantener presionado el botón izquierdo para el avance rápido o presionarlo y soltarlo para avanzar despacio.
6. Una vez terminada la configuración, mantener presionado el botón derecho durante aproximadamente 5 segundos. El analizador volverá automáticamente a la posición de medición.

El analizador se entrega con hora y fecha predefinidas. Esta configuración sólo se puede cambiar con el programa de PC (para más información, ver el manual separado relativo a la conexión a un PC).

CFR

La fonction date et heure du menu de configuration doit être activée pour que les données puissent être transférées à un PC.

1. Appuyer sur les deux touches en même temps.
2. Sur l'écran s'affiche maintenant un symbole QC clignotant.

3ab. Utiliser la touche droite pour faire défiler l'affichage jusqu'à ce qu'apparaisse un symbole audio dans le coin en haut à droite. Le signal peut être activé ou désactivé en appuyant sur la touche gauche.

4. Continuer à faire défiler le menu avec la touche droite jusqu'à affichage des caractères indiquant l'heure, la date et l'année. Le chiffre de l'heure doit alors clignoter.
5. Pour changer l'heure, vous pouvez soit garder la touche gauche appuyée pour avancer plus vite, soit l'appuyer et la relâcher pour avancer lentement. Quand vous voyez s'afficher l'heure adéquate, appuyez et relâchez la touche droite. Les minutes se mettent alors à clignoter. Procéder de la même manière, jusqu'à ce que vous ayez réglé l'heure, l'année et la date.
6. Quand tous les paramètres sont définis, maintenir appuyée la touche droite pendant 5 secondes environ. L'analyseur se remettra automatiquement en position de mesure.

L'analyseur est livré avec des paramètres heure et date par défaut. Ils ne peuvent être modifiés qu'en utilisant le logiciel PC (pour plus de renseignements, consulter le manuel de connexion PC).

PT

A função de hora e data no menú de regulação tem de ser activada antes de se poderem transferir dados para um PC.

1. Prima ambos os botões simultaneamente.
2. O écran exibe agora um símbolo QC a piscar.

3ab. Use a tecla da direita para desfolhar até que o écran mostre um símbolo de audio no canto superior direito. O sinal pode ser activado ou desactivado premindo-se a tecla esquerda.

4. Continue a desfolhar usando a tecla direita até que o écran mostre os caracteres de hora, data e ano. O caracter da hora estará a piscar.
5. Use a tecla direita para saltar entre horas, minutos, ano, e mês. Para mudar um número a piscar mantenha premido a tecla esquerda para avanço rápido, ou avance lentamente premindo a tecla e soltando-a rapidamente.
6. Quando tiver regulado tudo, mantenha a tecla premida durante 5 segundos, aproximadamente. O analisador volta automaticamente para a posição de medição.

O analisador está equipado de data e hora pré-reguladas. Esta configuração só pode ser alterada usando o programa do PC (para mais informações, ver o manual separado de conexão do PC).

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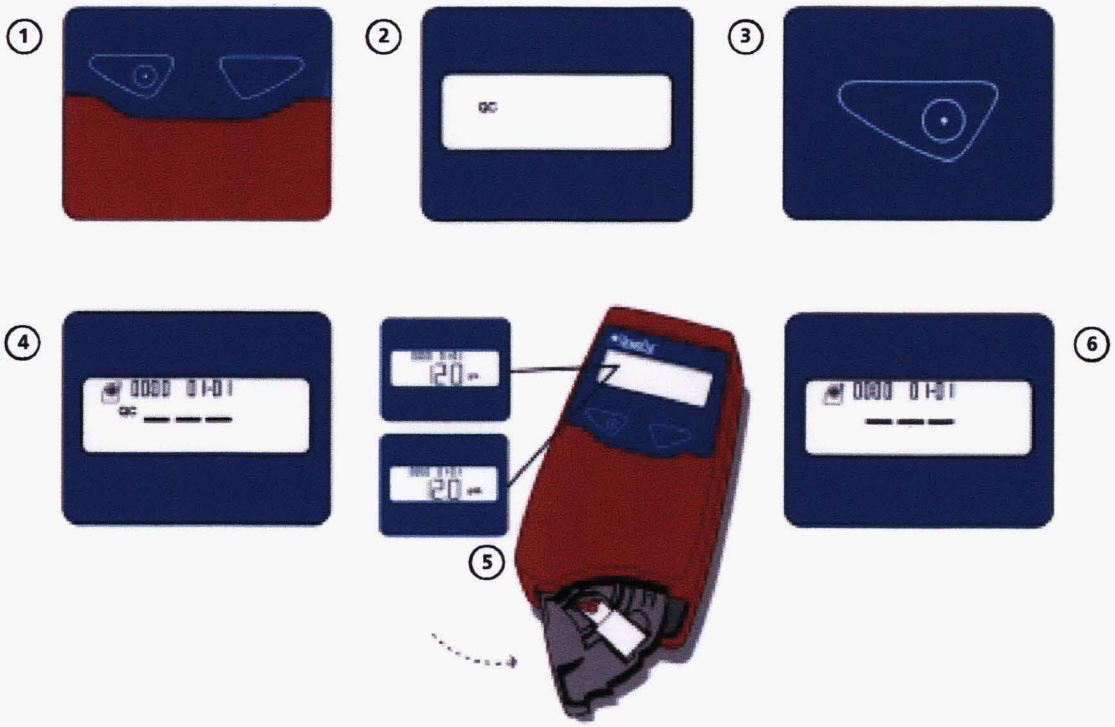
Set-up QC-test
Configuración Prueba de control de calidad (QC)
Configurer Test CQ
Configuração teste QC



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0125

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US

The HemoCue Hb 201 system can be verified on the days of testing through the use of commercially available hemotology controls recommended by HemoCue. To specifically identify QC results in the memory, proceed as follows.

1. Press both buttons at the same time.
2. The display shows a flashing QC-symbol.
3. Select QC-test by pressing the left button.
4. The analyzer automatically returns to the measuring mode and the QC-symbol appears in the display.
5. Fill the microcuvette with the control solution recommended by HemoCue and carry out the measurement in accordance with steps 12–16 on page 15.
6. Once the QC measurement has been made, the analyzer automatically returns to the measuring mode and the QC-symbol disappears from the display. Patient sampling can begin.

If more QC-tests are to be performed, proceed in the same way following steps 1–6.

ES

El sistema HemoCue se puede controlar diariamente con controles de sangre completa, hemolizado, o otros controles. Para obtener resultados fiables utilizar solamente los controles recomendados por HemoCue.

1. Presionar ambos botones simultáneamente.
2. La pantalla visualiza un símbolo de QC parpadeante.
3. Seleccionar la prueba QC presionando el botón izquierdo.
4. El analizador vuelve automáticamente a su posición de medición y se visualiza el símbolo de QC en la pantalla.
5. Llenar la cubeta con la solución de control recomendada por HemoCue y hacer la medición siguiendo los pasos 12–16 de la página 17.
6. Después de la medición, el analizador vuelve automáticamente a su posición de medición y el símbolo de QC desaparece de la pantalla. Puede iniciarse la toma de muestras del paciente.

Si son necesarias más pruebas de control de calidad, aplicar el mismo procedimiento de los pasos 1–6.

CFR

Le système HemoCue Hb 201 peut faire l'objet d'un contrôle qualité quotidien effectué sur des échantillons de contrôle disponibles dans le commerce, et recommandés par HemoCue. Pour identifier les résultats des tests de contrôle, procéder comme suit:

1. Appuyer sur les deux touches en même temps.
2. Un symbole QC clignotant apparaît à l'écran.
3. Sélectionner le test QC en appuyant sur la touche gauche.
4. L'analyseur se remet automatiquement en position de mesure et le symbole QC est affiché.
5. Remplir la cuvette avec la solution de contrôle recommandée par HemoCue et effectuer la mesure en exécutant les opérations de 12 à 16 de la page 15.
6. Une fois la mesure effectuée, l'analyseur retourne automatiquement en mode de mesure standard de mesure et le symbole QC disparaît de l'écran. L'appareil est prêt pour les tests sur les patients.

Si l'on doit réaliser plusieurs tests QC, procéder de la même manière en suivant les opérations de 1 à 6.

PT

O sistema HemoCue pode ser verificado diariamente com sangue total hemolisado ou outros controles. Para se obterem resultados fiáveis use apenas controles recomendados pela HemoCue.

1. Prima ambas as teclas simultaneamente.
2. O écran exibe um símbolo QC a piscar.
3. Seleccione o teste QC premindo a tecla da esquerda.
4. O analisador retorna automaticamente para a sua posição de medição e o símbolo QC aparece no écran.
5. Encha a cuvete com solução de controle recomendada pela HemoCue e faça as medições de acordo com os passos 12–16 na página 17.
6. Uma vez efectuada a medição, o analisador volta automaticamente à sua posição de medição, desaparecendo do écran o símbolo QC. Pode começar o teste ao doente.

Se tiver de fazer mais testes QC, proceda da mesma maneira seguindo os passos 1–6.

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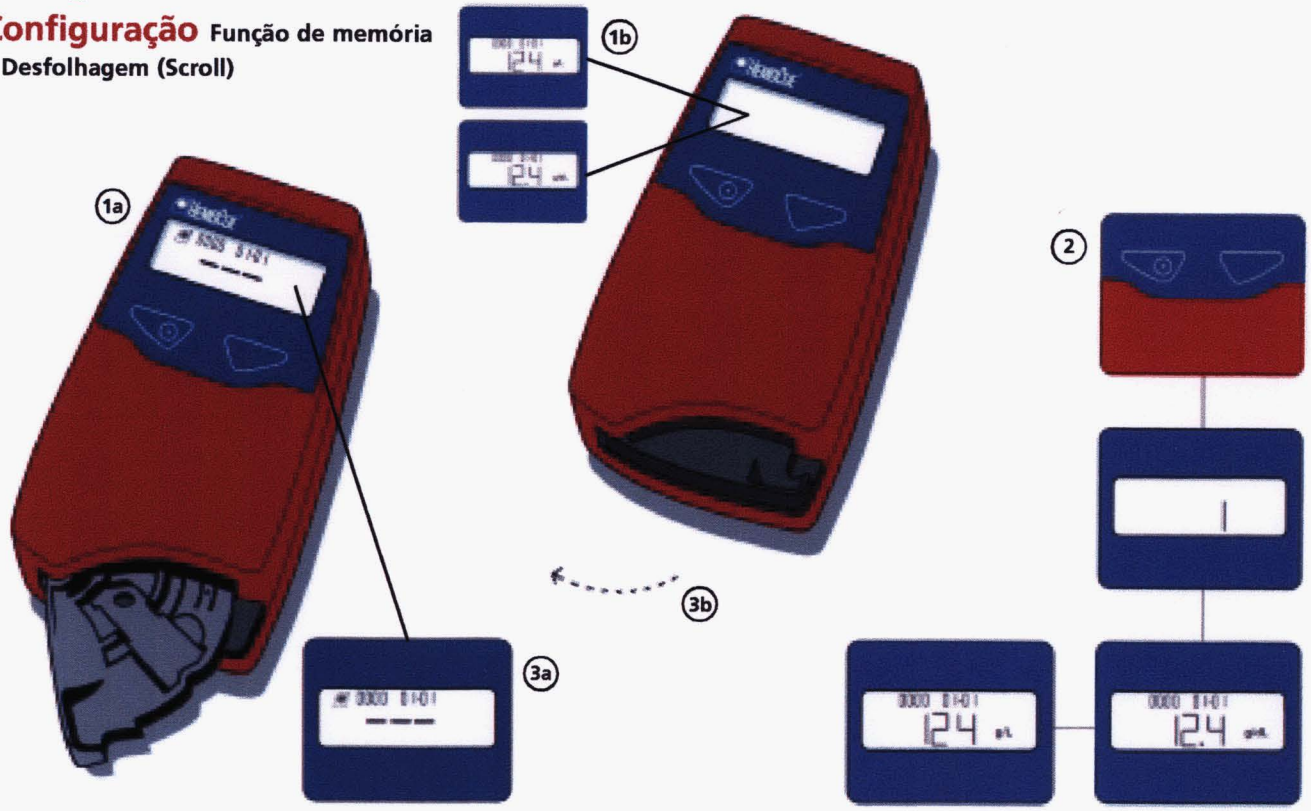
Set-up Memory function – Scroll

Configuración Función de memoria – Desplazamiento

Configurer Mode mémoire – Défilement

Configuração Função de memória – Desfolhagem (Scroll)



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0127

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US

The analyzer automatically stores up to 600 results. When the memory is full, the analyzer will automatically overwrite the oldest result. To view results stored in the memory, use the following procedure.

1ab. The cuvette holder may be in the loading position or in the measuring position. If in the measuring position, the most recent measurement is displayed.
2. Press the left or right button to scroll *backwards or forwards respectively* between the results. The stored values are now shown in the display. When the button is held down, the user can see the order of the results (the most recent measurement is always number 1) and when the button is released, the result is shown.
3ab. If no buttons are pressed while the cuvette holder is in the loading position, *the analyzer automatically* resets after 5 seconds and new measurements can be made. If in the measuring position, pull the cuvette holder out to the loading position and wait for the HemoCue symbol. The analyzer is then ready for a new measurement to be made.

Note: The analyzer will not respond to other *commands while a measurement is being* made. If the error code E35 is shown while scrolling through the results, the measurement has not been stored in the memory, see the trouble shooting guide on page 30.

ES

El analizador guarda automáticamente hasta *600 resultados. Cuando la memoria está llena,* el analizador sobrescribe automáticamente el resultado más antiguo. Procedimiento para ver los resultados guardados en la memoria:

1ab. El soporte de cubeta puede estar en la posición de carga o en la posición de medición. Si está en la posición de medición, se visualiza la medición más reciente.
2. Presionar el botón derecho o desplazar hacia atrás o adelante entre los resultados. Ahora, los valores guardados se visualizan en la pantalla. Manteniendo presionado el botón, el usuario puede ver el orden de los resultados (la medición más reciente tiene siempre el número 1). Al soltar el botón se visualiza el resultado.
3ab. Si no se presiona ningún botón mientras el soporte de cubeta está en posición de carga, el analizador se restablece automáticamente después de 5 segundos y se pueden hacer nuevas mediciones. Si el soporte de cubeta está en la posición de medición, sacarlo y esperar a que se visualice el símbolo de HemoCue: Entonces se puede hacer una nueva medición.

Nota: *El analizador no responderá a otras* órdenes mientras se está haciendo una medición. Si se visualiza el código de error E35 durante el desplazamiento por los resultados, es señal de que la medición no ha sido guardada en la memoria (ver la guía de resolución de problemas en la página 31).

CFR

L'analyseur garde en mémoire jusqu'à 600 *résultats de tests. Lorsque la mémoire est* pleine, chaque nouvelle mesure remplacera automatiquement le résultat stocké le plus ancien. Pour consulter les résultats mis en mémoire, procéder comme suit.

1ab. Le support de cuvette peut être en position de charge ou de mesure. S'il est en position de mesure, l'écran affiche le résultat du test le plus récent.
2. Appuyer sur la touche gauche ou sur la touche droite pour faire défiler les résultats les plus anciens ou les plus récents. Les valeurs mises en mémoire apparaissent maintenant à l'écran. Quand la touche est maintenue appuyée , l'utilisateur peut voir affiché le numéro d'ordre des résultats (au test le plus récent est toujours associé le numéro 1). Dès qu'on relâche la touche, le résultat de la mesure intéressée apparaît.
3ab. Si aucun bouton n'est actionné lorsque le support est en position de charge, l'analyseur se remet automatiquement en position initiale après un laps de temps de 5 secondes et de nouvelles mesures peuvent être effectuées. Si le support est en position de mesure, extraire le support de microcuvette et le remette en position de charge et attendre que s'affiche le symbole HemoCue. L'analyseur est alors prêt à effectuer une nouvelle analyse.

Remarque : lorsqu'une mesure est en cours, l'analyseur ne répondra à aucune autre commande. Si le message d'erreur E35 est affiché pendant le défilement des résultats, la mesure n'a pas été stockée en mémoire. Voir le guide de dépannage page 30.

PT

O analisador guarda automaticamente até 600 resultados. Quando não houver mais células de memória disponíveis, o analisador substitui os valores mais antigos. Para ver os resultados memorizados proceda assim:

1ab. O porta-cuvetes pode estar em posição de carga ou de medição. Se estiver na posição de medição, é exibido o valor mais recente.
2. Prima a tecla esquerda ou direita para desfolhar para trás ou para a frente pelos resultados. Os valores memorizados são exibidos no écran. Mantendo a tecla carregada, o utilizador pode ver a ordem dos resultados (a medição mais recente é sempre a número 1) e quando soltar a tecla é apresentado o resultado.
3ab. Se não forem premidas nenhumas teclas enquanto estiver em posição de carga, *o analisador repõe-se automaticamente* ao fim de 5 segundos, podendo-se fazer novas medições. Se estiver em posição de medição puxe o porta-cuvetes para fora e espere pelo símbolo HemoCue, após o qual pode fazer uma nova medição.

Nota: Enquanto faz uma medição, o analisador não responde a outros comandos. Quando *estiver a desfolhar os resultados,* se aparecer o código de erro E35, é porque a medição não foi memorizada, veja o guia de solução de problemas na página 34.

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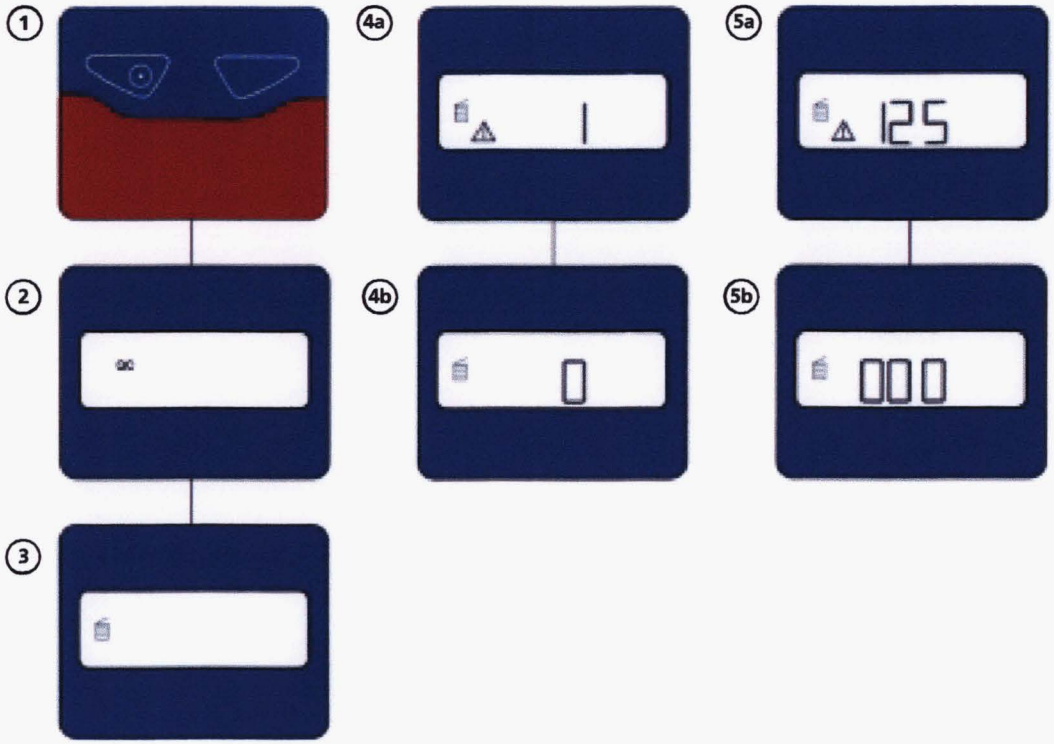
Set-up Delete results

Configuración Supresión de resultados

Congigurer Effacement des résultats

Configuração Apagar resultados



0129 153

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US

Note: Deleted results cannot be recovered. If results are to be saved, they must be printed out or downloaded to a PC before starting the deleting process.

1. Press both buttons at the same time.
2. The display now shows a flashing QC-symbol.
3. Scroll using the right button until the display shows a flashing trash can in the left corner.

4ab. To delete the current result, press and hold the left button. A warning triangle together with a "I" appears in the display for approximately 3 seconds.
The current result has now been deleted and the display shows a "0" to confirm that this has been done.
Only the current result can be deleted, which must be done immediatly after the measurement has been made.

5ab. To delete all stored results, hold both buttons down at the same time for 5 seconds. The display shows the trash can, the warning triangle and the total number of results stored. Continue to hold both buttons down until the number changes to "000" and the warning triangle disappears. All stored results have now been deleted.

ES

Nota: Los resultados suprimidos no se pueden recuperar. Si se desea conservar los resultados, imprimirlos o descargarlos a un PC antes de iniciar el proceso de supresión.

1. Presionar ambos botones simultáneamente.
2. La pantalla visualiza un símbolo de QC parpadeante.
3. Desplazar con el botón derecho hasta que se visualice un icono de cubo de basura parpadeante en la parte izquierda de la pantalla.

4ab. Para suprimir el resultado más reciente, mantener presionado el botón izquierdo. Se presenta en la pantalla un triángulo de advertencia junto con una "I" durante aproximadamente 3 segundos. Ahora se ha suprimido el resultado más reciente y la pantalla visualiza "0" para confirmar que se ha hecho esto. El resultado más reciente sólo se puede suprimir inmediatamente después de hacer la medición.

5ab. Para suprimir todos los resultados guardados, mantener presionados ambos botones simultáneamente durante unos 5 segundos. La pantalla visualiza el icono de cubo de basura, el triángulo de advertencia y el número total de resultados guardados. Mantener presionados ambos botones hasta que el número cambie a "000" y desaparezca el triángulo de advertencia. Ahora se han suprimidos todos los resultados.

CFR

Remarque : les résultats effacés ne peuvent pas être récupérés. Si certains résultats doivent être sauvegardés, il faut les imprimer ou les transférer sur un PC avant d'activer l'effacement.

1. Appuyer sur les deux touches en même temps.
2. L'écran affiche maintenant un symbole QC clignotant.
3. Faire défiler le menu en utilisant la touche droite jusqu'à ce qu'apparaisse une corbeille clignotante dans le coin gauche de l'écran.

4ab. Pour effacer le résultat le plus récent, presser et maintenir appuyée la touche de gauche. Un triangle d'avertissement et un "I" apparaissent à l'écran pendant environ 3 secondes. Le résultat le plus récent a maintenant été effacé et "0" s'affiche en guise de confirmation. Seul le résultat le plus récent peut être effacé, immédiatement après avoir exécutée la mesure.

5ab. Pour effacer tous les résultats enregistrés, maintenir appuyées les deux touches à la fois pendant 5 secondes. L'écran affiche la corbeille, le triangle d'avertissement et le nombre total de résultats mémorisés. Maintenir la pression sur les deux touches jusqu'à ce que le nombre affiché passe à "000" et que le triangle disparaisse.
Tous les résultats précédemment stockés en mémoire ont été effacés.

PT

Nota: Os resultados apagados não podem ser recuperados. Se quiser guardar resultados imprima-os em papel ou carregue-os num PC antes de iniciar o processo de eliminação.

1. Prima ambas as teclas simultaneamente.
2. O écran mostra um símbolo QC a piscar.
3. Desfolhe com a tecla direita até que o écran mostre um cesto de lixo no canto esquerdo.

4ab. Para apagar o resultado mais recente prima e segure a tecla esquerda. Um triângulo de advertência com um "I" aparece no écran durante uns 3 segundos. O resultado mais recente está apagado e o écran mostra um "0" para confirmar que o comando foi executado. O resultado mais recente só pode ser apagado logo depois de se fazer a medição.

5ab. Para apagar todos os resultados memorizados, segure ambas as teclas premidas simultaneamente durante 5 segundos. O écran mostra o cesto de lixo, o triângulo de advertência e o número total de resultados memorizados. Continue a manter as teclas carregadas até que o número mude para "000" e o triângulo de advertência desapareça. Agora todos os resultados memorizados estão apagados.

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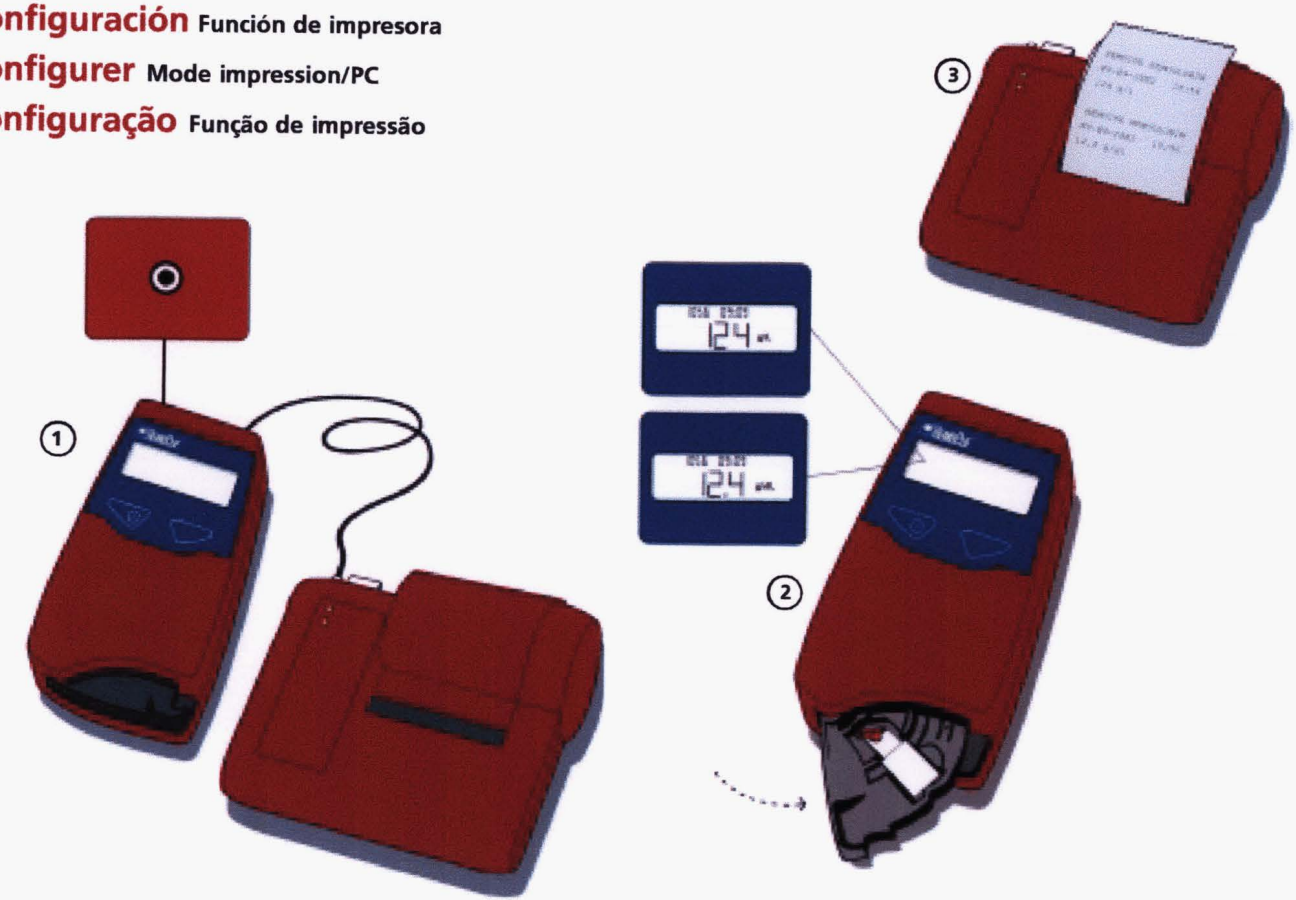
Set-up PC/Printer function

Configuración Función de impresora

Configurer Mode impression/PC

Configuração Função de impressão



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The analyzer can be on or off when connected to the printer. Only the current result can be printed out directly after the measurement.

1. Connect the cable* to the analyzer and printer*.
2. Perform the analysis by following the steps 12–16 on page 15.
3. When the result is shown on the display, the printer will automatically print the result, date and time.

Note: Only use ASCII printers recommended by HemoCue.
In order to connect the analyzer to a PC, a special CD program is required.

* Not included.

ES

El analizador puede estar conectado o desconectado cuando se conecta a una impresora. Sólo es posible imprimir el resultado más reciente inmediatamente después de la medición.

1. Conectar el cable* al analizador y a la impresora.*
2. Hacer el análisis siguiendo los pasos 12–16 de la página 17.
3. Cuando se visualice el resultado en la pantalla, la impresora lo imprimirá automáticamente, junto con la fecha y hora.

* No incluidos.

Nota: Utilizar solamente impresoras ASCII recomendadas por HemoCue.

CFR

L'analyseur peut être allumé ou éteint lorsqu'on le connnecte à l'imprimante. Seul le résultat le plus récent peut être imprimé directement après la mesure.

1. Brancher le câble* d'interface entre l'analyseur et l'imprimante*.
2. Effectuer l'analyse en exécutant les opérations de 12 à 16 décrites à la page15.
3. Lorsque la mesure est affichée à l'écran, l'impression du résultat, accompagné de la date et de l'heure de la mesure, s'effectue automatiquement.

Remarque : on utilisera exclusivement des imprimantes ASCII recommandées par HemoCue.
Pour connecter l'analyseur à un PC, il faut disposer d'un programme spécial, sur CD.

* Non fournis.

PT

O analisador pode estar ligado ou desligado quando conectado à impressora. Só o resultado mais recente pode ser impresso directamente depois da medição.

1. Conecte o cabo * ao analisador e à impressora *.
2. Faça a análise seguindo os passos 12–16 na página 17.
3. Quando o resultado aparece no écran, a impressora imprime imediatamente o resultado, a data e a hora.

* Não incluído.

Nota: Use apenas impressoras ASCII recomendadas pela HemoCue.

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(US) Trouble Shooting Guide

If you are unable to resolve the problem by following this Trouble Shooting Guide, please contact your local HemoCue distributor or HemoCue Inc. The analyzer has no serviceable parts.

Symptom	Explanation	Action
The analyzer shows an error code.	May be a temporary fault	Turn off the analyzer and turn it on again after 30 seconds. Take a new microcuvette and repeat the measurement. If the problem continues, see specific error code below.
E00	No stable endpoint is found within the time range. 1. The cuvette is faulty. 2. The circuit board is out of order.	1a. Check the expiration date for the microcuvettes. 1b. Take a new microcuvette and repeat the measurement. 2. The analyzer needs service. Contact your distributor.
E01–E05	1. Dirty optronic unit or faulty electronic or optronic unit	1a. Turn off the analyzer and clean the optronic unit as descriped in the maintance section. 1b. The analyzer needs service. Contact your distributor.
E06	1. Unstable blank value The analyzer might be cold.	1. Turn off the analyzer and allow it to reach room temperature. If the problem continues, the analyzer needs service. Contact your distributor.
E07	1. The battery power is too low.	1a. The batteries need to be replaced. Turn off the analyzer and replace the batteries, 4 type AA. 1b. Use the power adapter.
E08	The absorbance is too high. 1. Light blocking item in the cuvette holder	1a. Check that the analyzer and microcuvettes are being used according to the HemoCue Hb 201+ operating manual and instructions for use. 1b. The analyzer needs service. Contact your distributor.
E09–E30	1. Dirty optronic unit or faulty electronic or optronic unit	1a. Turn off the analyzer and clean the optronic unit as described in the maintance section. 1b. The analyzer needs service. Contact your distributor.
E35	1. The current measurement has been incorrectly stored and will remain as error code E35 until the entire memory has been deleted.	1a. No action is normally required. 1b. If storage problems continue, the analyzer needs service. Contact your distributor.

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Symptom	Explanation	Action
HHH	1. Measured value exceeds 25.6 g/dL (256 g/L, 15.9 mmol/L)	
No characters on the display	1. The analyzer is not receiving power. 2. If on battery power, the batteries need to be replaced. 3. The display is out of order.	1a. Check that the power adaptor is connected to the AC power supply. 1b. Check that the power adaptor is securely connected to the analyzer. 1c. Check that the cable is not damaged. 2. Turn off the analyzer and replace the batteries, 4 type AA. 3. The analyzer needs service. Contact your distributor.
The display gives erroneous characters.	1. The display is out of order. 2. The microprocessor is out of order.	1. The analyzer needs service. Contact your distributor. 2. The analyzer needs service. Contact your distributor.
The display shows "▭".	1. The batteries need to be replaced. 2. If on AC power, the power adaptor or the circuit board is out of order.	1. Turn off the analyzer and replace the batteries, 4 type AA. 2a. Check that the power adaptor is properly connected and working. 2b. The analyzer needs service. Contact your distributor.
The display does not switch from "⌛" and "Hb" to three flashing dashes and "" (ready for measuring).	1. The magnet in the cuvette holder may be missing. 2. The magnetic sensor is out of order.	1. The analyzer needs service. Contact your distributor. 2. The analyzer needs service. Contact your distributor.

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Symptom	Explanation	Action
Measurements on control materials are out of range – either too HIGH or too LOW.	1. The microcuvettes are beyond their expiration date, damaged or have been improperly stored. 2. The optical eye of the microcuvette is contaminated. 3. The control has not been mixed properly and/or is not at room temperature. 4. Air bubbles in the microcuvette 5. The optronic unit is dirty. 6. The control is not suitable for use with the HemoCue Hb 201+ system. 7. The calibration of the analyzer has been changed. 8. The controls are beyond their expiration dates or have been improperly stored.	1. Check the expiration date and the storage conditions of the microcuvettes. 2. Remeasure the sample with a new microcuvette. 3. Make sure that the control is mixed properly and at room temperature. 4. Check the microcuvette for air bubbles. Remeasure the sample with a new microcuvette. 5. Clean the optronic unit as described in the maintance section. 6. Only use controls intended for the HemoCue Hb 201+ system as recommended by HemoCue. 7. The analyzer needs service. Contact your distributor. 8. Check the expiration date and the storage conditions of the control. Take a new microcuvette and repeat the measurement.
Measurements on patient samples are higher or lower than anticipated.	1. Improper sampling technique 2. The microcuvettes are beyond their expiration date, damaged or have been improperly stored. 3. The optical eye of the microcuvette is contaminated. 4. Air bubbles in the microcuvette 5. The optronic unit is dirty. 6. The calibration of the analyzer has changed.	1. See pages 8-17 in this manual. 2. Check the expiration date and the storage conditions of the microcuvettes. 3. Remeasure the sample with a new microcuvette. 4. Check the microcuvette for air bubbles. Remeasure the sample with a new microcuvette. 5. Clean the optronic unit as described in the maintance section. 6. The analyzer needs service. Contact your distributor.

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(ES) Guía de resolución de problemas

Si no se consigue resolver un problema con ayuda de esta guía, consultar con el distribuidor local de HemoCue o directamente con HemoCue AB.

Síntoma	Explicación	Medida
El analizador presenta un código de error.	1. Puede ser un fallo temporal.	1. Desconectar el analizador y volver a conectarlo después de 30 segundos. Repetir la medición con una cubeta nueva. Si persiste el problema, ver el código de error específico más abajo.
E00	El punto final no es estable en el intervalo temporal. 1. La cubeta es defectuosa. 2. La tarjeta de circuitos está averiada.	1a. Ver la fecha de caducidad de las cubetas. 1b. Repetir la medición con una cubeta nueva. 2. El analizador requiere servicio. Contactar con el distribuidor.
E01–E05	1. Fallo en la unidad óptica o electrónica.	1a. Desconectar el analizador y limpiar la unidad óptica con limpiador HemoCue. 1b. El analizador requiere servicio. Contactar con el distribuidor.
E06	1. Valor nulo inestable. El analizador puede estar frío.	1. Desconectar el analizador y dejar que alcance la temperatura ambiente. Si el problema persiste, el analizador requiere servicio. Contactar con el distribuidor.
E07	1. La carga de las pilas es demasiado baja.	1a. Deben cambiarse las pilas. Desconectar el analizador y cambiar las pilas: 4 pilas tipo R6 o AA de 1.5 V. 1b. Usar el suministro de red.
E08	La absorbancia es excesiva. 1. Objeto que bloquea la luz en el soporte de cubeta.	1a. Comprobar que el analizador y las cubetas se utilicen según el manual de operación HemoCue Hb 201+ y las instrucciones de empleo.
E09–E30	1. El analizador requiere servicio. Contactar con el distribuidor.	1. Fallo en la unidad óptica o electrónica. Desconectar el analizador y limpiar la unidad óptica con limpiador HemoCue. 1b. El analizador requiere servicio. Contactar con el distribuidor.

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Síntoma	Explicación	Medida
E35	1. La medición actual ha sido guardada incorrectamente y se mantendrá como código de error E35 hasta que se haya borrado la memoria completa.	1a. Normalmente no se requieren medidas. 1b. Si persisten los problemas para guardar, el analizador requiere servicio. Contactar con el distribuidor.
HHH	1. El valor de medida excede de 256 g/L (25.6 g/dL, 15.9 mmol/L).	
No hay caracteres en la pantalla.	1. El analizador no recibe corriente. 2. Si está funcionando con pilas, éstas deben cambiarse. 3. La pantalla está averiada.	1a. Comprobar que el adaptador esté enchufado al suministro de red. 1b. Comprobar que el adaptador esté bien conectado en el analizador. 1c. Revisar el cable para ver si está dañado. 2. Desconectar el analizador y cambiar las pilas: 4 pilas tipo R6 o AA de 1.5 V. 3. El analizador requiere servicio. Contactar con el distribuidor.
La pantalla presenta caracteres erróneos.	1. La pantalla está averiada. 2. El microprocesador está averiado.	1. El analizador requiere servicio. Contactar con el distribuidor. 2. El analizador requiere servicio. Contactar con el distribuidor.
La pantalla visualiza "▭".	1. Deben cambiarse las pilas. 2. Si se usa el suministro de red, está averiado el adaptador o la tarjeta de circuitos.	1. Desconectar el analizador y cambiar las pilas: 4 pilas tipo R6 o AA de 1.5 V. 2a. Comprobar que el adaptador esté bien conectado y que funciona. 2b. El analizador requiere servicio. Contactar con el distribuidor.
La pantalla no cambia desde "⌛"y "Hb" a las tres rayas parpade-antes y "" (preparado para medir).	1. Puede haberse soltado el imán del soporte de cubeta. 2. El sensor magnético está averiado.	1. El analizador requiere servicio. Contactar con el distribuidor. 2. El analizador requiere servicio. Contactar con el distribuidor.

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Síntoma	Explicación	Medida
Las mediciones del material de control están fuera del intervalo: demasiado ALTAS o demasiado BAJAS.	1. Las cubetas han caducado, están dañadas o han sido guardadas de forma inadecuada. 2. El ojo óptico de la cubeta está contaminado. 3. El control no está bien mezclado y/o no está a la temperatura ambiente. 4. Hay burbujas de aire en la cubeta. 5. La unidad óptica está sucia. 6. El control no es adecuado para utilizar con el sistema HemoCue Hb 201+. 7. Se ha cambiado la calibración del analizador. 8. Los controles han caducado o han sido guardados de forma inadecuada.	1. Controlar la fecha de caducidad y las condiciones de almacenaje de las cubetas. 2. Volver a medir la muestra con una cubeta nueva. 3. Comprobar que el control está bien mezclado y a temperatura ambiente. 4. Ver si hay burbujas de aire en la cubeta. Volver a medir la muestra con una cubeta nueva. 5. Limpiar la unidad óptica con el limpiador HemoCue. 6. Utilizar solamente controles destinados al sistema HemoCue Hb 201+, recomendados por HemoCue. 7. El analizador requiere servicio. Contactar con el distribuidor. 8. Controlar la fecha de caducidad y las condiciones de almacenaje del control. Repetir la medición con una cubeta nueva.
Las mediciones de muestras de pacientes son más altas o más bajas de lo previsto.	1. Las cubetas han caducado, están dañadas o han sido guardadas de forma inadecuada. 2. El ojo óptico de la cubeta está contaminado. 3. Hay burbujas de aire en la cubeta. 4. La unidad óptica está sucia. 5. Se ha cambiado la calibración del analizador.	1. Controlar la fecha de caducidad y las condiciones de almacenaje de las cubetas. 2. Volver a medir la muestra con una cubeta nueva. 3. Ver si hay burbujas de aire en la cubeta. Volver a medir la muestra con una cubeta nueva. 4. Limpiar la unidad óptica con el limpiador HemoCue. 5. El analizador requiere servicio. Contactar con el distribuidor.

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CFR Guide de dépannage

Si vous ne réussissez pas à résoudre votre problème à l'aide de ce guide, contactez votre distributeur HemoCue ou la société HemoCue AB. L'analyseur n'a pas de pièce de service.

Symptômes	Causes	Solutions possibles
L'analyseur affiche un code d'erreur	Défaillance temporaire éventuelle	Eteindre l'analyseur et le rallumer après 30 secondes. Prendre une nouvelle microcuvette et recommencer la mesure. Si le problème persiste, consulter le code d'erreur ci-dessous.
E00	Le point final stable de la réaction n'a pas été détecté dans la plage de temps prévue. 1. Problème dans la cuvette. 2. Circuit imprimé en panne.	1a. Vérifier la date de péremption des cuvettes. 1b. Prendre une nouvelle cuvette et refaire la mesure. 2. L'analyseur a besoin d'une révision. Contactez votre distributeur.
E01–E05	1. Problème dans l'unité optique ou l'unité électronique	1a. Éteindre l'analyseur et nettoyer la cellule optique conformément aux instructions de la section Entretien. 1b. L'analyseur a besoin d'une révision. Contactez votre distributeur.
E06	1. Valeur vide instable. La température de l'analyseur peut être trop basse.	1. Éteindre l'analyseur et attendre qu'il atteigne la température ambiante. Si le problème persiste, l'analyseur a besoin d'une révision. Contactez votre distributeur.
E07	1. Piles trop faibles.	1a. Les piles doivent être remplacées. Éteindre l'analyseur et remplacer les piles 4 piles de type R6 ou AA,1.5 V. 1b. Utiliser l'alimentation secteur.
E08	Absorption trop élevée 1. Obstacle à la lumière dans le support de microcuvette.	1a. Vérifier que l'analyseur et les cuvettes sont utilisés conformément au manuel de l'utilisateur de l'analyseur HemoCue Hb 201+ et au mode d'emploi. 1b. L'analyseur a besoin d'une révision. Contactez votre distributeur.
E09–E30	1. Problème dans l'unité optique ou l'unité électronique.	1a. Éteindre l'analyseur et nettoyer la cellule optique conformément aux instructions de la section Entretien. 1b. L'analyseur a besoin d'une révision. Contactez votre distributeur.

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Symptômes	Causes	Solutions possibles
E35	Résultat de la mesure en cours i stocké non correctement. Le code d'erreur E35 lui sera associé jusqu'à effacement de la totalité des résultats mémorisés.	1a. En général, aucune action n'est requise. 1b. Si des problèmes de mise en mémoire persistent, l'analyseur a besoin d'une révision. Contactez votre distributeur.
HHH	1. Valeur mesurée supérieure à 256 g/L (25.6 g/dL, 15.9 mmol/L).	
Écran vide	1. Analyseur non alimenté. 2. Si l'alimentation est à piles, celles-ci doivent doivent être remplacées. 3. Écran en panne.	1a. Vérifier que l'adaptateur est branché sur la prise murale. 1b. Vérifier que l'adaptateur est bien branché à l'analyseur. 1c.. Vérifier que le câble n'est pas endommagé. 2. Éteindre l'analyseur et remplacer les piles (4 piles) de type R6 ou AA, 1.5 V. 3. L'analyseur a besoin d'une révision. Contactez votre distributeur.
L'écran affiche des caractères erronés	1. Écran en panne. 2. Microprocesseur en panne.	1. L'analyseur a besoin d'une révision. Contactez votre distributeur. 2. L'analyseur a besoin d'une révision. Contactez votre distributeur.
L'écran affiche le symbole " "	1. Les piles doivent être remplacées. 2. Si l'analyseur est branché sur le secteur, l'adaptateur ou le circuit imprimé est en panne	1. Éteindre l'analyseur et remplacer les piles, (4 piles e type R6 ou AA, 1.5 V) 2a. Vérifier que l'adaptateur secteur est bien connecté et qu'il fonctionne. 2b. L'analyseur a besoin d'une révision. Contactez votre distributeur.
L'affichage ne passe pas de " " et "Hb" aux trois tirets clignotants et " " (prêt à l'analyse d'un échantillon).	1. Absence d'aimant dans le support de cuvette. 2. Capteur magnétique en panne.	1. L'analyseur a besoin d'une révision. Contactez votre distributeur. 2. L'analyseur a besoin d'une révision. Contactez votre distributeur.

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Symptômes	Causes	Solutions possibles
Résultats du test de contrôle hors plage (trop ÉLEVÉS ou trop BAS).	1. Cuvettes endommagées ou conservées dans de mauvaises conditions, ou date de péremption des cuvettes dépassée. Œil optique de la cuvette contaminé. 3. Solutions de contrôle mal mélangées et/ou pas à la température ambiante. 4. Bulles d'air dans la microcuvette. 5. Unité optique sale. 6. La solution de contrôle ne doit pas être utilisée avec le système HemoCue Hb 201+. 7. Calibrage de l'analyseur modifié. 8. Solutions de contrôle conservées non correctement ou date de péremption dépassée.	1. Vérifier la date de péremption des cuvettes et leurs conditions de conservation. 2. Mesurer l'échantillon une deuxième fois avec une nouvelle microcuvette. 3. S'assurer que la solution de contrôle est bien mélangée et qu'elle est à température ambiante. 4. Vérifier que la cuvette ne contient pas de bulles d'air. Mesurer l'échantillon une deuxième fois avec une nouvelle microcuvette. 5. Nettoyer l'unité optique conformément aux instructions de la section Entretien. 6. Utiliser exclusivement les solutions de contrôle destinées au système HemoCue Hb 201+ recommandées par HemoCue. 7. L'analyseur a besoin d'une révision. Contactez votre distributeur. 8. Vérifier la date de péremption des solutions de contrôle et leurs conditions de conservation. Prendre une nouvelle microcuvette et refaire une mesure.
Résultats de tests sanguins d'un patient plus élevés ou plus bas que prévus.	1. Mauvaise technique de prise d'échantillon 2. Cuvettes endommagées ou conservées dans de mauvaises conditions, ou date de péremption des cuvettes dépassée. 3. Œil optique de la microcuvette contaminé. 4. Bulles d'air dans la microcuvette. 5. Unité optique sale. 6. Calibrage de l'analyseur modifié.	1. Voir les pages 8 à 17 de ce manuel 2. Vérifier la date de péremption des microcuvettes et leurs conditions de conservation. 3. Mesurer l'échantillon une deuxième fois avec une nouvelle microcuvette. 4. Vérifier que la microcuvette ne contient pas de bulles d'air. Mesurer l'échantillon une deuxième fois avec une nouvelle microcuvette. 5. Nettoyer l'unité optique conformément aux instructions de la section Entretien. 6. L'analyseur a besoin d'une révision. Contactez votre distributeur.

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(PT) Guia para Solução de Problemas

Se não conseguir resolver o problema seguindo este guia de solução de problemas, queira contactar o seu distribuidor local HemoCue ou a HemoCue AB.

Sintoma	Explicação	Solução
O analisador mostra um código de erro.	1. Talvez uma falha temporária.	1. Desligue o analisador e ligue-o de novo ao fim de 30 segundos. Pegue numa cuvete nova e repita a medição. Se o problema continuar, veja o código específico de erro abaixo.
E00	Não se encontra um ponto de estabilidade final dentro do tempo estipulado. 1. A cuvete está defeituosa. 2. A placa de circuitos está avariada.	1a. Verificar a data de expiração das cuvetes. 1b. Pegue numa cuvete nova e repita a medição. 2. O analisador precisa de serviço. Contacte o seu distribuidor.
E01–E05	1. Avaria na unidade óptica ou electrónica.	1a. Desligar o analisador e limpar a unidade optrónica usando o HemoCue Cleaner. 1b. O analisador precisa de serviço. Contacte o seu distribuidor.
E06	1. Valor nulo instável. O analisador deve estar frio.	1. Desligue o analisador e deixe-o atingir a temperatura ambiente. Se o problema continuar, o analisador precisa de serviço. Contacte o seu distribuidor.
E07	1. A pilha está fraca.	1a. É necessário mudar de pilha. Desligue o analisador e mude as pilhas, 4 de tipo R6 ou AA, 1.5 V. 1b. Use alimentação da rede eléctrica.
E08	A absorvância é demasiado elevada. 1. Obstrução no percurso da luz no porta-cuvete.	1a. Verificar se o analisador e cuvetes estão a ser usados de acordo com o manual de instruções de operação do HemoCue Hb 201+. 1b. O analisador precisa de serviço. Contacte o seu distribuidor.
E09–E30	1. Avaria nas unidades óptica ou electrónica.	1a. Desligar o analisador e limpar a unidade optrónica usando o HemoCue Cleaner. 1b. O analisador precisa de serviço. Contacte o seu distribuidor.

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Sintoma	Explicação	Solução
E35	1. A medida corrente foi incorrectamente memorizada e permanecerá como código de erro E35 até que se apague toda a memória.	1a. Não é necessário tomar medidas. 1b. Se continuar a haver problemas de memorização, o analisador precisa de serviço. Contacte o seu distribuidor.
HHH	1. O valor de medição excede 256 g/L (25.6 g/dL, 15.9 mmol/L).	
Não se vêm caracteres no écran	1. O analisador não recebe corrente. 2. Se alimentado por pilhas, estas devem ser substituídas. 3. O écran está avariado.	1a. Verificar se o transformador de corrente está conectado à tomada. 1b. Verificar se o transformador de corrente está bem conectado ao analisador. 1c. Verificar se o fio não está danificado. 2. Desligar o analisador e substituir as pilhas, 4 tipo R6 ou AA, 1.5 V. 3. O analisador precisa de serviço. Contacte o seu distribuidor.
O écran dá caracteres erróneos.	1. O écran está avariado. 2. O microprocessador está avariado.	1. O analisador precisa de serviço. Contacte o seu distribuidor. 2. O analisador precisa de serviço. Contacte o seu distribuidor.
O écran mostra "▭".	1. As pilhas precisam de ser substituídas. 2. Se alimentado pela rede, o transformador ou a placa de circuitos está avariada.	1. Desligue o analisador e substitua as pilhas, 4 tipo R6 ou AA, 1.5 V. 2a. Verifique se o transformador está bem conectado e a funcionar. 2b. O analisador precisa de serviço. Contacte o seu distribuidor.

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Sintoma	Explicação	Solução
O écran não muda de "⌛" e "Hb" para três traços a piscar "⌛" (pronto para medir).	1. O imã do porta-cuvete pode estar a faltar. 2. O sensor magnético está avariado.	1. O analisador precisa de serviço. Contacte o seu distribuidor. 2. O analisador precisa de serviço. Contacte o seu distribuidor.
Medições no controle fora da amplitude – demasiado ALTAS ou demasiado BAIXAS.	1. As cuvetes estão fora de prazo, danificadas ou foram guardadas impropriamente. 2. O olho óptico da cuvete está contaminado. 3. O controle não foi bem misturado e/ou não está à temperatura ambiente. 4. Bolhas de ar na cuvete. 5. A unidade optrónica está suja. 6. O controle não serve para o sistema HemoCue Hb 201+. 7. A calibração do analisador foi alterada. 8. Os controles estão fora de prazo ou foram guardados impropriamente.	1. Verificar a data de validade e as condições de armazenamento das cuvetes. 2. Torne a medir a amostra com uma nova cuvete. 3. Assegure-se de que o controle está bem misturado e à temperatura ambiente. 4. Verifique se a cuvete tem bolhas de ar. Torne a medir a amostra com uma nova cuvete. 5. Limpe a unidade optrónica com HemoCue Cleaner. 6. Use apenas controles destinados ao sistema HemoCue Hb 201+ recomendados pela HemoCue. 7. O analisador precisa de serviço. Contacte o seu distribuidor. 8. Verifique a data de expiração e as condições de armazenamento do controle. Pegue numa nova cuvete e repita a medição.
As medições em amostras de pacientes são mais elevadas ou mais baixas do que o previsto.	1. As cuvetes estão fora de prazo, danificadas ou foram guardadas impropriamente. 2. O olho óptico da cuvete está contaminado. 3. Bolhas de ar na cuvete. 4. A unidade optrónica está suja. 5. A calibração do analisador foi alterada.	1. Verifique a data de expiração e as condições de armazenagem das cuvetes. 2. Torne a medir a amostra com uma nova cuvete. 3. Veja se a cuvete tem bolhas de ar. Torne a medir a amostra com uma nova cuvete. 4. Limpe a unidade optrónica com o HemoCue Cleaner. 5. O analisador precisa de serviço. Contacte o seu distribuidor.

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(US) Specifications

General

The HemoCue Hb 201+ is a system used for the determination of the total amount of hemoglobin in whole blood. The system consists of a specially designed analyzer with specially designed microcuvettes containing dried reagents. The microcuvette serves as pipette, reaction vessel and as a measuring microcuvette. No dilution is required. The hemoglobin measurement takes place in the analyzer, which follows the progress of the reaction until the steady state has been reached. The system is factory calibrated against the hemoglobincyanide (HiCN) method, the international reference method for the determination of the hemoglobin concentration in blood.

Intended Use

Quantitative determination of hemoglobin in capillary, venous or arterial blood. The HemoCue Hb 201+ system is used for quantitative determination of hemoglobin in whole blood using a specially designed analyzer, the HemoCue Hb 201+ analyzer, and specially designed microcuvettes, the HemoCue Hb 201 Microcuvettes. HemoCue Hb 201 Microcuvettes are for In Vitro Diagnostic use only. The HemoCue Hb 201+ analyzer is only to be used with HemoCue Hb 201 Microcuvettes.

Theory

The reaction in the microcuvette is a modified azidemethemoglobin reaction. The erythrocyte membranes are disintegrated by sodium deoxycholate, releasing the hemoglobin. Sodium nitrite converts the hemoglobin iron from the ferrous to the ferric state to form methemoglobin, which then combines with azide to form azidemethemoglobin.

Reagents

40 % w/w Sodium Deoxycholate, 18 % w/w Sodium Azide, 20 % w/w Sodium Nitrite, 22 % w/w nonreactive ingredients.

Sample material

Capillary, venous or arterial blood may be used. Appropriate anti-coagulants in solid form (eg EDTA, heparin or heparin/fluoride) may be used. Mix all samples thoroughly on a mechanical mixer for at least 2 minutes or invert the tube 8-10 times by hand. Alternatively, follow the local recommendations. Hemoglobin remains unchanged for days, provided that the blood does not become infected. If the specimen has been stored in a refrigerator, it will be viscid and the blood should be allowed to warm up to room temperature before mixing.

Storage and environmental requirements of the HemoCue Hb 201 Microcuvettes

Use the HemoCue Hb 201 Microcuvettes prior to their expiration date. The expiration date is printed on each package.

Storage of microcuvettes kept in a vial

The microcuvettes are to be stored at room temperature (59 – 86 °F, 15 – 30 °C). Do not refrigerate. The microcuvettes are stable for two years from the date of manufacture.

Once the seal is broken, the microcuvettes are stable for three months. Always keep the container properly closed.

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Storage of the individually packaged cuvettes

The microcuvettes are to be stored at room temperature (59 – 86 °F, 15 – 30 °C). Do not refrigerate. The individually packaged microcuvettes are stable for fifteen months from the date of manufacture.

HemoCue Hb 201+ analyzer

The analyzer can be stored at 32-122 °F (0-50 °C). Operating temperature is 59-86 °F (18-30 °C). Allow the analyzer to reach ambient temperature before use. The analyzer should not be operated at high (i.e. > 90 % non-condensing) humidity.

Quality Control

The HemoCue Hb 201+ analyzer has an internal electronic "SELFTEST". Every time the analyzer is turned on, it will automatically verify the performance of the optronic unit of the analyzer. This test is performed every second hour if the analyzer remains switched on.

If quality control checks are required for regulatory reasons, they should be performed using liquid controls recommended by HemoCue.

Measuring range

0 – 25.6 g/dL (0 – 256 g/L, 0 – 15.9 mmol/L).
Results above 25.6 g/dL (256 g/L, 15.9 mmol/L) will be displayed as HHH. Values above 23.5 g/dL (235 g/L, 14.6 mmol/L) must be confirmed using a suitable laboratory method.

Limitations

HemoCue Hb 201 Microcuvettes are for in vitro diagnostic use only. The HemoCue Hb 201+ analyzer is only to be used together with HemoCue Hb 201 Microcuvettes. For further limitations of the procedure, see the HemoCue Hb 201 Microcuvettes package insert.

Expected values

Adult Males 13.0–17.0 g/dL (130 – 170 g/L, 8.1–10.5 mmol/L)
Adult Females 12.0–15.0 g/dL (120–150 g/L, 7.4–9.3 mmol/L)
Infants, after neonatal period 11.0–14.0 g/dL (110–140 g/L, 6.8–8.7 mmol/L)
Children, two years to teenage: gradual increase to adult normals.
Due to a wide range of conditions (dietary, geographical, etc) which affect normal values, it is recommended that each laboratory establish its own normal range.

Technical Specifications

Dimensions: 3.35 x 6.30 x 1.69 inches (85 × 160 × 43 mm)
Weight: 0.77 pounds (350 g) (with batteries installed)
4 batteries type AA
Power adaptor: CE marked
Only use adaptors recommended by HemoCue, as listed on page 44.
Pollution degree: 2
Overvoltage category: II
Atmospheric pressure: 700 hPa to 1060 hPa.
Equipment not suitable for use in the presence of flammable mixtures.
The instrument is tested according to IEC 61010-1, First edition, 1990 with Amendment 1, 1992 and Amendment 2, 1995 (EN 61010-1: 1993 with A2: 1995), EN 60601-1-2 and complies with the IVD Medical Device Directive 98/79/EC.

Signal input and signal output

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e. IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 601-1-1. Everybody who connects

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additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of IEC 601-1-1. If in doubt, contact HemoCue Inc. or your local HemoCue distributor.

Warranty

The analyzer carries a 24-month warranty from the day of receipt. After the warranty period, service/repair is carried out at fixed prices.

Spare parts – Accessories

The following spare parts and accessories are available:

Power adaptor
Battery Lid
PC program
Cables for PC and printer connection
Liquid controls
HemoCue Cleaners
Hard Carrying Case
HemoCue Lancets
HemoCue Hb 201+ Control Cuvette

Symbols used

Attention, see instructions for use

CE mark

Refers to Type BF Applied Part, Per EN60601-1

Class II equipment

The Medical Equipment with respect to electrical shock, fire and mechanical hazards only in accordance with UL-2601-1 and related collateral IEC 60601-1 standards for which the products has been found to comply by UL.

References

1. Makarem, A. In clinical Chemistry: Principles and Technics, 2nd ed., Henry, R.J., Cannon, D.C., and Winkelman, J.W., Harper and Row, Hagerstown, M.D., 1974, pp. 1125 – 1147.
2. Dacie and Lewis, Practical Haematology Ninth edition.
3. Jacques Wallach, M.D., Interpretation of Diagnostic Tests.

Manufacturer
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Fax: +46 431 45 82 25
E-mail: info@hemocue.se
www.hemocue.com

HemoCue Distributor USA:
HemoCue, Inc.
40 Empire Drive
Lake Forest, CA 92630
Phone 949-859-2630
Orders 800-323-1674
Technical support 800-426-7256
Fax 949-859-3066

Recommeded Adapter:

Country	Type	Manufacturer	Input	Output
USA/Canada	Mod nr FE3515060D035	FRIWO	120 V AC/60 Hz	6V DC, 350 mA

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ES Especificaciones

Generalidades

HemoCue Hb 201+ es un sistema para la determinación de la cantidad total de hemoglobina en sangre completa. El sistema está formado por un analizador especialmente diseñado y microcubetas especiales que contienen reactivos secos. La microcubeta sirve de pipeta, vasija de reacción y microcubeta de medición. No se requiere dilución. La medición de hemoglobina se hace en el analizador, el cual sigue la progresión de la reacción y presenta el resultado cuando se ha alcanzado el punto final de la reacción. El sistema se calibra en fábrica con el método de cianhemoglobina (HiCN), el método de referencia internacional para determinar la concentración de hemoglobina en la sangre.

Finalidad

Determinación de la cantidad de hemoglobina en sangre completa capilar, venosa y arterial. El sistema HemoCue 201 se utiliza para determinar la cantidad de hemoglobina en sangre completa, utilizando un analizador – HemoCue Hb 201+ – y microcubetas – microcubetas HemoCue Hb 201 –, especialmente diseñados. Las microcubetas HemoCue Hb 201 solamente están destinadas al uso con diagnóstico in vitro. El analizador HemoCue Hb 201+ sólo debe usarse junto con microcubetas HemoCue Hb 201.

Directiva CE relativa a productos médicos IVD

HemoCue Hb 201+ cumple con las disposiciones de la Directiva 98/79/CE relativa a productos médicos IVD y tiene la marca CE de conformidad.

Teoría

El deoxicolato de sodio hemoliza los eritrocitos y se libera hemoglobina. El nitrito de sodio convierte la hemoglobina en metahemoglobina, la cual, junto con la azida sódica, produce metahemoglobina azídica. La absorbancia se mide en dos longitudes de onda (570 nm y 880 nm) para compensar la turbidez de la muestra.

Reactivos

40 % w/w de deoxicolato de sodio, 18 % w/w de azida sódica, 20 % w/w de nitrito de sodio, 22 % w/w de ingredientes no reactivos.

Material de muestra

Puede usarse sangre capilar, venosa o arterial. Se recomiendan anticoagulantes apropiados en forma sólida como EDTA o heparina/fluoruro, con objeto de evitar el efecto de dilución. Si la sangre ha estado en una nevera, dejar que alcance la temperatura ambiente, 18 – 30 °C (64 – 86 °F), antes del análisis. La hemoglobina permanece inalterada durante días si la sangre no se infecta. Mezclar todas las muestras en una mezcladora mecánica durante un mínimo de dos minutos, o invertir el tubo 8 – 10 veces a mano. Alternativamente, seguir las recomendaciones locales.

Requisitos de almacenaje y medioambientales de las microcubetas HemoCue Hb 201.

Usar las microcubetas HemoCue Hb 201 antes de la fecha de caducidad. La fecha de caducidad está impresa en cada envase.

Almacenaje de las microcubetas colocadas en un contenedor.

Las microcubetas deben guardarse a temperatura ambiente (15 – 30 °C, 59 – 86 °F). No refrigerar. Las microcubetas tienen una estabilidad de dos años a partir de la fecha de producción. Una vez abierto el envase, las microcubetas tienen una estabilidad de 3 meses. Mantener siempre el envase adecuadamente cerrado.

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Almacenaje de microcubetas en envases individuales
Las microcubetas deben guardarse a temperatura ambiente (15 – 30 °C, 59 – 86 °F). No refrigerar. Las microcubetas en envases individuales tienen una estabilidad de quince meses a partir de la fecha de producción.

Analizador HemoCue Hb 201+

El analizador se puede guardar a una temperatura ambiente de 0 – 50 °C (32 – 122 °F). La temperatura de trabajo es de 18 – 30 °C (64 – 86 °F). Dejar que el analizador alcance la temperatura ambiente antes de usarlo. El analizador no debe funcionar cuando la humedad es alta (> 90 % sin condensación).

Control de calidad

El analizador HemoCue Hb 201+ tiene una "AUTOVERIFICACIÓN" electrónica interna. Esta función verifica automáticamente el funcionamiento de la óptica electrónica cada vez que se conecta el analizador. Este test se efectúa cada dos horas si el analizador está conectado. Si la normativa establece la realización de controles de calidad, éstos pueden hacerse utilizando controles líquidos recomendados por HemoCue.

Intervalo de medición

0 – 256 g/L (0 – 25.6 g/dL, 0 – 15.9 mmol/L).
Los resultados por encima de 256 g/L (25.6 g/dL, 15.9 mmol/L) se presentan como "HHH".

Limitaciones

Las microcubetas HemoCue Hb 201 solamente están destinadas al uso con diagnóstico in vitro. El analizador HemoCue Hb 201+ sólo debe usarse junto con microcubetas HemoCue Hb 201. Para más limitaciones del procedimiento, ver las instrucciones de empleo de las microcubetas HemoCue Hb 201.

Valores esperados

Varones adultos 130 – 170 g/L (13.0 – 17.0 g/dL, 8.1 – 10.5 mmol/L)
Mujeres adultas 120 – 150 g/dL (12.0 – 15.0 g/dL, 7.4 – 9.3 mmol/L)
Bebés, después del periodo neonatal 110 – 140 g/L (11.0 – 14.0 g/dL, 6.8 – 8.7 mmol/L)
Niños, de los dos años a la adolescencia: Incremento gradual hasta los valores normales para adultos. Debido a la gran variedad de condiciones (dietéticas, geográficas, etc.) que afectan a los valores normales, se recomienda que cada laboratorio establezca su propio intervalo normal.

Especificaciones técnicas

Dimensiones: 85 × 160 × 43 mm
Peso: 350 g (incluso pilas)
4 pilas tipo AA o R6 de 1.5 V
Adaptador de red: Marca CE
Usar solamente adaptadores recomendados por HemoCue
(ver la página 44)
Grado de contaminación: 2
Clase de sobrevoltaje: II
El instrumento ha sido probado de conformidad con IEC 61010-1, primera edición, 1990 con la enmienda 1 de 1992 y la enmienda 2 de 1995 (EN 61010-1: 1993 con A2: 1995), EN 60601-1-2, y cumple con las disposiciones de la Directiva 98/79/EC relativa a productos médicos IVD.

Garantía

El analizador tiene una garantía de 24 meses a partir de la fecha de recepción. Con posterioridad al periodo de garantía, los trabajos de servicio y reparación se hacen a precios fijos.

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Repuestos y accesorios

Hay disponibles las piezas de repuesto siguientes:
Adaptador de red
Pilas
Soporte de cubeta y tapa
Programa de PC
Cables para PC y conexión de impresora
Controles líquidos
Limpiadores HemoCue
Maletín rígido
Lancetas HemoCue
HemoCue Hb 201+ Control Cuvette

Símbolos utilizados

⚠ Atención, ver las instrucciones de empleo

CE Marca CE

Referencias

1. Makarem, A. In clinical Chemistry: Principles and Technics, 2nd ed., Henry, R.J., Cannon, D.C., and Winkelman, J.W., Harper and Row, Hagerstown, M.D., 1974, pp. 1125–1147.
2. Dacie and Lewis, Practical Haematology Ninth edition.
3. Jacques Wallach, M.D., Interpretation of Diagnostic Tests.

Fabricante

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www.hemocue.com

País	Tipo	Fabricante	Entrada
Europa	FW3199	FRIWO	230 V~/50 Hz/26 mA/6 VA
EE.UU.	Mod nr FE3515060D035	FRIWO	120 V~/60 Hz/6,6 VA

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Caractéristiques techniques

Généralités

L'HemoCue Hb 201+ est un système de mesure du taux d'hémoglobine sur sang total. Le système se compose d'un analyseur spécialement conçu et de microcuvettes spécifiquement adaptées contenant un réactif sous forme sèche. Chaque microcuvette sert à la fois de pipette, de support de réaction et de cuvette de mesure. Aucune dilution n'est nécessaire. La mesure de l'hémoglobine a lieu dans l'analyseur qui suit le déroulement de la réaction jusqu'à ce que celle-ci se soit stabilisée. Le système est calibré en usine par la méthode du cyanure-hémoglobine (HiCN), référence internationale pour la détermination du taux d'hémoglobine dans le sang.

Cadre d'utilisation

Le système permet la détermination quantitative du taux d'hémoglobine sur sang capillaire, veineux ou artériel. Le système HemoCue Hb 201 permet la détermination quantitative du taux d'hémoglobine sur sang total au moyen d'un anlyseur spécifique, l'HemoCue Hb 201+, et de microcuvettes HemoCue Hb 201 spécialement conçues et destinées uniquement au diagnostic in vitro. L'analyseur HemoCue Hb 201+ ne peut être utilisé qu'avec les microcuvettes HemoCue Hb 201.

Directive sur les dispositifs médicaux de diagnostic in vitro

Le système HemoCue Hb 201+ est conforme à la directive 98/79/CE sur les dispositifs médicaux de diagnostic in vitro et porte le marquage CE.

Théorie

La réaction dans la microcuvette est une réaction azide-méthémoglobine modifiée. Les membranes des érythrocytes sont dissoutes par le désoxycholate de sodium, ce qui libère l'hémoglobine. Le nitrite de sodium transforme le fer de l'hémoglobine de son état ferreux à son état ferrique, formant ainsi de la méthémoglobine, qui combinée alors avec l'azoture forme de l'azoture de méthémoglobine.

Réactifs

40 % de désoxycholate de sodium, 18 % d'azoture de sodium, 20 % de nitrite de sodium et 22 % de composants non réactifs.

Le prélèvement

Il est possible d'utiliser du sang capillaire, veineux ou artériel. on peut utiliser des anticoagulants appropriés sous forme solide, comme l'EDTA, l'héparine ou le fluorure. Tout échantillon prélevé doit être bien mélangé à l'aide d'un agitateur mécanique pendant au moins deux minutes, ou en retournant manuellement 8 à 10 fois le récipient avant la mesure. Autrement, se conformer aux recommandations locales. L'hémoglobine reste stable plusieurs jours ,à condition que le sang ne se soit pas infecté. Si le spécimen a été conservé au réfrigérateur, sa viscosité sera trop élevée et il faudra le laisser atteindre la température ambiante avant de le mélanger.

Conservation et exigences relatives aux conditions ambiantes des microcuvettes HemoCue Hb 201

Utiliser les microcuvettes HemoCue Hb 201 avant la date de péremption indiquée sur l'emballage.

Conservation des cuvettes conditionnées en flacon

Conserver les microcuvettes à température ambiante (15– 30 °C, 59 – 86 °F). Ne pas réfrigérer. Les microcuvettes sont stables pendant deux ans à compter de la date de production. Elles restent stables pendant 3 mois après l'ouverture du flacon. Il faut toujours conserver le flacon correctement fermé.

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Conservation des cuvettes conditionnées en emballage individuel
Conserver les microcuvettes à température ambiante (15 – 30 °C, 59 – 86 °F). Ne pas réfrigérer. Les microcuvettes conditionnées en emballage individuel sont stables pendant quinze mois à compter de la date de production.

L'analyseur HemoCue Hb 201+

L'analyseur peut être conservé entre 0 et 50 °C (32 – 122 °F)
La température d'utilisation est comprise entre 18 et 30 °C (64 – 86 °F). Laisser l'analyseur atteindre la température ambiante avant son utilisation. L'analyseur ne doit pas être utilisé dans des conditions d'humidité élevée, c'est-à-dire plus de 90 % non condensé.

Contrôle de qualité

L'analyseur HemoCue Hb 201+ est doté d'un contrôle électron que interne "SELFTEST". Chaque fois que l'analyseur est allumé, il vérifie automatiquement les performances de son unité optique. Si l'analyseur reste allumé, ce test se ré-exécute automatiquement toutes les deux heures. Si des contrôles de qualité sont exigés pour des raisons réglementaires, il est fortement conseillé d'utiliser les solutions de contrôle recommandées par HemoCue.

Plage de mesure

0 – 256 g/L (0 – 25.6 g/dL, 0 – 15.9 mmol/L).
Pour les résultats supérieurs à 256 g/L (25.6 g/dL, 15.9 mmol/L), l'écran affichera le code HHH. Les valeurs supérieures à 235 g/L (23,5 g/dL, 14,6 mmol/L) doivent être confirmées au moyen d'une méthode de laboratoire agréée.

Limites du test

Les microcuvettes HemoCue Hb 201 sont destinées au diagnostic in vitro uniquement. L'analyseur HemoCue Hb 201+ ne doit être utilisé qu'avec les microcuvettes HemoCue Hb 201. Pour toutes autres limites de la procédure, se reporter au mode d'emploi des microcuvettes.

Valeurs de référence

Hommes adultes 130 – 170 g/L (13.0 – 17.0 g/dL, 8.1 – 10.5 mmol/L)
Femmes adultes 120 – 150 g/L (12.0 – 15.0 g/dL, 7.4 – 9.3 mmol/L)
Nourrissons, après la période néonatale 110 – 140 g/L (11.0 – 14.0 g/dL, 6.8 – 8.7 mmol/L)
Enfants, de deux ans à l'adolescence : augmenter progressivement jusqu'aux valeurs adultes.
Compte tenu des variations importantes (diététiques, géographiques, etc.) affectant les valeurs normales, il est recommandé à chaque laboratoire d'établir sa propre fourchette de valeurs normales.

Caractéristiques techniques

Dimensions : 85 x 160 x 43 mm
Poids: 350 g (piles incluses)
4 piles de type AA ou R6, 1.5 V
Adaptateur secteur : porte le marquage CE
N'utiliser que des adaptateurs recommandés par HemoCue, voir page 44.
Degré de pollution : 2
Catégorie de surtension : II
Cet équipement ne doit pas être utilisé en présence de composés inflammables.
L'instrument est testé conformément à IEC 61010-1, première édition, 1990 avec amendement 1, 1992 et amendement 2, 1995 (EN 61010-1: 1993 avec A2: 1995), EN 60601-1-2, et il est conforme à la directive 98/79/EC sur les dispositifs médicaux de diagnostic in vitro.

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Signal d'entrée et signal de sortie

Les équipements accessoires branchés aux interfaces analogiques et digitales doivent être certifiés selon les normes IEC (par ex. IEC 950 pour l'équipement informatique et IEC 601-1 pour l'équipement médical). De plus, toutes les configurations doivent être compatibles avec la norme IEC 601-1-1. Toute personne qui connecte un équipement supplémentaire aux signaux d'entrée et/ou de sortie configure un système médical, il sera donc responsable de la conformation du système aux directives IEC 601-1-1. En cas de doute, contacter HemoCue AB, ou votre distributeur HemoCue.

Garantie

L'analyseur est garanti pour une période de 24 mois à compter de la date de réception. Après la période de garantie, la maintenance et les réparations seront effectuées selon un tarif fixe.

Pièces de rechange – Accessoires

Les pièces de rechange et accessoires suivants sont disponibles :
Adaptateur secteur
Couvercle de compartiment piles
Support de microcuvette
Logiciel PC
Câbles interface pour PC et imprimante
Solutions de contrôle
Tampons HemoCue Cleaner
Malette de transport
Lancettes HemoCue
Cuvette de contrôle HemoCue Hb 201[1]

Symboles utilisés

⚠ Attention, voir mode d'emploi

CE Marquage CE

Se référer au Type BF Applied Part, selon EN60601-1

Equipement de classe II

Ce produit est classé dans la liste des normes UL agréées et des conditions de UL 2601-1.

Références

1. Makarem, A. In clinical Chemistry: Principles and Technics, 2nd ed., Henry, R.J., Cannon, D.C., and Winkelman, J.W., Harper and Row, Hagerstown, M.D., 1974, pp. 1125–1147.
2. Dacie and Lewis, Practical Haematology Ninth edition.
3. Jacques Wallach, M.D., Interpretation of Diagnostic Tests.

Fabricant

HemoCue AB
Box 1204
SE-262 23 Ängelholm Suède
Téléphone : + 46 431 45 82 00
Fax : + 46 431 45 82 25
E-mail : info@hemocue.se
www.hemocue.com

Recommeded Adapter:

Pays	Type	Fabricant	IEntrée	Sortie
USA/Canada	Mod nr FE3515060D035	FRIWO	120 V ca/60 Hz	6V cc, 350 mA

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PT Especificações

Geral

O HemoCue Hb 201+ é um sistema usado para a determinação da quantidade total de hemoglobina no sangue. O sistema consiste de um analisador especialmente concebido com microcuvetes também especialmente concebidas contendo reagentes secos. A microcuvete serve de pipeta, de recipiente de reacção e de microcuvete de medição. Não é necessário diluir. A medição da hemoglobina tem lugar no analisador, que segue o progresso da reacção e apresenta o resultado só depois de atingir o ponto final da reacção. O sistema é calibrado de fábrica com o método do cianeto de hemoglobina (HiCN), o método internacional de referência para a determinação da concentração de hemoglobina no sangue.

Propósito

Determinação quantitativa de hemoglobina em sangue capilar, venoso ou arterial. O sistema HemoCue Hb 201 é usado para determinação quantitativa da hemoglobina em sangue total usando-se um analisador especialmente concebido, o HemoCue Hb 201+, e microcuvetes especialmente concebidas, as microcuvetes HemoCue Hb 201. As microcuvetes HemoCue Hb 201 destinam-se apenas para uso em diagnósticos In Vitro. O analisador HemoCue Hb 201+ destina-se apenas a ser usado com microcuvetes HemoCue Hb 201.

Directiva de Unidade Médica IVD

O HemoCue Hb 201+ está de acordo com a Directiva de Unidade Médica IVD 98/79/EC e é portador da marca CE

Teoria

O desoxicolato de sódio hemolisa os eritrócitos, libertando hemoglobina. O nitrito de sódio converte a hemoglobina em metahemoglobina que, junta com azida de sódio, dá azidametahemoglobina. A absorvência é medida em dois comprimentos de onda (570 nm e 880 nm) de modo a compensar a turvação da amostra.

Reagentes

40% w/w de Desoxicolato de Sódio, 18% w/w de Azida de Sódio, 20% w/w de Nitrito de Sódio, 22% w/w de ingredientes inertes.

Material da amostra

Pode ser usado sangue capilar, venoso ou arterial. São recomendados anti-coagulantes sólidos tais como EDTA ou Heparina/Fluoreto de forma a evitar o efeito de diluição. Se o sangue tiver sido guardado num frigorífico, tem de se permitir que ele atinja a temperatura ambiente 18 – 30 °C (64 – 86 °F) antes da análise. A hemoglobina permanece intacta durante dias, desde que não seja infectada. Misture as amostras num misturador mecânico durante pelo menos dois minutos ou inverta os tubos à mão 8 – 10 vezes, ou então siga as recomendações locais.

Armazenagem e requisitos ambientais das microcuvetes HemoCue Hb 201

Use as microcuvetes HemoCue Hb 201 antes da sua data de expiração. A data de expiração está impressa em cada embalagem.

Armazenagem de microcuvetes embaladas em frasco

As microcuvetes devem ser armazenadas à temperatura ambiente (15 – 30 °C, 59 – 86 °F). Não refrigerar. As microcuvetes mantêm-se estáveis durante dois anos a partir da data de produção. Uma vez rompido o selo, as microcuvetes mantêm-se estáveis durante três meses. Mantenha sempre a embalagem devidamente fechada.

Armazenagem de microcuvetes embaladas individualmente

As microcuvetes devem ser armazenadas à temperatura ambiente (15 – 30 °C, 59 – 86 °F). Não refrigerar. As microcuvetes individuais mantêm-se estáveis durante quinze meses a partir da data de produção.

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Analisador HemoCue Hb 201+

O analisador pode ser armazenado a 0 – 50 °C (32 – 122 °F).
A temperatura de trabalho é 18 – 30 °C (64 – 86 °F). Permita que o analisador atinja a temperatura ambiente antes de o usar. O analisador não deve ser usado a níveis elevados de humidade (quer dizer > 90 % sem condensar).

Controle de Qualidade

O analisador HemoCue Hb 201+ dispõe de um "AUTO-TESTE" electrónico. Cada vez que se liga o analisador, ele verifica automaticamente a realização da sua unidade optrónica. Se o analisador se mantiver ligado, o teste é realizado de duas em duas horas. Se forem exigidas verificações para controle de qualidade por razões de regulamentação, elas devem ser efectuadas com líquidos recomendados pela HemoCue.

Alcance de medição

0 – 256 g/L (0 – 25.6 g/dL, 0 – 15.9 mmol/L).
Resultados superiores a 256 g/L (25.6 g/dL, 15.9 mmol/L) serão exibidos como HHH.

Limitações

As microcuvetes Hb 201 foram concebidas unicamente para uso em diagnósticos In Vitro. O analisador HemoCue Hb 201 + foi concebido para uso apenas com as microcuvetes HemoCue Hb 201. Para outras limitações de procedimento, queira ver as instruções de uso das microcuvetes HemoCue Hb 201.

Valores esperados

Homens adultos 130 – 170 g/L (13.0 – 17.0 g/dL, 8.1 – 10.5 mmol/L)
Mulheres adultas 120 – 150 g/L (12.0 – 15.0 g/dL, 7.4 – 9.3 mmol/L)
Crianças, após o período neonatal 110 – 140 g/L (11.0 – 14.0 g/dL, 6.8 – 8.7 mmol/L)
Crianças, dos dois anos até à adolescência: aumento gradual até valores normais de adultos. Devido à vasta gama de condições (dietéticas, geográficas, etc) que afectam os valores normais, recomenda-se que cada laboratório estabeleça a sua própria gama de valores normais.

Especificações Técnicas

Dimensões: 85 × 160 × 43 mm
Peso: 350 g (incluindo as pilhas)
4 pilhas de tipo AA ou R6, 1.5 V
Transformador de corrente: com marca CE
Use apenas transformadores recomendados pela HemoCue, ver na página 47.
Grau de poluição: 2
Categoria de sobrevoltagem: II
O instrumento foi testado de acordo com IEC 61010-1, Primeira edição, 1990 com Ressalva 1, 1992 e Ressalva 2, 1995 (EN 61010-1: 1993 com A2: 1995), EN 60601-1-2 e está de acordo com a Directiva de Unidade Médica IVD 98/79/EC.

Garantia

O analisador tem uma garantia de 24 meses a partir da data do recibo. Após a expiração do prazo de garantia, as reparações e serviços são efectuados a preços fixos.

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Peças sobressalentes – Acessórios

Estão acessíveis as seguintes peças e acessórios:

Transformador de corrente
Portador de pilhas
Porta-cuvetes
Programa de PC
Cabos para conexão do PC e da impressora
Controles líquidos
Limpadores HemoCue
Estojo de carcaça rígida
Lancetas HemoCue
HemoCue Hb 201+ Control Cuvette

Símbolos usados

⚠ Atenção, ver instruções de uso

CE Marca CE

Referências

1. Makarem, A. In clinical Chemistry: Principles and Technics, 2nd ed., Henry, R.J., Cannon, D.C., and Winkelman, J.W., Harper and Row, Hagerstown, M.D., 1974, pp. 1125–1147.
2. Dacie and Lewis, Practical Haematology Ninth edition.
3. Jacques Wallach, M.D., Interpretation of Diagnostic Tests.

Fabricante

HemoCue AB
Box 1204
SE-262 23 Ängelholm, Suecia
Télefone: +46 431 45 82 00
Faks: +46 431 45 82 25
Correio electrónico: info@hemocue.se
www.hemocue.com

Países	Tipo	Fabricante	Tomada
Europa	FW3199	FRIWO	230 V~/50 Hz/26 mA/6 VA
EUA	Mod nr FE3515060D035	FRIWO	120 V~/60 Hz/6,6 VA

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

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BERGSTENS, HBG 991705 030508

HemoCue AB, Box 1204, SE-262 23 Ängelholm, Sweden. Phone +46 431 45 82 00. Fax +46 431 45 82 25.
info@hemocue.se www.hemocue.com

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

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HemoCue® Hb 201+

Accurate Hemoglobin results anytime, anywhere.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@ gov or

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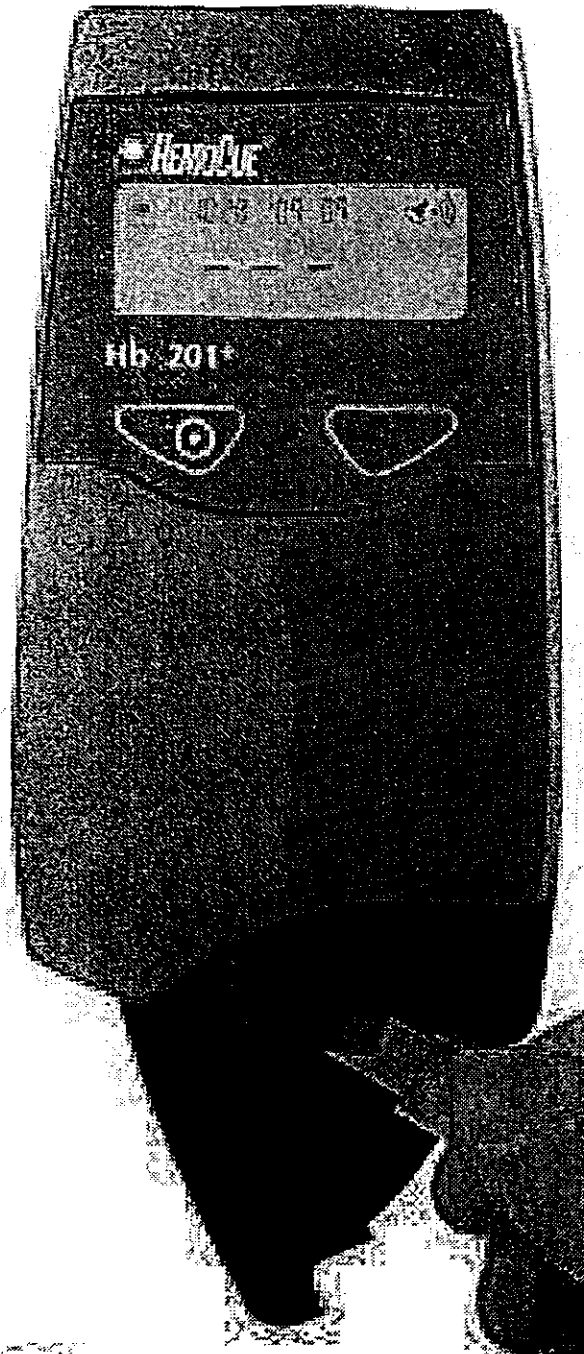
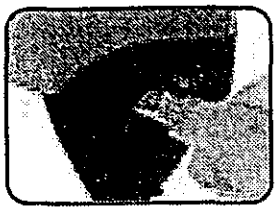
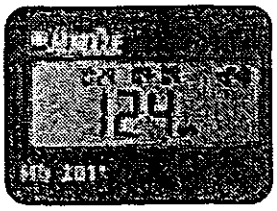


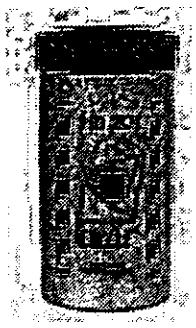
Fill the cuvette by placing the tip of the cuvette in the drop of blood.



Place the filled cuvette into the cuvette holder and slide the cuvette holder into the analyzer.



The result appears on the display within 15–60 seconds.



The unique, disposable microcuvette is the heart of the HemoCue system. The correct volume of blood is drawn into the cuvette by capillary action which initiates the reaction.

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New look. Same excellent accuracy and precision.

Appreciated by users all over the world for *simplicity, speed and small sample volume*, the HemoCue B-Hemoglobin System is the long-standing original choice for lab-quality hemoglobin testing at point of care. The system uses a specially designed analyzer with specially designed microcuvettes.

The new HemoCue Hb 201+ system offers the same important benefits as its predecessor. In addition, a smaller analyzer will give you more flexibility and mobility to use the system anytime, anywhere.

Laboratory accuracy and precision

The accuracy of the Hb 201+ system is ±1.5% when compared to the international reference method for Hemoglobin determination (the ICSH method). Many studies also show excellent correlation with different laboratory systems. Since there is no variation in cuvettes from batch-to-batch, there is no need for instrument re-calibration when new batches are put into use. Additionally, by measuring at two wavelengths, the system automatically compensates for turbidity (e.g. high WBC and lipids) in the sample, improving accuracy.

User friendliness and minimal maintenance

The system is easy to learn and easy to use. After a brief instruction, even non-laboratory personnel can perform the test safely and accurately. The analyzer is factory calibrated which is automatically verified every time the instrument i switched on. This new self test eliminates the need for a control cuvette.
An optional audio signal will alert you when the result is displayed. The new cuvette holder design reduces the need for cleaning by minimizing the contamination of the optronic unit.

Data storage possibilities

To make the system even more useful, the Hb 201+ system has the possibility to store up to 600 results together with date and time. Results can be transferred to a small label printer or to a PC for storage or further analysis. Control values are differentiated from the patient results with a flag function.

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HemoCue Hb 201+ Specification

System

The HemoCue Hb 201+ system consists of two parts: a disposable microcuvette containing dry reagent and a factory calibrated analyzer. To ensure accuracy and precision, the HemoCue Hb 201+ analyzer and the HemoCue Hb 201+ microcuvettes must be used together as a system.

Method

The Hb 201+ system uses a modification of Vanzetti's reagents, utilizing an azidmethemoglobin reaction, which yields results within one minute. This method correlates very well with the international reference method for hemoglobin determination (ICSH).

Analyzer

Measurements are made at two wavelengths, 570 nm for hemoglobin measurement and 880 nm for turbidity compensation. Data storage of up to 600 results together with date and time.

Specimen requirement

10 µL of capillary, venous or arterial blood are needed for the assay.

Results

Results are displayed in g/dL within 15–60 seconds depending on the hemoglobin concentration.

Measuring range

The measuring range is 0–25.6 g/dL.

Quality Control

The HemoCue Hb 201+ has an internal electronic selftest. The calibration of the analyzer is automatically verified each time the analyzer is switched on and every second hour therafter.

If quality control testing is required for regulatory reasons it should be performed using liquid controls recommended by HemoCue.

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HEMOCUE®

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HemoCue Inc. 40 Parkside Drive, Lake Forest, California 92630 Tel (800) 323-1674 Fax (800) 333-7063 www.hemocue.com

Questions? Contact FDA/ODRH/OCE/DHS at ODRH-FOIS Phone@fda.hhs.gov or 301-796-3118

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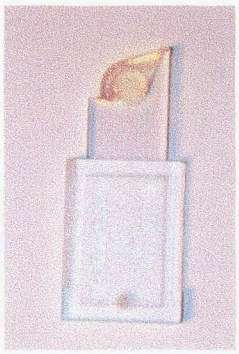
Packaging, Storage and Expiration Dating

The optical sample area, volume, and reagents in the HemoCue Hb 201 Microcuvette are identical to the marketed B-Hemoglobin Microcuvette. However, the shape of the HemoCue Hb 201 Microcuvette is "keyed" such that it will only fit in the HemoCue Hb 201$^+$ Analyzer. Similarly, the B-Hemoglobin Microcuvette will only fit in the B-Hemoglobin Analyzer. In all other respects the Hb 201 Microcuvette is identical to the existing B-Hemoglobin Microcuvette.

The packaging vial for the HemoCue Hb 201 Microcuvette is the one used for our marketed HemoCue B-Hemoglobin Microcuvettes. Labeling, of course, is updated to show the HemoCue Hb 201$^+$ name and Article number.

The Hb 201 Microcuvettes are packaged with the same Storage, Handling and Expiration Date specifications as the existing B-Hemoglobin Microcuvettes.

Existing B-Hemoglobin Microcuvette **New Hb 201 Microcuvette**



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

510(k) Premarket Notification Database

Device Classification Name	SYSTEM, HEMOGLOBIN, AUTOMATED
Regulation Number	864.5620
510(k) Number	K832020
Device Name	HEMOCUE PHOTOMETER TECHNICAL MANUAL
Applicant	AKTIEBOLAGET LEO DIAGNOSTICS
Product Code	GKR
Date Received	06/15/1983
Decision Date	10/28/1983
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	Hematology
Review Advisory Committee	Hematology
Statement/Summary/Purged Status	Purged, no summary or statement
Type	Traditional
Reviewed by Third Party	No

Database Updated 6/9/2003

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

510(k) Premarket Notification Database

Device Classification Name	SYSTEM, HEMOGLOBIN, AUTOMATED
Regulation Number	864.5620
510(k) Number	K961312
Device Name	HEMOCUE B-HEMOGLOBIN SYSTEM
Applicant	HEMOCUE, INC. C/O ROBERT JOEL SLOMOF 9229 CRANFORD DRIVE POTOMAC, MD 20854
Contact	ROBERT J SLOMOF
Product Code	GKR
Date Received	04/04/1996
Decision Date	09/24/1996
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	Hematology
Review Advisory Committee	Hematology
Statement/Summary/Purged Status	Statement/purged 510(k)
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No

Database Updated 6/9/2003

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HemoCue® B-Hemoglobin

Three simple steps to accurate hemoglobin testing

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HEMOCUE®

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

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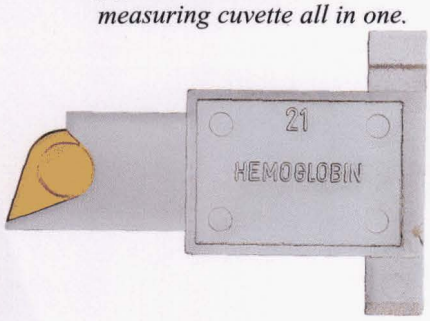
The HemoCue B-Hemoglobin System provides lab-quality hemoglobin values in less than 60 seconds.

The self-filling microcuvette is disposable and serves as a pipette, test tube and measuring cuvette all in one.



Hemoglobin – the preferred method

Measurement of hemoglobin is the most precise, accurate and useful laboratory test for distinguishing between anemia, normal and polycythemia.[1]

It is the preferred test for following the status of a patient in such clinical situations as hemorrhage, hemolysis, dehydration and other changes in plasma volume – and for verifying the results of transfusion, or treatment of other deficiency states, such as malnutrition.[1]

Hemoglobin concentrations in a healthy population vary considerably with age, sex and altitude. However, the variation in a given healthy individual is small. Ideally then, a hemoglobin value should be assessed by comparing it with a value for the same individual. This would permit detection of significant changes in the patient's hemoglobin level, which could still be within the normal population range and yet motivate further investigation. Therefore, periodic monitoring of a patient's hemoglobin level can provide information of great importance.

An easy-to-use test

The HemoCue B-Hemoglobin System only requires the photometer, a microcuvette and a drop of blood. The basic ability to take a proper sample is necessary, but no laboratory training is needed to obtain fast and accurate results.

Fast results

The chemical reaction takes place in the cuvette and the photometer automatically displays the result in less than 60 seconds.

The result is available while the patient is still present, and decisions about patient care can be made immediately!

Accurate

Clinical evaluations have shown that a correlation of 0.99 can be obtained when the HemoCue B-Hemoglobin test is compared to the reference method.[2]

The accuracy of the system has been proven to be ±1.5%.[3]

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Correction for turbidity

The most common causes of turbid blood samples are high white blood cell count and excessive concentration of lipids.

When a turbid sample is analyzed with traditional methods, the test will often result in an erroneously high hemoglobin reading.

The HemoCue B-Hemoglobin System automatically compensates for turbidity by measuring at two wavelengths.[4,5]

Safe

The microcuvette, which automatically draws a precise volume of blood, allows for safe and hygienic handling.

There is no dispensing, pipetting or mixing of blood and reagents as with traditional hemoglobin methods. There is no risk of broken glass as with the hematocrit method.

Quality assurance

The HemoCue B-Hemoglobin System is produced under a comprehensive quality control program.

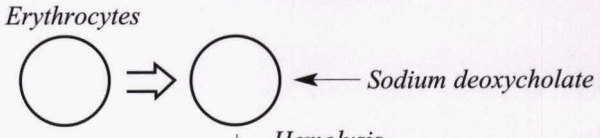
There are no significant batch-to-batch variations between cuvettes, which makes recalibration of the photometer unnecessary.

The photometer automatically zeroes itself after measurement, and automatically checks the intensity of the light source and the operation of the photocell. The control cuvette, supplied with each photometer, provides a simple method of verifying the calibration of the photometer.

Technical data

Method: *Azidemethemoglobin.*
Photometer: *Measurement at 570 nm and 880 nm ensures automatic compensation for turbidity. Operates from an AC adapter or five 1.5 V dry cell batteries.*
Results: *Displayed within 45–60 seconds.*
Measurement range: *0–25.6 g/dl (0–256 g/l).*

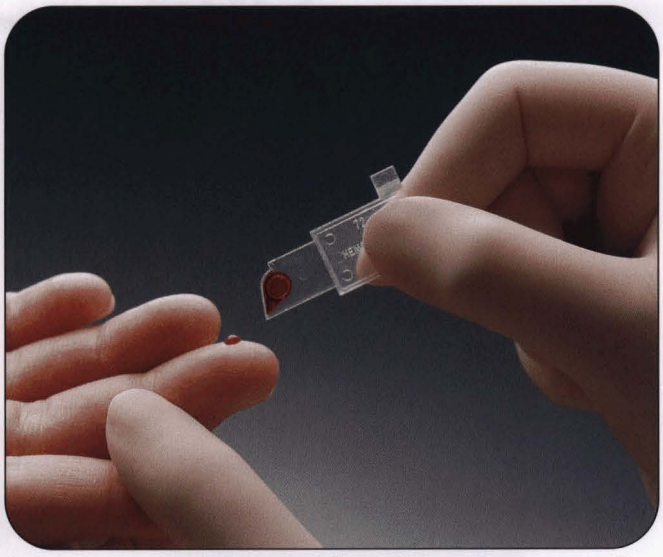
Chemical reaction



Hemolysis

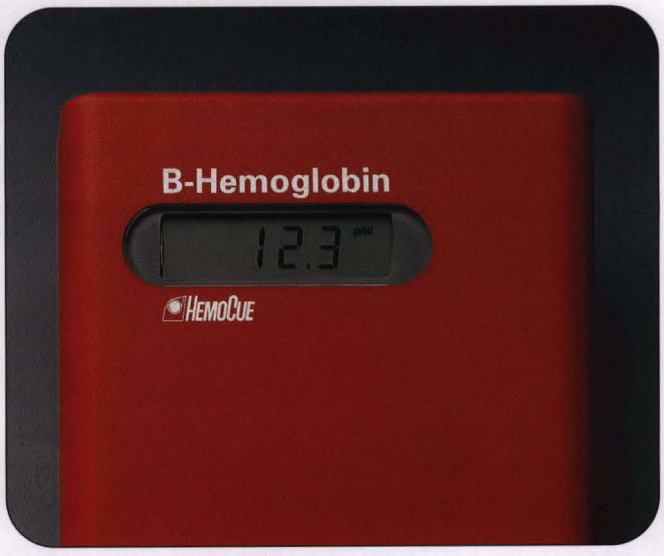
Hemoglobin + NO_2- → Methemoglobin
Methemoglobin + N_3- → Azidemethemoglobin

Three simple steps



1. Apply the microcuvette to a drop of blood. It automatically draws up 10 µl by capillary action.

2. Insert the microcuvette into the HemoCue photometer.



3. The result is displayed within 45–60 seconds.

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One technique. Two tests.

HemoCue® B-Hemoglobin System

HemoCue® Glucose 201 System

Hemoglobin Reimbursement

CPT Code		National Ceiling
85018QW	Hemoglobin	$3.31

Glucose Reimbursement

CPT Code		National Ceiling
82947QW	Quantitative Glucose Determination	$5.48
82950QW	Glucose post dose (includes glucose), direct measurement	$6.64
82951QW	GTT, direct measurement, 3 specimens (includes glucose)	$17.99
82952QW	GTT, direct measurement, each additional beyond 3 specimens (includes glucose)	$5.48

References

1. American Medical Association, Council on Scientific Affairs. *Laboratory Tests in Medical Practice*. Editors:Jones R J, Palulonis R M. First Edition 1980: pp 95–106.
2. Bridges N, Parvin R M, van Assendelft O W. *Evaluation of a New System for Hemoglobin Measurement*. Am Clin Prod Rev 1987, April:22–5.
3. Kwant G, Oeseburg B, Zwart A, Zijlstra W G. *Calibration of a practical hæmoglobinometer*. Clin Lab Haemat 1987, 9:387–393.
4. von Schenck H, Falkensson M, Lundberg B. *Evaluation of HemoCue, a New Device for Determining Hemoglobin*. Clin Chem 1986, 32:562–9.
5. Oeseburg B, Kwant G. *Disturbance of the Determination of Hemoglobin Concentration in Patients with High Leukocyte Counts*. Clin Chem 1989, 35:515–516.

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DACIE AND LEWIS

PRACTICAL HAEMATOLOGY

NINTH EDITION

EDITED BY
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B J BAIN
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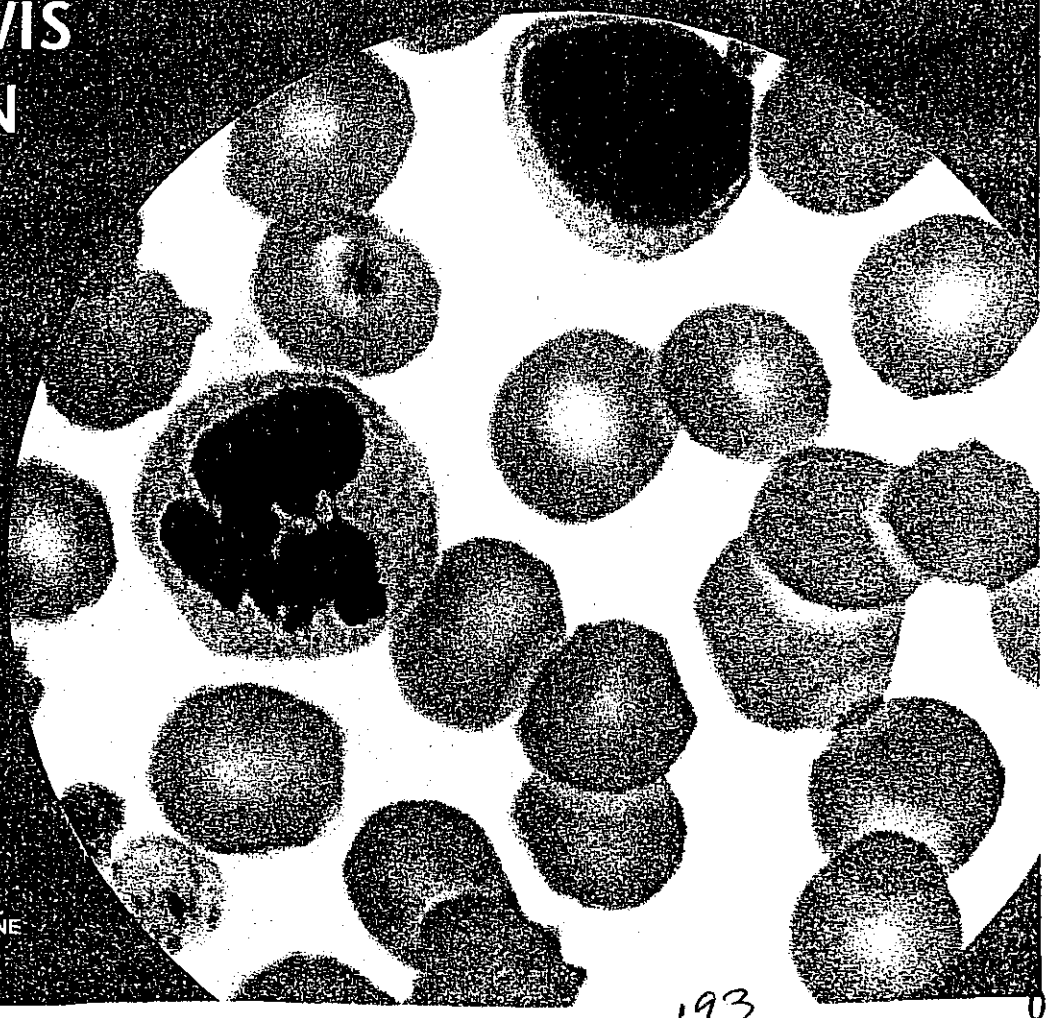

CHURCHILL LIVINGSTONE

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1

Collection and handling of blood

S. Mitchell Lewis

Biohazard precautions	1	Serum	4
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Differences between capillary and venous blood	4	Sample homogeneity	7

In investigating physiological function and malfunction of blood, it is essential that, as far as possible, tests do not give misleading information because of technical errors. It is therefore important to avoid faults in specimen collection, storage and transport to the laboratory. Venous blood is preferred for most haematological examinations. Peripheral capillary samples can be almost as satisfactory for some purposes if a free flow of blood is obtained (see p. 3), but in general they should be restricted to children and to some direct 'point-of-care' screening tests.

BIOHAZARD PRECAUTIONS

When collecting a blood sample, the operator should, wherever possible, wear disposable plastic or thin rubber gloves*, especially if he or she has any cuts, abrasions or skin breaks on the hands. Care must be taken to prevent injuries when handling syringes, needles and lancets. Disposable syringes, needles and lancets should be used if at all possible, and they should not be re-used. They should be placed (without separating needles from syringes) in a puncture-resistant container for disposal or subsequent decontamination (see p. 557). Specimens should be sent to the laboratory in individual closed plastic bags, separated from the request forms to prevent their contamination should there be any leakage from the specimens. Tubes which minimize the risk of leakage are described on page 557.

*Some individuals may have an allergic reaction to either plastic or rubber gloves.

STANDARDIZED PROCEDURE

The method used for blood collection may affect the sample. The constituents of the blood may be altered by a number of factors as listed in Table 1.1. It is thus important to have a standard procedure for the collecting and handling of blood specimens.

Recommendations for standardizing the procedure have been published.[1,2]

Table 1.1 Causes of misleading results from discrepancies in specimen collection

Precollection
Toilet within 30 min
Meal within 2 h
Smoking
Physical activity (including fast walking) within 20 min
Stress
During collection
Different times of day: diurnal variance
Posture: lying/standing/sitting
Haemoconcentration from prolonged tourniquet pressure
Excessive negative pressure when drawing blood into syringe
Capillary or venous blood
Handling of specimen
Insufficient or excess anticoagulant
Inadequate mixing of blood with anticoagulant
Patient and/or specimen identification error
Delay in transit to laboratory

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VENOUS BLOOD

It is now common practice for specimen collection to be undertaken by specially trained phlebotomists, and there are published guidelines which set out an appropriate training programme.[1,3]

Blood is best withdrawn from an antecubital vein by means of either an evacuated tube or a disposable plastic or glass syringe. The needles should not be too fine or too long; those of 19 or 21G* are suitable for most adults, and 23G for children, the latter especially with a short shaft (about 15 mm). It is usually recommended that the skin should be cleaned with 70% alcohol (e.g. isopropanol) and allowed to dry before being punctured; however, some doubts have been expressed on the utility of this practice for preventing infection at the venepuncture site.[4] Care must also be taken when using a tourniquet (see below) to avoid contaminating it with blood.[5]

When a series of samples is required or when the blood sampling is to be followed by an infusion, it is convenient to collect the blood by means of an intravenous cannula or winged ('butterfly') needle connected to a length of plastic tubing attached to the patient's arm by adhesive tape.

Except in the case of very young children, it should be possible with practice to obtain venous blood even from patients with difficult veins. Successful venepuncture may be facilitated by keeping the subject's arm warm, applying to the upper arm a sphygmomanometer cuff kept at approximately diastolic pressure and tapping the skin over the site of the vein a few times. In obese patients, it may be easier to use a vein on the dorsum of the hand, after warming it by immersion in warm water. When the hand is dried and the fist clenched, veins suitable for puncture will usually become apparent. If the veins are very small, a 23G needle should enable at least 2 ml of blood to be obtained satisfactorily. Vein punctures in the dorsum of the hand tend to bleed more readily than at other sites. The arm should be elevated after withdrawal of the needle and pressure should be applied for several minutes before an adhesive dressing is placed over the puncture site.

*The International Organization for Standardization has established a standard (ISO 7864) with the following diameters for the different gauges: 19G = 1.1 mm; 21G = 0.8 mm; 23G = 0.6 mm.

If possible, compression of the vein should be completely avoided so as to prevent haemoconcentration. In practice, it is usually necessary to use a tourniquet. This should be loosened once the needle has been inserted into the vein. The piston of the syringe should be withdrawn slowly and no attempt made to withdraw blood faster than the vein is filling. After detaching the needle, the blood should be delivered carefully from the syringe into a container and, if it is desired to prevent coagulation, it should be promptly and thoroughly but gently mixed with the anticoagulant. It is convenient to use as containers for blood samples disposable glass or plastic flat-bottomed tubes fitted with caps; except for coagulation studies, the choice between glass and plastic is a matter of availability or personal preference. Because of the possibility of infection of personnel when blood has leaked from the container or when removing the cap causes an aerosol discharge of the contents, it is essential to use containers designed to minimize these risks, e.g. an evacuated tube system or a container with a piercable cap through which the blood can be sampled.

Haemolysis can be avoided or minimized by using clean apparatus, withdrawing the blood slowly, not using too fine a needle, delivering the blood gently into the receiver and avoiding frothing during the withdrawal of the blood and subsequent mixing with the anticoagulant.

The most common disposable containers available from commercial sources contain dipotassium or tripotassium or disodium ethylenediamine tetra-acetic acid (EDTA) as anticoagulant and are marked at a level to indicate the correct amount of blood to be added (see p. 5). Containers are also available containing trisodium citrate, heparin or acid citrate dextrose.

Evacuated tube systems are becoming increasingly popular. They consist of a glass tube (with or without anticoagulant) under vacuum, a needle and a needle holder which secures the needle to the tube. The main advantage is that it is not necessary to remove the stopper to fill the tube. The vacuum controls the amount of blood which enters the tube, ensuring an adequate specimen for the subsequent tests and the correct proportion of anticoagulant, when this is present. Evacuated tube systems can be used for routine coagulation screening tests; activation of coagulation factors is prevented by using siliconized tubes: special

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precautions for collecting blood for coagulation tests are described on p. 349.

Design requirements and other specifications for evacuated and non-evacuated specimen collection containers have been described in a number of national and international standards, e.g. that of the International Organization for Standardization (ISO 6710).

Ideally, blood films should be made immediately the blood has been withdrawn. In practice, blood samples are often sent to the laboratory after a variable delay. Films should be made in the laboratory from such blood as soon as is practicable. After careful and thorough mixing of the blood, a glass or plastic capillary can be used to take up a sample and deliver a drop of the right size on to a slide so that films can be made. The differences between films made of fresh blood (no anticoagulant) and anticoagulated blood are dealt with on page 6.

CAPILLARY (PERIPHERAL) BLOOD

Capillary blood is liable to give erroneous results[6] and there is greater likelihood of contamination and risk of transmission of disease than with venesection. It should be a used only with infants under 1 year or when it is not possible to obtain venous blood.

Collection of capillary blood[7]

Skin puncture is carried out with a needle or lancet. After use, they should be placed in a puncture-resistant container for disposal or subsequent decontamination (see p. 558), and they must never be re-used on another individual. In infants, satisfactory samples can be obtained by a deep puncture of the plantar surface of the heel in the area shown in Figure 1.1. As the heel should be really warm, it may be necessary to bathe it in hot water. The central plantar area and the posterior curvature should not be punctured in small infants to avoid the risk of injury to the underlying tarsal bones. In an older child and adult, the blood can be obtained from the distal digit of the third or fourth finger on its palmar surface, about 3–5 mm lateral from the nail bed.

A free flow of blood is essential, and only the very gentlest squeezing is permissible; ideally, large drops of blood should exude slowly but spontaneously. If it is necessary to squeeze firmly in order to obtain blood, the results are unreliable. If the poor flow is due to the part being cold and cyanosed, too high figures for Hb† red cell count, and leucocyte count are usually obtained.

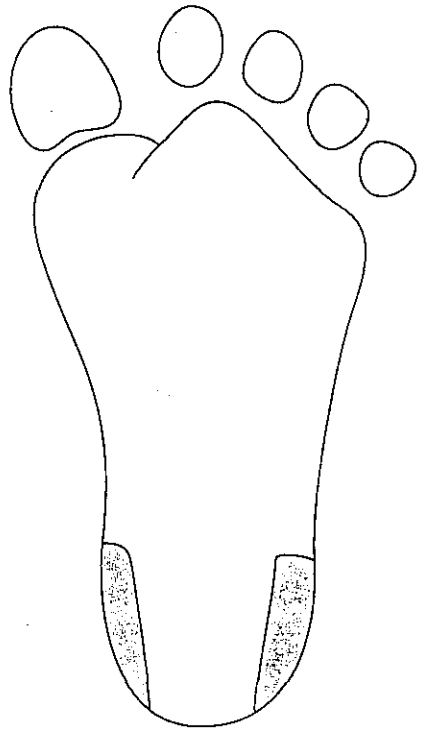

Fig. 1.1 Skin puncture in infants. Puncture must be restricted to the outer medial and lateral portions of the plantar surface of the foot where indicated by the shaded area.

Clean the area with 70% alcohol (e.g. isopropanol) and allow to dry. Puncture the skin to a depth of 2–3 mm with a sterile disposable lancet. Wipe away the first drop of blood with dry sterile gauze. If necessary, squeeze very gently to encourage a free flow of blood. Collect a sample directly onto a reagent strip or by a 10 µl or 20 µl micropipette for immediate dispensing into diluent. There are also methods for collecting the blood into a capillary tube fixed into the cap of a microcontainer to allow the blood to pass by capillary action into the container[8] (e.g. Microtainer*; Microvette**). In another system (Unopette*), a calibrated capillary is completely filled with blood

† Throughout the book, Hb is used as an abbreviation for either *haemoglobin* or *haemoglobin concentration* where appropriate.

* Becton Dickinson; ** Sarstedt.

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and linked to a pre-measured volume of diluent.[9] An adequate puncture with a free flow of blood can also enable a larger volume to be collected, drop by drop, into a plastic or glass container.[7]

DIFFERENCES BETWEEN CAPILLARY AND VENOUS BLOOD

Venous blood and capillary blood are not quite the same, even if the latter is freely flowing, and it is likely that free-flowing blood obtained by skin puncture is more nearly arteriolar in origin. The packed cell volume (PCV), red cell count (RBC) and Hb of capillary blood are slightly greater than in venous blood. The total leucocyte and neutrophil counts are higher by about 8%, the monocyte count by about 12%, and in some cases by as much as 100%, especially in children.[10,11] Conversely, the platelet count appears to be higher in venous than in capillary blood; this is on average by about 9% and in some cases by as much as 32%.[10,11] This may be due to adhesion of platelets to the site of the skin puncture.

SERUM

Blood collected in order to obtain serum should be delivered into sterile tubes or screw-capped bottles and allowed to clot undisturbed for about 1 h at room temperature.* Then loosen the clot gently from the container wall by means of a wooden stick, or a thin plastic or glass rod. If it is roughly treated, lysis is certain to follow. Close the tube with a stopper and centrifuge for 10 min at about 1200 *g*. Pipette the supernatant serum into another tube and centrifuge for 10 min at about 1200 *g*. Transfer the serum to tubes for tests or for storage. For most tests, serum should be kept at 4°C, before use, but if testing is delayed, serum can be stored −20°C for up to 3 months and at −40°C or lower for long-term storage. Frozen specimens should be thawed on the bench or in a water-bath at room temperature, then inverted several times to ensure homogeneity before use for a test. Do not refreeze thawed specimens.

* Room temperature is usually taken as 18–25°C.

Defribrinating whole blood

When serum is required urgently or when both serum and cells are required, as in the investigation of certain types of haemolytic anaemia, the sample can be defibrinated. This can be simply performed by placing the blood in a receiver such as a conical flask containing a central glass rod on to which small pieces of glass capillary have been fused (Fig. 1.2). The blood is whisked around the central rod by moderately rapid rotation of the flask. Coagulation is usually complete within 5 min, most of the fibrin collecting upon the central rod. When fibrin formation seems complete, the defibrinated blood may be centrifuged and serum obtained quickly and in relatively large volumes. Blood defibrinated in this way should not undergo any visible degree of lysis. The morphology of the red cells and the leucocytes is well preserved.

Cold agglutinins

If cold agglutinins are to be titrated, the blood must be kept at 37°C until the serum has separated, and if cold agglutinins are known to be

Fig. 1.2 Flask for defibrinating 10–50 ml of blood. The glass rod has had some small pieces of drawn-out glass capillary fused to its lower end.

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present in high concentration, it is best to bring the patient to the laboratory and to collect blood into a previously warmed syringe and then to deliver the blood into containers which have been kept warm at 37°C. When filled, the containers should be promptly replaced in the 37°C water-bath. In this way, it is possible to obtain serum free from haemoglobin even when cold antibodies are present capable of causing agglutination at temperatures as high as 30°C. A practical way of warming the syringe is to place it in its container for 10 min in an oven at approximately 50°C or for 30 min or so in a 37°C incubator. When the clot has retracted in the sample and clear serum has been expressed, the serum is removed by a Pasteur pipette and transferred to a tube which has been warmed by being allowed to stand in a water-bath. It is then rapidly centrifuged so as to rid it of any suspended red cells.

ANTICOAGULANTS

For various purposes, a number of different anticoagulants are available. EDTA and sodium citrate remove calcium which is essential for coagulation. Calcium is either precipitated as insoluble oxalate (crystals of which may be seen in oxalated blood) or bound in a non-ionized form. Heparin works in a different way; it neutralizes thrombin by inhibiting the interaction of several clotting factors in the presence of a plasma co-factor, antithrombin III. Sodium citrate or heparin can be used to render blood incoagulable before transfusion. For better long-term preservation of red cells for certain tests and for transfusion purposes, citrate is used in combination with dextrose in the form of acid–citrate–dextrose (ACD), citrate–phosphate–dextrose (CPD) or Alsever's solution (see p. 603).

Ethylenediamine tetra-acetic acid

The sodium and potassium salts of EDTA are powerful anticoagulants and they are especially suitable for routine haematological work. EDTA acts by its chelating effect on the calcium molecules in blood. To achieve this requires a concentration of 1.2 mg of the anhydrous salt per ml of blood (*c* 4 μmol). The anticoagulant recommended by the International Council for Standardization in Haematology[12] is the dipotassium salt at a concentration of 1.50 ± 0.25 mg/ml of blood. At this concentration, the tripotassium salt produces some shrinkage of red cells which results in a 2–3% decrease in PCV and followed by a gradual increase in mean cell volume (MCV) on standing, whereas there are negligible changes when the dipotassium salt is used.[3]

Excess of EDTA, irrespective of which of its salts, affects both red cells and leucocytes, causing shrinkage and degenerative changes. EDTA in excess of 2 mg/ml of blood may result in a significant decrease in PCV by centrifugation and increase in mean cell haemoglobin concentration (MCHC).[3] The platelets are also affected; excess of EDTA causes them to swell and then disintegrate, causing an artifically high platelet count, as the fragments are large enough to be counted as normal platelets. Care must therefore be taken to ensure that the correct amount of blood is added, and that by repeated inversions of the container the anticoagulant is thoroughly mixed in the blood added to it. The dipotassium salt is very soluble (1650 g/l) and is to be preferred on this account to the disodium salt which is considerably less soluble (108 g/l).[13] Coating the inside surface of the container with a thin layer of EDTA improves the speed of its uptake by the blood.

The dilithium salt of EDTA is equally effective as an anticoagulant,[14] and its use has the advantage that the same sample of blood can be used for chemical investigation. However, it is less soluble than the dipotassium salt (160 g/l).

Blood films made from EDTA blood may fail to demonstrate basophilic stippling of the red cells in lead poisoning. Nor is it suitable for use in the investigation of coagulation problems and should not be used in samples for the prothrombin time test. It has been shown to cause leuco-agglutination affecting both neutrophils and lymphocytes,[15] and it is responsible for the activity of a naturally occurring antiplatelet auto-antibody[16] which may sometimes cause platelet adherence to neutrophils in blood films (see p. 98).

Trisodium citrate

100–120 mmol/l trisodium citrate (32 g/l $Na_3C_6H_5O_7.2H_2O$) is the anticoagulant of choice in coagulation studies. Nine volumes of blood are added to 1 volume of the sodium citrate solution and immediately well mixed with it. Sodium citrate

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is also the anticoagulant for the erythrocyte sedimentation rate (ESR); for this, 4 volumes of venous blood are diluted with 1 volume of the sodium citrate solution.

Heparin

This may be used at a concentration of 10–20 iu per ml of blood. Heparin is an effective anticoagulant and does not alter the size of the red cells; it is a good dry anticoagulant when it is important to reduce to a minimum the chance of lysis occurring after blood has been withdrawn. However, heparinized blood should not be used for making blood films as it gives a faint blue colouration to the background when the films are stained by Romanowsky dyes. This is especially marked in the presence of abnormal proteins. Heparin is the best anticoagulant to use for osmotic fragility tests and is suitable for immunophenotyping; otherwise, it is inferior to EDTA for general use and should not be used for leucocyte counts as it tends to cause the leucocytes to clump.

EFFECTS OF STORAGE ON BLOOD CELL MORPHOLOGY

If blood is allowed to stand in the laboratory before films are made, degenerative changes occur. The changes are not solely due to the presence of an anticoagulant for they also occur in defibrinated blood.

Irrespective of anticoagulant, films made from blood which has been standing for not more than 1 h at room temperature are not easily distinguished from films made immediately after collection of the blood. By 3 h, changes may be discernible and by 12–18 h these become striking. Some but not all neutrophils are affected; their nuclei may stain more homogeneously than in fresh blood, the nuclear lobes may become separated and the cytoplasmic margin may appear ragged or less well defined; small vacuoles appear in the cytoplasm (Fig. 1.3A,B). Some or many of the large monocytes develop marked changes; small vacuoles appear in the cytoplasm and the nucleus undergoes irregular lobulation which may almost amount to disintegration (Fig. 1.3C). Lymphocytes undergo similar changes: a few vacuoles may be seen in the cytoplasm, nuclei stain more homogeneously than usual and in some the nucleus undergoes budding, giving rise to nuclei with two or three lobes (Fig. 1.3D–F). These artefactual changes must be distinguished from apoptosis which is natural cell degradation owing to programmed cell death.[17] It is characterized by shrinking of the cell with cytoplasmic condensation and nuclear fragmentation (Fig. 1.4). At least an occasional apoptotic cell may be seen in any blood film.[18]

Normal red cells are little affected by standing for up to 6 h at room temperature. Longer periods

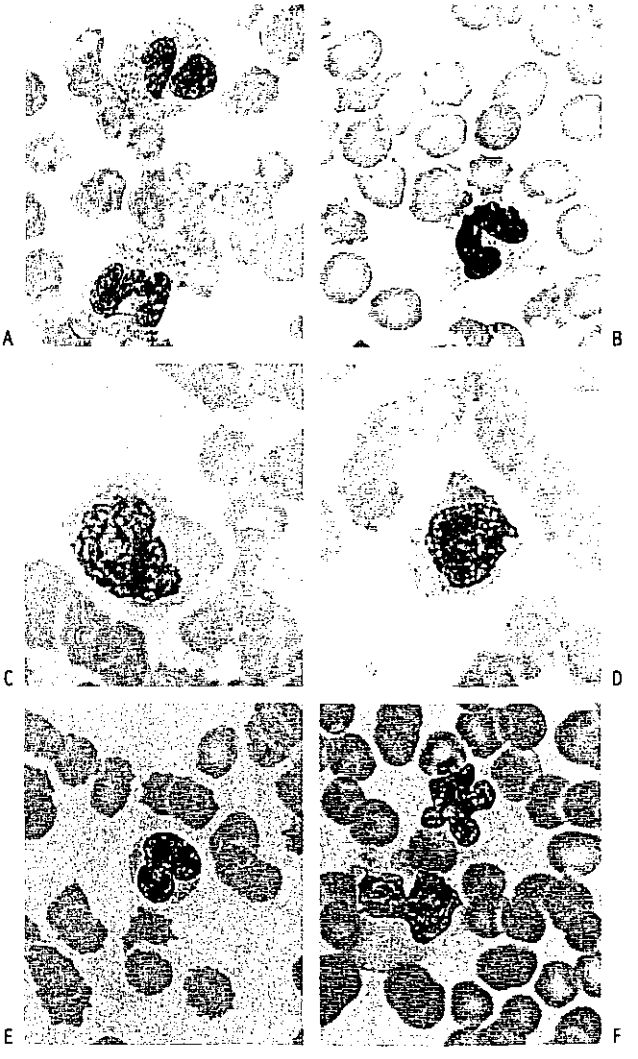

Fig. 1.3 Effect of storage on blood cell morphology. Photomicrographs from films made from EDTA-blood after 24 h at 20°C. (A) and (B): Polymorphonuclear neutrophils; (C): Monocytes; (D), (E) and (F): Lymphocytes. Red cell crenation is prominent in (B) and (E).

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Fig. 1.4 Morphological features of apoptosis. See text.

lead to progressive crenation and sphering (Fig. 1.3 B, E and F). With an excess of EDTA (p. 5), a marked degree of creation occurs within a few hours.

All the above changes are retarded but not abolished in blood kept at 4°C. Their occurrence underlines the importance of making films as soon as possible after withdrawal. But delay of up to 1–3 h or so is certainly permissible.

Where possible, the practice of making films of blood before it is added to the anticoagulant is to be commended, especially when screening for lead toxicity, as the granules of punctuate basophilia may stain less obviously in anticoagulated blood. In fresh blood films, however, the platelets usually clump and it is less easy to estimate the platelet count from inspection of the films. Such films are nevertheless of particular value in investigating patients suffering from purpura, as in certain rare conditions the absence of platelet clumping is a useful pointer to the diagnosis (see p. 97).

QUANTITATIVE EFFECTS OF STORAGE ON BLOOD

In addition to the morphological changes described above, other changes take place when blood is allowed to stand in vitro at room temperature (18–25°C), and more rapidly at higher ambient temperatures. These occur regardless of the anticoagulant, although they are less marked in blood in ACD, CPD or Alsever's solution than in EDTA blood and, as described above, are greater in the tripotassium salt than in the dipotassium salt of EDTA. The red cells start to swell, with the result that the PCV and MCV increase, osmotic fragility and prothrombin time slowly increase and the sedimentation rate decreases; the leucocyte and platelet counts gradually fall.[3] If the blood is kept at 4°C, there is no significant change in PCV and MCV for up to 24 h. Other changes, too, take place more slowly at this temperature, so that for many purposes blood may safely be allowed to stand overnight in the refrigerator if precautions against freezing are taken. Nevertheless, it is best to count leucocytes and especially platelets within 2 h. The fall in leucocyte count, however, may become marked within 1–2 h if there is an excessive amount of EDTA (>4.5 mg/ml).[19] Degenerative changes in leucocyte morphology will especially affect automated differential counts, but can be largely prevented for up to 24 h if the blood is kept at 4°C. Reticulocyte counts are unchanged when the blood is kept in either EDTA or ACD anticoagulant for 24 h at 4°C, but at room temperature the count begins to fall within 6 h. Nucleated red cells disintegrate in the blood specimen within 1 to 2 days at room temperature. The advisability of making films as soon as possible has already been stressed.

Haemoglobin remains unchanged for days, provided that the blood does not become infected, as shown by turbidity or discolouration of the specimen. However, within 2 to 3 days, and especially at high ambient temperatures, the blood begins to lyse, resulting in a decrease in the red cell count and PCV, with an increase in MCH and MCHC.

SAMPLE HOMOGENEITY

In order to ensure homogeneity of blood, it is essential that specimens are effectively mixed immediately prior to taking a sample for testing. Place the specimen tube on a mechanical rotating mixer for at least 2 min or invert the tube 8 to 10 times by hand. If the specimen has been stored at 4°C, it will be viscid and the blood should be allowed to warm up to room temperature before mixing.

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REFERENCES

1 National Committee for Clinical Laboratory Standards 1991 Procedures for the collection of diagnostic blood specimens by venipuncture. Document H3-A3 Vol 11. NCCLS, Villanova, PA.

2 International Committee for Standardization in Haematology 1982 Standardization of blood specimen collection procedures for reference values. Clinical and Laboratory Haematology 4:83–86.

3 Van Assendelft OW, Simmons A 1995 Specimen collection, handling, storage and variability. In: Lewis SM, Koepke JA (eds) Hematology laboratory management and practice. Butterworth Heinemann, Oxford, p 109–127.

4 Sutton CD, White SA, Edwards R 1999 A prospective controlled trial of the efficacy of isopropyl alcohol wipes before venesection in surgical patients. Annals of the Royal College of Surgeons 81:183–186.

5 Golder M, Chan CLH, O'Shea S, et al 2000 Potential risk of cross-infection during peripheral-venous access by contaminated tourniquets. Lancet 355:44.

6 Conway AM, Hinchliffe RF, Earland J, et al 1998 Measurement of haemoglobin using single drops of skin puncture blood: is precision acceptable? Journal of Clinical Pathology 51:248–250.

7 Meitis S 1988 Skin puncture and blood collecting techniques for infants: updates and problems. Clinical Chemistry 34:1890–1894.

8 Hicks JR, Rowland GL, Buffone GJ 1976 Evaluation of a new blood collection device ('Microtainer') that is suitable for pediatric use. Clinical Chemistry 22:2034–2036.

9 Freundlich MH, Gerarde HW 1963 A new, automatic, disposable system for blood counts and hemoglobin. Blood 21:648–655.

10 Daae LNW, Hallerud M, Halvorsen S 1988 A comparison between haematological parameters in 'capillary' and venous blood samples from hospitalized children aged 3 months to 14 years. Scandinavian Journal of Clinical and Laboratory Investigation 51:651–654.

11 Daae LNW, Halvorsen S, Mathison PM, et al 1988 A comparison between haematological parameters in 'capillary' and venous blood from healthy adults. Scandinavian Journal of Clinical and Laboratory Investigation 48:723–726.

12 International Council for Standardization in Haematology 1993 Recommendations for EDTA-anticoagulation of blood for hematology testing. American Journal of Clinical Pathology 100:371–372.

13 Hadley GG, Weiss SP 1955 Further notes on use of salts of ethylenediamine tetraacetic acid (EDTA) as anticoagulants. American Journal of Clinical Pathology 25:1090–1093.

14 Sacker LS, Saunders KE, Page B, et al 1959 Dilithium sequestrene as an anticoagulant. Journal of Clinical Pathology 12:254–257.

15 Deal I, Hernandez AM, Pierre RV 1995 Ethylenediamine tetraacetic acid-associated leukoagglutination. American Journal of Clinical Pathology 103:338–340.

16 Bizzaro N 1995 EDTA-dependent pseudothrombocytopenia: a clinical and epidemiological study of 112 cases with 10-year follow-up. American Journal of Cancer 26:239–257.

17 Kerr JF, Wylie AH, Currie AR 1972 Apoptosis: a basic biological phenomenon with wide-ranging implications in tissue kinetics. British Journal of Cancer 26:239–257.

18 Lach-Szyrma V, Brito-Babapulle F 1999 The clinical significance of apoptotic cells in peripheral blood smears. Clinical and Laboratory Haematology 21:277–280.

19 Goosens W, Van Duppen V, Verwilghen RL 1991 K_2 or K_3 EDTA: the anticoagulant of choice in routine haematology? Clinical and Laboratory Haematology 13:291–295.

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Journal of Clinical Pathology, 1978, 31, 139-143

International Committee for Standardization in Haematology

Recommendations for reference method for haemoglobinometry in human blood (ICSH Standard EP 6/2: 1977) and specifications for international haemiglobincyanide reference preparation (ICSH Standard EP 6/3: 1977)

PREAMBLE Scientific symposia on haemoglobinometry were held at the 9th Congress of the European Society of Haematology, Lisbon, 1963 (Erythrocytometric methods and their standardization. *Bibliotheca Haematologica* (*Basel*), 1964, 18), and the 10th Congress of the International Society of Haematology, Stockholm, 1964 (Standardization, documentation, and normal values in haematology. *Bibliotheca Haematologica* (*Basel*), 1965, 21).

An expert panel on haemoglobinometry was set up in Stockholm on 2 September 1964. On the basis of discussions by this panel the International Committee for Standardization in Haematology (ICSH) made recommendations for a reference method for haemoglobinometry and for the manufacture and distribution of an international reference preparation. These recommendations were endorsed by the General Assembly of ICSH in Sydney on 23 August 1966.

Further symposia on haemoglobinometry were held at the 12th Congress of the International Society of Haematology, New York, 1968 (*Standardization in Hematology*, (1970). Edited by G. Astaldi, C. Sirtori, and G. Vanzetti. Fondazione Carlo Erba, Milan, Italy). and at the 13th Congress of the International Society of Haematology, Munich, 1970 (*Modern Concepts in Hematology*. (1972). Edited by G. Izak and S. M. Lewis. Academic Press, New York).

On the basis of continued experimental studies the reference method and the specifications for the international reference preparation have been modified.

Recommendations for reference method for haemoglobinometry in human blood (ICSH Standard EP 6/2: 1977)

Haemoglobin is a chromoproteid. On the basis of the chemical structures of two α and two β chains and of four haem groups it is calculated to have a relative molecular mass of 64 458 (anhydrous) (Braunitzer *et al.*, 1961, 1964; Hill *et al.*, 1962). The mass fraction of haemoglobin iron is then 0·003 47.

At its 9th Assembly in Kyoto, Japan, in September 1976 ICSH recommended that at the present time the haemoglobin content of blood should be expressed as mass concentration in grammes per litre. In conformity with the joint recommendation for use of the international system of units (SI) in clinical laboratory measurements, as agreed by the International Committee for Standardization in Haematology (ICSH), the International Federation of Clinical Chemistry (IFCC), and the World Association of Societies of Pathology (WASP) (1972, 1973), it is, however, permitted to use substance concentration (mmol per l). In that case the elementary entity (monomer or tetramer) should be specified—that is, by use of the notation (Fe) or (4 Fe). For measurement of the reference preparation the expert panel recommends relating molar absorp-

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tion coefficient and relative molecular mass to one haem group and one quarter of the total globin moiety.

PRINCIPLE

Photometric determination of haemiglobincyanide[1] is recommended as the reference method. If any other method is used (for example, photometric determination of oxyhaemoglobin, iron determination, gas analytic methods) it should be adjusted to obtain comparability with the haemiglobincyanide method. The determination of haemoglobin as haeminchloride (acid haematin) is not recommended because of the unreliability of this method.

REAGENT

The haemoglobin derivatives existing in blood, with the exception of verdoglobin (sulphaemoglobin), are converted into haemiglobincyanide by the use of an appropriate reagent. This must be of such a quality that after dilution of the blood there is no turbidity[2]. To assure complete conversion the photometric determination must be delayed until the reaction is completed.

EXTINCTION MEASUREMENT

When a spectrophotometer is used the blood should be diluted suitably (1:251) with the reagent and measured at 540 nm (or with a mercury lamp at the mercury line 546 nm)[3] against an appropriate blank.

When a photoelectric colorimeter (filter photometer) is used the blood should be diluted suitably 1:251) with the reagent and measured through a narrow band yellow-green filter with maximal transmission near 540 nm against an appropriate blank.

In each case the instrument must be calibrated and the linearity verified by means of a sterile or membrane-filtered (at pore size 0·20-0·25 μm) haemiglobincyanide calibration standard using a procedure such as that described, for example, by Eilers and Crocker (1972). Even minor changes in the set up of the method may cause significant deviations in calibration.

When a photoelectric colorimeter is used the condition of the filter should also be checked at intervals to ensure that no defect has developed.

CALIBRATION STANDARD

The haemiglobincyanide calibration standard should be an aqueous solution of haemiglobincyanide with a concentration in the range of 550-850 mg/l.[4] It is strongly recommended that it be dispensed as a sterile solution in individual doses in sealed ampoules of amber glass. The spectrophotometric characteristics must conform to the following specifications.

Content

The HiCN (equivalent haemoglobin) content is calculated from

$$c(\text{mg/l}) = \frac{A^{540}_{\text{HiCN}} \times 16\,114{\cdot}5}{11{\cdot}0 \times 1} = 1465 \times A^{540}_{\text{HbCN}}$$

where A^{540}_{HiCN} = absorbance of the solution at $\lambda = 540$ nm,

16 114·5 relative molecular mass of haemoglobin $\left(\text{derived from } \frac{64\,458}{4}\right)$,

11·0 = $\epsilon^{540}_{\text{HiCN}}$ (millimolar absorption coefficient),[5]

1 = light-path length in cm, to be known with an accuracy to three decimal places.

[1]Alternative terms are cyanmethaemoglobin and cyanferrihaemoglobin.

[2]A suitable reagent (recommended by van Kampen and Zijlstra (1961)) is prepared as follows. Dissolve 200 mg of $K_3Fe(CN)_6$, 50 mg of KCN, 140 mg of KH_2PO_4 (analytic grade chemicals), and an appropriate amount of non-ionic detergent in water and dilute to 1 litre. The pH should be 7·0-7·4 (pH meter). If stored at room temperature in a brown borosilicate glass bottle the solution keeps for several months. It should be controlled regularly. It must not be allowed to freeze. Examples of non-ionic detergents are Nonic 218 (Pennsalt Chemicals) 1 ml/l, Nonidet P40 (Shell International) 1 ml/l, Quolac Nic 218 (Unibasic) 1 ml/l, Sterox SE concentrated (Hartman Leddon) 0·5 ml/l, Triton X-100 (Rohm and Haas) 1 ml/l. They are available in general from laboratory chemical suppliers.

This reagent has a conversion time of 3 min in contrast to the original or the modified Drabkin's reagent with a conversion time of 10 min or more. Drabkin's reagent consists of $NaHCO_3$ 1 g, $K_3Fe(CN)_6$ 200 mg, KCN 50 mg, and distilled water to 1 litre. It has a pH of 8·6. The modified reagent without the $NaHCO_3$ has a pH of 9·6. Because of the longer conversion time as well as the greater danger of turbidity, these Drabkin's reagents are not recommended.

[3]More precisely 546·1.

[4]Solutions of lower concentration are not reliable.

[5]See Zijlstra and van Kampen (1960) and van Assendelft and Zijlstra (1975).

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Using an appropriate blank A^{540}_{HiCN} is measured on a spectrophotometer, the wavelength scale of which has been calibrated with the aid of the Hg (or H) emission spectrum and absorption checks have been performed using calibrated glass filters or other means which have been tested by independent standardising laboratories.[6] Its slit width is so chosen that the half intensity band-width is less than 1 nm. The cuvettes in which the calibration standard is measured are plan-parallel with an inner wall-to-wall distance of 1·000 cm, tolerance 0·5% (0·995-1·005). The measurements are carried out at 20-25 °C.

Purity

The purity is controlled by (1) Judging the shape of an absorption spectrum between λ = 450 and 750 nm, light-path length 1·000 cm.[7] (2) Determining the quotient $\frac{A^{540}_{HiCN}}{A^{504}_{HiCN}}$. The value of this quotient should lie between 1·59 and 1·63. (3) Measuring in near infrared to check turbidity (between λ = 710 and 800 nm—for example, at λ = 750 nm). The absorbance should be less than 0·002 per cm light-path length.

Stability

The label of the container must indicate an expiry date after which the material must not be used (see below under 'Stability' of haemiglobincyanide reference preparation).

DETERMINATION OF HAEMOGLOBIN CONCENTRATION

If measured on a photoelectric colorimeter (filter photometer) the haemoglobin concentration is read from a previously constructed calibration graph or, where applicable, directly from the scale.

If measured on a spectrophotometer the haemoglobin concentration is calculated using the equation

$$c(g/l) = \frac{A^{540}_{HiCN} \times 16\,114{\cdot}5 \times F}{11{\cdot}0 \times 1}$$

where A^{540}_{HiCN} = absorbance of the solution at λ = 540 nm,

16 114·5 = relative molecular mass of haemoglobin $\left(\text{derived from } \frac{64\,458}{4}\right)$,

F = dilution factor used (for example, 1:251),

11·0 = ϵ^{540}_{HiCN} (millimolar absorption coefficient),

1 = light-path length in cm.

For a dilution (F) of 1:251

$c(g/l) = 367{\cdot}7 \times A^{540}_{HiCN}$. (→ 1,465 × 251)

Specifications for International haemoglobincyanide reference preparation (ICSH Standard EP 6/3: 1977)

MANUFACTURE

The international haemiglobincyanide reference preparation is manufactured at three-year intervals on behalf of ICSH by the Rijks Instituut voor de Volksgezondheid, Bilthoven, the Netherlands. Details of the method are given by Holtz (1965). It is made from washed human red cells, haemolysed by toluene, and centrifuged free from debris. The haemoglobin is converted to haemiglobincyanide. The final solution is equivalent to a haemoglobin content of approximately 600 mg/l. It is dispensed as a sterile solution (membrane filtration) in sealed 10-ml ampoules of amber glass.[8] A batch of this reference preparation has been designated by WHO (1968) as International Haemiglobincyanide Reference Preparation.

EVALUATION AND CONTROL

Each batch is tested in laboratories,[9] nominated by

[6]See Menzies (1960) and National Bureau of Standards (1975).

[7]See van Kampen *et al.* (1965) and van Assendelft (1970).

[8]It was agreed that whereas the international reference preparation would be aqueous national boards might provide glycerinated solutions if preferred.

[9]At present these laboratories are Atlanta (USA), Hematology Division, Center for Disease Control (O. W. van Assendelft); Cleveland (USA), Standards Laboratory of the College of American Pathologists, Cleveland Clinic (C. E. Willis); Freiburg i.Br. (Germany), Institut für Standardisierung und Dokumentation im Medizinischen Laboratorium, Medizinische Universitätsklinik (A. von Klein-Wisenberg); Groningen (the Netherlands), Diaconessenhuis (E. J. van Kampen), and Laboratorium voor Vegetatieve Fysiologie, Rijks Universiteit (W. G. Zijlstra); Kumamoto (Japan), Department of Laboratory Medicine, Kumamoto University Medical School Hospital (T. Matsubara); London (England), King's College Hospital Medical School (J. M. White); Rome (Italy), Istituto Superiore di Sanità (L. Tentori); Washington (USA), Bio-organic Standards Section, Analytical Chemistry Division, National Bureau of Standards (R. Schaffer).

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the ICSH Board, in accordance with the principles set out below. The results are analysed by a consultant who advises the ICSH Secretariat on the control of the preparation.

Content

The HiCN (equivalent haemoglobin) content is calculated from the results of at least five laboratories, using the equation

$$c(\text{mg/l}) = \frac{A^{540}_{HiCN} \times 16\,114{\cdot}5}{11{\cdot}0 \times 1} = 1465 \times A^{540}_{HiCN},$$

where A^{540}_{HiCN} = absorbance of the solution at $\lambda = 540$ nm,

16 114·5 = relative molecular mass of haemoglobin $\left(\text{derived from } \frac{64\,458}{4}\right)$,

11·0 = ϵ^{540}_{HiCN} (millimolar absorption coefficient),[10]

1 = light-path length in cm, to be known with an accuracy to three decimal places.

Using an appropriate blank, A^{540}_{HiCN} is measured on a spectrophotometer the wavelength scale of which has been calibrated with the aid of the Hg (or H) emission spectrum and absorption checks have been performed using calibrated glass filters or other means which have been tested by independent standardising laboratories.[11] Its slit width is so chosen that the half intensity band-width is less than 1 nm. The cuvettes in which the solution is measured are plan-parallel with an inner wall-to-wall distance of 1·000 cm, tolerance 0·5% (0·995-1·005). The measurements are carried out at 20-25 °C.

The results are correlated at the Rijks Instituut voor de Volksgezondheid. The statistical mean of the results of the laboratories is recorded after erratic results have been discarded in accordance with statistical practice. Experience with this procedure has shown that the confidence limits of the final results are within ±1%.

Purity

The purity is controlled by (1) Judging the shape of an absorption spectrum between $\lambda = 450$ and 750 nm, light-path length 1·000 cm.[12] (2) Determining the quotient $\frac{A^{540}_{HiCN}}{A^{504}_{HiCN}}$. The value of this quotient should lie between 1·59 and 1·63. (3) Measuring in near infrared to check turbidity (between $\lambda = 710$ and 800 nm—for example, at $\lambda = 750$ nm). The absorbance should be less than 0·002 per cm light-path length, using an appropriate blank.

Stability

The International Reference Preparation is kept at 4 °C. It has a stability of at least six years.[13] This stability is checked by the testing laboratories repeating the primary standardisation several times per year. The manufacturing laboratory repeats absorbance measurements at more frequent, regular intervals.

Sterility[14]

In conformity with current practice of sterility control the contents of the ampoules to be tested are inoculated in aerobic and anaerobic media and incubated at 22 and 37 °C.

LABELLING

The International Reference Preparation is labelled with the batch number, the value of its haemoglobin content (mean and standard error, see above under 'content'), and an expiry date which is considered well within safe limits (see under 'Stability'). The producer notifies all consumers if continuing control of stability indicates that a particular batch is no longer acceptable.

DISTRIBUTION[15]

The International Reference Preparation is made available for reference use only to national standards committees for haematological methods or to official government-nominated holders. When there is no committee or official holder it is distributed to an individual appointed by ICSH.

The national holder must ensure that an opportunity is given to manufacturers and distributors to use the International Haemiglobincyanide Reference Preparation as a reference material if so desired, in conformity with national requirements.

Information about national committees, official

[10]See Zijlstra and van Kampen (1960) and van Assendelft and Zijlstra (1975).
[11]See Menzies (1960) and National Bureau of Standards (1975).
[12]See van Kampen *et al.* (1965).
[13]See van Assendelft *et al.* (1976).
[14]Optional but always checked by the producer.
[15]This distribution is sponsored by the World Health Organization (see World Health Organization, 1968).

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holders, and other contact persons may be obtained from the ICSH Secretariat, c/o Dr. S. M. Lewis, Royal Postgraduate Medical School, Ducane Road, London W12 OHS, United Kingdom.

References

van Assendelft, O. W. (1970). *Spectrophotometry of Haemoglobin Derivatives*. Van Gorcum, Assen, The Netherlands.

van Assendelft, O. W., Buursma, A., Holtz, A. H., van Kampen, E. J., and Zijlstra, W. G. (1976). Quality control in haemoglobinometry with special reference to the stability of haemiglobincyanide reference solutions. *Clinica Chimica Acta*, 70, 161-169.

van Assendelft, O. W., and Zijlstra, W. G. (1975). Extinction coefficients for use in equations for the spectrophotometric analysis of haemoglobin mixtures. *Annales de Biochimie*, 69, 43-48.

Braunitzer, G., Gehring-Müller, R., Hilschmann, N., Hilse, K., Hobom, G., Rudloff, V., and Wittmann-Liebold, B. (1961). Die Konstitution des normalen adulten Humanhämoglobins. *Hoppe-Seylers Zeitschrift für physiologische Chemie*, 325, 283-286.

Braunitzer, G. (1964). The molecular weight of haemoglobin. *Bibliotheca Haemotologica (Basel)*, 18, 59-60.

Eilers, R. J., and Crocker, C. (1972). The value of Ringbom curves in hemoglobinometry. In *Modern Concepts in Hematology*, edited by Izak, G. and Lewis, S. M., pp. 58-65. Academic Press, New York, London.

Hill, R. J., Konigsberg, W., Guidotti, G., and Craig, L. C. (1962). The structure of human hemoglobin. Parts 1-5. *Journal of Biological Chemistry*, 237, 1549-1554; 2184-2195; 2547-2561; 3151-3156; 3157-3162.

Holtz, A. H. (1965). Some experience with a cyanhemiglobin solution. *Bibliographica haematologica*, 21, 75-78.

ICSH, IFCC, and WASP (1972). Recommendations for use of SI in clinical laboratory measurements. *British Journal of Haematology*, 23, 787; (1973) *Zeitschrift für klinische Chemie und Biochimie*, 11, 93.

van Kampen, E. J., and Zijlstra, W. G. (1961). Standardization of hemoglobinometry. II. The hemiglobincyanide method. *Clinica Chimica Acta*, 6, 538-544.

van Kampen, E. J., Zijlstra, W. G., van Assendelft, O. W., and Reinkingh, W. A. (1965). Determination of hemoglobin and its derivatives. *Advances in Clinical Chemistry*, 8, 141-187.

Menzies, A. C. (1960). Report on calibration of wavelength and photometric scales of non-recording spectrophotometers. *Pure and Applied Chemistry*, 1, 147-162.

National Bureau of Standards (1975). Standard reference materials No. 51; Glass filters as a standard reference material for spectrophotometry. *NBS Special Publication*, 260.

World Health Organization (1968). WHO Expert Committee on Biological Standardization, 20th Report. *WHO Technical Report Services* No. 384, 12-13; 86-87.

Zijlstra, W. G., and van Kampen, E. J. (1960). Standardization of hemoglobinometry. I. The extinction coefficient of hemiglobincyanide at $\lambda = 540$ mμ: ϵ^{540}_{HiCN}. *Clinica Chimica Acta*, 5, 719-726.

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EP5-A
Vol. 19 No. 2
Replaces EP5-T2
Vol. 12 No. 4

February 1999

Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline

This document provides guidance for designing an experiment to evaluate the precision performance of clinical chemistry devices; recommendations on comparing the resulting precision estimates with manufacturer's precision performance claims and determining when such comparisons are valid; as well as manufacturer's guidelines for establishing claims.

NCCLS

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Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline

Abstract

Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline (NCCLS Document EP5-A) provides guidance and procedures for evaluating the precision of in vitro diagnostic devices and includes recommendations for manufacturers in evaluating their devices and methods when establishing performance claims. Included are guidelines for the duration, procedures, materials, data summaries, and interpretation techniques that are adaptable for the widest possible range of analytes and device complexity. Experiments and analysis procedures presented in this document are applicable to a wide variety of methods and instrumentation. A balance is created in the document between complexity of design and formulae, and simplicity of operation. Definitions for "between day," "between run," "within run," and "total," when applied to precision, are provided.

(NCCLS. *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline.* NCCLS document EP5-A [ISBN 1-56238-368-X]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA, 1999.)

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Proposed Guideline

NCCLS Document EP7-P
Vol. 6 No. 13

Interference Testing in Clinical Chemistry

Background information and procedures for characterizing the effects of interfering substances on test results.

PROFESSIONS GOVERNMENT INDUSTRY

This NCCLS document was published before Centers for Disease Control publication of **universal precautions** for the prevention of transmission of infectious disease. **Universal precautions** should be observed when handling specimens from **all patients.** See NCCLS M29-T, "Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue; Tentative Guideline." (Vol. 9 No. 1)

PROFESSIONS GOVERNMENT INDUSTRY

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statistical test would lack sufficient power to reliably detect a clinically important bias. If it can be decided in advance how small a discrepancy is clinically important, then the methods described in Section 4.3 may be used to determine the amount of replication required for a statistically significant effect to reliably reflect a clinically important effect.

1.6 Applicable Methods

All analytical methods are potentially subject to interference. Therefore, this guideline can be applied to a broad spectrum of analyzers and methods. Modifications may be necessary to accommodate the particular characteristics of the method being evaluated. Two special cases, assays based on separation techniques and immunochemical principles, are discussed in more detail in Appendix C.

Users are cautioned about generalizing results from the evaluation of one method to others based on the same principle. Although different assays for a particular analyte may be based on the same well-accepted procedure, interference characteristics may differ from product to product due to subtle factors not readily apparent to the end user [8,9,10].

The guidelines are intended to apply to any type of clinical sample including serum, plasma, whole blood, cerebrospinal fluid, and urine.

1.7 Overview of the Experimental Approaches

There are two basic approaches to evaluating the susceptibility of a method to interference. Each

PROPOSED GUIDELINE

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suffers from inherent limitations. We recommend that they be used together to provide complementary information.

The first approach is to add the potential interferent to a portion of a pool of clinical samples and to look for a bias relative to a control portion of the same pool. This is called "paired-difference" testing. The analyte concentration in the pools should be adjusted to a medical decision point; testing at more than one decision level may be appropriate depending on the analyte. It is usually most efficient to conduct a preliminary screen of a series of compounds at relatively high concentrations. If no clinically significant effect is observed, the substance is considered not to be an interferent and no further testing is required. Compounds that show a clinically significant effect must be further evaluated to determine the relationship between the concentration of the interferent and the degree of interference. This type of test is called a "dose-response" series.

The second approach is to look for inaccurate results in selected groups of patient specimens. Selection should be made on the basis of:

- disease (e.g., specimens from patients with cardiac, liver, or renal disorders)
- medication (e.g., specimens from patients known to be taking the drugs of interest)
- other abnormal constituents (e.g., samples containing abnormal levels of bilirubin, lipids, hemoglobin, or protein).

This approach requires a Reference Method, that is, a well-characterized method with low susceptibility to interference, in order to establish the "true value" in a comparison study.

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Limitations of the first approach stem from the artificial nature of the samples.

(1) The actual interferent in the clinical sample may not be the original drug but a metabolite.

(2) The test sample matrix may not represent typical pathological specimens for the analyte in question.

(3) The substance added may not be identical to the interferent in pathological specimens due to, for example, protein binding, precipitation, or heterogeneity.

(4) Test levels chosen may be too high or too low to be realistic.

Limitations of the second approach are chiefly related to the lack of control over test variables.

(1) This method cannot demonstrate a cause-and-effect relationship; it can only show a correlation of bias with the level of a suspected interferent.

(2) Some labile constituents (e.g, acetoacetate) will be lost if the specimens are not fresh.

(3) Patients are usually on multiple drug regimens, so identifying the cause of interference is difficult.

(4) Prospectively grouping patients by disease and medication can be very difficult, if not impossible, in many laboratories.

(5) The procedure is "hit-or-miss." Success depends on an interferent being present in the sample of the patient population being tested.

(6) There are few recognized Reference Methods. When such methods are published, they are not easily adapted to a routine laboratory. Furthermore, the Reference Method could also be affected by the same interferent.

Nevertheless, the second approach can be valuable in providing clues to interferents that might otherwise be missed, and may be the only approach that can detect

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interference by a drug metabolite. It also provides a means of confirming an interference in actual patient specimens.

2.0 SELECTING POTENTIAL INTERFERENTS

2.1 Scope of Testing Required

An enormous number of possible interents can appear in patient specimens. Therefore, some elimination process must be used. The number and type of interfering substances to be tested will depend on the purpose of the evaluation.

2.1.1 Comprehensive Characterization

A comprehensive interference characterization should be done at some point for each method. It is not necessary for each user to repeat such an extensive study. A comprehensive evaluation for interferences should be done by:

(1) A manufacturer before marketing a new product. The results should be disclosed to users and to regulatory agencies.

(2) An independent evaluating organization intending to approve or accredit a new method or to validate the claims of a manufacturer. The results should be made available to users, preferably through publication in the clinical chemistry literature.

(3) A laboratory that has developed a new method. Interference results should be

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APPENDIX B

Preparation of Test Pools for Selected Potential Interferents

1. Hemolysis

- High Test Level: 500 mg/dL Hemoglobin

- Osmotic Shock Procedure:

  - Collect 5 mL heparinized blood.
  - Centrifuge 10 min to pack cells.
  - Discard plasma and replace with 10 mL isotonic saline. Invert tube slowly 10 times. Centrifuge 10 min and discard saline wash. Repeat wash with saline twice again.
  - Dilute the cells with an equal volume of distilled water. Invert tube and mix well 10 times. Freeze overnight.
  - Thaw cells and bring to room temperature.
  - Centrifuge 30 min to remove the stroma. Save supernatant (hemolysate). Discard red cell debris in pellet.
  - Analyze hemolysate to determine hemoglobin concentration.
    (Reference: Meites, S. Reproducibly simulating hemolysis for evaluating its interference with chemical methods. Clin. Chem. 19, 1319, 1973.)

- Mechanical Lysis Procedure:

  - Collect 10 mL whole blood.
  - Wait 30 min for coagulation.
  - Centrifuge.
  - Decant the amount of serum needed for the analysis.
  - Triturate the clot with a glass rod.
  - Centrifuge.
  - Decant hemolysed serum.
  - Analyse to determine hemoglobin concentration.

- Test Pool: Add measured volume of hemolysate to 10 mL serum to make 500 mg/dL hemoglobin.

- Control Pool: Add equivalent volume of saline to 10 mL of same serum pool. Determine actual hemoglobin levels in the pools by analysis.

- Stability: Stock and serum solutions may be kept frozen for 6 months.

- Caution: Paired-difference testing cannot differentiate between interference effects of hemoglobin and other constituents of red

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blood cells, such as K^+, $NH4^+$, LDH, AST, etc.

2. L-Ascorbic Acid

- High Test Level: 3 mg/dL

- Stock solution: Prepare 300 mg/dL in cold (0-5 °C) water, deoxygenated previously by nitrogen bubbling. Keep stock and serum solutions on ice before testing. Determine actual concentration spectrophotometrically (aM 15,000 1/mol-cm at 265 nm).

- Test Sample: Add 0.1 mL to 10 mL serum. Minimize exposure to air.

- Control Sample Add 0.1 mL water to 10 mL serum.

- Stability Test all solutions within two hours after preparation of original stock solution.

3. Free Fatty Acids (FFA)

- High Test Level: 3 mmol/L total

- Test Materials: Palmitic acid, stearic acid, oleic acid

- Test Pool: Procedure involves transfer of FFA from particulate absorbant (Celite) to serum. Spread dried Celite evenly in beaker to thickness of 5 mm. Add 1 mmol FFA dissolved in hexane per 10 g Celite. Particles should be completely immersed in hexane. Evaporate with gentle warming under N_2 stream. Transfer 200 mg/dL dried particles to screw-cap vial, mix thoroughly, and add 4 mL fresh human plasma (EDTA anticoagulant). Gently stir for 30 min (under N_2 for unsaturated FFA). Remove particles by decantation and centrifugation. Adjust pH to match control pool with NaOH. Expect 3-4 mmol/L. Determine exact amount by analysis.

- Control Pool: Repeat the above procedure with a portion of the same fresh human plasma but omitting FFA from the hexane. Expect 0.5-0.8 mmol/L endogenous FFA. Determine exact amount by analysis.

- Stability: use fresh

- Reference: Spector, A. A. and Hoak, J. C. An improved method for the addition of long-chain fatty acid to protein solutions. Anal. Biochem. 32, 297-302, 1969.

4. Lipemia

- High Test Level: 3000 mg/dL triglycerides

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- Lipid Addition Method:
  - Test Material: Commercial fat emulsion, 20% preparation (Liposyn, Abbott Laboratories; Intralipid, Cutter Laboratories).
  - Test Pool: Add 0.5 mL of 20% Liposyn or Intralipid to a 10-mL volumetric flask. Make up to volume with pooled serum.
  - Control Pool: Identical, except use 0.5 mL water in place of the lipemic stock.
- Centrifugation method:
  - Test Material: Lipemic serum pool with triglyceride level 3000 mg/dL.
  - Test Pool: Untreated portion of the lipemic serum pool.
  - Control Pool: Clarify the lipemic sample using an ultracentrifuge (e.g., Beckman Airfuge, 90,000 RPM, 10 min). Assay the clear portion of the sample.
- Stability: Use fresh. Do not freeze.

5. Drugs

- High Test Level: See Appendix A.
- Test Material: Obtain drug in pure form. Pharmaceutical preparations should be used only if no pure alternative. Specify form (acidic, basic, salt) and purity when results reported.
- Stock Solution: Dissolve in order of preference, in water, 50 mmol/L phosphate (pH 7), ethanol/methanol, chloroform. Prepare stock at 20 X 100 X final concentration of Test Pool.
- Test Pool: Quantitatively make up 0.1-0.5 mL stock to 10 mL with fresh human serum pool.
- Control Pool: Quantitatively make up equivalent volume of solvent used to 10 mL with same human serum pool.
- Stability: Depends on drug.
- Reference: Baer, D. M., et al., Protocol for the study of drug interferences in laboratory tests: Cefotaxime interference in 24 laboratory tests. Clin. Chem. 29, 1736-1740, 1983.

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6. Bilirubin

- Caution: Do all preparation in yellow or subdued light.
- High Test Level: 20 mg/dL
- Unconjugated bilirubin
  - Stock Solution: Dissolve 20 mg unconjugated bilirubin in 2 mL 0.1N NaOH.
  - Test Pool: Add 0.1 mL of stock solution to 5 mL serum with stirring.
  - Control Pool: Add 0.1 mL 0.1N NaOH to 5 mL starting serum pool.
- Conjugated bilirubin
  - Stock Solution: Dissolve 20 mg ditaurobilirubin in 2 mL water.
  - Test Pool: Add 0.1 mL of stock to 5 mL serum with stirring.
  - Control Pool: Add 0.1 mL H_2O to 5 mL starting serum pool.
- Stability: Test solutions on the day the solutions are prepared. Keep refrigerated; avoid exposure to white light.

7. Bicarbonate/CO_2

High Test Level: 40 mM

- Bicarbonate Addition Method
  - Test Pool: Weigh 6.5 mg $NaHCO_3$ into 5 mL serum.
  - Control Pool: Starting serum pool (CO_2 25 mM).
- CO_2 Addition Method:
  - Test Pool: Bubble CO_2 into sample. Measure CO_2 periodically until desired CO_2 level is reached. Measure pH and cap tightly with minimum air space.
  - Control Pool: Starting serum pool. Measure CO_2 and pH.
- Stability: Unstable; use promptly.

8. pH

- Test Levels: 6.8 and 8.8

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- Test Pools: Add 20 uL 2N LiOH or 30 uL 2N HCl to 5 mL serum pool.

- Control Pool: Add 20/30 uL distilled water to 5 mL starting serum. pH of fresh pool should be about 7.8.

- Stability: Unstable; use promptly.

9. Protein

- High Test Level: 12 g/dL

- Concentrated Serum method:

  - Prepare concentrate from fresh serum using ultrafiltration (e.g., Amicon Centrifree Micropartition System).

  - Save ultrafiltrate to make intermediate concentrations.

- Specific Protein Addition:

  - Add 0.50 g gamma-globulin to 10 mL fresh serum.

- Control Pool: Starting serum pool

10. Bile Acids

- Test Level: 6 mg/dL

- Test Materials: Trihydroxy bile acids - as cholic acid

- Test Pool: Prepare a solution of 300 mg cholic acid in 100 mL methanol. Add 100 mL water. Add 0.4 mL of this solution to 10 mL serum.

- Control Pool: Add 0.4 mL of a 1:1 methanol-water solution to 10 mL serum.

- Stability: use fresh

11. Keto-acids (acetoacetate, pyruvate, etc.)

- High Test Level: See Appendix A

- Stock Solution: Dissolve keto acids in cold water to make 20X test level.

- Test Pool: Add 0.1 mL stock solution to 10 mL serum (pH of serum should be adjusted to between 6.0-7.0 using 1N HCl, taking care not to precipitate proteins).

- Control Pool: Add 0.1 mL water to 10 mL starting serum.

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Fundamentals of Clinical Chemistry

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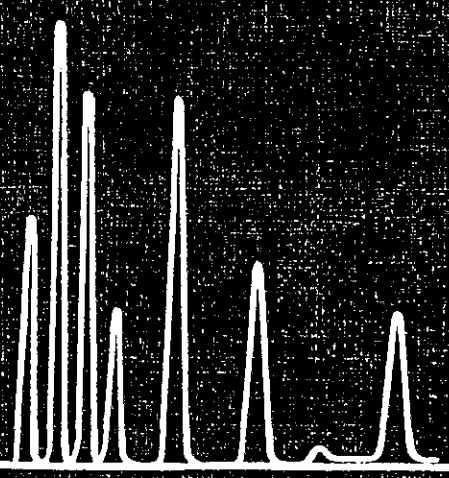

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Dialysis and Membrane Filtration

Some toxic substances are difficult to separate by standard procedures, either because of their physical properties or because the substance itself is so labile that it becomes chemically modified during the separation process. Some toxic anions fall into this category, and dialysis has been used successfully for these separations. Conventional dialysis across a semipermeable membrane is effective but time consuming. More recently, a technique has been applied that separates compounds by centrifugation or vacuum filtration through a membrane or special filter that permits passage of substances of limited molecular size. This technique has also been suggested for the separation of protein-bound substances in plasma from those in the free unbound state. The rapidity with which this type of procedure can be carried out makes this means of separation particularly attractive for the clinical laboratory. Few studies have been conducted, however, on the recovery of analytes by this separation procedure.

Immunoassay Procedures

The application of immunoassay procedures to the detection of drugs in biological specimens has developed into an important area of toxicological analysis. Small volumes of specimens and a minimum of specimen preparation, frequently with no separation step, are required. Since few manipulations are involved, the methods are easily adaptable to automation for screening large numbers of patients. The principles of this technique are described more completely in Chapter 3. Although immunoassay procedures are extremely valuable in laboratories engaged in therapeutic drug monitoring, they have had only limited application in toxicological analysis. This is primarily due to the following factors:

1. The nature of the toxic substances must be known and an immunoassay kit must be available for such an assay.
2. Although immunoassays are highly specific, frequently there are cross reactions with structurally similar compounds or metabolites.
3. When immunoassays are performed on a single specimen, the cost of this assay may be high because standards and controls are included with each assay. If the test is performed infrequently, the limited shelf life of reagents also increases the cost.

For some toxic substances, immunoassays are the only practical approach for the clinical laboratory. This applies to such substances as cardiac glycosides, lysergic acid diethylamide (LSD), and Δ^9-tetrahydrocannabinol (THC). LSD and THC are only rarely encountered as causes of acute toxic emergencies.

Detection of Toxic Substances by Specific Procedures

Recommending specific procedures for every toxic substance is impractical, since hundreds of methods are available and for each substance several analytical methods may be equally meritorious. In addition, methods may be quickly outdated as new knowledge is gained and technical advancements are made. Therefore, references should be consulted when specific procedures are needed.[1,2,42,44]

The methods outlined or cited in this chapter have the merit that they perform as described and have been used in the authors' laboratories. In addition, they have been selected in order to illustrate a variety of analytical or instrumental applications.

CARBON MONOXIDE

Carbon monoxide, the product of incomplete combustion of organic substances, is the most common of the gaseous poisons. It is present in the free state in manufactured gas (coal gas) but not in natural gas. Furnaces and other appliances, as well as internal combustion engines, release carbon monoxide as one of the combustion products and

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are frequently causes of carbon monoxide poisoning when used under conditions of poor ventilation or improper operation.

Carbon monoxide combines reversibly with hemoglobin in a manner almost identical to oxygen, but with a bond that is about 210 times stronger. As a result, carbon monoxide is not readily displaced from hemoglobin except at high oxygen tension; accidental poisonings can occur even with prolonged exposure to low levels of carbon monoxide in the atmosphere. In these instances the carbon monoxide level in blood builds up slowly until toxic levels are reached.

The detection and estimation of carbon monoxide in biological specimens can be approached in two general ways: (1) release of the gas from the hemoglobin complex with subsequent direct or indirect measurement of the gas, or (2) estimation of carboxyhemoglobin by its typical color or absorption bands. The first approach can be carried out by gasometric techniques, gas chromatography,[22] microdiffusion (pages 878–881), or infrared spectrophotometry.[41] The second approach utilizes spectrophotometric[46] or spectrographic analysis or simple color comparison.

Specimen. Regardless of the analytical method used, the specimen to be analyzed must contain hemoglobin. Relatively little carbon monoxide dissolves in the aqueous or lipid fractions of tissue, compared with that bound to hemoglobin. This rather obvious statement is made since some clinicians request serum, spinal fluid, or even urine carbon monoxide levels. The most satisfactory specimen is whole blood. Clotted blood is less desirable and must be homogenized before analysis with a minimum exposure to air.

Determination of Carbon Monoxide by Spectrophotometry

Hemoglobin and its derivatives have characteristic absorption bands in the visible region that can be utilized to detect carboxyhemoglobin and to measure the quantity present. In alkaline solution the absorption maxima for oxygenated hemoglobin are 576–578 and 540–542 nm; for carboxyhemoglobin they are 568–572 and 538–540 nm (Figure 27-4,*A*). Deoxygenated hemoglobin has a single broad band at 555 nm (Figure 27-4,*B* and *C*). If a weakly alkaline dilution of blood is treated with sodium hydrosulfite (dithionite), oxygenated hemoglobin (and any methemoglobin present) is converted to deoxygenated hemoglobin (Figure 27-4,*C*). Carboxyhemoglobin is unaffected by such treatment (Figure 27-4,*D*).

This is the basis of several methods for the determination of percent saturation of hemoglobin by carbon monoxide. The method to be described[46] works satisfactorily with fresh, oxalated blood but is not satisfactory with postmortem blood or specimens containing denatured hemoglobin.

Principle.[46] A dilute hemolysate of blood is treated with sodium dithionite, which reduces methemoglobin and oxyhemoglobin but does not affect carboxyhemoglobin. The absorbance of this solution is measured at 541 and 555 nm, the absorbance ratio A_{541}/A_{555} is calculated, and the per cent carboxyhemoglobin is determined from the standard curve.

Reagents

1. NH_4OH, 0.12 mol/L. Dilute 15.9 mL of concentrated NH_4OH to 1.0 L with deionized water. This solution is stable.
2. Sodium hydrosulfite (sodium dithionite), reagent grade. Preweigh 10-mg portions of sodium dithionite into individual small tubes. Stopper the test tubes or cover with Parafilm.
3. Carbon monoxide. Lecture bottle (Matheson Gas Products, Division of Will Ross, Inc., East Rutherford, NJ 07073).
4. Oxygen, CP.
5. Nitrogen.

Special apparatus. A narrow-bandpass (<2 nm) spectrophotometer with 10-mm cuvets is required, although the use of a recording spectrophotometer with the same specifications is desirable.

It is imperative that the spectrophotometer be checked regularly for wavelength and spectrophotometric accuracy with appropriate calibrating filters (e.g., NBS Reference Material 930) and with liquid photometric standards (e.g., NBS Reference Material 931).

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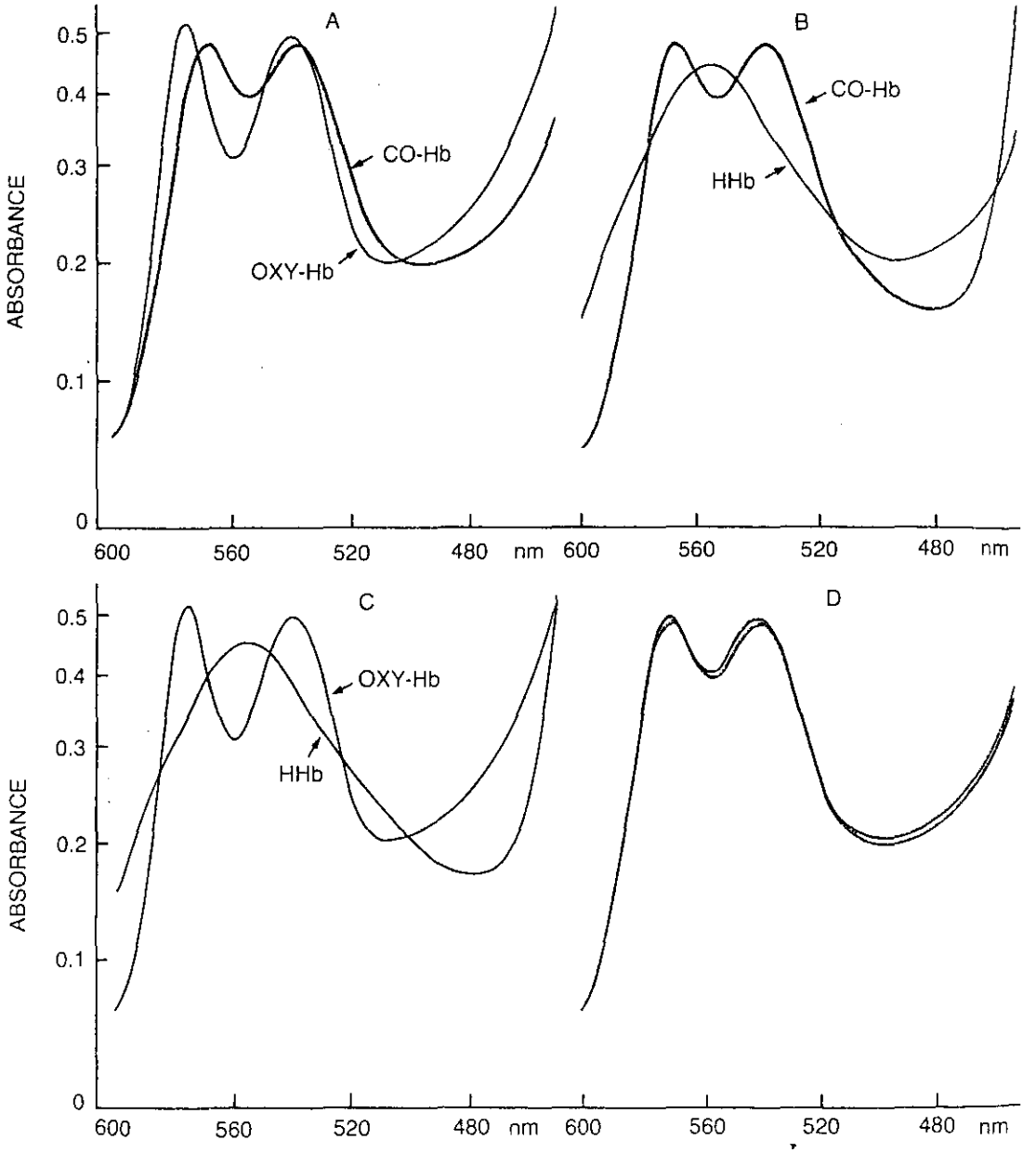

Figure 27-4. Spectral curves (overtraced) of (*A*) 100% oxyhemoglobin (OXY-Hb) and 100% carboxyhemoglobin (CO-Hb) before treatment with sodium dithionite; (*B*) 100% oxyhemoglobin (now HHb) and 100% carboxyhemoglobin after treatment of both with sodium dithionite; (*C*) 100% oxyhemoglobin before and after treatment with sodium dithionite; and (*D*) 100% carboxyhemoglobin before and after treatment with sodium dithionite. (Reproduced by permission of the Institute for Clinical Science, from Tietz, N. W., and Fiereck, E. A.: The spectrophotometric measurement of carboxyhemoglobin. Ann. Clin. Lab. Sci., *3*:36–42, 1973.)

Procedure

1. Add 100 μL of whole heparinized blood to 25 mL of NH_4OH, 0.12 mol/L. Mix the solution and allow it to stand for 2 min. This is the hemolysate.
2. Transfer 3.0 mL of NH_4OH and 3.0 mL of the hemolysate into separate 10-mm cuvets. (Analyze the sample in triplicate.)
3. At timed intervals add 10 mg of sodium dithionite to each cuvet. Cover the cuvets with Parafilm and invert gently 10 times. If a number of hemolysates are analyzed, space the addition of the reducing agent so that each can be read after exactly 5 min.

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4. Exactly 5 min after the addition of dithionite to the hemolysates, read the absorbance at 541 and 555 nm against the NH_4OH blank.

5. Calculate the ratio of the absorbance at 541 nm to that at 555 nm, A_{541}/A_{555}, and determine the per cent carboxyhemoglobin from the calibration curve. *Note*: For confirmation and for the purpose of record, the sample without and with dithionite (steps 1 and 3, respectively) may be scanned between 450 and 600 nm (see Figure 27-4).

Preparation of the Standard Curve

Caution: Use a fume hood when working with carbon monoxide gas.

1. Collect 20 mL of heparinized blood from a healthy person who does not smoke.

2. Transfer a 4.0-mL portion of the fresh, heparinized blood sample into each of two 125-mL separatory funnels. Allow pure oxygen to flow through one funnel and pure carbon monoxide through the other for 15 min while the funnels are gently rotated. After the addition of the gases, close the separatory funnels and rotate them gently for an additional 15 min. Analyze the fully saturated samples immediately, in triplicate, according to the procedure given above. Use these results to establish the 0 and 100% carboxyhemoglobin calibration points. These samples may not be used to establish the intermediate calibration points.

Plot the ratio of the absorbance at 541 nm to that at 555 nm for the 0% and for the 100% carboxyhemoglobin samples and draw a line between the two points (see Figure 27-5).

3. Fill the funnel containing the 100% carboxyhemoglobin sample with nitrogen gas and rotate it for 5 min. Treatment with nitrogen removes the physically dissolved CO from the sample, but a small amount of CO will also dissociate from hemoglobin. Determine the exact carboxyhemoglobin content of this sample by the method described, using the standard curve just prepared. Prepare intermediate standards by mixing appropriate proportions of the nitrogen-treated sample with the oxygen-treated sample.

4. Analyze each of the diluted blood samples from step 3 in triplicate, according to the procedure given above.

5. Plot the calculated concentrations against the absorbance ratios obtained. These points should fall on the line drawn for the fully saturated samples, since the curve is linear over the entire range (see Figure 27-5).

Interpretation. Normal carbon monoxide levels depend on the degree of exposure to this gas without signs and symptoms of poisoning being produced. For example, in smokers levels may reach up to 8–9% saturation of hemoglobin with carbon monoxide, whereas non-smokers may show only 0.5–1.5% saturation.

In our experience, patients can survive brief periods of 70–75% saturation. Prolonged periods at these high levels can, of course, be fatal. Interpretation of lethal levels must be related to other factors in each case; i.e., time of exposure, normal hemoglobin level of the patient, age and general health of the patient, degree of activity, and so on.

In patients treated with oxygen, carbon monoxide is fairly rapidly released from hemoglobin. Frequently, a patient is treated with oxygen while being transported to the hospital. By the time a blood sample is drawn and analyzed, the carbon monoxide level may be close to normal. These patients should be kept quiet with good oxygenation to ensure that all tissue-bound carbon monoxide (e.g., with myoglobin and heme-containing enzymes) is dissipated before the patient is discharged. Effects of carbon monoxide toxicity at various carboxyhemoglobin concentrations are shown in Table 27-6.

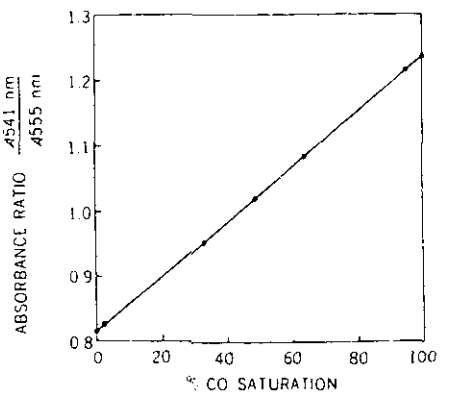

Figure 27-5. Example of a standard curve for conversion of absorbance ratio, A_{541}/A_{555}, to per cent carboxyhemoglobin saturation. (Reproduced by permission of the Institute for Clinical Science, from Tietz, N. W., and Fiereck, E. A.: The spectrophotometric measurement of carboxyhemoglobin. Ann. Clin. Lab. Sci., 3:36–42, 1973.)

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HemoCue, Inc.
Special 510(k) Device Modification
HemoCue® Hb 201+ System
June 30, 2003

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HemoCue, Inc.
Special 510(k) Device Modification
HemoCue® Hb 201+ System
June 30, 2003

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Overview of Included Documents, Volume II

Sections 1-6 include descriptions, specifications and risk analyses of the HemoCue Hb201$^+$ system:

1. Software description of the Hb 201+ system
2. Risk analyses for Hb201+ system
3. Product specification Hb 201+
4. Requirement specification Hb201+ photometer
5. User Interface specification Hb 201+
6. Risk analyses Hb201+ photometer

Sections 7-13 include descriptions, specifications, test specifications and the pertinent test reports of the HemoCue Hb201$^+$ software:

7. General description, software Hb201+
8. Test specification Software Hb 201+
9. Software test report *(Results according to test specification above, section 8)*
10. Specification of software change for Hb and Glucose 201+
11. Test specification software change for Hb and Glucose 201+
12. Test report software change Hb 201+ version 1.01 *(Results according to test specification above, section 11)*
13. Software versions Hb 201+

Sections 14-15 include the test specification and the pertinent test report for the HemoCue Hb201$^+$ electronics:

14. Test specification, Electronics Hb 201+
15. Test report hardware Hb 201+ *(Results according to test specification above, section 14)*

Sections 16-20 include environmental tests of the Hb 201+ photometer:

16. Low temperature test on photometer Hb 201+
17. High temperature test on photometer Hb 201+
18. Humidity test on Hb201+
19. Drop test on Hb201+
20. Vibration test on Hb201+

Section 21 in matrix form shows which of the requirements for the Hb201$^+$ in section 4, have been tested:

21. Requirement matrix, Hb201

Sections 22-23 include proof of compliance with EN standard and CB Test Certificate:

22. Compliance with EN 61010-1 standard
23. CB Test Certificate 60601-1

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Attachment 1 : pictures.

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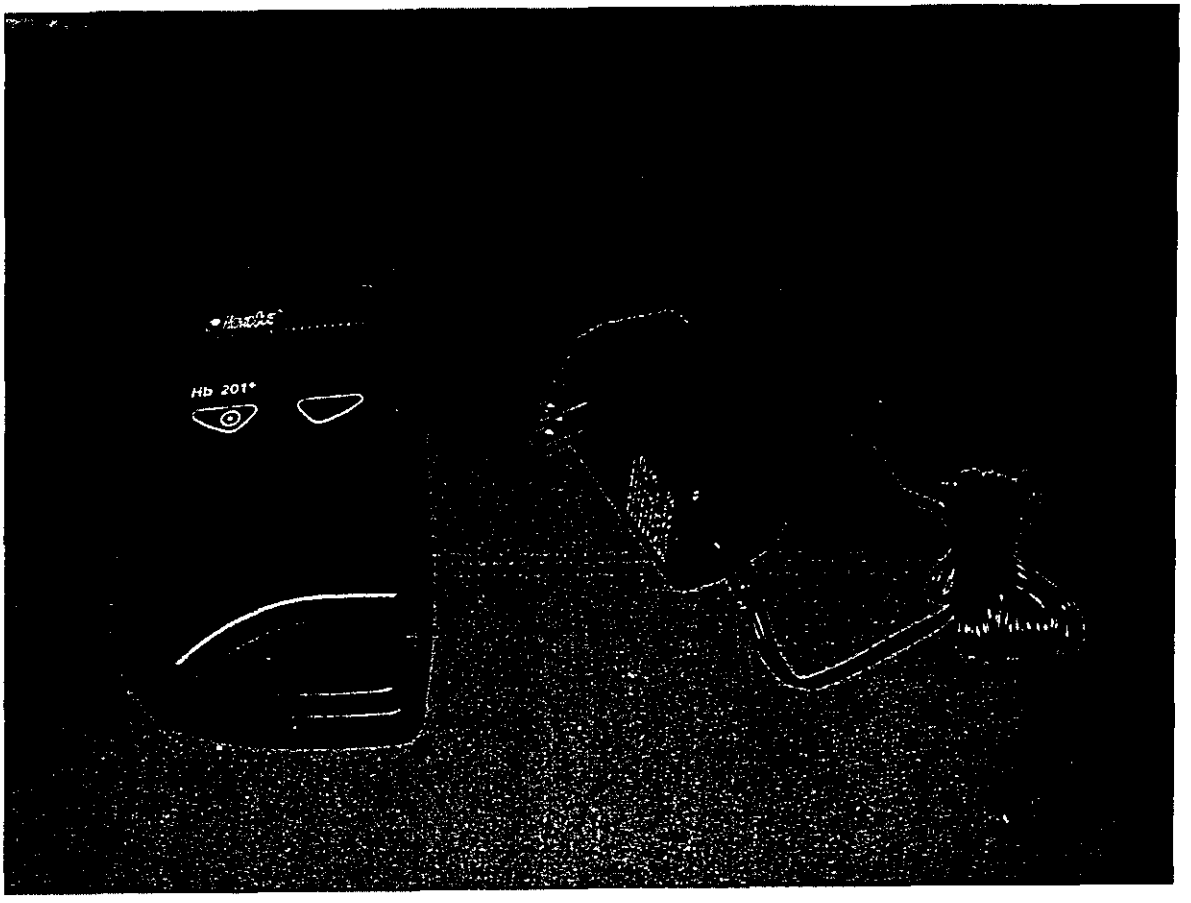

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www.ul-europe.com
CVR-nr. 19195597

An Affiliate of
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Kuwettgatan 1
S-262 23 Ängleholm
Sweden

Contact Person	Examiner	Our reference	Direct phone	Date
	Mona H. Nielsen	133509-01	+45 4485 6272	2003.05.06

Dear Sirs,

Your order executed by UL International Demko A/S

UL International Demko A/S has the pleasure of enclosing CB Certificate No. 6565.

Enclosed please find invoice for the costs involved.

Your attention is also drawn to UL International Demko A/S Standard Terms and Conditions. Should you have any questions regarding the above, please contact UL International Demko A/S.

UL International Demko A/S is at your disposal should you require additional information about our services, such as information on the LVD, EMC, Machinery Directives, ISO Certification, export certification or seminars tailored to meet the needs of your company.

We would like to take the opportunity to thank you for the co-operation and hope you will make use of our services in the future.

Yours sincerely,

Karina Christiansen
Certification Manager

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

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UL International Demko A/S Terms and Conditions

1. General Remarks.

Applicant agrees to be bound by the Application Form ("Application"), and these Terms and Conditions (collectively referred to as the "Agreement"), unless changes concerning specific items have been agreed upon in writing by both parties.

This Agreement shall govern the relationship between the Applicant and UL International Demko A/S (here after "UL Int. Demko A/S") which, in its capacity as an independent testing and certification company, authorizes the use of trademark(s) owned or controlled by UL Int. Demko A/S ("trademark(s)") or other certification documents (collectively referred to as "Certifications") with respect to products UL Int. Demko A/S evaluates and judges to comply with national and International Standards and requirements.

The Application covers one examination and one set of tests judged appropriate for the product specified. In the event of further examination and tests of improved or additional samples, a new Application will be required.

2. Scope of Work.

Once the Application has been accepted by UL Int. Demko A/S, UL Int. Demko A/S shall carry out the work described in the Application for the product described in the Application ("Product") in accordance with the applicable Standards and/or requirements requested by Applicant in the Application and agreed to by UL Int. Demko A/S ("Work").

The Applicant shall provide UL Int. Demko A/S with all test samples, documents, and relevant information necessary for UL Int. Demko A/S to perform the Work under the Application. UL Int. Demko A/S shall not be liable in any respect to the extent that any such material provided by the Applicant is defective or insufficient or otherwise incomplete.

3. Certification.

Provided UL Int. Demko A/S determines that the Product tested is in compliance with the relevant Standards or requirements in effect at the time of testing as described in the Application, UL Int. Demko A/S shall authorize the use of the ®-Mark; other appropriate trademark(s); or other relevant Certifications.

If applicable, the Product will be entered in UL Int. Demko A/S' List of Approved and Registered Equipment.

The Applicant shall inform UL Int. Demko A/S about any Product alterations or complaints concerning the Product that may affect the Certification. The Applicant agrees that it will cooperate with and assist UL Int. Demko A/S in ascertaining the facts if it is reported that Applicant's Product is not in compliance with relevant standards or requirements, including sharing such information as the Applicant acquires regarding the reported noncompliance, and to take and report to UL Int. Demko A/S on such corrective action (including recall) as is necessary to correct any substantial hazard that is found to exist.

The UL Int. Demko A/S name, or trademark(s) shall not be used on or in connection with the Product or its container or packaging, unless and until expressly authorized by UL Int. Demko A/S and then only in the form or manner specified by UL Int. Demko A/S pursuant to this Agreement.

UL Int. Demko A/S will permit the use of appropriate references to the trademark(s) or the UL Int. Demko A/S name in promotional or advertising materials solely in connection with the products receiving relevant Certification under this Agreement, provided that in the opinion of UL Int. Demko A/S the promotional or advertising material is not in conflict with the findings of UL Int. Demko A/S and that the reference to the trademark(s) or the UL Int. Demko A/S name in no way tends to create a misleading impression as to the nature of UL Int. Demko A/S' Work, its findings or trademark(s). All rights concerning the trademark(s) and the UL International Demko A/S name are the property of UL International Demko A/S. Any unauthorized use of the trademark(s) or the UL Int. Demko A/S name shall be strictly prohibited. In the event of an infringement by Applicant of UL Int. Demko A/S' trademarks or similar rights, the Applicant shall pay liquidated damages of DKK 250,000 for each such infringement. UL Int. Demko A/S is entitled to protect its trademark rights by an interlocutory injunction. Payment of such damages shall not validate such infringement nor preclude UL Int. Demko A/S from claiming additional damages from the infringing party.

The trademark(s) may be used only on Products approved through testing as determined by UL Int. Demko A/S. The duration of the Certificate follows the rules for each certification agreement or is listed on the individual Certificate. The Products may display the trademark(s) for as long as the Certification is valid.

UL Int. Demko A/S may, without notice, cancel and withdraw authorization to use the trademark(s) and any applicable Certifications, if the Applicant does not comply with its financial commitments to UL Int. Demko A/S under this Agreement, if the Applicant's obligations under the Agreement are not fulfilled, if a Certification is invalid due to the expiration of the relevant standards transition period or if the Applicant requests withdrawal of the authorization to use any trademark(s) or other applicable Certifications.

4. Sample Disposal.

Applicant recognizes that samples of Products subjected to UL Int. Demko A/S' examination and test program may be damaged or completely destroyed. After UL Int. Demko A/S completes its testing on the Product, the Product shall be disposed of as directed by the Applicant in the Application. Applicant agrees that UL Int. Demko A/S is not responsible for damage to or loss of submitted Product samples while in transit or during performance under this Agreement.

5. Factory Inspection/Production Control.

It shall be the Applicant's responsibility to ensure that Products receiving Certification under this Agreement are produced in conformity with the relevant Standards and/or requirements. The Applicant shall ascertain that the factory locations of Products covered by this Agreement will provide and maintain adequate and sufficient facilities, equipment and procedures so as to ensure that Products continuously comply with the relevant Standards or requirements in order to secure continued validity of the Certification. The Applicant's compliance hereunder shall be established by Factory Inspection(s) by UL Int. Demko A/S or its representatives at the factory locations or by Production Control, in accordance with established procedures or as otherwise determined by UL Int. Demko A/S. UL Int. Demko A/S or its representatives shall have free access to the factory location and all relevant parts of the production process as to establish compliance. It is the responsibility of the Applicant to ensure that all relevant persons and organizations involved in the production of the Products receiving Certification hereunder are informed and agree to the contents of this Agreement. Applicant agrees to pay for all costs associated with the Factory Inspection and Production Control at UL Int. Demko A/S' current rates. Additionally, representatives of any accreditation body shall have free access to the factory location to monitor UL Int'l Demko A/S inspector representatives conducting inspections at the factory. Such access by UL Int'l Demko A/S or any accreditation body shall not be conditioned upon the execution of any agreement, waiver, or release which in any way purports to affect the rights or obligations of UL Int'l Demko A/S, the accreditation body, or any of their representatives, and any such document executed in contravention of this provision shall be without force and effect. UL Int'l Demko A/S shall direct its representatives to exercise due care in complying with any safety regulations which may be applicable generally to the factory location, employees or property and shall have no responsibility for the actions of the accreditation body or its representatives.

6. Terms of Payment and Fees.

Unless otherwise agreed in writing, fees charged by UL Int. Demko A/S shall be calculated pursuant to UL Int. Demko A/S' current rates in effect at the time of acceptance of the Application. Hourly rates charged by UL Int. Demko A/S depend on the requirements of the Application and shall be made available to Applicant upon request. The Applicant agrees that its obligation for all charges accruing under this Agreement continues in full force and effect irrespective of whether UL Int. Demko A/S' investigation does or does not result in Certification of the product by UL Int. Demko A/S.

Advances and reimbursable expenses directly identified with the project (e.g. freight) are charged independently and payable by Applicant.

UL Int. Demko A/S will invoice Applicant indicating the fees due. Applicant agrees to pay each invoice within thirty (30) days [forty-five (45) days for overseas Applicants] of its receipt. Notwithstanding the Applicant's designation of receipt of the invoice by a third party, Applicant acknowledges that it is principally responsible for payment for all invoices issued hereunder. Applicant agrees to pay a monthly interest of one percent (1%) of the outstanding account balance, but not in excess of the maximum allowed by law, in the event any account is over thirty (30) days past due. Applicant further agrees to pay UL Int. Demko A/S' costs of collection, including attorney's fees incurred in collecting any past due amounts.

UL Int. Demko A/S reserves the right at any time to request full or partial payment in advance, during performance hereunder or in satisfaction of fees for the Work through the date of the invoice. UL Int. Demko A/S reserves the right to suspend its performance, including but not limited to, the refusal to issue Certification, until payment is received in full for the Work.

AN AFFILIATE OF Underwriters Laboratories Inc.

592

0565

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

Records processed under FOIA Request 2014-5422; Released 10/29/14

7. Annual Maintenance Fee.

An annual maintenance fee is payable by Applicant at UL Int. Demko A/S' current rates, based on the number of product categories for which Applicant holds Certification. The annual maintenance fee is charged independently of any other fee charged by UL Int. Demko A/S.

8. VAT, Excises or Other Similar Taxes.

The fees for the Work rendered hereunder do not include any relevant VAT, excises or other similar taxes, which shall be payable by Applicant where applicable.

9. Limit of Liability.

(I) General. Applicant agrees that UL Int. Demko A/S, in performing its functions in accordance with its objects and purposes, does not assume or undertake to discharge any responsibility of the Applicant to any other party or parties. Applicant recognizes that the opinions and findings of UL Int. Demko A/S represent its judgment given with due consideration to the necessary limitations of practical operation and in accordance with its objects and purposes and agrees that UL Int. Demko A/S does not warrant or guarantee its opinions or that its findings will be recognized or accepted. Any statements made by UL Int. Demko A/S or any other documentation in connection with this Agreement are opinions based upon engineering judgment and are not to be construed as representations of fact.

The Applicant recognizes that many tests specified in the relevant Standards or requirements are inherently hazardous and agrees that UL Int. Demko A/S neither assumes nor accepts any responsibility for any injury or damage to the Applicant's property or personnel that may occur during or as a result of tests, wherever performed, whether performed in whole or in part by the Applicant or UL Int. Demko A/S, and whether or not any equipment, facility or personnel for or in connection with the test is furnished by the Applicant or UL Int. Demko A/S, except when such injury or damage results solely from negligence on the part of UL Int. Demko A/S' personnel.

(II) Delay/non-performance. The estimated date of completion of the Work is an estimate only and is not binding upon UL Int. Demko A/S unless there is a separate written agreement to that effect. No oral agreements shall be binding upon the parties. UL Int. Demko A/S shall not be responsible for any claims or damages for delay or non-performance unless such damages were caused by the gross negligence or an intentional act of UL Int. Demko A/S. In the event of a delay caused by UL Int. Demko A/S, the Applicant grants UL Int. Demko A/S an adequately extended period of time in which to complete the Work. If the execution of the Work is not possible for reasons for which UL Int. Demko A/S is responsible, the Applicant's sole remedy is to cancel the Agreement.

(III) Product liability. Apart from what is expressly stated in mandatory law, UL Int. Demko A/S shall not be liable in any respect for any claim based on product liability by any party, whether the claim is raised by a third party or by Applicant. If the Applicant has suffered a loss or a damage for which UL Int. Demko A/S is found to be liable by a Court of competent jurisdiction, UL Int. Demko A/S' liability shall not exceed ECU 1 million. To the extent any claim is brought against UL Int. Demko A/S by Applicant or any third party alleging a product liability, the Applicant shall indemnify and hold UL Int. Demko A/S harmless against any such liability, damage and expense.

(IV) Force Majeure. Any loss, damage or penalty of any kind, which is a consequence of force majeure shall not be the responsibility of UL Int. Demko A/S.

(V) Consequential damages. UL Int. Demko A/S shall not be liable for loss of profit, business, revenue, goodwill, anticipated sales or like economic loss, nor for any damages, regarding indirect or consequential loss.

(VI) Limitation of damages. Without prejudice to subclause 9 (III), UL Int. Demko A/S shall not be liable to pay to the Applicant or any third party any sum by way of damages or expense in excess of ECU 50,000. The provision of this sub section shall apply to all liability UL Int. Demko A/S may incur under or in connection with or in relation to the subject matter of this Agreement, whatever the circumstances and whether liability arises in contract, tort or otherwise, whether for breach of UL Int. Demko A/S' obligations under this Agreement or any other agreement between the parties, or for any acts, statement, advice or recommendation of UL Int. Demko A/S, its employees, agents, associated companies or subcontractors.

Any claim alleging UL Int. Demko A/S' liability for damage or injury or any other claim by Applicant or third party arising out of this Agreement shall be filed within a period of one year from UL Int. Demko A/S' completion of the work hereunder or shall be forever waived.

10. Indemnification.

The Applicant agrees to hold UL Int. Demko A/S harmless and to defend and indemnify UL Int. Demko A/S against any loss, expense, liability or damage, including reasonable attorney fees, arising out of any misuse by the Applicant of the trademark(s) or Certification or arising out of any violation by the Applicant of the terms and conditions of this Agreement.

11. Confidentiality.

UL Int. Demko A/S will refrain, without the Applicant's prior authorization in writing, from voluntarily disclosing to third parties secret information which is obtained by UL Int. Demko A/S in confidence from the Applicant and which is not already known to UL Int. Demko A/S, already available to the public or subsequently acquired from other sources.

Notwithstanding the foregoing, the Applicant agrees that UL Int. Demko A/S is permitted to make and retain copies, in its sole discretion, of any information which has been submitted to UL Int. Demko A/S in relation to the Work it provides. Applicant further agrees that UL Int. Demko A/S is permitted to provide Applicant's information to certification bodies as required by UL Int. Demko A/S' performance of the Work for Applicant. Applicant further recognizes that, as an independent organization testing for public safety, UL Int. Demko A/S may from time to time notify the public concerning products then or previously marketed which its investigations and tests disclose are extremely dangerous and unsuspectedly hazardous.

12. Intellectual Property Rights.

UL Int. Demko A/S shall own all copyrights and ownership interests to any information provided to Applicant by UL Int. Demko A/S under this Agreement. This information includes, but is not limited to, all documents, reports, opinions, drawings, Certifications, or other information whatsoever given to Applicant by UL Int. Demko A/S.

The Applicant can freely use the UL Int. Demko A/S report as a whole, whereas use of extracts or worked up results requires acceptance in writing by UL Int. Demko A/S.

13. Disputes, Governing Law and Consent to Jurisdiction.

The validity, construction and interpretation of this Agreement and all rights and duties of UL Int. Demko A/S and Applicant arising thereunder shall be governed by and subject to Danish law.

If a dispute arises between the parties in connection with the present Application, Applicant hereby irrevocably submits to the jurisdiction of the Maritime and Commercial Court (Sø- og Handelsretten) of Copenhagen, Denmark as the proper venue for any dispute. Applicant hereby irrevocably agrees that all claims in respect to such action or proceeding may be heard and determined in such court. Nothing herein shall effect the right of UL Int. Demko A/S to bring any action or proceeding against Applicant or its property or assets in the courts of any other jurisdictions.

14. Entire Agreement.

This Agreement constitutes the entire understanding of the parties, and there are no representations, warranties or undertakings made other than as set forth herein. This Agreement may be amended or modified only in writing signed by each of the parties hereto.

15. Language.

For those Applicants whose principal place of business is located in Denmark, this Agreement shall be entered into the Danish language, which shall exclusively govern the meaning of this Agreement. For all other Applicants, this Agreement shall be entered into solely the English language, which shall exclusively govern the meaning of the Agreement. Any other language which may be adopted for this Agreement by the parties hereto shall be deemed as a translation and shall not affect the meaning of this Agreement.

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
Memorandum

From: Reviewer(s) - Name(s) Barry J. Brumbaugh

Subject: 510(k) Number K032203

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. 21 CFR 864.5620 Automated Hemoglobin System
- ☐ 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	☑
Is this device subject to the Tracking Regulation?	☐ YES	☑
Was clinical data necessary to support the review of this 510(k)?	☑ YES	☐
Is this a prescription device?	☑ YES	☐
Was this 510(k) reviewed by a Third Party?	☐ YES	☑
Special 510(k)?	☑ YES	☐
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑

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) N/A

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☑ Confidentiality for 90 days ☐ Continued Confidentiality exceeding

Predicate Product Code with class: 81 GKR II

Additional Product Code(s) with panel (optional):

Review: Josephine Bartinda DIHD 8/25/03
(Branch Chief) (Branch Code) (Date)

Final Review: [illegible] 8/25/03
(Division Director) (Date)

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

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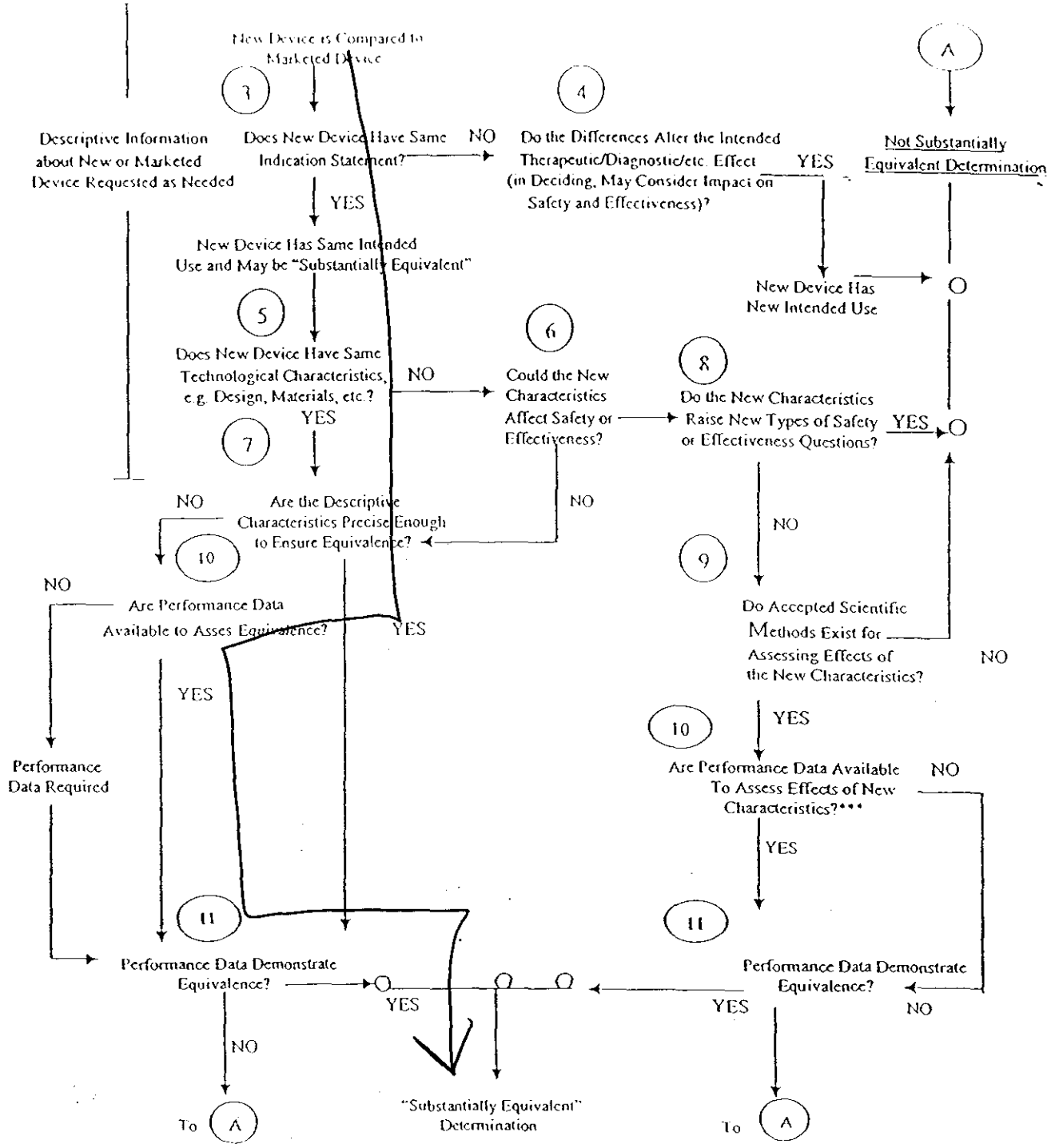
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear
- This decision is normally based on descriptive information alone, but limited testing information is sometimes required
- Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature

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

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REVISED:3/14/95

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K032203 Special

Reviewer: Larry J. Brindza

Division/Branch: OIVD/Division of Immunology and Hematology Devices

Device Name: HemoCue® Hb 201+ System

Product To Which Compared (510(K) Number If Known): HemoCue® B-Hemoglobin System (K961312, K832020)

	YES	NO	
1. Is Product A Device	X		If **NO** = Stop
2. Is Device Subject To 510(k)?	X		If **NO** = Stop
3. Same Indication Statement?	X		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?	X		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?	X		If **NO** = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision:SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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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. **Intended Use:** The HemoCue Hb 201 System is used for the quantitative determination of hemoglobin in blood using a specially designed analyzer, the HemoCue Hb 201+ analyzer, and specially designed microcuvettes, the HemoCue Hb 201 Microcuvettes. The HemoCue Hb 201 analyzer is only to be used with HemoCue Hb 201 Microcuvettes.

2. **Device Description:** The HemoCue technique is based on an optical measuring microcuvette of a small volume and a short light path. The microcuvette cavity contains reagents deposited on its inner walls. The blood sample is drawn into the cavity by capillary action and is mixed spontaneously with the reagents. The microcuvette is then placed in the HemoCue Hb 201+ analyzer in which the transmittance is assured and the hemoglobin level calculated. The microcuvette is made of polystyrene and comprises a body having a cavity with a volume of about µL. The distance between the walls of the optical window is 0.130 mm. which permits photometric determination of hemoglobin in undiluted blood. The reaction in the microcuvette is a modified azidemethemoglobin reaction. The erythrocyte membranes are disintegrated by sodium deoxycholate, releasing the hemoglobin. Sodium nitrite converts the hemoglobin iron from the ferrous to the ferric state to form methemoglobin which then combines with azide to form azidemethemoglobin. The predicate device was modified by making the analyzer dimensions smaller. This was achieved by conveying the light over a plastic bridge, instead of reflecting it off a beam splitting mirror. The light itself has not been changed. The shape of the microcuvette was changed so that it will fit only in the Hb 201+ analyzer.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

7. **Explain how descriptive characteristics are not precise enough:**

   Performance data are necessary to assure the effectiveness of the device.

11. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:**

    Accuracy, precision, linearity, and interference data demonstrate the substantial equivalence of the device.

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

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SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing o Inadequat
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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

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Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequ or Missi
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity (For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which		9

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

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is posted with the 510(k) boilers on the H drive.)		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequat or Missin
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No
Reviewer: _____
Concurrence by Review Branch: _____

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

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Date:

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

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

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Internal Administrative Form

	YES
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? 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.	

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

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SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER **K032203**

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This change was for reducing the size of the physical dimensions of the analyzer and to change the shape of the microcuvette.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, clinical performance data (accuracy, precision, linearity, and interference), and software documentation.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Larry J. Brinkley (Reviewer's Signature) 8-22-03 (Date)

Comments

revised:3/27/98

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

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PHONE MEMO

Date: 8-22-03

Between: Larry J. Brindza., Scientific Reviewer, Division of Immunology and Hematology Devices,
OIVD, HFZ-440 LJB

And: Mr. Joel Slomoff, Consultant to HemoCue AB of Sweden

Subject: HemoCue Hb 201+ System

To: The Record: K032203, Special

Phone call to Mr. Slomoff to clarify a notation on his cover letter for the submission. A notation is made on the first page of the cover letter: Device Modification, HemoCue Incorporated, Blood Glucose Analyzing System. I didn't see anything in the submission attempting to claim the HemoCue glucose test was a part of the Hb 201+ System and so I just wanted to confirm that the glucose test was not a part of this submission. Mr. Slomoff said the term "Blood Glucose Analyzing System" was a mistake and should not have appeared on the cover letter. I told Mr. Slomoff I was finishing the submission.

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