U.S. Department of Health & Human Services

Food and Drug Administration

FOIA RESPONSE

USER:	(jrc)
FOLDER:	K090413 - 132 pages (FOI:01003283)
COMPANY:	BAYER HEALTHCARE, LLC (BAYEHEAL)
PRODUCT:	ASSAY, GLYCOSYLATED HEMOGLOBIN (LCP)
SUMMARY:	Product: A1CNOW+ (10 TEST KIT, PROFESSIONAL USE) MODEL 3024, A1CNOW+(20 TEST KI
DATE REQUESTED:	Mar 12, 2012
DATE PRINTED:	Mar 12, 2012
Note:	Releasable Version

MAY 14 2009

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

A1CNow® for Home and Professional Use

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K090413

Prepared:	February 17, 2009
Submitter:	Bayer HealthCare Diabetes Care
Address:	510 Oakmead Parkway Sunnyvale, CA 94085 Phone (408) 524-2255; FAX (408) 524-2252
Contact:	Cathy Peters, Manager, Regulatory Affairs
Device:	Trade/Proprietary Names: A1CNow+ (Professional Use) A1CNow Self Check (Home Use)
Common/Usual Name:	Percent Hemoglobin A1c (percent glycosylated hemoglobin)
Classification:	Assay, Glycosylated Hemoglobin; 21 CFR 864.7470
Predicate Device:	A1cNow® Multi-Use for Home and Professional Use (InView™) K051321
Device Description:	The A1CNow+ tests provides quantitative measurement of the percent of glycated hemoglobin (%A1C) levels in capillary (fingerstick) or venous whole blood samples. The test is used to monitor glycemic control in people with diabetes. A1cNow+™ consists of 1) a semi-disposable plastic-encased device (the monitor), 2) a plastic cartridge enclosing dry reagent strips, and 3) a sample dilution kit for: collecting the blood sample, mixing the sample with the required pre-treatment solution, and delivering the sample to the cartridge. When testing with A1CNow+, an unmeasured whole blood mixture (diluted) is directly applied to the

sample port, and the results are displayed in numeric form on the Monitor's liquid crystal display after 5 minutes.

Intended Use:	The A1CNow multi-use test provides quantitative measurement of the percent of glycated hemoglobin (%HbA1c, %A1C) levels in whole blood samples. The test is for home use and professional use for monitoring glycemic control in people with diabetes.
Technological Characteristics:	There were no changes to the intended use or fundamental scientific technology.
Comparison to Predicate device:	A1CNow is the same in fundamental technology and intended use to the predicate device, A1CNow, K051321, but has increased product stability and a simplified hemolysate preparation kit.
Assessment of Performance:	The performance was assessed in two separate clinical validation studies. The studies showed that changes to the hemolysate kit and product stability had no negative impact on product safety and efficacy. In addition, completed and ongoing product stability studies show no negative impacts of increased room temperature shelf life.
Conclusion:	The results of the verification and validation studies of A1CNow demonstrated that the product is safe and effective in the hands of lay users and healthcare professionals. The product is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 2009

Bayer HealthCare, LLC
c/o Ms. Cathy Peters
Regulatory Affairs Manager
510 Oakmead Parkway
Sunnyvale, CA 94085

Re: k090413
Trade/Device Name: A1CNow Self Check, A1CNow+
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP
Dated: April 14, 2009
Received: April 15, 2009

Dear Ms. Peters:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): K090413

Device Name: A1CNow+ (professional use), A1CNow Self Check (Home Use)

Indications for Use:
The A1CNow multi-use test provides quantitative measurement of the percent of glycated hemoglobin (%HbA1c, %A1C) levels in whole blood samples. The test is for home use and professional use for monitoring glycemic control in people with diabetes.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) **AND/OR** Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) K090413

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 2009

Bayer HealthCare, LLC
c/o Ms. Cathy Peters
Regulatory Affairs Manager
510 Oakmead Parkway
Sunnyvale, CA 94085

Re: k090413
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Acting Director
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Enclosure

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K090413

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

April 03, 2009

BAYER HEALTHCARE, LLC
510 OAKMEAD PKWY.
SUNNYVALE, CALIFORNIA 94085
UNITED STATES
ATTN: CATHY PETERS

510k Number: K090413
Product: A1CNOW+ (10 TEST KIT, PROFESSI

Extended Until: 09/18/2009

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

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

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

Sincerely yours,

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

WollBio
WollBioOrthopedics LLC

April 1, 2009

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

Re: K090413
Trade Name: Woll BioOrthopedics Intramedullary Fixation System

Dear Document Mail Clerk;

We are currently in an extended period for providing information requested by the reviewer regarding the above listed 510(k) Premarket Notification Application. The extension ends on April 10th , 2009. While we have much of the information requested by the reviewer has been organized for our response, some information requested has required additional testing involving multiple product samples. Delays encountered the final testing has forced us to request additional time to respond to FDA's questions.

We respectfully request an additional 180 days to assure our response is complete.

Sincerely yours,

Duane Dickens
Project Manager
Woll BioOrthopedics,LLC
Fax: 949-498-3123
Phone: 949-466-2272

K31

195 Harvard Rd.
Littleton, MA 01460

office 978-486-4077
fax 978-486-8474
web WollBio.com

WollBio
WollBioOrthopedics LLC

April 1, 2009

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

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Duane Dickens
Project Manager
Woll BioOrthopedics,LLC
Fax: 949-498-3123
Phone: 949-466-2272

195 Harvard Rd.
Littleton, MA 01460

office 978-486-4077
fax 978-486-8474
web WollBio.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

March 25, 2009

510k Number: K090413
Product: A1CNOW+ (10 TEST KIT, PROFESSI

BAYER HEALTHCARE, LLC
510 OAKMEAD PKWY.
SUNNYVALE, CALIFORNIA 94085
UNITED STATES
ATTN: CATHY PETERS

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

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

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

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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

Sincerely yours,

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

February 25, 2009

BAYER HEALTHCARE, LLC
510 OAKMEAD PKWY.
SUNNYVALE, CALIFORNIA 94085
UNITED STATES
ATTN: CATHY PETERS

510k Number: K090413
Received: 2/25/2009
Product: A1CNOW+ (10 TEST KIT, PROFESSI

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), 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.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

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

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"

(http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires the categorization of commercially marketed test systems by level of complexity. If your device is a test system that requires categorization you will be notified of your complexity as an enclosure with any clearance letter.

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 regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural questions, or want information on how to check on the status of your submission, please contact DSMICA at (240) 276-3150 or its toll-free number (800)638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or the 510k staff at (240) 276-4040.

Sincerely yours,

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

February 18, 2009

BAYER HEALTHCARE, LLC
510 OAKMEAD PKWY.
SUNNYVALE, CALIFORNIA 94085
UNITED STATES
ATTN: CATHY PETERS

510k Number: K090413
Received: 2/18/2009
User Fee ID Number: 6039597
Product: A1CNOW+ (10 TEST KIT, PR

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 all 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 Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

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

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma. In addition, the 510k Program Video is now available for viewing on line at www.fda.gov/cdrh/video/510k.wmv.

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

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-fee number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Diane Garcia at Diane.Garcia@fda.hhs.gov or directly at (240)276-4027. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane M. Garcia
Public Affairs Specialist
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

K090413

Bayer HealthCare
Diabetes Care

Bayer Diabetes Care
A1CNow+ Division
510 Oakmead Parkway
Sunnyvale CA 94085

Tel. (408) 252-2255
Fax (408) 773-8168

February 17, 2009

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

Reference: K051321, A1CNow Multi-Use for Home and Professional Use

Bayer HealthCare hereby submits this **Special 510(k): Device Modification** to request modifications and update our 510(k) documentation for the A1CNow Multi-Use for Home and Professional Use product. The modifications are to increase our product's room temperature stability and update the instructions for use (OTC) for clarity, and to update the 510(k) technical information to include an incremental change (simplification of hemolysate preparation) that has occurred since our last 510(k) clearance for this device. We believe these modifications are eligible for the Special 510(k) process since they have the same fundamental scientific technology and intended use as the predicate device.

We consider our intent to market this device as confidential commercial information and request that it be treated as such by the FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331 (q).

Thank you in advance for consideration of our application. If you have any questions regarding this information, please don't hesitate to contact me.

Sincerely,

Cathy Peters, RAC
Manager, Regulatory Affairs
Bayer HealthCare LLC
Diabetes Care – A1CNow+
Catherine.peters.b@bayer.com
408-524-2255, ext. 236

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: **MD6039597-956733** Write the Payment Identification number on your check.

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

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
BAYER HEALTHCARE LLC 430 S. BEIGER ST. Mishawaka IN 46544 US	Roger Sonnenburg 2.1 E-MAIL ADDRESS roger.sonnenburg.b@bayer.com 2.2 TELEPHONE NUMBER (include Area code) 574-2563441
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 061653795	2.3 FACSIMILE (FAX) NUMBER (Include Area code) 574-2563519

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

Select an application type:	3.1 Select one of the types below
[X] Premarket notification(510(k)); except for third party	[X] Original Application
[ ] 513(g) Request for Information	Supplement Types:
[ ] Biologics License Application (BLA)	[ ] Efficacy (BLA)
[ ] Premarket Approval Application (PMA)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Modular PMA	[ ] Real-Time (PMA, PMR, PDP)
[ ] Product Development Protocol (PDP)	[ ] 180-day (PMA, PMR, PDP)
[ ] Premarket Report (PMR)	
[ ] Annual Fee for Periodic Reporting (APR)	
[ ] 30-Day Notice	

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

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

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms

[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

$3,693.00 05-Nov-2008

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Bayer HealthCare	2954361		
Division Name *(if applicable)*	Phone Number *(including area code)*		
Diabetes Care	(408) 524-2255, ext. 236		
Street Address	FAX Number *(including area code)*		
510 Oakmead Parkway	(408) 524-2252		
City	State / Province	ZIP/Postal Code	Country
Sunnyvale	CA	94085	USA
Contact Name			
Cathy Peters			
Contact Title	Contact E-mail Address		
Regulatory Affairs Manager	catherine.peters.b@bayer.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	( )		
Street Address	FAX Number *(including area code)*		
	( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

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

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

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

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:
  Increased stability and changes to hemolysate preparation kit.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LCP	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached
☐ 510 (k) statement

ormation on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K051321	1	A1CNow Multi-Use for Home and Professional Use (Inview)	1	Metrika (has since been acquired by Bayer)
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Percent Hemoglobiin A1c (percent glycosylated hemoglobin)

	Trade or Proprietary or Model Name for This Device		Model Number
1	A1CNow+ (10 test kit, Profcssional Use)	1	3024
2	A1CNow+ (20 test kit, Professional Use)	2	3021
3	A1CNow Self Check (OTC Use)	3	3030
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K051321	2 K033847	3 K022661	4 K020234	5 K020235	6 K000885
7 K000887	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
LCP		☐ Class I ☒ Class II
Classification Panel 81		☐ Class III ☐ Unclassified

Indications *(from labeling)*

The A1CNow multi-use test provides quantitative measurement of the percent of glycated hemoglobin (%HbA1c, %A1C) levels in whole blood samples. The test is for home use and professional use for monitoring glycemic control in people with diabetes.

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

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Bayer HealthCare LLC		Establishment Registration Number: 2954361
Division Name *(if applicable)*: Diabetes Care		Phone Number *(including area code)*: (408) 524-2255, ext. 236
Street Address: 510 Oakmead Parkway		FAX Number *(including area code)*: (408) 524-2252
City: Sunnyvale	State / Province: CA	ZIP/Postal Code: 94085 — Country: USA
Contact Name: Cathy Peters	Contact Title: Regulatory Affairs Manager	Contact E-mail Address: catherine.peters.b@bayer.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )
Street Address		FAX Number *(including area code)*: ( )
City	State / Province	ZIP/Postal Code — Country
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )
Street Address		FAX Number *(including area code)*: ( )
City	State / Province	ZIP/Postal Code — Country
Contact Name	Contact Title	Contact E-mail Address

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K051321

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] 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(k)] Manual.	√	
Statement of Indications for Use that is on a separate page in the pre-market 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(k)] 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).]	NA	
Class III Certification and Summary. **	NA	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	√	
510(k) Kit Certification ***	NA	

* - 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.

Section 4: Additional Requirements for ABBREVIATED or TRADITIONAL 510(k) submission (if applicable):

	Present	Inadequate or Missing
a) Biocompatibility for all patient-contacting materials OR certification of identical material/formulation	NA	
b) Sterilization and expiration dating information:	NA	
i) sterilization process	NA	
ii) validation method of sterilization process	NA	
iii) SAL	NA	
iv) packaging	NA	
v) specify pyrogen free	NA	
vi) ETO residues	NA	
vii) radiation dose	NA	
viii) Traditional method or non-traditional method	NA	
c) Software documentation	NA	

SPECIAL 510(k)
DEVICE MODIFICATION for K051321

A1CNow® Multi-Use for Home and Professional Use

February 17, 2009

TABLE OF CONTENTS

SECTION 1

STATUTORY REQUIREMENTS

SECTION 1
STATUTORY REQUIREMENTS

SECTION 21 CFR PART 807.87
Information Required in a Premarket Notification Submission

807.87 (a): Device name- trade name and common name, and classification

Trade name:
A1CNow+ (Professional Use)
A1CNow Self Check (Home Use)

Common Name:
Percent Hemoglobin A1c (percent glycosylated hemoglobin)

Classification Name(s):
Assay, Glycosylated Hemoglobin; 21 CFR 864.7470

807.87 (b): Establishment registration

Bayer Sunnyvale's establishment registration number is 2954361.

807.87 (c): Class and panel

FDA has classified HbA1c assays as Class II, Product Code LCP, under Panel 81 HE (Hematology).

807.87 (d): Performance standards

FDA has not promulgated performance standards for HbA1c assays, nor is it expected that any will be promulgated.

807.87 (e): Proposed (Revised) labeling

Labeling may be found in Attachments A, B and C. Attachment A consists of Home Use labeling, and Attachment B consists of the original home use labeling cleared in K051321 (for reference). Attachment C consists of professional use labeling, the content of which was previously reviewed and accepted by the FDA on 1/24/08 as part of a CLIA review.

807.87 (f): Statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution

As this is a Special 510(k): Device Modification, the modified device is similar to its predecessor product. There is no change in the device's intended use, and no change in the device's fundamental scientific technology.

This Special 510(k) is being submitted for two changes to the A1CNow device- improved room temperature stability and minor changes to device instructions for use to improve user comprehension. In addition, one incremental change that has occurred since the last 510(k) clearance for this device is included to update the technical information- a simplification of the Hemolysate Preparation from a 3-step to a 2-step process (along with associated updates to the product insert). The changes are described below.

1) **Product Stability**- To ensure product stability at room temperature for at least 15 months, two minor adjustments to non-active ingredients in the assay are being made. The first is to increase the percent of sucrose in the antibody latex striping solution from 10% to 25%; this ensures more uniform release of the latex over time. The second is a reduction in one of the surfactants in the sample treatment buffer. With the improved release achieved with the higher sucrose, less surfactant is required in the test. The actual materials used in the product remain the same; just the percentages have changed. Any changes in materials and/or processes have been validated and have undergone design control as specified in 21 CFR Part 820.30. The Design Control Declaration of Conformity is provided in Section 5.

2) **Simplification of the Hemolysate Preparation**- This change involved enhancing the sampling accessory (the "Sampler") which combines blood collection, dilution, mixing and delivery to the A1CNow device. The Sampler was simplified from a three piece accessory to a two piece accessory (capillary collection component and dilutent/delivery component). There were no changes to the fundamental technology or intended use, and the regulatory route for this change was internal validation only. This decision was based on Bayer's completion of the "when-to-refile checklist," and e-mail communication with FDA (Ruth Chesler, August 4, 2006) stating that internal validation and documentation should be sufficient if the labeled performance claims are met. Validation studies assessing user interface (both professional and lay users) have shown that the performance did not change. The Sampler was instituted in June 2007 with no appreciable increase in complaints as a result.

3) **Instructions for Use-** The written instructions for the OTC version of this product were changed to improve reading comprehension (see Appendix A). In the OTC version, the Sampler is called the "Shaker," as consumer studies revealed this nomenclature was easier for OTC users to understand (the "Shaker" and "Sampler" are exactly the same). A DVD was also created as an additional, supplemental delivery method of communicating the instructions for use. These changes were validated in a clinical evaluation intended to ensure that the modified device continues to meet user requirements (see Section 4).

The Professional use written instructions were previously revised for clarity and to include information on use of the Sampler and controls. With the introduction of the Sampler, labeling also was updated to recommend heparinized whole blood vs. EDTA whole blood when testing venous samples and to add a "Limitations" for rheumatoid factor. These were reviewed and accepted by the FDA on January 24, 2008 as part of a CLIA review, and are included in Appendix C for reference.

807.87 (g): Significant changes to an existing device

As described in Attachment 2 of the Final Guidance Document ("Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications"), "appropriate supporting data" may be used to address the impact of any changes on the existing device. In this instance, validation studies were performed at elevated temperatures so as to develop an accelerated model, as well as in real time. The results (supporting data) from these studies confirm extending room temperature from 6 months to 15 months. In addition, clinical studies for both the Sampler- and stability-related changes were performed to show that this version of A1CNow continues to meet user requirements. Summaries of these results are provided in Section 4.

807.87 (h): Request for a 510(k) summary, or a 510(k) statement

A summary of 510(k) Safety and Effectiveness is provided in Section 6.

807.87 (i): Financial certification/disclosure

Payments to investigators for these studies (two) were based solely on pre-negotiated budgets for time and materials. Financial disclosure information and Forms 3454 pertaining to clinical validation studies (see Section 4) are included in Appendix D.

807.87 (j): Information for devices classified into Class III

Not applicable; A1CNow is not a Class III device.

807.87 (k): Truthful and accurate statement

"I certify that, to the best of my knowledge, all data and information submitted in the premarket notification is truthful and accurate and that no material fact has been omitted."

Cathy Peters
Regulatory Affairs Manager

2/17/09
Date

807.87 (l): Request for additional information

Bayer understands the Commissioner may request additional information in order to make the determination of substantial equivalence.

SECTION 2

INTENDED USE/INDICATIONS FOR USE

STATEMENT OF INTENDED USE

510(K) Number (if known): K090413

Device Name: A1CNow+ (professional use), A1CNow Self Check (Home Use)

Indications for Use:
The A1CNow multi-use test provides quantitative measurement of the percent of glycated hemoglobin (%HbA1c, %A1C) levels in whole blood samples. The test is for home use and professional use for monitoring glycemic control in people with diabetes.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) **AND/OR** Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K090413

SECTION 3

COMPARATIVE CHART

SECTION 3
COMPARATIVE CHART

As stated previously, this Special 510(k) is being submitted for two changes to the A1CNow device- an increase in product stability and minor changes to device instructions for use (OTC version) to improve user comprehension. In addition, one incremental change that has occurred since the last 510(k) clearance for this device is included- a simplification of the Hemolysate Preparation from a 3-step to a 2-step process. As noted in the comparison chart below, all other product characteristics remain the same as the predicate device.

Comparisons Between A1CNow-cleared and A1CNow-modified

CHARACTERISTIC	A1CNow® *Cleared* K051321	A1CNow® *Modified*
Intended Use	Quantitative measurement of the percent of glycated hemoglobin	SAME
Indications for Use	Used in the management and treatment of diabetes, for monitoring long term glycemic control	SAME
Risk to Patient	Not a critical analyte – reflects glucose monitoring over time	SAME
Sample	Whole blood	SAME
Visual Display	LCD readout	SAME
Hemolysate Preparation	Manual (3 piece Sample Dilution Kit)	Manual (2 piece Sample Dilution Kit)
Calibration	Not required by end-user; each unit is factory calibrated	SAME
Methodology	Immunoassay	SAME
Detection Method	4-channel reflectance photometer	SAME
Testing Environment	Home Use and Professional Use	SAME
Throughput	5 minutes per sample – multiple samples run sequentially	SAME
Pre-analysis Steps (after sample dilution)	Single-use cartridge inserted, then diluted sample is added directly to Sample Well	SAME
Quality Control	On-board QC checks -each run	SAME
Room Temperature Stability	6 months room temperature (refrigerated stability-12 months from day of manufacture)	15 months room temperature

SECTION 4

RISK ANALYSIS
VERIFICATION and VALIDATION

SECTION 4
RISK ANALYSIS
VERIFICATION and VALIDATION

The risk analysis method used to assess the impact of the modifications was a Failure Mode and Effects Analysis (FMEA). The required verification and validation activities per this analysis, including the tests used and acceptance criteria that were applied, along with the results are listed in the tables below. A declaration of conformity with design controls is included in Section 5.

A. Simplification of Hemolysate Preparation ("Sampler") and Related Instructions for Use Updates (OTC and Professional Use):

Table of Risk Assessment: HEMOLYSATE PREPARATION ("SAMPLER")

Risk	Verification/ Validation Testing	Acceptance Criteria	Results		
The result displayed is significantly different from the true value in terms of diagnostic indication	A clinical validation study (DVR-07-01-002) was performed to validate the use of the Sampler in the hands of both lay and professional users. Approximately 40 subjects at each site performed one A1CNow+ test on themselves after viewing a short (~3 minute) video, and then by following the written instructions. The subjects were mostly people with diabetes, but some non-diabetics were included in order to evaluate the lower end of the test's dynamic range.	Clinical Accuracy: Three-site average bias for subjects and HCPs at 6, 7 and 8% A1C must be within ±3% (estimated average bias) of the NGSP value, as determined by linear regression.	*Self*	*Calculated from linear regression*	*±3% limit*
			6	6.01	5.82-6.28
			7	7.12	6.79-7.21
			8	8.23	7.76-8.24
			PASS		
			HCP	*Calculated from linear regression*	*±3% limit*
			6	6.05	5.82-6.18
			7	7.09	6.79-7.21
			8	8.13	7.76-8.24
			PASS		

Table of Risk Assessment: HEMOLYSATE PREPARATION ("SAMPLER")			
Risk	Verification/ Validation Testing	Acceptance Criteria	Results
	Analytical validation: Accuracy	Meets NGSP minimum- 95% of values within 1% A1C by Bland-Altman when tested against reference method; testing protocol= 40 samples that spread dynamic range, tested in duplicate (samples are targeted at certain A1C concentrations).	Testing performed with two lots: 100% of results were within 1% A1C. PASS
	Analytical validation: Precision	% CVs not statistically different from 4% at two levels (Low and High)	Testing performed with two lots: Lot 1: Low (mean 5.1%) %CV= 2.74 High (mean 9.4%) %CV=4.02 Lot 2: Low (mean 5.2%) %CV= 3.61 High (mean 9.1%) %CV=3.86 PASS
	Analytical validation: Interference testing	Interference not statistically different from labeled	No interference from biological compounds, common OTC drugs, and drugs related to diabetes therapy. PASS
Device fails to display a clinical result, inconveniencing the customer	Clinical validation study	Error codes: the rate of errors attributable to the Sampler may not exceed 15% overall. The rate of error codes must be approximately equal across all sites.	Site 1: 2 errors/5.0% Site 2: 2 errors/5.1% Site 3: 3 errors/7.9% Total errors attributable to the sampler, overall 7/117, 6.0% PASS

Table of Risk Assessment: HEMOLYSATE PREPARATION ("SAMPLER")			
Risk	Verification/ Validation Testing	Acceptance Criteria	Results
		Error- in procedure (attempts resulting in the need to replace Sampler parts). The rate of error codes must be approximately equal across all sites.	Site 1: 5 failures/44 attempts= 11% Site 2: 6 failures/45 attempts= 13% Site 3: 3 failures/41 attempts= 7% Overall: 14 failures/130 attempts= 11% PASS
	Quiz results (quiz on understanding of product insert instructions for use)	At least 80% of subjects must have no more than 2 wrong answers.	111 of 117 (94.9%) of subjects had no more than 2 wrong answers. PASS
	Questionnaire results	At least 90% of subjects must find that using the Sampler was easy or somewhat easy.	115 of 117 (98%) subjects found the test easy or somewhat easy to perform. PASS

B. Product Stability Change and Instructions for Use (OTC) Updates:

Table of Risk Assessment: PRODUCT STABILITY AND OTC INSTRUCTIONS FOR USE CHANGES

Risk	Verification/Validation Testing	Acceptance Criteria	Results
The result displayed is significantly different from the true value in terms of diagnostic indication	Design Change DC101 (DVR-07-11-002) testing performed to validate initial performance (T=0) of the product continues to meet all product release requirements.	All current product release specifications, including accuracy, precision and reliability	All requirements were met
	Equivalence to current strip for key performance attributes (Sample arrival times, Precision over time). (DVR-07-11-002)	No significant difference from the existing product	All requirements were met
	Verification of stability of the (b) (4) value over time. This is the key parameter impacted by the increase of the sucrose in the Antibody:Latex striping solution. (DVR-07-11-002)	Reduced variation over time with the revised formulation	All requirements were met
	Verification of cartridge exposure time: Samples were exposed to high humidity environments for up to 5 minutes prior to testing. Two levels of commercially available A1c Controls were used. (DVR-07-11-002)	Results ±10% from the "0" exposure condition	PASS
	Sample Volume Sensitivity: Sample volumes of ±20% and ±30% were compared to the recommend test volume of 185uL. Two levels of commercially available A1c Controls were used. (DVR-07-11-002)	Results ±10% of the target volume	PASS

Table of Risk Assessment: PRODUCT STABILITY AND OTC INSTRUCTIONS FOR USE CHANGES			
Risk	Verification/Validation Testing	Acceptance Criteria	Results
Device produces significantly erroneous result.	DVR-07-11-002	Product stability requirements of (b) (4) of initial value through 4 months at room temperature (RT) and 12 months refrigerated*	All requirements were met.
	Studies initiated under DVP 07-11-002 continue to be monitored for long term performance at room temperature	Accelerated stability testing and extrapolation of real time stability testing predicts that at the end of a 15 month shelf life, a mean shift within ±10.14% will be achieved.	All requirements were met.
The result displayed is significantly different from the true value in terms of diagnostic indication Device fails to display a clinical result, inconveniencing the customer	A clinical validation study (CTD-REP-2009-03) was performed to assure that consumers can successfully use the OTC version of A1CNow (A1CNow Self Check) with the instructional materials provided (DVD and written instructions, # of samples analyzed =101, vs. written instructions only, # of samples analyzed =77). A total of 110 subjects, (93 with diabetes and 17 without diabetes) completed the study, which included one *in-clinic* visit. Each subject completed 2 self tests, and the health care professional (HCP) completed 1 test on each subject. A venous sample was also taken from each subject for testing on the laboratory analyzer (TOSOH) at Bayer Diabetes Care, Sunnyvale, CA.	**Accuracy:** At least 95% of results shall be within ±13.5% (total error) of the reference method value. The allowable error limits are statistically determined from the allowable bias, and precision of the reference and test methods. The reference method is an NGSP-certified level II laboratory (TOSOH).	When subjects were given instructional materials that will be shipped with the product (written instructions and DVD, n=101), the critical value is calculated to be 93 or greater in order to meet the accuracy objective. 94 accurate results obtained. PASS
		Comprehension: Evaluate comprehension of instructional materials by lay users. Subject comprehension was measured via first time failure rate (FTFR).** FTFR must be less than 20%.	When subjects were given instructional materials that will be shipped with the product (written instructions and DVD), the FTFR was 11.32% PASS

Table of Risk Assessment: PRODUCT STABILITY AND OTC INSTRUCTIONS FOR USE CHANGES			
Risk	Verification/Validation Testing	Acceptance Criteria	Results
		Customer Satisfaction: Assessed via lay-user and HCP survey.	When asked to rate the overall usability of the product, a large majority (94%) gave a rating of "very good" to "excellent".

*Although A1CNow (OTC and professional use) is cleared for 6 months room temperature, up to 12 months refrigerated stability from date of manufacture, current labeling for A1CNow+ (professional use) product lists 4 months RT stability, up to 12 months refrigerated. Therefore this data point was included in the validation report.

**The FTFR was developed as a more concrete measure of measuring comprehension as compared to questionnaires, which were used in past evaluations of user comprehension. A first time failure occurs whenever a user encounters the following scenarios during his/her first usage of the product (as observed by staff members): 1) cannot figure out how to use the product based on the instructional materials provided without assistance; 2) attempts to complete the test, realizes a mistake was made but cannot continue because one or more of the parts has been rendered unusable (due to user error); or 3) manages to complete the test after one or more mistakes and gets an error code instead of a result.

SECTION 5

DESIGN CONTROLS DECLARATION OF CONFORMITY

SECTION 5
DESIGN CONTROLS DECLARATION OF CONFORMITY

1) As required by the risk analysis, all verification and validation activities for these modifications were performed by appropriate and designated individuals(s), and demonstrated that the predetermined acceptance criteria were met.

Cathy Peters
Regulatory Affairs Manager

2/13/2009
Date

Ben Irvin, PhD.
Director Research and Development and Engineering

2/13/2009
Date

2) Bayer Sunnyvale's 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.

Joseph Ruggiero
Senior Director of Manufacturing Technology

2/13/09
Date

SECTION 6

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

A1CNow® for Home and Professional Use

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K090413.

Prepared:	February 17, 2009
Submitter:	Bayer HealthCare Diabetes Care
Address:	510 Oakmead Parkway Sunnyvale, CA 94085 Phone (408) 524-2255; FAX (408) 524-2252
Contact:	Cathy Peters, Manager, Regulatory Affairs
Device:	Trade/Proprietary Names: A1CNow+ (Professional Use) A1CNow Self Check (Home Use)
Common/Usual Name:	Percent Hemoglobin A1c (percent glycosylated hemoglobin)
Classification:	Assay, Glycosylated Hemoglobin; 21 CFR 864.7470
Predicate Device:	A1cNow® Multi-Use for Home and Professional Use (InView™) K051321
Device Description:	The A1CNow+ tests provides quantitative measurement of the percent of glycated hemoglobin (%A1C) levels in capillary (fingerstick) or venous whole blood samples. The test is used to monitor glycemic control in people with diabetes. A1cNow+™ consists of 1) a semi-disposable plastic-encased device (the monitor), 2) a plastic cartridge enclosing dry reagent strips, and 3) a sample dilution kit for: collecting the blood sample, mixing the sample with the required pre-treatment solution, and delivering the sample to the cartridge. When testing with A1CNow+, an unmeasured whole blood mixture (diluted) is directly applied to the

sample port, and the results are displayed in numeric form on the Monitor's liquid crystal display after 5 minutes.

Intended Use:	The A1CNow multi-use test provides quantitative measurement of the percent of glycated hemoglobin (%HbA1c, %A1C) levels in whole blood samples. The test is for home use and professional use for monitoring glycemic control in people with diabetes.
Technological Characteristics:	There were no changes to the intended use or fundamental scientific technology.
Comparison to Predicate device:	A1CNow is the same in fundamental technology and intended use to the predicate device, A1CNow, K051321, but has increased product stability and a simplified hemolysate preparation kit.
Assessment of Performance:	The performance was assessed in two separate clinical validation studies. The studies showed that changes to the hemolysate kit and product stability had no negative impact on product safety and efficacy. In addition, completed and ongoing product stability studies show no negative impacts of increased room temperature shelf life.
Conclusion:	The results of the verification and validation studies of A1CNow demonstrated that the product is safe and effective in the hands of lay users and healthcare professionals. The product is substantially equivalent.

A1CNow®, SELFCHECK At-Home A1C System
OVERVIEW AND HELPFUL HINTS

INTENDED USE
The A1CNow® SELFCHECK test provides quantitative measurement of the percent of glycated hemoglobin (%A1C) levels in capillary (fingerstick) blood samples. The test is for home use to monitor glycemic control in people with diabetes.

Before using this test, please read all instructions carefully. If you need help, call XXX-XXX-XXXX. We invite you to call and we will walk you through the test.

INTRODUCTION
The percent (%) of A1C in your blood today tells you how well you have been controlling your glucose levels over the past 2-3 months. About 50% of the A1C result is from the past 30 days of glucose levels; about 25% is from the past 30-60 days and about 25% is from the past 60-90 days.[1]

The American Diabetes Association (ADA) recommends that you test your A1C levels at least 2 times per year if your blood sugar target range is stable. If you are taking insulin, your treatment changes or your blood sugar is too high, the ADA recommends that you test at least every 3 months.[2]

The A1CNow SELFCHECK test is an easy-to-use test to measure your A1C levels at home. By measuring your levels at home, you can be better informed prior to your doctor visits and feel more in control of your diabetes.

KIT CONTENT
The box contains materials for two A1C tests. Make sure all of the following parts are in the box. DO NOT open the pouches until ready to use.

- A1CNow SELFCHECK Monitor (1)
- Cartridge Pouch (2)
- Shaker Pouch (2), each containing:
  - Shaker (1)
  - Blood Collector (1)
  - Lancet, disposable (1)
- Extra lancets (1)
- Quick Reference Guide (1)
- Instructional DVD (1)
- Overview and Helpful Hints (1)

PREPARING TO TAKE THE TEST
You may take your fingerstick blood sample and do your A1C test any time of the day. No special diet is necessary (you do not have to be fasting when taking this test). You may want to do this test at the same time as you do a blood glucose test.

Avoid running the test in direct sunlight, on hot or cold surfaces or near sources of hot or cold. If the test has recently been at high temperatures (greater than 82° F or 28° C) or at cold temperatures, allow the kit parts to come to room temperature (64°-82° F or 18°-28° C) for at least one hour before you do your test. Leave the parts in their sealed pouches while waiting.

WHAT TO DO WITH THE RESULT
The Monitor will not store your result in memory, so write down the result and the test date on the log page on your Educational Information as soon as possible to prevent loss of information.

WHAT THE TEST RESULT MEANS
Your A1C result shows your overall glucose control over the last 2-3 months. The ADA recommends a goal of 7% or lower and suggests action when the A1C level is above 8%.[3] Your health care professional will tell you what level is right for you.

HOW DOES THIS TEST COMPARE WITH THE A1C TEST FROM THE DOCTOR'S OFFICE OR THE LABORATORY?
The A1CNow SELFCHECK test is annually certified by the National Glycohemoglobin Standardization Program (NGSP). The American Diabetes Association (ADA) recommends that A1C tests be certified by the NGSP. For information about NGSP certified methods, please visit the website: www.NGSP.org.

STORAGE
- Store at room temperature (below 82° F or 25° C). Do not freeze.
- DO NOT use the test after the expiration date shown on the box.
- If the temperature label, placed on the outside of the kit is exposed to a temperature in excess of

122°F/50°C, the dot on the label will turn red and the product should not be used.

WARNINGS AND PRECAUTIONS

- Leave the Cartridge Pouch sealed until ready for use.
- Carefully read and follow the Quick Reference Guide and watch the DVD to ensure proper test performance.
- DO NOT reuse the Shaker or the Cartridge. Throw these parts away after using them once.
- DO NOT use the test kit if any parts are cracked or broken.
- **DO NOT adjust your medication unless instructed to do so by your doctor or health care professional.**
- DO NOT substitute this test for glucose monitoring.
- DO NOT eat or drink any parts of this kit.
- If the solution from inside the Shaker touches your skin or your eyes, flush with water.
- For use outside of the body only (in-vitro diagnostic use).
- People with hemophilia (bleeding disorder) or on anti-coagulant therapy (blood thinning medicine) should consult their doctor or health care professional before using this kit.
- Keep out of reach of children under the age of 7 years. When children are performing the test, be sure that testing is done under adult supervision.
- DO NOT use any other body fluids or food to perform this test. Use ONLY your fingerstick blood sample.
- DO NOT add your blood directly to the cartridge. Your blood must first be added to the Shaker.
- DO NOT handle the white circle area of the Cartridge.

LIMITATIONS

- This test is NOT for the screening or diagnosis of diabetes.
- This test is to be used at temperatures between 64° and 82° F (18° and 28° C). Using the test outside this temperature range will give you an error code.
- This test is not a substitute for regular visits to your health care professionals or for monitoring your glucose levels.
- If you have high levels of hemoglobin F, S or C (or any other variant hemoglobin) you may get incorrect results.
- If you have hemophilia or are on anticoagulant therapy, talk to your doctor before using this test.

TROUBLESHOOTING

See the table below for a description of A1CNow+ operating and error codes (OR =Out of Range; QC = Quality Control, E= Monitor Error)

MESSAGE	DESCRIPTION AND RESOLUTION
OR 1	The blood sample may have too little hemoglobin for the test to work properly. Or you added too little blood. Call customer service.
OR 2	The blood sample may have too much hemoglobin for the test to work properly, or you added too much blood. Call customer service.
OR 3	The blood sample may have too little Hemoglobin A1C for the test to work properly, or you added too little blood. Call customer service.
OR 4	The blood sample may have too much hemoglobin A1C for the test to work properly, or you added too much blood. Call customer service.
OR 5	The Monitor temperature is below 18°C (64°F). The test must be repeated with a new kit at room temperature (18-28°C).
OR 6	The Monitor temperature is above 28°C (82°F). The test must be repeated at room temperature (18-28°C).
<4.0	The %A1C is less than 4%. Call your doctor.
>13.0	The %A1C is greater than 13%. Call your doctor.
QC 2	Occurs when you insert a Cartridge that already has sample added to it. Do not remove and reinsert a Cartridge after adding sample.
QC 6	Sample was added to Cartridge before "SMPL" display. This counts down one test on the Monitor. Remove and discard Cartridge. To avoid this error, do not add sample until the "WAIT" prompt clears and "SMPL" appears.
QC 7	The Cartridge remained in the Monitor without sample addition for 2 minutes after "SMPL" prompt. This counts down one test on the Monitor. Discard the Test Cartridge and insert a fresh one when you are ready to dispense the Shaker.
All other QC Codes	The quality control checks inside the Monitor did not pass. The test will need to be repeated with another kit. Call customer service.
E	The Monitor is not working. This is a fatal error. Call customer service.

Customer Service: XXX-XXX-XXXX

DISPOSAL OF MATERIALS

Throw away all the kit part (except the Lancet) in your daily household waste. The Lancet, Shaker, Blood Collector and Cartridge can be used only once. The Monitor may be used again, if you purchased a 2-test kit.

Since the Lancet has a sharp point it should be disposed of in an appropriate sharps container in the same way you dispose of your glucose testing lancets.

FREQUENTLY ASKED QUESTIONS

When should I do the A1CNow SELFCHECK test?

The A1CNow SELFCHECK test can be performed at any time of day. No fasting is required. You may wish to do the test at the same time you do your glucose test.

My Lancet accidentally went off before I pressed it against my finger. What should I do?

There is one extra Lancet included in the box. You should use that one.

Sometimes I have trouble getting a blood drop that is large enough. What can I do?

Try washing your hands in warm water. Warm water will help increase blood flow for a better fingerstick. You may also massage the finger before the fingerstick.

What is the best way to fill the Blood Collector?

Hold the Blood Collector horizontally relative to the blood drop. Touch the tip gently to the drop of blood and allow the tube to fill. It will stop itself when it is filled completely.

My Blood Collector is not filled completely. What should I do?

Apply pressure to your finger to get more blood. Again, touch the tip gently to the drop of blood and allow the tube to fill. You may have to re-stick your finger to get the necessary blood. If the Blood Collector does not fill, call customer service.

There is extra blood on the tip of the Blood Collector. What should I do?

Carefully wipe the tip of the Blood Collector with a piece of gauze or tissue. If some of the blood comes out while doing this, touch the tip gently to the blood drop to re-fill the Blood Collector.

The Shaker seemed to leak when I pushed the Blood Collector into it. What should I do?

Call customer service.

The Cartridge will not insert into the Monitor. What should I do?

Make sure you are inserting Cartridge right side up with the Shaker well and the Test Code on top. Also, be sure the Cartridge is facing the right way. You should be able to read the Test Code as you insert the Cartridge into the Monitor.

I accidentally opened the Cartridge pouch too early. What should I do?

You can use the second Cartridge in the kit. Do not use the already opened Cartridge. Throw away the Cartridge that has been opened too long.

The Test Codes on the Cartridge and the Monitor do not match. What should I do?

Do not use the Cartridge. Save the packing materials and call customer service.

The Monitor did not turn on after I inserted the Cartridge. What should I do?

Take the Cartridge out. Re-insert in until it 'clicks'. If the Monitor still does not turn on, this means that it may have a problem and can't be used. Call customer service.

I did not see 'RUN' and a countdown after I added the sample using the Shaker. What should I do?

Call customer service.

My result says 'QCOK' and a number. What should I do?

'QCOK' means the Monitor is working correctly. The number you see is your A1C result. Write your result down in the result log in the Quick Reference Guide. Review your result with your Health Care Professional.

The A1CNow SELFCHECK test does not match the result my doctor got from the laboratory. Why is this?

Test results will rarely match exactly. This is true even for tests done in the same lab. The A1CNow SELFCHECK is certified by NGSP. 95% of the time, certified A1C results are expected to be within +/- 0.85% range of the true result. Your difference in

A1C results may be due to: slight differences between labs, normal variation within each test and the time between two tests.

My result is not 'QCOK' and a number. What should I do?

Refer to the troubleshooting section. You can also call customer service.

What should I do with the test after I am done with it?

After you write down your result, you can throw away the used Blood Collector, Shaker and Cartridge in your daily household trash. These items can be used only once. Save the Monitor for your second test. Once you used the second test, you can throw away the Monitor in your daily household trash. Note that the Lancet is also a single-use item and should be disposed of in a sharps container.

QUESTIONS OR COMMENTS
Call customer service at XXX-XXX-XXXX

Bayer HealthCare, LLC
510 Oakmead Parkway
Sunnyvale, CA 94085-4022
tel XXX-XXX-XXXX
fax XXX-XXX-XXXX
www.A1CNow.com

90867-00 TEXT

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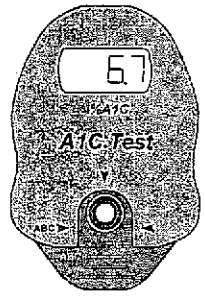
[1] Burtis, C.A., Ashwood, E.R., Tietz Textbook of Clinical Chemistry, 3rd Edition, W.B. Saunders Co., 1999
[2] www.diabetes.org
[3] www.diabetes.org

METRIKA

A1cNow

A1C Home Test Overview & Helpful Hints

Supplemental Information



For the Quantitative Measurement of the Percent of Glycated Hemoglobin (%A1C) Levels in Whole Blood. For Home Use by People with Diabetes to Monitor Glycemic Control. Need help? Call 1-877-212-4968.

BEFORE USING THIS KIT, PLEASE READ ALL THE DIRECTIONS CAREFULLY.

INTRODUCTION

The percent (%) of A1C in your blood today tells you how well you have been controlling your glucose levels over the past 2-3 months. About 50% of the A1C result is from the past 30 days of glucose levels; about 25% is from the past 30-60 days and about 25% is from the past 60-90 days[1]. It is important to keep control over your glucose levels so you lower the risks of getting diabetes–related problems (for example, blindness and circulatory problems) in the future.

The American Diabetes Association (ADA) recommends that you test at least 2 times per year if your blood sugar target range is stable. If you are taking insulin, your treatment changes or your blood sugar is too high, the ADA recommends that you test at least every 3 months.

A1C Home Test is an easy-to-use test to measure your A1C levels at home. By measuring your levels at home, you can have this information ready before you have your checkups. Also, you can phone or mail your results to your health care professional.

WARNINGS AND PRECAUTIONS

- *Leave the A1C Test Cartridge (Pouch 2) sealed until ready to use.*
- *DO NOT reuse the Sample Dilution Kit or Test Cartridge. Throw all these parts away after you use them once.*
- *DO NOT use the test kit if any parts are cracked or broken.*
- *DO NOT adjust your medication unless instructed to do so by your doctor.*
- *DO NOT substitute this test kit for glucose monitoring.*
- *DO NOT eat or drink any parts of this kit.*
- *If yellow solution touches eyes, flush with water.*
- *For use outside of the body only (in vitro diagnostic use).*
- *People with hemophilia (blood clotting disease) or on anticoagulant therapy (blood thinning medicine) should consult their doctor or health care professional before using this kit.*
- *Keep out of reach of children under the age of 7 years. When children are performing this test, be sure that testing is done under adult supervision.*
- *DO NOT use any other body fluids or food to perform this test. Use ONLY your fingerstick blood sample.*
- *DO NOT add your blood directly to the Test Cartridge. Your blood must first be added to the tube.*
- *Refer to the enclosed Quick Start Guide for step-by-step directions for using this test kit.*

STORAGE

- *Store at room temperature (below 82°F, or 28°C - Do not freeze)*
- *DO NOT use the test after the expiration date shown on the box.*

KIT CONTENTS

This box contains materials for an A1C test. Make sure all of the following parts are in the box. DO NOT open the pouches until ready to use.

- *A1C Home Test Monitor*
- *Quick Start Guide with A1C Result Log*
- *One time use Lancet*
- *Sample Dilution Kit (Pouch 1), containing Tube. Affixed to the backside in a plastic bag are: Blood Collector, Sample Dropper, and Tube Holder.*
- *A1C Home Test Cartridge (Pouch 2)*

PREPARING TO TAKE THE TEST

You may take your fingerstick blood sample and do your A1C test at any time of day. No special diet is necessary (you do not have to be fasting to do this test). You may wish to do this test at the same time you do a glucose test.

Avoid running the test in direct sunlight, on hot or cold surfaces, or near sources of heat or cold. If the test kit has recently been at high temperatures (greater than 82°F or 28°C) or at cold temperatures, allow the kit parts to come to room temperature (64°-82°F, or 18°-28°C) for at least one hour before you do your test. Leave the parts in their sealed pouches while doing this.

WHAT TO DO WITH THE RESULT

Write down your result, the test date, and your kit's lot number from the outside of the A1C Home Test box on the Result Log as soon as possible to prevent loss of information.

You and your health care professional should review your test result and discuss your goals.

WHAT THE TEST RESULT MEANS

Your A1C result shows your overall glucose control over the last 2-3 months. The American Diabetes Association recommends a goal of 7% or lower, and suggests action when the A1C level is above 8%. Your health care professional will tell you what level is right for you.

RELATIONSHIP OF A1C TO AVERAGE PLASMA GLUCOSE LEVELS

Studies show a direct relationship between your A1C and your average or mean plasma glucose (MPG) levels. For every 1% change in A1C there is a change of about 35 mg/dL in MPG[1]. Refer to the chart below to find your approximate average plasma glucose value from your A1C result[2]. DO NOT change your diabetes management program without your doctor's approval.

A1C %	Mean Plasma Glucose (mg/dL)	Interpretation
4	65	
5	100	Typical Non-Diabetic Range
6	135	
7	170	ADA Target for Diabetes in Control
8	205	
9	240	
10	275	Action suggested according to ADA guidelines
11	310	
12	345	

OTHER RESULTS/TROUBLESHOOTING

If you get a message on the display of your Monitor with letters and/or symbols, follow "Reasons/What to Do" in the table below. If you get a message like those below, you will NOT get a test result number. The A1C Home Test will have to be repeated with another test kit to get your A1C result. Call 1-877-212-4968

Message	Reasons/What to do
OR1	Your blood sample may have too little hemoglobin for the test to work properly. Or, you added too little blood. Call Metrika for assistance.
OR2	Your blood sample may have too much hemoglobin for the test to work properly. Or, you added too much blood. Call Metrika for assistance.
OR3	Your blood sample may have too little hemoglobin A1C for the test to work properly. Or, you added too little blood. Call Metrika or your doctor.
OR4	Your blood sample may have too much Hemoglobin A1C for the test to work properly. Or, you added too much blood. Call Metrika or your doctor.
OR5	The Monitor temperature is below 64°F (18°C). The test must be repeated with a new kit at room temperature (64°-82°F or 18°-28°C).
OR6	The Monitor temperature is above 82°F (28°C). The test must be repeated with a new kit at room temperature (64°-82°F or 18°-28°C).
<4.0	Your A1C is less than 4%. Call your doctor.
>13.0	Your A1C is greater than 13%. Call your doctor.
QC1 or QC2	The quality control checks inside the Monitor did not pass. Call Metrika. The test will need to be repeated with another A1C Home Test Kit.
E	The Monitor is not working. This is a fatal error, call Metrika. The Monitor needs to be replaced.

Over

Pat 8,551,780
July 17, 2013

METRIKA

A1cNow®

A1C Home Test Overview & Helpful Hints

DISPOSAL OF MATERIALS

Recap the Tube. Throw away all the kit parts (except the Lancet) in your daily household waste. The Sample Dilution Kit and Test Cartridge can be used only once. The Monitor may be used again if you purchased a 2-test kit.

Since the Lancet has a sharp point, it should be disposed of in an appropriate sharps container in the same way that you dispose of your glucose testing lancets.

TEST LIMITATIONS

- *This test is NOT for the screening or diagnosis of diabetes.*
- *A1C Home Test is to be used at temperatures between 64° and 82°F (18° and 28°C). Using the test outside this temperature range will give you an error code.*
- *This test is not a substitute for regular visits to your diabetes health care professional(s), or for monitoring your glucose levels.*
- *If you have high levels of Hemoglobin F, S, or C (or any other variant hemoglobin), you may get incorrect results.*
- *If you have hemophilia or are on anticoagulation therapy, talk to your doctor before using this test.*

HOW DOES THIS TEST COMPARE WITH THE TEST FROM THE DOCTOR'S OFFICE OR HOSPITAL LABORATORY?

A1C Home Test is NGSP-certified. The American Diabetes Association recommends that A1C tests be certified by the NGSP. For more information about NGSP-certified methods, please visit the following website, http://www.ngsp.org

A1C Home Test was compared to an NGSP-certified laboratory method in clinical studies with 189 untrained users. These studies showed that an individual result will fall within -1.2 to + 1.1 %A1C from the true result 95% of the time. This study also showed that results obtained by the untrained lay users were the same as results obtained by professionally-trained health care workers.

FREQUENTLY ASKED QUESTIONS

When should I do the A1C Home Test?
The A1C Home Test can be performed at any time of day. You may wish to do the test at the same time you do your glucose test.

My Lancet accidentally went off before I pressed it against my finger. What should I do now?
You may use the lancet that you normally use for glucose testing, or you may call Metrika for a replacement Lancet.

Sometimes I have trouble getting a blood drop that is large enough. What can I do?
Try washing your hands in warm water. Warm water will help increase blood flow for a better fingerstick. You may also massage the finger before the fingerstick.

What is the best way to fill the Blood Collector?
Hold the Blood Collector near the bottom of the Bulb (at the top of the flat part). Hold it horizontal to the blood drop. Touch the Tip gently to the blood drop and allow the Blood Collector to fill by itself without squeezing the Bulb. It will stop by itself when it reaches the line. Fill just to the line. DO NOT squeeze the Bulb until you are ready to add your blood to the Tube.

My Blood Collector is not filled to the line. What should I do?
Apply pressure to the finger to get more blood. Again, touch the tip of the Blood Collector to the blood drop until filled to the black line. You may have to re-stick your finger to get the necessary blood. If the Blood Collector does not fill, please call Metrika for help.

There was excess blood on the outside of the Blood Collector. I wiped the blood off, but some of the blood from inside the Tube also came out. Should I still use this blood sample?
Squeeze the remaining blood out of the Blood Collector onto some gauze or a cotton ball. Then refill the Blood Collector up to the black line. You may have to lance your finger again if it is no longer bleeding.

There was blood left in the Blood Collector after I added the blood to the Red Capped Tube. Is this OK?
All the blood should be washed out of the Blood Collector when you squeezed the bulb 2-3 times. A small amount of diluted sample in the Blood Collector is OK. Any blood still in the Blood Collector should be squeezed into the Tube so that your results are accurate.

The Test Cartridge will not go in the Monitor, what should I do?
Make sure you are inserting the Test Cartridge face up, with the word "SAMPLE" showing on the top. Also, make sure the Test Cartridge is facing the right way: you should be able to read "SAMPLE" as you insert the Test Cartridge into the Monitor.

I accidentally opened the Test Cartridge pouch too early. What do I do?
Call Metrika. If you purchased at two-test kit, you can use the second Test Cartridge that came in the kit. **Do not use the previously opened Test Cartridge.**

The codes on the Monitor and Test Cartridge do not match. What should I do?
Check the lot number on the pouch of the Test Cartridge to see if it matches the lot number on the back of the Monitor. If it does, continue with the test. If it does not, call Metrika for help.

The Monitor did not turn on after I inserted the Test Cartridge, what should I do?
Take the Test Cartridge out. Reinsert it until it comes to a complete stop. If the Monitor still does not turn on, this may mean it has used up all of its available tests (check the lot numbers of your Test Cartridge and Monitor), or the Monitor has had a fatal error and can't be used anymore. Call Metrika for help.

The Sample Dropper does not look like it is filled correctly. What do I do?
If the Sample Dropper looks like the picture that says "Too Little" you can squeeze the liquid back into the Tube and refill it correctly by following the instructions.

There were some bubbles in the Sample Dropper when I added my diluted sample to the test. Is this OK?
A few (3-4) small bubbles are OK. It's normal to see a few small bubbles float to the top of the barrel of the Sample Dropper. If you see a large number of bubbles, call Metrika for help.

I touched the Sample Well with the Sample Dropper when I added my sample and some liquid splashed out. Is the test OK?
Touching the Sample Well with the Sample Dropper may cause splashing of the diluted sample when you add it to the test or you might accidentally pull some diluted sample back up into the Sample Dropper. If you see "QCOK" and a number, enough sample was added and the result is OK.

I did not see "—" and a countdown after I added my diluted sample. What should I do?
Call Metrika for help.

My result says "QCOK" and a number. What should I do?
This means the test is working correctly. The number you see is your A1C result. Write this number down on the Result Log that is part of the Quick Start Guide. Review your result with your healthcare professional.

The A1C Home Test result does not match the result I got from my laboratory. Why is this?
Test results will rarely match exactly – this is even true for tests done in the same lab. A1C Home Test is certified by the national certification body for A1C (the NGSP), and certified A1C tests can differ from the true results by up to 1% A1C, 95% of the time. Your difference in A1C results may be due to: slight differences between labs, normal variation within each test system, and the time between the two tests.

My result is not "QCOK" and a number. What should I do?
Refer to, "Other Results/Troubleshooting "in this "Overview and Helpful Hints". You may also call Metrika for help.

What should I do with the test after I'm done with it?
After you write down your result, recap the Tube and throw everything except the Monitor away in your daily household trash. These items can only be used once.

How should I dispose of the Lancet that came with my test kit?
Since the Lancet has a sharp point, it should be disposed of in an appropriate sharps container in the same way that you dispose of your glucose testing lancets.

REFERENCES

[1] *Burtis, C.A., Ashwood, E. R., Tietz Textbook of Clinical Chemistry, 3rd Edition, W.B. Saunders Co., 1999*

[2] *Diabetes Care 1999; 22 (Suppl. 1): S32-S41*

Questions or comments?
Call Metrika 1-877-212-4968

Metrika, Inc.
510 Oakmead Parkway
Sunnyvale, CA 94085

P/N 90043-Rev-B
May 17 2005

START HERE

METRIKA A1cNow

A1C Home Test Quick Start Guide

Know your A1C level in 3 easy steps!

FOR INVESTIGATIONAL USE ONLY - The performance characteristics of this product have not been established

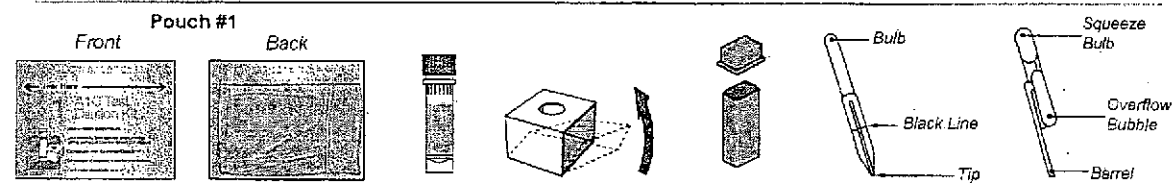
BEFORE RUNNING THIS TEST, READ INSTRUCTIONS TO FAMILIARIZE YOURSELF WITH THE PROCEDURE

DO NOT OPEN POUCHES UNTIL INSTRUCTIONS INDICATE

READ FIRST!

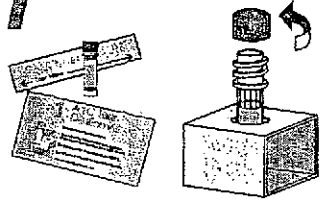
- Make sure all parts are at room temperature (64 to 82 °F)
- Complete test within 15 minutes
- Lot numbers must be the same for Dilution Kit, Test Cartridge, and Monitor
- Do not apply blood directly to Test Cartridge; dilute blood first
- **Use Test Cartridge within 2 minutes after opening Pouch #2**
- Read detailed information in Overview and Helpful Hints before doing a test

The following items from your A1C Home Test are required for Step 1: Prepare Sample

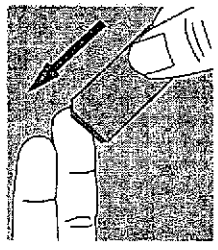


A1C Test Dilution Kit | (See back of Pouch #1 for the Blood Collector, Sample Dropper, and Tube Holder) | Tube | Tube Holder | Single-use Lancet | Blood Collector | Sampler Dropper

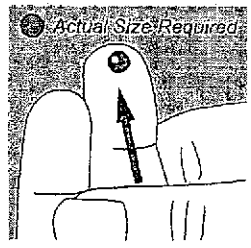
1 Prepare Sample



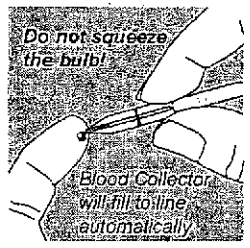
To start, tear open the A1C Test Dilution Kit. Place the Tube in the Tube Holder and remove the Red Cap from the Tube.



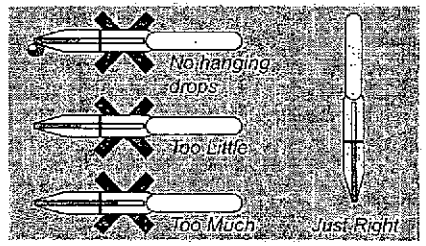
Place the red end of the Lancet firmly against your finger and push down until it clicks.



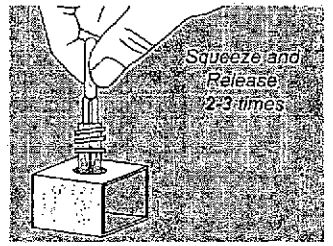
Gently massage your finger until you see a large drop of blood.



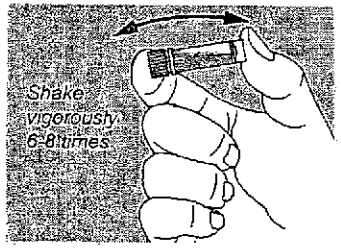
Hold the Blood Collector at a slight angle and gently touch the tip to the drop of blood. **Do not squeeze the bulb.**



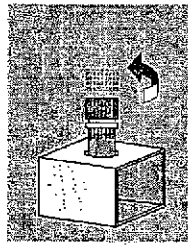
The Blood Collector will automatically fill to the Black Line and stop. If slightly overfilled, touch the Tip with tissue to remove excess. Also wipe away any hanging drops (if present).



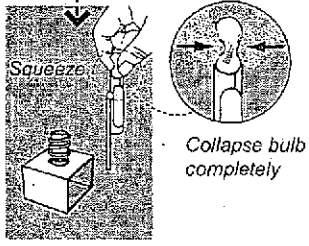
Drop the Blood Collector tip-first into the liquid. Squeeze and release the Bulb two or three times to rinse the blood out of the Blood Collector.



Recap the Tube tightly and shake the Tube to completely mix the blood and liquid. It is OK to have bubbles. The diluted sample will be red-orange in color.



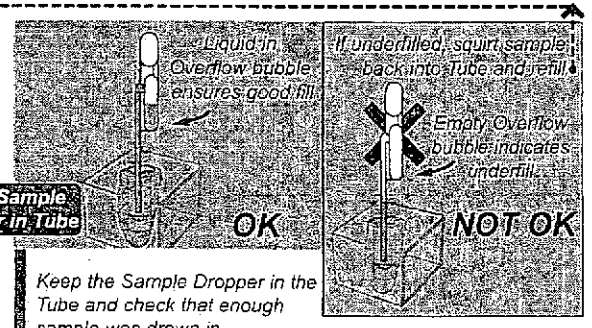
Return Tube to Tube Holder and remove red cap.



With the Sample Dropper outside of the Tube, squeeze the bulb so that the bulb is **completely** collapsed.

While Bulb is still collapsed, place the Sample Dropper to the bottom of the Tube.

Release the bulb, allowing it to pull up the sample.



Keep the Sample Dropper in the Tube and check that enough sample was drawn in.

LEAVE SAMPLE DROPPER IN TUBE. CONTINUE TO STEP 2: PREPARE MONITOR

070150-51 Rev-00
May 17 2009

PROFESSIONAL PROCEDURE GUIDE

A1CNow+

A1CNow+

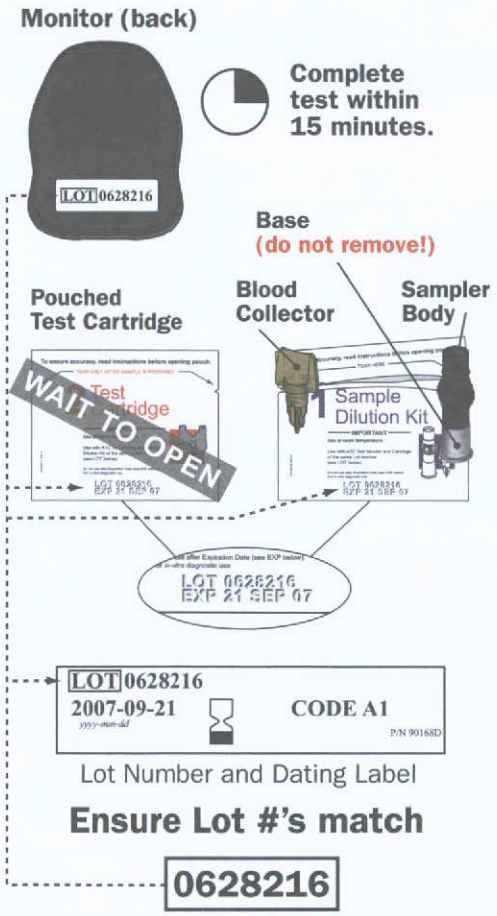
PROFESSIONAL PROCEDURE GUIDE

Preparation

1 BEFORE YOU BEGIN

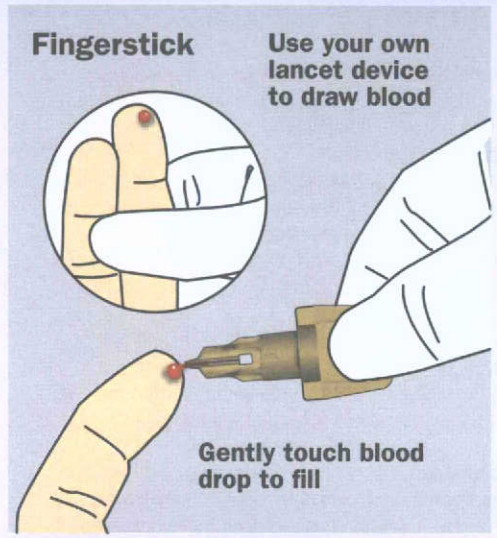
- Run the test with all parts of the test kit at the same temperature within the specified range.

- If the kit has recently been at high temperatures (above 82°F) or in the refrigerator, keep the kit at room temperature for at least one hour before use.
- Avoid running the test in direct sunlight, on hot or cold surfaces, or near sources of heat or cold.
- Quality control materials should be used to confirm the test kit is working properly. Refer to the product insert for information on when to run controls.



Blood Collection

2 COLLECT BLOOD



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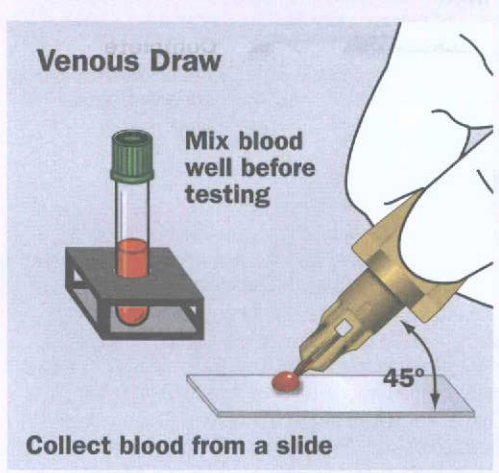
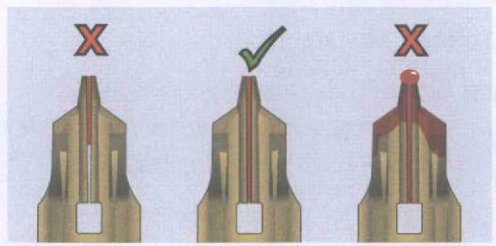
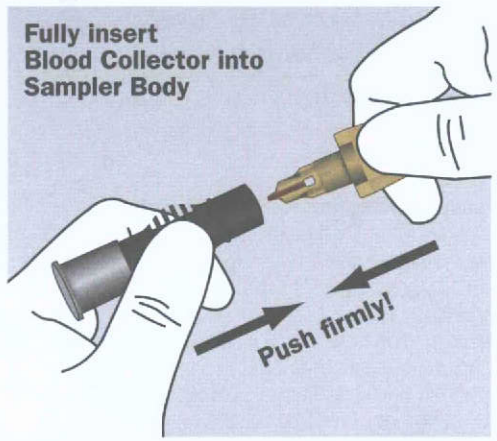
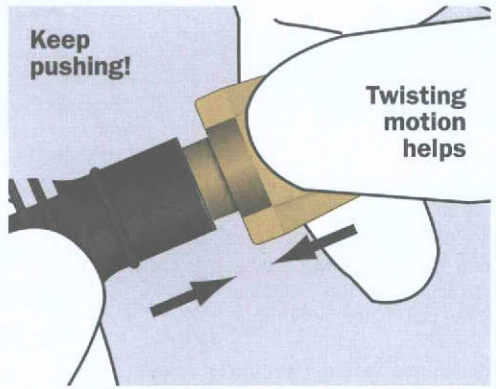


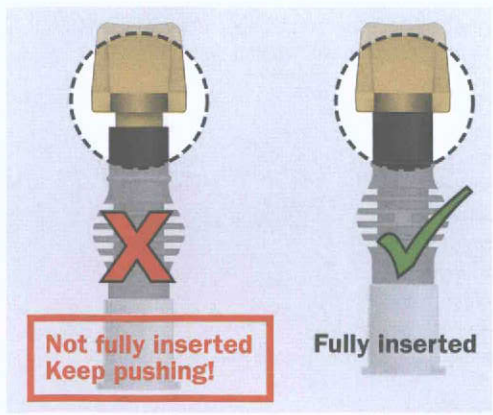


Blood Dilution

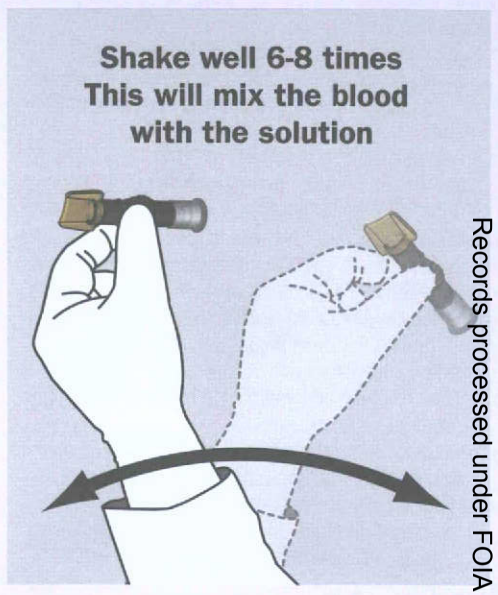
3 INSERT BLOOD COLLECTOR

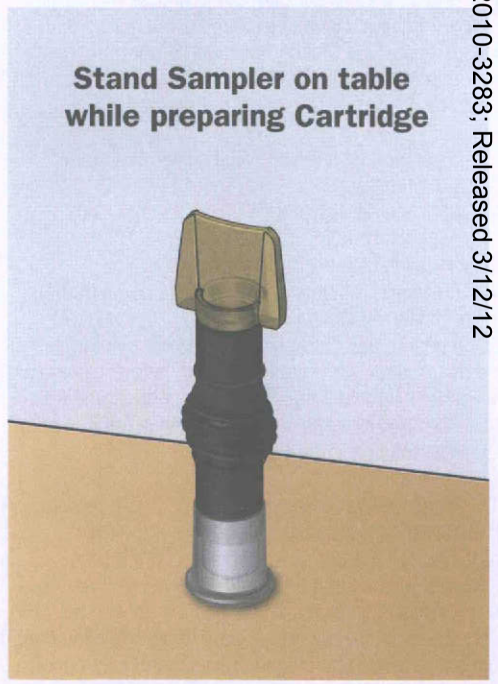






4 SHAKE





This test is WAIVED under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

If a laboratory modifies the test instructions, the test will no longer be considered waived.

Limitations

- This test is NOT for the screening or diagnosis of diabetes.
- If the patient has high levels of Hemoglobin F, Hemoglobin S, Hemoglobin C, or other hemoglobin variants, the A1CNow system may report incorrect results.
- Any cause of shortened red cell survival (e.g., hemolytic anemia or other hemolytic diseases, pregnancy, recent significant blood loss, etc.) will reduce exposure of red cells to glucose. This results in a decrease in %A1C values. Percent A1C results are not reliable in patients with chronic blood loss and consequent variable erythrocyte life span.
- Rheumatoid Factor in high amounts will cause low results, or an error code. It is recommended that A1C be re-checked by alternate methodology such as boronate affinity.
- This test is not a substitute for regular healthcare provider visits and blood glucose monitoring.
- As with any laboratory procedure, a large discrepancy between clinical impression and test results usually warrants investigation.

Controls

Each A1CNow+ Monitor performs over 50 internal chemical and electronic quality control checks, including potential hardware and software errors (e.g. cartridge alignment, programming), and potential reagent strip errors (e.g. insufficient sample volume, invalid calculations). The Monitor has been programmed to report an error code if these quality checks are not passed.

Quality control testing should be performed at the following times:

1. With each new shipment.
2. With each new lot.
3. With each new operator.
4. Whenever problems (storage, operator, instrument, or other) are identified.
5. To ensure that storage conditions have not affected the product, run a control sample before running a patient sample if the test kit has been stored for more than a month and it has been at least a month since the last control testing.

The measured value should be within the acceptable limits stated for the control material. If the results obtained are outside the acceptable limit, please review the procedure and re-test the control material. If the measured value continues to fall outside the acceptable limit, please refrain from analyzing additional patient samples and contact Bayer Technical Support (877-212-4968).

Good laboratory practices include a complete quality control program. This entails proper sample collection and handling practices, ongoing training of testing personnel, ongoing evaluation of control results, proper storage of test kits, etc. A permanent record of control results should be retained.

Performance

Expected Values (non-diabetic population)

The expected normal range for %A1C using the A1CNow system was determined by testing blood samples from 118 presumptively non-diabetic individuals (fasting glucose levels <127 mg/dL) across three US sites. The population included 33 males and 85 females, and an age range from 19 to 76 with a mean age of 43. The mean %A1C result was 5.2% ±0.71% (1 SD). The 95% confidence limits were 3.9% to 6.5%. These values are similar to those reported in the literature. Each laboratory should determine its own reference range to conform to the population being tested.

Linearity

Studies were performed to evaluate the linearity of the A1CNow system across its dynamic range. Clinical samples representing low and high %A1C levels were identified, and were mixed in various proportions into nine preparations. These samples were tested in replicates of at least five (n = 5). The observed results were compared to the expected results and analyzed in terms of percent recovery. The test is linear for %A1C levels between 4% and 13%, and produces reliable results with hematocrits between 20% and 60% packed cell volume (PCV).

Interference Testing/Specificity

Studies were performed to assess the effect of common test interferents, various common over-the-counter therapeutic agents, and oral antihyperglycemic agents commonly used to treat Type II diabetes. Two levels of %A1C (low and high, approximately 4% and 10%, respectively) were tested. See table below.

INTERFERENT	TEST CONCENTRATION
Bilirubin (unconjugated)	20 mg/dL
Triglyceride	3000 mg/dL
Hemoglobin	500 mg/dL
Acetaminophen	80 µg/mL
Ascorbic acid	5mg/dL
Ibuprofen	120 µg/mL
Acetylsalicylic acid	1mg/dL
Glyburide (glibenclamide)	240 ng/mL
Metformin (1,1-dimenthylbiguanide HCl)	25 µg/mL

The studies showed no effect from any of these potential interferents at concentrations up to approximately 5-times their normal levels or therapeutic doses.

Studies showed no interference from modified hemoglobins, including labile glycated hemoglobin when tested at two levels of %A1C (low and high, approximately 5% and 11% respectively). The modified hemoglobins, and the levels evaluated, were: labile hemoglobin with 1400 mg/dL glucose, carbamylated hemoglobin at a final concentration of 5 mM potassium cyanate, and acetylated hemoglobin at a final concentration of 14 mM acetylsalicylic acid.

There were mixed results from the testing of high levels of Hemoglobin F, Hemoglobin S, and Hemoglobin C. Unreliable results may be obtained from patients with elevated levels of variant hemoglobins.

Precision

Precision testing was done under a specialized protocol. Following this protocol, two whole blood samples, one of approximately 6 %A1C (low), and one of approximately 9 %A1C (high), were tested over 20 days and four runs per day, for a total of 80 assays per level. The overall imprecision (including within-day and between-day) was 3.00% CV at the low level and 4.02% CV at the high level. This performance meets the requirements of NGSP certification.

Accuracy

Accuracy studies were conducted with 189 diabetic and non-diabetic subjects across three US sites. Fingerstick sampling was performed on each subject for testing with A1CNow+, and venous blood was collected from each subject for comparative testing using an NGSP-certified method. A1CNow+ results were compared to the NGSP reference results. The A1C results ranged from 5.0 %A1C to 12.8 %A1C, with a mean of 7.3 %A1C (reference results). Data analysis consisted of least squares linear regression (x = reference results), bias calculation, and Bland Altman limits. The data are provided below.

A1CNow+ Fingerstick Comparative Testing

(NGSP-certified method is the Tosoh A1c 2.2 Plus)

n	189	Bias at 6% A1C (% difference)	5.89 (- 1.83%)
Slope	1.02	Bias at 7% A1C (% difference)	6.91 (-1.29%)
y-intercept	- 0.23	Bias at 9% A1C (% difference)	8.95 (- 0.56%)
"r"	0.95	Avg. % diff.	- 1.23%

The results showed that the accuracy of A1CNow+, with fingerstick samples was, on average, 99%. This means that, on average, a true 7 %A1C could read approximately 6.9 %A1C. An individual A1CNow+ result may differ by as much as -1.0 %A1C to +0.8 %A1C from the true result. This represents the 95% confidence limits of a Bland-Altman plot.

A1CNow+ Venous Comparative Testing

(NGSP-Certified method is the Tosoh A1c 2.2 Plus)

Venous blood was collected from 110 diabetic subjects, and each sample was tested on one of three different lots. Aliquots of the venous samples were also tested by the NGSP-certified method, providing comparative results. Data analysis again consisted of least squares linear regression (x = reference results), bias calculation and Bland-Altman limits. The data are provided below.

n	110	Bias at 6% A1C (% difference)	5.95 (-0.8%)
Slope	1.03	Bias at 7% A1C (% difference)	6.98 (-0.3%)
y-intercept	-0.237	Bias at 8% A1C (% difference)	8.01 (+0.1%)
"r"	0.97	Avg. % diff.	-0.3%

The results showed that the accuracy with venous sampling was, on average, 99.7%. An individual result may differ by -0.8 %A1C to +0.7 %A1C from the true result. This represents the 95% confidence limits of the Bland-Altman plot. A1CNow+ may be used with either fingerstick (capillary) or venous (heparin-anticoagulated) whole blood samples.

Expected Performance in Waived Laboratories

Clinical studies were performed at three US sites with over 180 untrained people (most with diabetes). These study subjects read the instructions and then performed one A1CNow+ test on themselves. A venous blood sample was collected from each subject, and this sample was tested by an NGSP-certified laboratory method for %A1C. The two results were then compared.

Untrained User A1CNow+ and an NGSP-certified method

(Tosoh A1c 2.2 Plus)

n	188	Bias at 6% A1C (% difference)	6.02 (+ 0.33%)
Slope	0.99	Bias at 7% A1C (% difference)	7.01 (+0.14%)
y-intercept	0.08	Bias at 9% A1C (% difference)	8.99 (- 0.11%)
"r"	0.93	Avg. % diff.	+ 0.12%

The results showed that untrained users could perform A1CNow+ testing on themselves with the same accuracy as trained individuals.

References

1. Burls, C.A., Ashwood, E.R. *Tietz Textbook of Clinical Chemistry*, 3rd Edition, W.B. Saunders Co., 1999.
2. Nathan, D.M., et al. *The clinical information value of the glycosylated hemoglobin assay.* N Engl J Med 1984; 310; 341-346.
3. The Diabetes Control and Complications Trial Research Group. *The effect of intensive treatment of diabetes on the development and progression of longterm complication in insulin-dependent diabetes mellitus.* N Engl J Med 1993; 329; 977-986.
4. American Diabetes Association. *Standards of medical care for patients with diabetes mellitus.* Diabetes Care.1999; 22 (suppl 1): S32–S41.
5. Fogh-Anderson, N., D'Orazio, P. *Proposal for standardizing direct-reading biosensors for blood glucose.* Clin Chem 1998; 44(3); 655-659.
6. MLO Supplement. *Point-of-Care Testing*, 1992.
7. Cagliero, E., Levina, E.V., Nathan, D.M. *Immediate feedback of A1C levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients.* Diabetes Care 1999; 22(11): 1785-1789.
8. Goldstein, D.E., Little, R.R., Wiedmeyer, H.M., et al. *Glycated hemoglobin: Methodologies and clinical applications.* Clin Chem 1986; 32: B64-B70.
9. American Diabetes Association: *Clinical Practice Recommendations 2006.* Diabetes Care, 2006; 29 (Suppl. 1).

INTERNATIONAL SYMBOLS	
	MANUFACTURER
Σ_N	CONTAINS SUFFICIENT FOR <n> TESTS
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	STORE REFRIGERATED (2-8°C, 36-46°F)

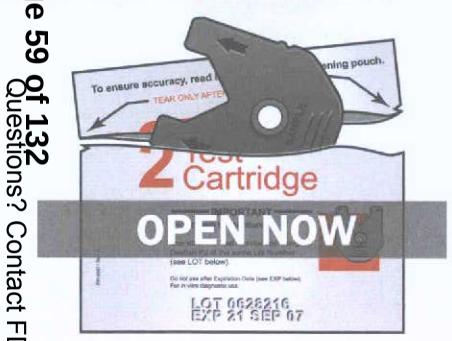
CE

Bayer HealthCare, LLC
510 Oakmead Parkway
Sunnyvale, CA 94085-4022
tel 1 877 212 4968 x1
fax 408 524 6595
www.A1CNow.com

Blood Testing

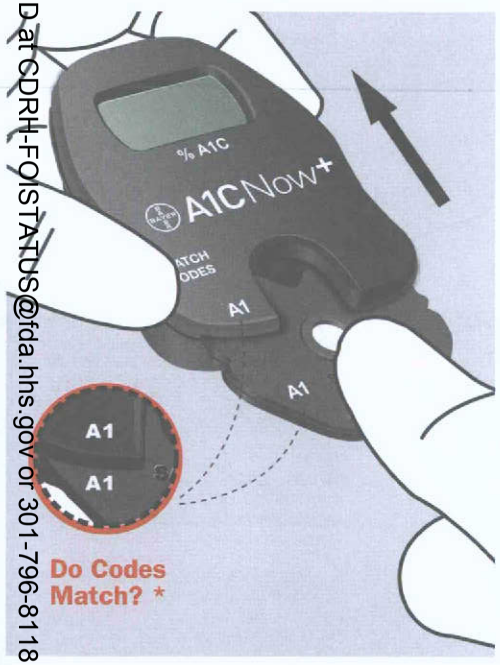
Results

5 INSERT CARTRIDGE



Use within 2 minutes.

"Click" Test Cartridge into place



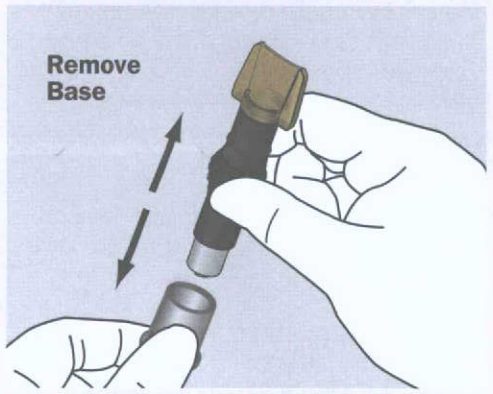
Monitor and Test Cartridge codes must match

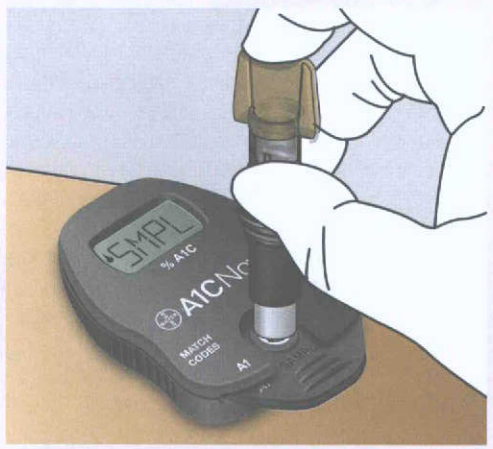
*** If not, Call Technical Support at 1-877-212-4968 x1**

6 PREPARE SAMPLER

WAIT for SMPL to display

Ready for Sampler

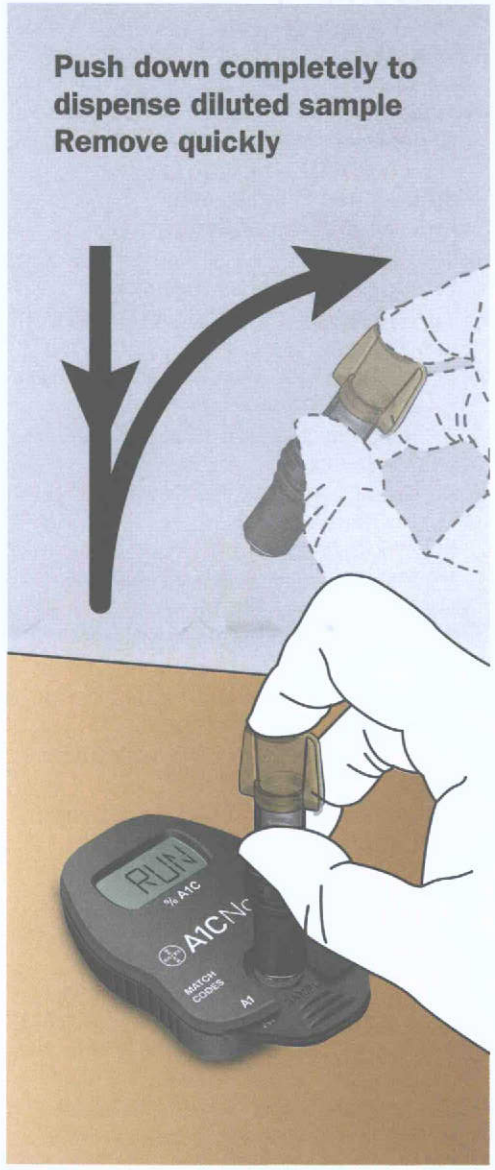




Ensure Monitor is on level surface

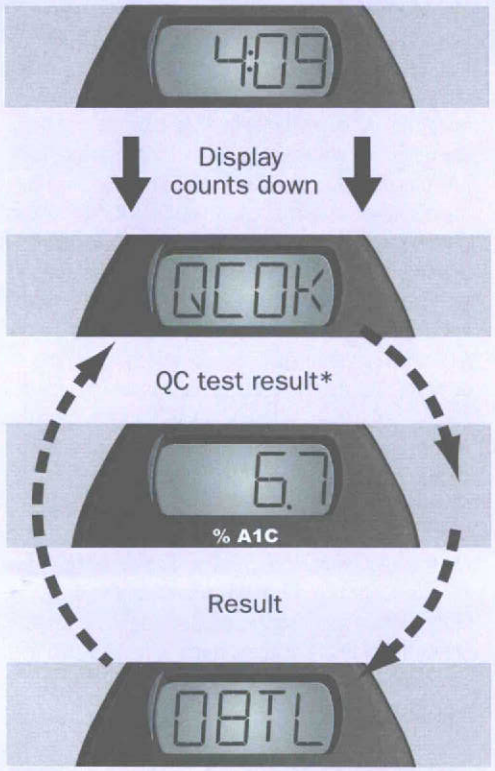
7 DISPENSE SAMPLE INTO CARTRIDGE

Push down completely to dispense diluted sample Remove quickly



Do not handle Monitor again until test is complete!

8 5 MINUTES TO RESULTS



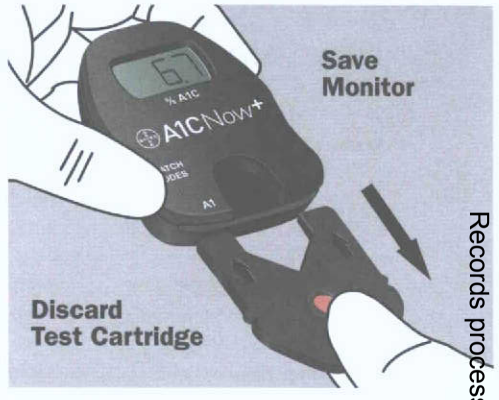
# of tests left

This result cycle remains displayed for 60 minutes or until the next Test Cartridge is inserted.

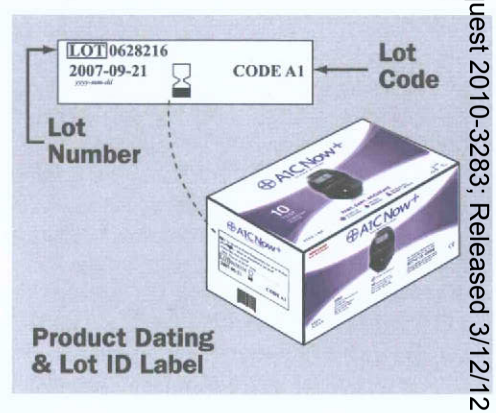
* If "QCOK" is not displayed, please see list of error codes on reverse side.

If you cannot resolve an error, please call Technical Support at 1-877-212-4968 x1.

9 REUSE MONITOR



THE MONITOR IS REUSABLE
To run another test, use a new Sampler and Test Cartridge from the same kit and return to Step 1, "**PREPARATION**."



ALWAYS MATCH LOT NUMBERS
Use Monitor ***only*** with the materials included in the original kit. The Monitor will expire after the programmed number of tests have been run. If another Test Cartridge is inserted, the Monitor will display "00 TL."

90821B 04/2008

A1CNow+ PROFESSIONAL-USE PRODUCT INS

Intended Use

The A1CNow+® test provides quantitative measurement of the percent of glycated hemoglobin (%A1C) levels in capillary (fingerstick) or venous whole blood samples. The test is for professional use to monitor glycemic control in people with diabetes.

Summary and Explanation

High levels of blood glucose result in over-glycation of proteins throughout the body including hemoglobin.[1] Glycation of hemoglobin can occur at the amino termini of the alpha and beta chains, as well as other sites with free amino groups.[1] Hemoglobin A undergoes a slow glycation with glucose that is dependent on the time-average concentration of glucose over the 120-day life span of red blood cells.

The most prevalent and well-characterized species of glycated hemoglobin A is A1C, making up approximately 3% to 6% of total hemoglobin in healthy individuals.[1] The correlation of A1C and blood glucose levels make it a useful method of monitoring long-term blood glucose levels in people with diabetes.[2] Previous studies, such as the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS), used glycated hemoglobin as a way to measure overall glycemic control during the studies. These studies, and others, have shown that tight glycemic control is associated with fewer diabetes-related complications (e.g., vision problems, cardiovascular problems, and kidney problems).[3] The National Glycohemoglobin Standardization Program (NGSP) was established to assure traceability of hemoglobin A1C (A1C) results to the DCCT. Studies show a direct relationship from %A1C to average blood glucose (MBG) levels. For every 1% change in A1C there is a change of about 30 mg/dl in MBG.[4] The formula used to calculate the mean (average) blood glucose levels from the A1C levels is MBG = (31.7 x HbA1c) -86.1. To convert to mean plasma glucose (MPG) use[5] MPG = MBG x 1.11.

A1C can be measured by a variety of techniques, and over the past decade they have expanded to include point-of-care assays. Point-of-care assays are well suited to environments such as healthcare providers' offices and clinics, because they are generally easy to perform, require no laboratory equipment, and provide rapid turn-around-time from sampling to result.[6] This immediate feedback of results enhances provider/patient interaction and, therefore better enables disease management.[7]

Principle of the Assay

Bayer has developed an enabling technology that incorporates microelectronics, optics, and dry-reagent chemistry strips within a reusable, self-contained, integrated hand held monitor and a single-use test cartridge. An unmeasured whole blood mixture (diluted) is directly applied to the sample port, and results are displayed in numeric form on the Monitor's liquid crystal display after 5 minutes. Having no switches or buttons, the Monitor self-activates upon insertion of the Test Cartridge. The A1CNow+ Monitor utilizes both immunoassay and chemistry technology to measure A1C and total hemoglobin, respectively. Upon the addition of a diluted blood sample, blue microparticles conjugated to anti-A1C antibodies migrate along the reagent strips. The amount of blue microparticles captured on the strips reflects the amount of A1C in the sample.

For the total hemoglobin (Hb) portion of the test, the sample diluent converts Hb to met-Hb. The intensity of met-Hb color measured on the reagent strips is proportional to the concentration of hemoglobin in the sample. Test results are expressed as %A1C (A1C ÷ total Hb x 100).

Calibration of the A1CNow+ is performed with a set of blood samples that have been value-assigned by a National Glycohemoglobin Standardization Program (NGSP) certified laboratory using an NGSP reference method. Total Hb calibration values for those samples are obtained with a Total Hb analyzer (HemoCue Hemoglobin Test System, HemoCue, Inc., Lake Forest, CA). The calibration of the A1CNow+ test is thus traceable to the NGSP and to an NGSP Certified Network reference method.

Specimen Collection and Storage

Note: No fasting or special diet is necessary

Fingerstick

The A1CNow+ test requires 5 microliters (µL) of whole blood (1 large drop). Fingerstick blood is obtained by standard techniques with any lancing system. If alcohol is used for cleansing, be sure the finger is completely dry before lancing.

Venipuncture/Sample Collection for Venous Draw

Venous blood should be collected into heparin tubes (sodium or lithium, "green tops"). Blood samples should be well-mixed and tested at room temperature. Venous blood samples are stable for up to 8 hours at room temperature and up to 14 days in the refrigerator.

Warnings and Precautions

1. For in vitro diagnostic use only.
2. Carefully read and follow the Professional Procedure Guide to ensure proper test performance.
3. If refrigerated, bring sealed pouches and Monitor to room temperature for one hour.
4. The A1CNow+ Monitor and Test Cartridges should not be used if either are cracked or broken.
5. The Test Cartridges should not be used if the foil pouch is damaged.
6. Add sample to A1CNow+ Test Cartridge within 2 minutes after pouch is opened.
7. All components of the A1CNow+ system are potentially biohazardous. Dispose of as biohazardous waste.
8. The Dilution Buffer in the Sampler contains ferricyanide in a buffered detergent solution. Do Not Ingest. In case of contact with skin or eyes, flush the area with large amounts of water.
9. Do not reuse Test Cartridges or Sample Dilution Kits.

Do not mix Monitors with Cartridges & Sample Dilution Kits from different lots.

Kit Storage and Stability

- Pouched Test Cartridges, A1CNow+ Monitors, and Sample Dilution Kits may be stored at room temperature (18-28°C) for up to **four months** prior to use. Monitors, Test Cartridges, and Dilution Kits stored at room temperature must be thrown away if not used within the **four months**.
- If the temperature label, placed on the outside of every kit, is exposed to a temperature in excess of 122°F/50°C, the dot on the label will turn red and the product should not be used.
- The Monitors, Test Cartridges, and Sample Dilution Kits may be used until the expiration date printed on the box and pouches when stored refrigerated (2-8°C). Monitors, Test Cartridges, and Sample Dilution Kits stored in the refrigerator must be thrown away if not used by the expiration date.
- Leave all components in their sealed pouches until use. If refrigerated, ensure pouches are at room temperature before use.
- Do not mix pouches and Monitors from different lots.

Package Components

- A1CNow+ Monitor (1)
- A1CNow+ Test Cartridges (10, or 20) Each Test Cartridge includes the following chemistries: antibody to HbA1c, antigen conjugate that binds to the antibody, and membranes.
- Sample Dilution Kit (10, or 20), each containing:
  - Sampler (1) containing 0.37 ml of buffered detergent solution with ferricyanide
  - Blood Collector (1)
- Product insert (1)
- Patient result labels (10, or 20)

Materials Required but Not Supplied

- Fingerstick sample: lancet, or other blood fingerstick collection device or,
- Venous Sample: Heparin (sodium or lithium ["green top"]) preferred, venous collection supplies.
- Gauze pad or cotton ball
- Bandage
- Liquid control solution. Contact Bayer Technical Support (877-212-4968) for a list of liquid controls that may be used.

Result Interpretation

Percent A1C monitors glucose control over the last three months. About 50% of the A1C result is from the past 30 days; about 25% is from the past 30-60 days and about 25% is from the past 60-120 days.[1] Depending on the test methodology used, laboratory methods show that the reference range of the A1C test is approximately 4.0-6.5% A1C, and 6% to 9% in people with well to moderately controlled diabetes.[1] Levels can be as high as 20% in people with poorly controlled diabetes.[8] The American Diabetes Association's (ADA's) most recent Clinical Practice Recommendation for diabetes specifies a treatment goal for patients in general of less than 7% with a treatment goal for the individual patient of as close to normal (less than 6%) as possible without significant hypoglycemia.[9]

Troubleshooting

See the table below for a description of A1CNow+ operating and error codes (OR =Out of Range; QC = Quality Control, E= Monitor Error)

MESSAGE	DESCRIPTION AND RESOLUTION
OR 1	The blood sample may have too little hemoglobin (less than 20% hematocrit), not enough blood was collected, or the blood was not well mixed inside the Sampler.* You may wish to check hematocrit by another method.
OR 2	The blood sample may have too much hemoglobin (greater than 60% hemocrit), or excess blood was collected.* You may wish to check hemocrit by another method.
OR 3	The blood sample may have too little A1C, or insufficient blood was collected.*
OR 4	The blood sample may have too much A1C, or excess blood was collected.*
OR 5	The Monitor temperature is below 18°C (64°F). Repeat the test at room temperature (18-28°C).
OR 6	The Monitor temperature is above 28°C (82°F). Repeat the test at room temperature (18-28°C).
<4.0	The %A1C is less than 4%.
>13.0	The %A1C is greater than 13%.
QC 2	Occurs when you insert a Test Cartridge that already has sample added to it. Do not remove and reinsert a Test Cartridge after adding sample.*
QC 6	Sample was added to Test Cartridge before "SMPL" display. This counts down one test on the Monitor. Remove and discard Test Cartridge. To avoid this error, do not add sample until the "WAIT" prompt clears and "SMPL" appears.
QC 7	The Test Cartridge remained in the Monitor without sample addition for 2 minutes after "SMPL" prompt. This counts down one test on the Monitor. Discard the Test Cartridge and insert a fresh one when you are ready to dispense the Sampler.
QC30-33	The Monitor was unable to obtain a valid initial reading. Be sure to remove the Sampler within one second after dispensing it into the sample port, and do not disturb the Monitor while the test is running.*
QC 50 to 51 QC 55 to 56	Insufficient sample was delivered to the Test Cartridge. To avoid this error be sure to fully insert the Blood Collector into the Sampler and shake immediately.*
All other QC codes	The quality control checks did not pass. Call Bayer Technical Support toll free at 877-212-4968 x1. The test will have to be repeated with another Test Cartridge and Sample Dilution Kit.
E1 to E99	The Monitor has a Fatal Error. Call Bayer Technical Support toll-free at 877-212-4968 x1.

*Carefully repeat the test using a new Test Cartridge and a new Sample Dilution Kit.

A1CNOW+ QUICK REFERENCE GUIDE

Materials Needed for Testing

Monitor
FRONT

Monitor
BACK

Example Lot Number

IMPORTANT!

- Follow all steps on reverse side after reviewing DVD instructions.
- Do Not open pouches until instructed.
- Make sure lot number on Monitor matches lot numbers on the Red and Blue pouches.
- Use indoors between 64°F (18°C) and 82°F (28°C)

DVD Instructions

Lancet

Blood Collector

Shaker

Base
Do Not Remove!

Open End

Example Lot Number and Expiration Date

Cartridge

Example Lot Number and Expiration Date

WAIT TO OPEN

Blood Collection

Open blue pouch ONLY!

1 Stick Finger

Press Lancet into finger.

Squeeze finger to get adequate blood.

Actual size required

2 Collect Blood

Gently touch Blood Collector to top of blood drop.

Make sure tube is adequately filled.

3a Insert Blood Collector into Open End of Shaker

Push firmly to fully insert! Twisting helps.

3b Check for Full Insertion of Blood Collector into Shaker

There should be **NO GAP** between the Blood Collector and the Shaker.

4 SHAKE for 5 Seconds and Set Aside

After shaking, stand Shaker on table.

Blood Testing

Open red pouch AFTER blood collection!
ONCE OPENED USE CARTRIDGE WITHIN 2 MINUTES

5 Insert Cartridge

Push firmly to fully insert!
Cartridge will click into place.

6 "WAIT" for "SMPL" Display

"SMPL" means ready for Shaker.

7a Remove Base from Shaker

7b Press Shaker into Cartridge and Remove Quickly when "RUN" Appears

"RUN" will appear

8 Leave Monitor Flat on Table

Do not handle until countdown is completed.

Following a 5 minute countdown, result will alternate with "QCOK".

Refer to Educational Information enclosed for details on the result.

Remove Cartridge and discard with Shaker.

Save Monitor for second test.

A1CNOW+

FOR INVESTIGATIONAL USE ONLY

A1CNOW+

Remember that your A1C number is a "big picture" measurement:

- Don't use it for short-term daily blood glucose measurement.
- Do not adjust your medication unless instructed to do so by your doctor or healthcare provider.

For additional information, see Overview and Helpful Hints.

Have a question, call **1-877-212-4968.**

Turn to reverse side for step-by-step instructions

A1CNOW+ QUICK REFERENCE GUIDE

Materials Needed for Testing

IMPORTANT!

- Follow all steps on reverse side after reviewing DVD instructions.
- Do Not open pouches until instructed.
- Make sure lot number on Monitor matches lot numbers on the Red and Blue pouches.
- Use indoors between 64°F (18°C) and 82°F (28°C)

Blood Collection

Open blue pouch ONLY!

WAIT TO OPEN

1 Stick Finger

Press Lancet into finger.

Squeeze finger to get adequate blood.

Actual size required

2 Collect Blood

Gently touch Blood Collector to top of blood drop.

Make sure tube is adequately filled.

3a Insert Blood Collector into Open End of Shaker

Push firmly to fully insert! Twisting Helps.

3b Check for Full Insertion of Blood Collector into Shaker

There should be **NO GAP** between the Blood Collector and the Shaker.

Do Not remove Base

4 SHAKE for 5 Seconds and Set Aside

After shaking, stand Shaker on table.

Blood Testing

Open red pouch AFTER blood collection!

ONCE OPENED USE CARTRIDGE WITHIN 2 MINUTES

5 Insert Cartridge

Push firmly to fully insert!

Cartridge will click into place.

6 "WAIT" for "SMPL" Display

"SMPL" means ready for Shaker.

7a Remove Base from Shaker

7b Press Shaker into Cartridge and Remove Quickly when "RUN" Appears

"RUN" will appear

8 Leave Monitor Flat on Table

Do not handle until countdown is completed.

Following a 5 minute countdown, result will alternate with "QCOK".

Refer to Educational Information enclosed for details on the result.

Remove Cartridge and discard with Shaker.

Save Monitor for second test.

A1CNOW+

Remember that your A1C number is a "big picture" measurement.

- Don't use it for short-term daily blood glucose measurement.
- Do not adjust your medication unless instructed to do so by your doctor or healthcare provider.

For additional information, see Overview and Helpful Hints.

FOR INVESTIGATIONAL USE ONLY

Have a question, call **1-877-212-4968**.

Turn to reverse side for step-by-step instructions

A1CNOW+ QUICK REFERENCE GUIDE

Materials Needed for Testing

Monitor front

Monitor back

Example Lot Number

IMPORTANT!

- Follow all steps on reverse side after reviewing DVD instructions.
- Do Not open pouches until instructed.
- Make sure lot number on Monitor matches lot numbers on the Red and Blue pouches.
- Use Indoors between 64°F (18°C) and 82°F (28°C)

DVD Instructions

Lancet

Blood Collector

Shaker

Base
Do Not Remove!

Open End

Example Lot Number and Expiration Date

Cartridge

Example Lot Number and Expiration Date

WAIT TO OPEN

Blood Collection

Open blue pouch ONLY!

1 Stick Finger

Press Lancet into finger.

Squeeze finger to get adequate blood.

2 Collect Blood

Gently touch Blood Collector to top of blood drop.

Make sure tube is adequately filled.

TOO LITTLE add more blood

JUST RIGHT

TOO MUCH wipe away excess

3a Insert Blood Collector into Open End of Shaker

Open End

Push hard!

Push firmly to fully insert! Twisting helps.

3b Check for Full Insertion of Blood Collector into Shaker

There should be NO GAP between the Blood Collector and the Shaker.

GAP

Not fully inserted Keep pushing!

Fully inserted

Do Not remove Base

4 SHAKE for 5 Seconds and Set Aside

After shaking, stand Shaker on table.

Blood Testing

Open red pouch AFTER blood collection!

ONCE OPENED USE CARTRIDGE WITHIN 2 MINUTES

5 Insert Cartridge

Push firmly to fully insert!

Cartridge will click into place.

6 "WAIT" for "SMPL" Display

"SMPL" means ready for Shaker.

7a Remove Base from Shaker

7b Press Shaker into Cartridge and Remove Quickly when "RUN" Appears

"RUN" will appear

8 Leave Monitor Flat on Table

Do not handle until countdown is completed.

Following a 5 minute countdown, result will alternate with "OCOK".

Refer to Educational Information enclosed for details on the result.

Remove Cartridge and discard with Shaker.

Save Monitor for second test.

A1CNOW+

Actual size required

A1CNOW+

Remember that your A1C number is a "big picture" measurement:

- Don't use it for short-term daily blood glucose measurement.
- Do not adjust your medication unless instructed to do so by your doctor or healthcare provider.

For additional information, see Overview and Helpful Hints.

FOR INVESTIGATIONAL USE ONLY

Turn to reverse side for step-by-step instructions

Have a question, call 1-877-212-4968.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: April 30, 2009

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).

Clinical Investigators		

☑ (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
Cathy Peters	Regulatory Manager
FIRM/ORGANIZATION: Bayer HealthCare LLC	
SIGNATURE: [signature]	DATE: 2/17/09

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

FORM FDA 3454 (4/06)

PSC Graphics (301) 443-1090 EF

CLINICAL STUDY INFORMATION

1. SAMPLER STUDY (not reported to clinical trials.gov; study was conducted prior to reporting requirement)

SITE #	SITE NAME	LOCATION	INVESTIGATOR
1	Consumer Product Testing Company	Fairfield, NJ	Joy Frank, RN
2	International Diabetes Center	Minneapolis, MN	Richard Bergenstal, MD
3	John Muir Physician Network Clinical Research Center	Concord, CA	Roy A Kaplan, MD

2. STABILITY/OTC LABELING STUDY (NCT00798486)

SITE #	SITE NAME	LOCATION	INVESTIGATOR
1	Consumer Product Testing Company	Fairfield, NJ	Joy Frank, RN Richard Eisenberg, MD
2	John Muir Physician Network Clinical Research Center	Concord, CA	Anna Chang, MD Genevieve Yue, MD

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Christine King

Subject: 510(k) Number K090413/S1

To: The Record

Please list CTS decision code CS

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist. http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 -<21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number	**Class***	**Product Code**
864.7470	II	LCP

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: _____ (Branch Chief) (Branch Code) 5/13/09 (Date)

Final Review: _____ (Division Director) 5/14/09 (Date)

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER k090413
Bayer A1CNow+ (Professional Use), Bayer A1CNow Self Check (OTC Use)

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.) k051321
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 (labeling changes are permitted as long as they do not affect the intended use).
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 modification to the sampling device design and modifications to increase test cartridge stability and name change for the OTC device to Bayer A1CNow Self Check.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, NGSP certification, and user studies.
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 FMEA
   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.

Christina Kay 5/11/09

(Reviewer's Signature) (Date)

Comments
Validation Protocols were adequate to address the identified causes of hazards identified in the Risk Analysis (FMEA)
revised:8/1/03

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: CE

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication: There is no difference in indication for use between the predicate and candidate devices.

2. Explain why there is or is not a new effect or safety or effectiveness issue: The sponsor has demonstrated through their validation and verification activities that there are no new safety or effectiveness issues.

3. Describe the new technological characteristics: There are no new technological characteristics. The sponsor has increased stability of the device and has obtained NGSP certification.

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough: See 8.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed: The sponsor performed the necessary validation and verification activities for this device.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: The technology between the candidate device has not changed from the predicates. The risk of the proposed changes have been addressed and mitigated by the sponsor. All changes are adequately addressed in the labeling.

MEMO TO FILE

DATE: 5/11/09
TO: File
RE: k090413 Bayer A1CNow+ (Professional Use) and A1CNow Self Check (OTC Use)
FROM: Christine King, Scientific Reviewer, CDRH/OIVD/DCTD

This special 510k is submitted for three changes to the Bayer A1CNow:

1. Product Stability: The sponsor has made two modifications to non-active ingredients in the assay to extend the product stability to at least 15 months. First, they have increased the sucrose concentration in the antibody latex striping solution from 10% to 25%. This ensures a more uniform release of latex over time. Second, they have reduced a surfactant in the pretreatment buffer.
2. Simplification of the hemolysate procedure: This system includes a sampling device that allows the user to collect the fingerstick blood and add it to a hemolyzing reagent. The sampling device also acts as a capillary pipette to dispense the hemolysate onto the meter test strip. The sponsor changed the design of the sampler in 2008 so that it is now a two part device instead of a three part device. They obtained NGSP certification in July, 2008 using this device.
3. A1CNow Home Use labeling changes: Labeling changes for over the counter use were made to reflect the modifications described above and the name of the OTC device is changed to A1CNow Self Check. Name change from Metrika to Bayer occurred in the predicate, k051321/A003.

Intended Use Population Validation and Verification Activities

The sponsor performed two studies to address the changes, both of which included ease of use studies with lay users.

One study, CTD-REP-2009-3 was performed using the modified sampler and the modified test strips with the increased sucrose and decreased surfactant. The study enrolled 110 subjects and 8 Health Care Providers (HCPs) at two sites. Both non-diabetic and diabetic subjects were included. Three lots of test cartridges and 115 meters were used among the subjects. In order to determine precision in the hands of the lay user, each person collected two fingersticks on themselves. The HCP collected a third fingerstick and a venous blood sample from each individual. Regression analysis was performed on the first fingerstick collected by the lay user and the fingerstick obtained by the HCPs. HbA1c results ranged from 4.8%-13.2%. There were 69 matched pairs of lay user first-time fingersticks and HCP results. The regression was: $y = 0.90x + 0.72$, $r^2 = 0.904$. Accuracy was defined as 95% of results within ± 13.5% bias of the reference method (HCP) and the sponsor met the criteria.

HCP accuracy was evaluated by analyzing the venous samples in an NGSP certified laboratory on a Tosoh 2.2 Plus and comparing them to the fingersticks they obtained

from the lay users on the Bayer A1C Now. Regression was calculated on 99 pairs, $y = 0.99x + 0.35$, $r^2 = 0.93$.

In order to evaluate the effectiveness of the labeling changes, comprehension studies were also performed. These consisted of splitting the lay users into two groups, those that read the labeling and viewed the DVD that came with each system (D group), and those that just read the instructions (W group). First time failure rate (FTFR) was determined using the null hypothesis for both groups. The sponsor's criterion was that the FTFR must be less than 20%. The FTFR for both groups was 11.3%. The results of the "ease of use" questionnaire were 94% of respondents rated the device as "very good" to "excellent".

The second study, DVP-07-01-02, was performed prior to the modifications to the test strip and pretreatment buffer and only included the modifications to the sampling device. The purpose of the study was to evaluate the clarity of the product labeling for the modified sampling device in the hands of the lay user, and to determine if the device performed accurately in the hands of both professional and lay users. The performance activities were not used for determining substantial equivalence because this study did not include all of the modifications in this submission, and we had concerns regarding part of the study design whereby users received instructions from Bayer staff if they were unable to perform the first fingerstick correctly. However, the sponsor did evaluate error codes for their risk analysis and user comprehension of the labeling and DVD instructions for the modified sampler with a quiz and questionnaire prior to testing. These were included in the review.

Acceptance criteria for the quiz was ≥ 80% and 90% of subjects needed to respond that the device was easy or somewhat easy to use. They obtained 94.9% (111/117) of users with no more than 2 wrong answers on the quiz and 98% (115/117) found the test easy or somewhat easy to perform, based on the questionnaire.

See Risk Analysis Activities for error code summary.

Analytical Performance Validation and Verification Activities

1. Precision:
   Separate precision and accuracy studies were performed using the modified system and comparing it to the predicate method. The sponsor provided a summary of 22 replicates on six lots which were tested for precision using two controls (5%-6% and 8.5%-9.5%) on multiple meters. The studies were performed during one day of testing. The acceptance criterion for precision for each level was ± 4%. The device met the criterion.

2. Accuracy:
   Accuracy of the A1cNow, with the modified formulations, used one lot tested with heparin whole blood samples according a modified NGSP protocol. According to the standard NGSP testing procedure, 40 samples should be tested on a single instrument in 5 different days (test 8 samples per day). In the sponsor's modified protocol, samples were tested with 16 different instruments in a single day. Other than this

change, the procedure was the same as the standard NGSP protocol. Venous whole blood samples collected in heparinized tubes were distributed over a clinical range as follows:

- 8 samples from 4-6%A1c
- 12 samples from 6-8%A1c
- 12 samples from 8-10%A1c
- 8 samples from 10-12%A1c

Each specimen was analyzed in duplicate with the A1CNow. Using an in-house NGSP-certified TOSOH G7 as the reference method, the results were within the NGSP agreement criteria for Manufacturer Certification of ± 0.85 %HbA1c. A summary of the results are below:

Mean difference	Std. Dev.	95% CI
-0.12	0.31	-0.73 to 0.50

In addition, the sponsor received NGSP certification in July, 2008 for this device with the sampler modification in this submission. NGSP criterion for the certification was ± 0.85%. Copies of the certification letter and certificate are included with the submission. The sponsor is listed on the NGSP website http://www.ngsp.org.

3. Quality Control and Calibration:
The sponsor does not market quality control material for their system. They recommend and assign ranges for control materials made by three manufacturers: BioRad, Thermo Fisher, and Nova One. They found that results with those materials using the modified device fall within the same ranges established with the predecessor device and no significant shifts occurred. They also verified that the modifications do not warrant a change in the factory calibration release criteria.

4. Stability:
Stability of the modified device was conducted on four lots using commercially available control material values to determine stability. Control values must be within ± 10.1% of the initial value. The goal was to extend shelf life from 6 months to 15 months at room temperature. Four lots were split and evaluated with accelerated stress testing and real-time testing. Using Arrhenius modeling techniques the sponsor determined that lots stored at 45°C for 4 weeks demonstrated comparable stability at 25°C for 15 months. These lots met the criterion.

Real-time testing is being performed at 5°C, 23°C, 30°C, 37°C with control evaluation occurring at 1, 2, 4, 8, 13, 20, 26, 39, 52, 65, and 78 weeks. One lot started stability testing 3 months before the other three. Testing is now completed through week 52 for one lot and 39 for the other three lots. All lots are meeting the acceptance criterion.

Humidity studies were also performed on 10 meters, 2 lots of cartridges and sampling devices (which includes the pretreatment buffer solution). All components were

stored at 28° C at 85% relative humidity and tested with commercially available control material at 0, 1, 2, 3, and 5 minutes. Controls needed to be within ± 10% from time 0. All components met the predetermined acceptance criterion.

5. Interference:
   The sponsor performed a risk analysis to determine if new interference studies were needed. He determined that the potential impact of the formulation changes posed a very low risk of increased interferences. He based his decision on the following:
   a. No new components were introduced into the chemistry system.
   b. The increased sucrose in the antibody:latex striping solution increased the consistency of the release of latex from the membrane and was unlikely to impact the immunochemical reactions critical to the test.
   c. Surfactant concentrations lower and higher than the current modification have been used in the device with no change in sensitivity to interfering substances.

Risk Analysis Activities:

1. Sample volume sensitivity:
   Diluted sample volumes of +/-20% and +/-30% of the target 185uL were evaluated. BioRad 1 and 2 controls were bulk diluted (1:70 dilution) and tested at volumes of 100, 130, 148, 185, 222, and 240 microliters across 12 monitors. The acceptance criteria was ±10% from the target of 180ul sample volume. The devices met the criterion.

2. Error codes:
   Error codes were validated during the lay user study DVP-07-01-02 for malfunction of the sampling device with the meter. The sampler error rate should not exceed 15% and the rate of errors across all test sites should be approximately equal. Errors across all sites ranged from 5.0%-7.9%. Total errors attributable to the sampler were 7/117 or 6.0%. The device met the criteria.

The risk mitigation and labeling provided was judged to be sufficient to review and make a decision of equivalency on this submission as a special 510(k).

The labeling for this modified subject device has been reviewed to verify that the indication for intended use for the device is unaffected by the modifications. In addition, the submitter's description of the particular modifications 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 devices be determined substantially equivalent to the previously cleared (or their preamendment) device.

Truthful and Accurate Statement
K090413
5/11/2009

807.87 (k): Truthful and accurate statement

"I certify that, to the best of my knowledge, all data and information submitted in the premarket notification is truthful and accurate and that no material fact has been omitted."

Cathy Peters
Regulatory Affairs Manager

5/11/09
Date

King, Christine

From: Catherine Peters [catherine.peters.b@bayer.com]
Sent: Monday, May 11, 2009 4:07 PM
To: King, Christine
Subject: Re: Follow up question for k090413 5/8 response

Attachments: pic07355.jpg; pic13289.jpg; files.zip

pic07355.jpg (22 KB) pic13289.jpg (3 KB) files.zip (3 MB)

Hi Chris,

Thank you again for a thorough review of our current submission and helpful hints for future submissions. In response to your earlier e-mail and our discussions today, please see the following information:

1) Please see our response to your e-mail question below (in blue).

As mentioned, a total of 110 subjects were enrolled in the study; however, only 69 pairs of subject first test results/HCP test results were available to be included in the accuracy analysis for the following reasons:

3 subject first test results were excluded as previously mentioned due to protocol deviations

28 subject first tests had no result (due to either an error in usage by the subject or a cartridge failure)

11 subjects had no HCP test result (due to an error in usage by the HCP)

Thus, a total of 41 of the original 110 subjects were excluded leaving 69 subjects who had both a result for the first self-test and a reason for the HCP test. Note that the reason this number (41) doesn't match the sum of the above three bullet points (which equals 42) is because one of the subjects excluded had no test result for both the first self test and the HCP test).

2) In the process of responding to the question above, I realized that we had neglected to send you information addressing your comments under Q3 on 5/7/09- "Also in response to #1 on 3/19, you presented summarized data for the HCPs compared to the Tosoh and n=97." After talking further with our clinical group, our biostatistician noted that n=97 should have been n=99, and that this was an inadvertent error. The corrected graph is below.

Regression of HCP Result by TOSOH
Bivariate Fit of HCP numeric reslt By TOSOH %A1c
(Embedded image moved to file: pic07355.jpg)

(Embedded image moved to file: pic13289.jpg)

Linear Fit

HCP numeric reslt = 0.3489686 + 0.9928561*TOSOH %A1c

Summary of Fit

RSquare	0.932114
RSquare Adj	0.931414
Root Mean Square Error	0.504013
Mean of Response	7.716162
Observations (or Sum Wgts)	99

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio
Model	1	338.33327	338.333	1331.866
Error	97	24.64087	0.254	Prob > F
C. Total	98	362.97414		<.0001

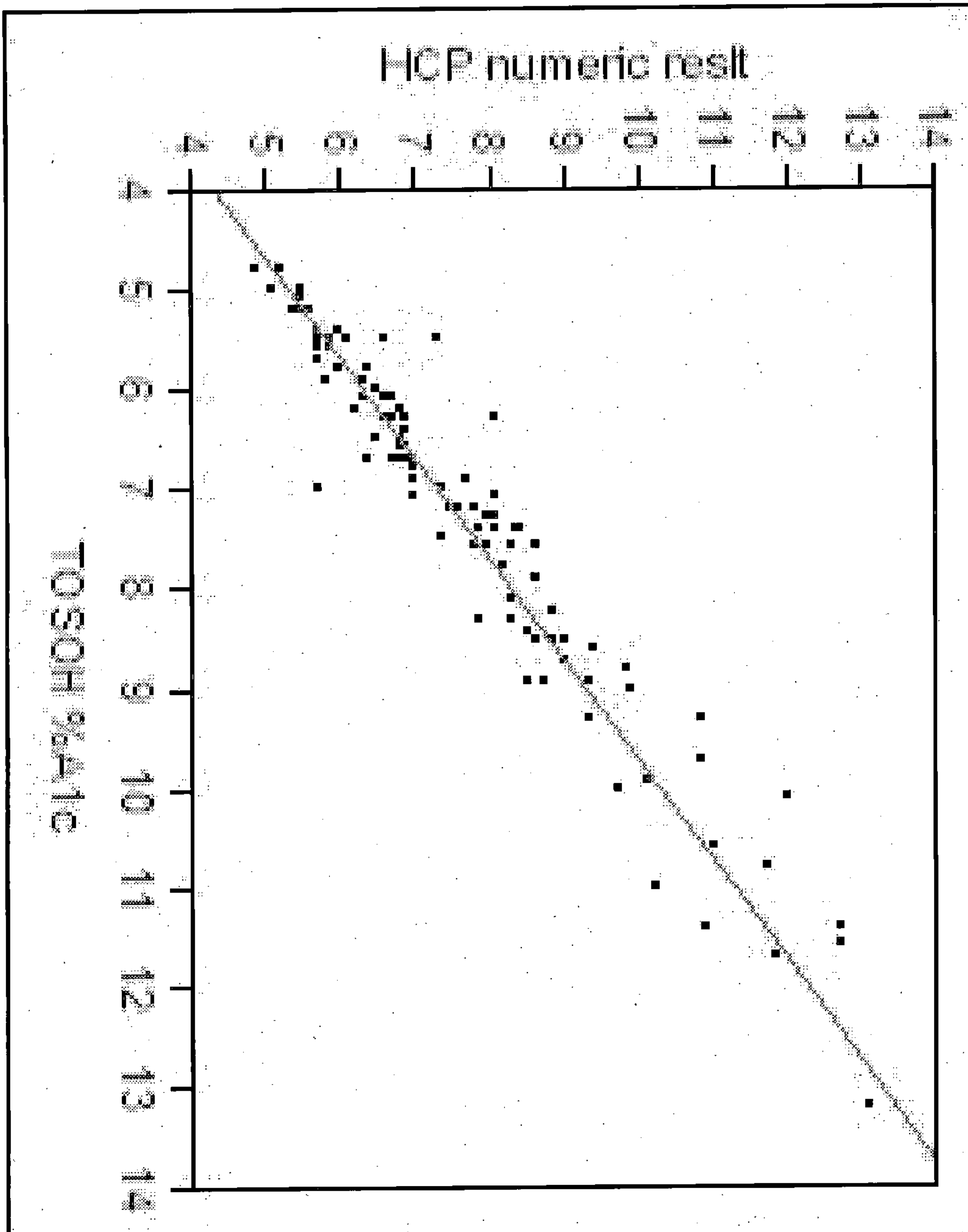
Parameter Estimates

Term		Estimate	Std Error	t Ratio	Prob>|t|
Intercept		0.3489686	0.208128	1.68	0.0968
TOSOH %A1c		0.9928561	0.027205	36.49	<.0001

The reason why only 99 HCP results were summarized in this graph is that there were 11 cases where there was no HCP result (or the result was excluded). The reasons are as follows:

Table 10: HCP Failure Modes

Site	Individual HCP	Total No. of Tests	No. of Tests resulting in evaluableA1C value	Errors
Site 1	HCP #1 (JH)	21	21 (100%)	n/a



	HCP #2 (CP)	12	12 (100%)	n/a
	HCP #3 (PW)	6	6 (100%)	n/a
	HCP #4 (CS)	10	9 (90%)	1 result not used in analysis: During HCP test the subject picked the monitor up during countdown.
	HCP #5 (SS)	3	3 (100%)	n/a
Site 2	HCP #6 (DB)	20	12 (60%)	8 errors occurred: All OR2 – upon observation this HCP appeared to be performing the test properly
	HCP #7 (DL)	20	19 (95%)	1 error occurred: QC6 – added sample prior to "SMPL" on display
	HCP #8 (SW)	18	17 (94%)	1 error occurred: QC6 – added sample prior to "SMPL" on display

3) Finally, I've attached updated copies of our OTC labeling which include the toll-free number for users.

(See attached file: files.zip)

Per our discussion, I will fed ex you an updated Truthful and Accurate statement today. If you have any additional questions or comments, please don't hesitate to contact me at my e-mail/office or cell # below.

Best regards,

Cathy

Cathy Peters, RAC
Regulatory Affairs Manager
Bayer HealthCare Diabetes Care- A1CNow+

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"King, Christine"
<Chris.king@fda.hhs
.gov>

05/10/2009 07:46 PM

To
catherine.peters.b@bayer.com
cc

Subject
Follow up question for k090413 5/8 response

Hi Cathy,

Thanks for the information. I still need some additional clarification for 3a and b because there seems to be some information missing. There were 110 subjects originally enrolled. Of those, 5 had to be excluded for various reasons. Based on this information, there should have been 105 first-time fingerstick results that could be compared to the HCP results. However, there were only 69 matched pairs. Please clarify what the outcome was for the other 36 first-time fingerstick matched pairs.

Also, can you please send an updated Truth and Accuracy statement? Please FedEx it to my attention at the address below.

Thanks,

Chris

Christine King, MS, CLS(NCA)

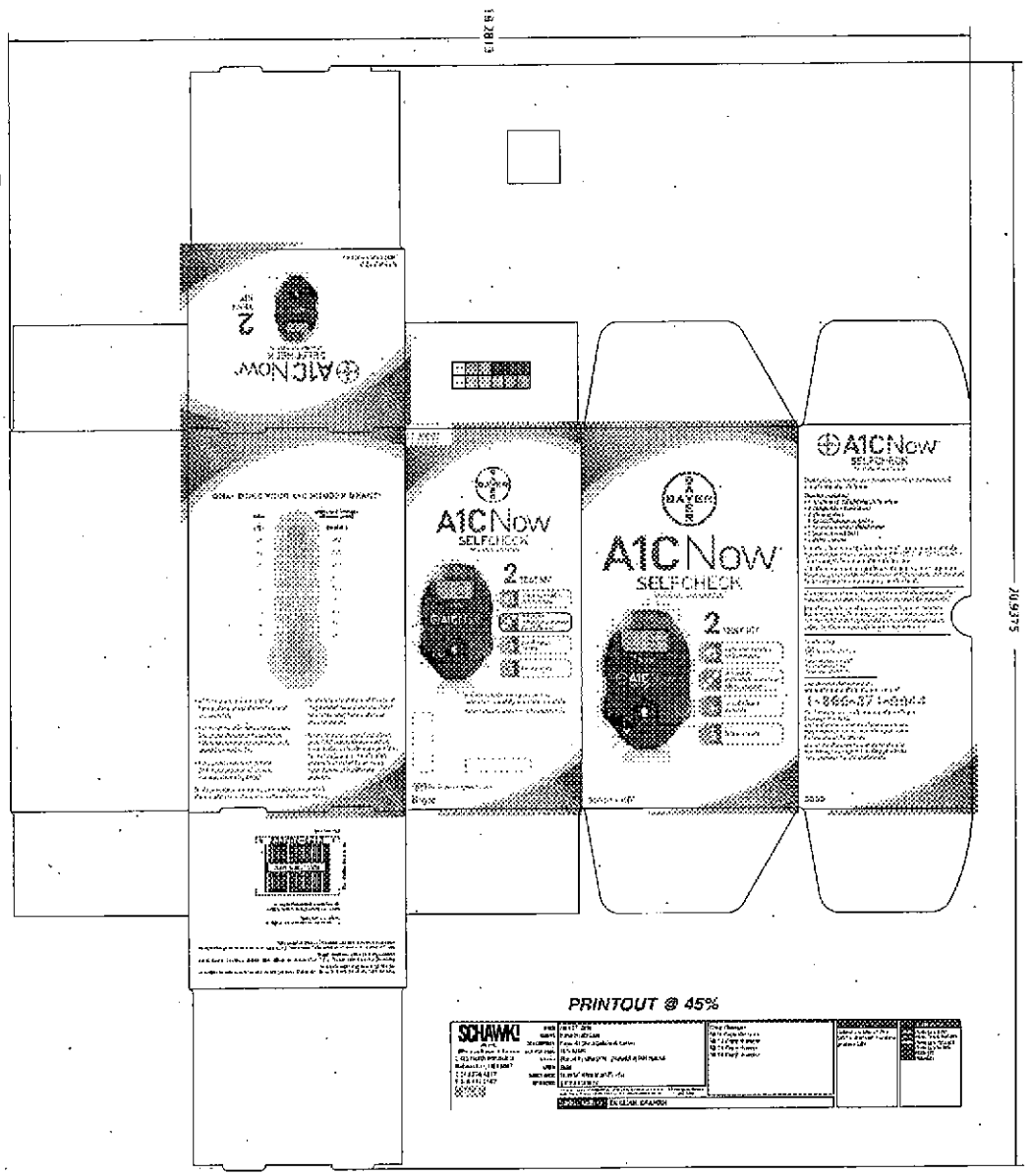
Scientific Reviewer

FDA/CDRH/OIVD/DCTD

2098 Gaither Road HFZ-440

Rockville, MD 20850

240.276.0384



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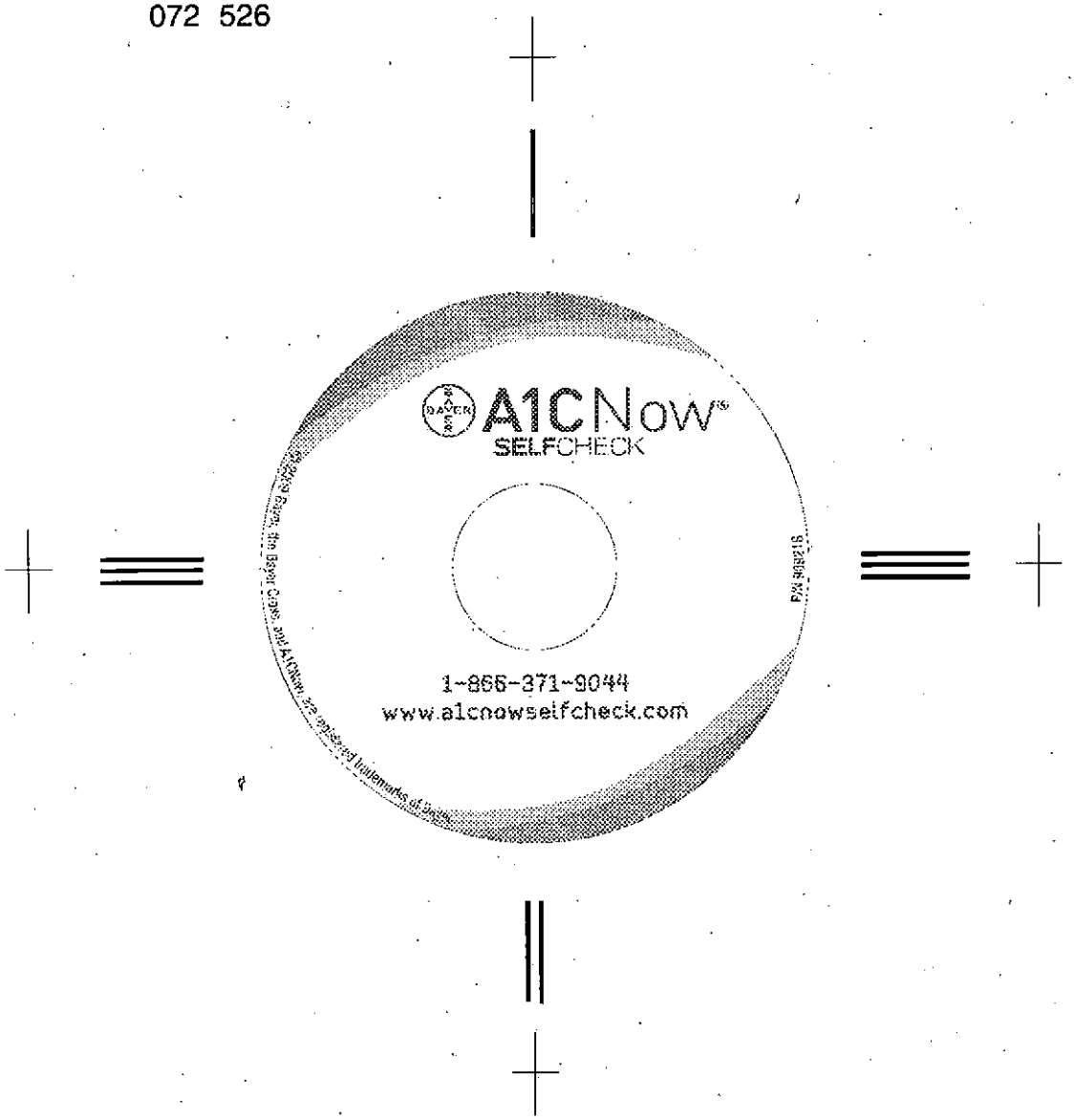

A1CNow SELFCHECK

At-Home A1C System

OVERVIEW AND HELPFUL HINTS

INTENDED USE
Bayer's A1CNow SELFCHECK test provides quantitative measurement of the percent of glycated hemoglobin (A1C) in whole blood fingerstick blood samples. The test is for home use to monitor glycemic control in people with diabetes.

Before using this test, please read all instructions carefully. If you need help, call 1-866-371-9044. We invite you to call and we will walk you through the test.

INTRODUCTION
The percent (%) of A1C in your blood today tells you how well you have been controlling your glucose levels over the past 2-3 months. About 50% of the A1C result is from the past 30 days of glucose levels; about 25% is from the next 30-60 days and about 25% is from the past 60-90 days.

The American Diabetes Association (ADA) recommends that you test your A1C levels at least 2 times per year if your blood sugar is stable. If changes are taking place in your treatment changes or your blood sugar is too high, the ADA recommends that you test at least every 3 months.

The A1CNow SELFCHECK test is an easy to use test to measure your A1C levels at home. By measuring your levels at home, you can be better informed in-between your doctor visits and take more control of your diabetes.

KIT CONTENT
The box contains materials for two A1C tests. Make sure all of the following parts are in the box. DO NOT open the pouches until ready to use.

- A1CNow SELFCHECK Monitor (1)
- Cartridge Pouch (2)
- Shaker Pouch (2), each containing:
  - Shaker (1)
  - Blood Collector (1)
  - Lancet, disposable (1)
- Extra lancet (1)
- Quick Reference Guide (1)
- Instructional DVD (1)
- Overview and Helpful Hints (1)

PREPARING TO TAKE THE TEST
You may take your fingerstick blood sample and do your A1C test any time of the day. Remember to wash your hands prior to performing the test.

No special diet is necessary (you do not have to be fasting when taking this test). You may want to do this test at the same time as you do a blood glucose test.

In order to help ensure an accurate result, please complete the test from beginning to end in 15 minutes. Avoid running the test in direct sunlight, on hot or cold surfaces or near sources of hot or cold air. If the test has recently been used, the monitor should be at room temperature (64° - 77°F / 18° - 25°C) or at cold temperatures, allow the kit parts to come to room temperature (64° - 77°F / 18° - 25°C) for at least one hour before you do your test. Leave the parts in their sealed pouches while waiting.

WHAT TO DO WITH THE RESULT
The Monitor will not store your result in memory, so write down the result and the test date on the log area in the Quick Reference Guide as soon as possible to prevent loss of information.

WHAT THE TEST RESULT MEANS
For most people with diabetes, the American Diabetes Association (ADA) recommends that your A1C should be under 7%. Your health care professional will tell you what level is right for you.

HOW DOES THIS TEST COMPARE WITH THE A1C TEST PERFORMED IN A DOCTOR'S OFFICE OR THE LABORATORY?
The A1CNow SELFCHECK test is annually certified by the National Glycohemoglobin Standardization Program (NGSP). The American Diabetes Association (ADA) recommends that A1C tests be certified by the NGSP. For information about NGSP certified methods, please visit the website: www.NGSP.org.

STORAGE
- Store and use at room temperature (64° - 77°F / 18° - 25°C) and out of direct sunlight.
- If you cannot conveniently store the kit under these recommended conditions you have the option of refrigerating the kit. However, you must bring the kit to room temperature for at least one hour prior to use.
- DO NOT use the test after the expiration date shown on the box.
- If the temperature label, placed on the outside of the kit is exposed to a temperature in excess of 122°F/50°C, the test on the label will turn red and the product should not be used.

WARNINGS AND PRECAUTIONS
- DO NOT adjust your medication unless instructed to do so by your doctor or health care professional.
- Conditions such as hemoglobin (Hb) variants, anemia, recent significant blood loss, a recent blood transfusion, or high amounts of rheumatoid factor may affect the accuracy of your A1C result.
- People with hemophilia (bleeding disorder) or anti-coagulant therapy should not perform this test. Please consult their doctor or health care professional before using this kit.
- Leave the Cartridge Pouch sealed until ready for use.
- Carefully read and follow the Quick Reference Guide and watch the DVD to ensure proper test performance.
- DO NOT reuse the Shaker or the Cartridge. Throw these parts away after using them once.
- DO NOT use the test kit if any parts are missing or damaged.
- DO NOT use the test kit for glucose monitoring.
- DO NOT substitute this test for glucose monitoring.
- DO NOT adjust your medication unless instructed to do so by your doctor or health care professional.
- DO NOT eat or drink any parts of this kit.
- If the solution from inside the Shaker touches your skin or your eyes, flush with water.
- For use outside of the body only (in-vitro diagnostic use).
- Keep out of reach of children under the age of 7 years. When children are performing the test, be sure that testing is done under adult supervision.
- DO NOT use any other body fluids or food to perform this test. Use ONLY your fingerstick blood sample.
- DO NOT add your blood directly to the cartridge. Your blood must first be added to the Shaker.
- DO NOT handle the white circle area of the Cartridge.
- This test is NOT for the screening or diagnosis of diabetes.
- This test is to be used at room temperature between 64° and 77°F (18° and 25°C). Using the test outside this temperature range will give you an error code.
- This test is not a substitute for regular visits to your health care professional or for monitoring your glucose levels.

TROUBLESHOOTING
See the Quick Reference Guide for a description of A1CNow operating and error codes ("OK" = Out of Range; "QC" = Quality Control; "E" = Monitor Error).

MESSAGE	DESCRIPTION AND RESOLUTION
OK 1	[illegible]
OK 2	[illegible]
OK 3	This is a normal message and is not an error. Your test is complete. Remove the Cartridge from the Monitor.
OK 4	[illegible]
OK 5	The kit is expired. Do not use. Use a new kit.
OK 6	The kit is expired. Do not use. Use a new kit.
OK 7	The kit is expired. Do not use. Use a new kit.
OK 8	The monitor temperature is above 77°F (25°C). The monitor will not work properly. Move to a cooler room temperature (64°-77°F).
E01	[illegible]
E02	[illegible]
E03	[illegible]
E04	[illegible]
E05	[illegible]
E06	[illegible]
E07	[illegible]
E08	[illegible]
E09	[illegible]
E10	[illegible]
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"ERR"	The test is shorter than 15 minutes.
"HI"	The test is longer than 15 minutes.
"LOW"	The test is longer than 15 minutes.
OC-6	Contact customer service. Refer to the troubleshooting section.
"QCOK"	Contact customer service.
"QCNO"	Contact customer service.
All other Codes	The ATCNow SELFCHECK test can be performed at any time of day. No fasting is required. You may wish to do the test at the same time you do your glucose test.

Customer Service: 1-866-371-9644

DISPOSAL OF MATERIALS

Keep the monitor to run the second test and dispose of it after the second test has been performed. Throw away all of the other used components (except the Lancet) in your daily household waste. The Lancets, Shaker, Blood Collector and Cartridge can be used only once.

Since the Lancet has a sharp point, it should be disposed of in an appropriate sharps container in the same way you dispose of your glucose testing Lancets.

FREQUENTLY ASKED QUESTIONS

When should I do the ATCNow SELFCHECK test?

The ATCNow SELFCHECK test can be performed at any time of day. No fasting is required. You may wish to do the test at the same time you do your glucose test.

My Lancet accidentally went off before I pressed it against my finger. What should I do?

There is one extra Lancet included in the box. You should use that one.

Sometimes I have trouble getting a blood drop that is large enough. What can I do?

Try washing your hands in warm water. Warm water will help increase blood flow for a better fingerstick. You may also massage the finger before the fingerstick.

What is the best way to fill the Blood Collector?

Hold the Blood Collector horizontally or at a 45° angle relative to the blood drop. Touch the tip gently to the drop of blood and allow the tube to fill. It will stop automatically when it is filled completely.

My Blood Collector is not filled completely. What should I do?

Apply pressure to your finger to get more blood. Again, touch the tip gently to the drop of blood and allow the tube to fill. You may have to re-stick your finger to get the necessary blood. If the Blood Collector does not fill, call customer service.

There is extra blood on the tip of the Blood Collector. What should I do?

Carefully wipe the tip of the Blood Collector with a piece of gauze or tissue. If some of the blood comes out while doing this, touch the tip gently to the blood drop to re-fill the Blood Collector.

The Shaker seemed to leak when I pushed the Blood Collector into it. What should I do?

Call customer service.

The Cartridge will not insert into the Monitor. What should I do?

Make sure you are inserting the Cartridge right side up with the Test Code on top. Also, be sure the Cartridge is facing the right way. You should be able to read the Test Code as you insert the Cartridge into the Monitor.

I accidentally opened the Cartridge pouch too early. What should I do?

You can use the second Cartridge in the kit. Do not use the already opened Cartridge. Throw away the Cartridge that has been opened more than 3 minutes.

The Test Codes on the Cartridge and the Monitor do not match. What should I do?

Do not use the Cartridge. Save the packing materials and call customer service.

The Monitor did not turn on after I inserted the Cartridge. What should I do?

Take the Cartridge out. Re-insert it until it 'clicks'. If the Monitor still does not turn on, this means that it may have a problem and can't be used. Call customer service.

I did not see 'HUM' and a countdown after I pulled the sample using the Shaker. What should I do?

Call customer service.

My result says 'QCOK' and a number. What should I do?

Refer to the troubleshooting section. You can also call customer service.

What should I do with the test after I am done with it?

After you write down your result, you can throw away the used Blood Collector, Shaker and Cartridge in your daily household trash. These items can be used only once. Note that the Lancet is also a single-use item and should be disposed of in a sharps container.

The ATCNow SELFCHECK test does not match the result my doctor got from the laboratory. Why is this?

Test results will rarely match exactly. This is true even for tests done in the same lab. A1C results may be different due to slight differences between labs. Normal variation within each test and the time between two tests.

My result is not 'QCOK' and a number. What should I do?

Refer to the troubleshooting section. You can also call customer service.

What should I do with the test after I am done with it?

After you write down your result, you can throw away the used Blood Collector, Shaker and Cartridge in your daily household trash. These items can be used only once. Note that the Lancet is also a single-use item and should be disposed of in a sharps container.

Save the Monitor for your second test. Monitor will display "0:11," showing that there is one test left. When Monitor is displaying "0011," it indicates that you have used both tests. Once you used the second test, you can throw away the Monitor in your daily household trash. Test results will rarely match exactly. This is true even for tests done in the same lab.

QUESTIONS OR COMMENTS

Call customer service at 1-866-371-9644

A1CNow SELFCHECK

King, Christine

From: Catherine Peters [catherine.peters.b@bayer.com]
ent: Friday, May 08, 2009 3:30 PM
To: King, Christine
Subject: RE: Additional clarifications k090413

Attachments: K090413_response_5_8_09.pdf.zip

K090413_response
_5_8_09.pdf.zi...

Hi Christine,

Thanks for your message below. I'm actually at our Indiana facility right now, but will be leaving soon to catch a flight back to California.

I've attached our response to this message. Since it's getting very close to the 30 day mark, would it be easier for you to address any questions you may have regarding this reponse (or otherwise) via telephone early next week? My calendar is fairly open, so please let me know when would work best for you.

Best regards,

(See attached file: K090413_response_5_8_09.pdf.zip)

Cathy

Cathy Peters, RAC
Regulatory Affairs Manager
Bayer HealthCare Diabetes Care- A1CNow+
510 Oakmead Parkway
Sunnyvale, CA 94085
Phone: 408-524-2255, ext. 236
Cell: 408-220-4086

"King, Christine"
<Chris.king@fda.hhs.gov>
05/08/2009 10:19 AM

To: "Catherine Peters" <catherine.peters.b@bayer.com>
cc:
Subject: RE: Additional clarifications k090413

Hi Cathy,
I'm supposed to be off this morning. I'm on my way to a meeting this afternoon at White Oak. You can either call me at home, or email me and I'll get back to you. I won't be back from the meeting until about 5

EDT.

Chris

-----Original Message-----
rom: Catherine Peters [mailto:catherine.peters.b@bayer.com]
Sent: Friday, May 08, 2009 10:41 AM
To: King, Christine
Subject: Re: Additional clarifications k090413

Hi Chris,

Yes, we should be able to respond to the questions below by the end of today.
We would like to get clarification on a few questions, however. Would you be
available sometime between 11 am-12 pm this morning (your time) for a phone call
with me and our clinical and R&D team members? Please let me know.

Thank you,

Cathy

Cathy Peters, RAC
Regulatory Affairs Manager
Bayer HealthCare Diabetes Care- A1CNow+
510 Oakmead Parkway
Sunnyvale, CA 94085
Phone: 408-524-2255, ext. 236
Cell: 408-220-4086

"King, Christine"
<Chris.king@fda.hhs
.gov>

To: catherine.peters.b@bayer.com

05/07/2009 12:24 PM

cc:

Subject: Additional clarifications k090413

Response to Questions re: K090413 5/8/09
Bayer HealthCare

1. Precision studies: you sent tables showing precision with 6 of the candidate lots compared to 2 of the predicate lots. There are no details in the description of the study indicating how many replicates were tested over what time period. The CVs, etc. presented in the tables do not indicate if this is total precision, or repeatability. Please provide the protocol and summarized data for repeatability and total precision of the device compared to the predicate and include your predetermined acceptance criteria and conclusions for both.

As noted on page 2 of the response dated 3/25, the sample size can vary depending on the size of the lot being evaluated. For each lot, cartridge samples are pulled during the manufacturing process. There is a minimum of 20 samples required for each level evaluated (the sample sizes used are provided in the table on p. 2 of the 3/25 response). This testing is to assess total precision (a single testing event) of the lot using multiple monitors. Due to the disposable nature of our product, there is no repeatability testing (testing across multiple days) required during our release process.

The 3/25 response includes data for both the predicate and modified device along with the predetermined acceptance criteria (<6%CV with 90% Confidence). All lots passed these criteria.

2. Accuracy studies: you stated in the response to #1 on 3/19 that 15 replicates for two control levels were tested. It is not clear how this differed from the precision study. Were these samples also performed on another analyzer for comparison? Please provide the protocol, the predetermined acceptance criteria for determining accuracy, and your conclusions.

This testing is completed by selecting random kit components (5 monitors, 30 cartridges and 30 Samplers) after all of the calibration has been completed. It is a separate confirmation of accuracy in addition to the precision step described above. The blood samples are assayed on the TOSOH G7 to determine the 'True" value for comparison. In our response dated 3/25 (page 3), a summary of the data, pre-determined acceptance criteria, results and conclusions are provided.

3. CTD-REP-2009-03: It is still not clear from the protocol you sent and the various descriptions in the study how many lay users and HCPs participated in this study. Table B states that there were 110 subjects (93 diabetics and 17 non-diabetics). In your response from 3/19 you stated that there were 101 subject results obtained from 53 lay users. Also in the response to #1 on 3/19, you presented summarized data for the HCPs compared to the Tosoh and n=97. In an email from 4/14 you state that there were 69 subjects that had a first test result and a HCP result Please clarify these discrepancies. Clarification of these discrepancies is provided in our responses to a and b below.

a. How many lay users and HCPs participated at each site in the study.

It is correct that there were a total of 110 subjects enrolled in the study (93 diabetics and 17 non-diabetics). There were also a total of 8 HCPs. The breakdown is as follows:

Site#	Total Subjects	Total HCPs
1	52	5
2	58	3

During the analysis of this study, subjects/samples were excluded for the following reasons:

Protocol Deviations and Sample Size Reconciliation

Protocol Deviations

1. In two cases (subjects 1.042 and 2.059) the HCPs inadvertently helped the subjects during the first self-test.
2. In one case (subject 1.042) the HCP erroneously instructed a subject to perform a third self-test.
3. One subject (2.011) used a personal lancing device during the 2 self-tests.

Sample Size Reconciliation

One hundred ten (110) subjects were enrolled and completed all portions of the study. There were a total of 221 subject tests and 110 HCP tests completed. The following were excluded from noted portions of the data analysis:

- The HCP result for subject 1.025 was excluded due to the subject inadvertently picking the monitor up while it was counting down.
- Subject 1.042's first test was excluded from all analyses due to inadvertently receiving help. The third self-test (done in error) was also excluded from all analyses.
- Subject 2.059's first test was excluded from all analyses due to inadvertently receiving help.
- Subject 2.011's self tests were excluded from all analyses due to use of a personal lancing device. However, the HCP test for this subject (during which the required kit lancing device was used), was included.
- Subject 2.057 got a QC8 error when inserting a cartridge on the first self-test. This is indicative of a damaged cartridge which should have been replaced by the HCP prior to the subject delivering the sample. This was not done, thus this subject was excluded from the FTFR analysis.

Thus a total of 215 subject tests and 109 HCP tests were included in the analysis. The results of these tests include A1C values, error codes or blank screens at the completion of each Redwood test attempt.

b. How many discreet whole blood samples were collected and how many first fingersticks were collected and used for the comparison with the HCPs. If this is different from the number of subjects, please explain why.

The accuracy assessment was done two ways: 1) using samples from both groups (DVD and no-DVD) combined, and 2) analyzing each group (DVD and no-DVD) separately.

The number of samples (n= 101) refers to the DVD group. The samples included in this accuracy analysis included only samples that were not excluded (as mentioned above) and results that included a value (thus if a subject did not get a value, no values were included in the accuracy analysis). Thus, 53 of the 110 subjects had watched the DVD and had a value that was not excluded from the analysis for reasons mentioned above.

Regarding the regression of HCP results vs. subject first test results (4/14 e-mail): In some cases, the HCP made an error testing the subject's blood (thus there was no A1c value) and in some cases the subject made an error during his/her first test (thus there was no A1c value). Thus, the total number of subjects who obtained an A1c value who also had the HCP obtain an A1c value = 69 subjects.

c. Provide the testing protocol for the whole blood samples on the Tosoh, state the predetermined acceptance criteria, and your conclusions.

The Tosoh is our internal reference method used to establish the "true values" against which the clinical values are compared. We follow the Tosoh manufacturer's recommended testing procedures, therefore we are not evaluating the Tosoh method itself in our studies. The official name of the TOSOH is TOSOH GlycoHemoglobin Analyzer A1c 2.2.

d. Please clarify how you determined that the first time failure rate was 11.3% in this study.

On p. 16 of protocol, the following section states how first time failure rate was determined:

"Definition of First Time Failure
The rate of FTF (FTFR) will be evaluated for the purpose of product improvement initiatives. When a user encounters the following scenarios during his/her first usage of the product (as observed by study staff members) it will be considered an FTF:

- Cannot figure out how to use the product based on the instructional materials provided without assistance. (Subject requests professional assistance.)
- Attempts to complete the test, realizes a mistake was made but cannot continue because one or more of the parts has been rendered unusable (due to user error).
- Manages to complete the test after one or more mistakes and gets an error code instead of a result.

Note: Cartridge exposure time (i.e. the length of time between when the subject opens the cartridge and delivers the blood sample to the cartridge or decides that s/he can no longer continue with the test without assistance) will be measured and analyzed separately but will not be considered a failure mode in this study.

With and Without DVD

Non-inferiority hypotheses will be tested for both groups with and without the DVD.

The null hypothesis: Ho: First Time Failure Rate > 20%

will be tested against the alternative: Ha: First Time Failure Rate <= 20%

independently for each group of subjects (with and without DVD). The critical value of Xc = 13 subjects who experience a first time failure out of n = 50 yields about a 90% chance of rejecting the null hypothesis (i.e., concluding that the users will have less than or equal to a 20% FTFR) if the true (population) FTFR is 20%. In other words, if in a group of n = 50 subjects, 13 or fewer of them experience a first time failure, then we reject the null in favor of the alternative hypothesis.

> In addition, a direct comparison of first time failure rates (FTFR) will be made between the subject group given the instructional materials and the DVD and the group that had only the written instructional materials. With a sample size of n = 50 per group, there is approximately 80% power to detect a difference of about 0.18 (18%) between the two groups (two-sided test)."

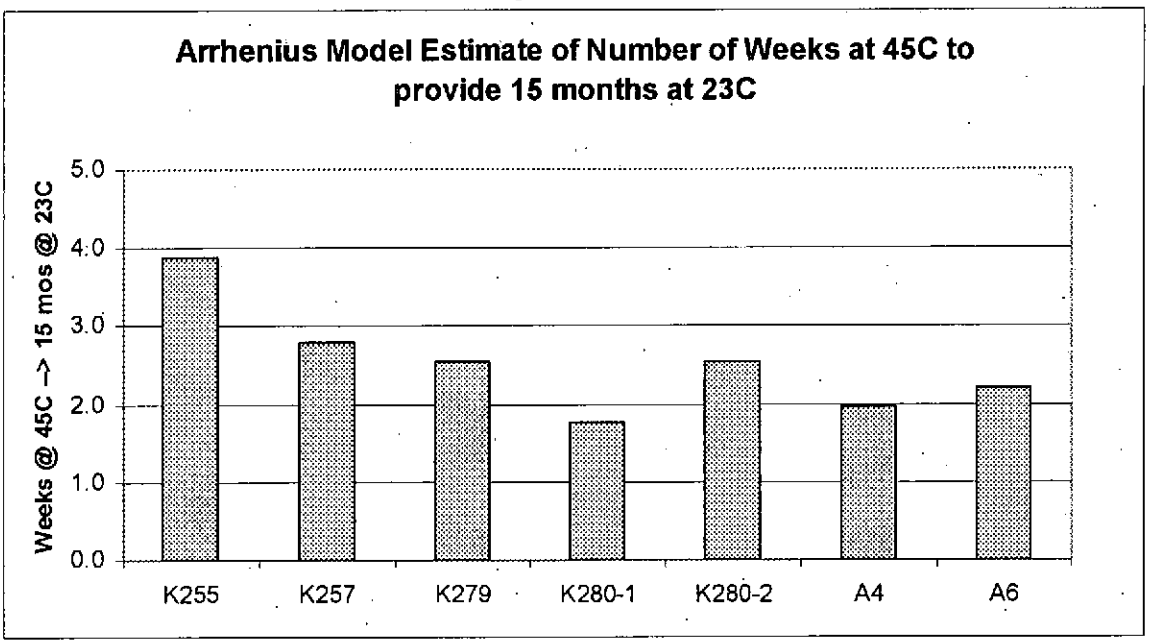
Note that the 11.3% refers to the DVD group only. The product will be sold with a DVD.

4. Stability studies: It isn't clear from the information sent on 3/19 what was used as a control for the studies and there were no conclusions presented for the 45 degree stress study. Also in table B you state that cartridges were "exposed to high humidity environments for up to 5 minutes prior to testing". There is no description of this study. Please provide this information.

Per my 5/01/09 e-mail, the test solutions were the BioRad Lyphocheck Diabetes Control levels 1 and 2. There is no separate control condition for these studies; the data are monitored against their initial checkpoint.

Stability testing of the revised formulation for the A1CNow test cartridge consists of accelerated high temperature stress testing as well as long term room temperature evaluations. The data from several pre-production runs were evaluated using Arrhenius modeling techniques to predict how long product would be required to store at 45°C to be equivalent to storage at room temperature for 15 months (65 weeks). Figure 1 below provides a summary of that analysis.

Figure 1



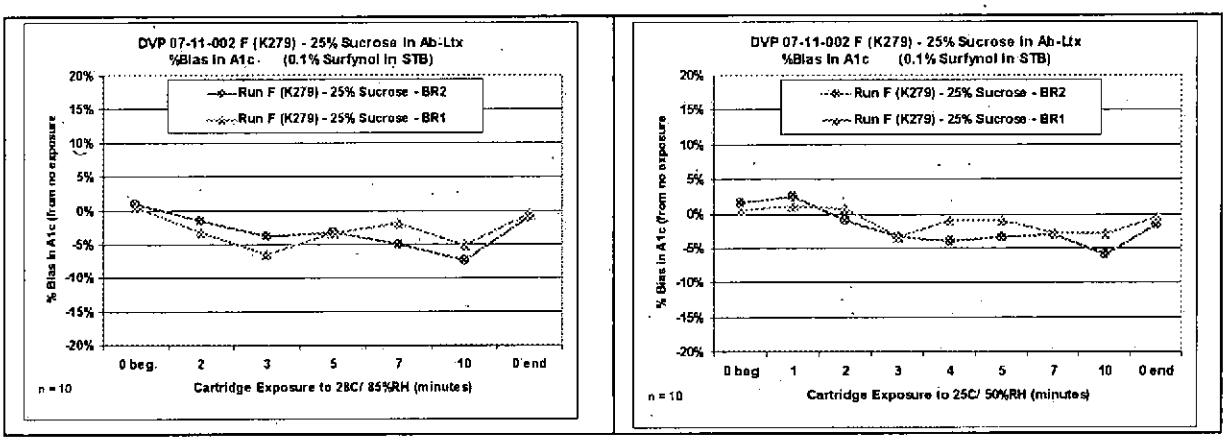
There is no case of an equivalent time of more than 4 weeks, while the mean equivalent time is about 2 ½ weeks.

The data provide in the response dated 3-19 includes both the room temperature and 45°C data. The 45°C data is all within our specification limit after 4 weeks of storage, indicating the product will be stable through 15 months at room temperature.

High Humidity Testing Protocol

After equilibrating monitors, cartridges, and diluted sample inside the 28°C, 85% Relative Humidity chamber, cartridges were tested after exposing to the extreme operating conditions of 28°C, 85% RH conditions for different amounts of time. (b) 1 and 2 controls were bulk diluted (1:70 dilution) and tested at exposure times of 0 (beginning and end of testing), 1, 2, 3, and 5 minutes across 10 monitors.

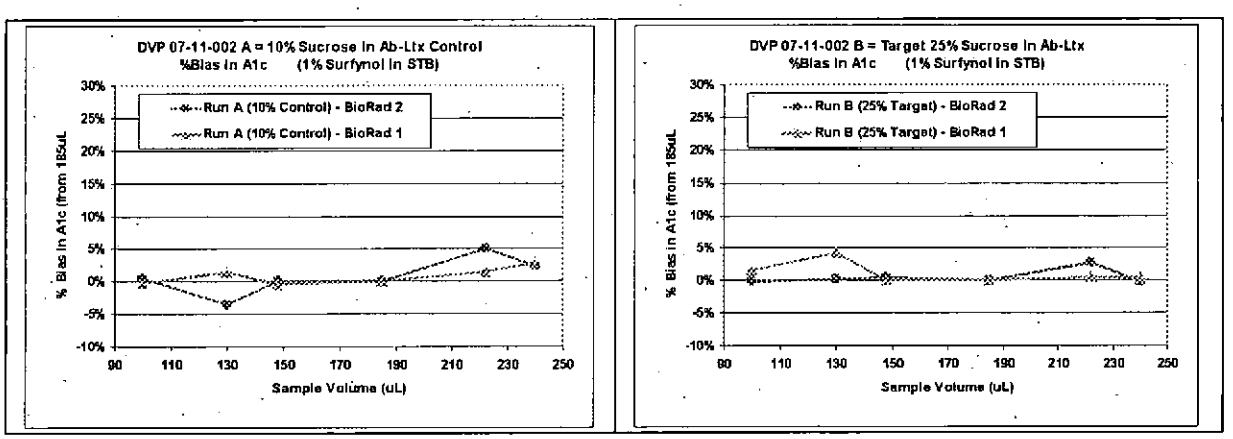
As indicated in Table B, the acceptance criterion is ±10% from the 'no exposure' condition. The following charts provide a summary of the results for two different lots.



5. Sample volume sensitivity: There is no description of these studies. Please provide this information.

Diluted sample volumes of +/-20% and +/-30% of the target 185uL were evaluated. BioRad 1 and 2 controls were bulk diluted (1:70 dilution) and tested at volumes of 100, 130, 148, 185, 222, and 240 microliters across 12 monitors.

As indicated in Table B the acceptance criteria was ±10% from the target of 180ul sample volume. The following two charts provide the results. The following charts provide a summary of the results.



King, Christine
From: King, Christine
Sent: Thursday, May 07, 2009 3:25 PM
To: 'catherine.peters.b@bayer.com'
Subject: Additional clarifications k090413

Hi Cathy,
I have a few more questions regarding some specifics in the information you've sent previously for both the analytical studies and the clinical studies. As I mentioned in our telephone conversation on 5/5, we are looking at the Redwood study CTD 2008-14 (CDT-REP-2009-03) as the more relevant study for clearance of this device because it includes all of the modifications of this special 510k. Based on your feedback, it is our understanding that DVR-07-01-02 only includes modifications to the sampling device.

1. Precision studies: you sent tables showing precision with 6 of the candidate lots compared to 2 of the predicate lots. There are no details in the description of the study indicating how many replicates were tested over what time period. The CVs, etc. presented in the tables do not indicate if this is total precision, or repeatability. Please provide the protocol and summarized data for repeatability and total precision of the device compared to the predicate and include your predetermined acceptance criteria and conclusions for both.

2. Accuracy studies: you stated in the response to #1 on 3/19 that 15 replicates for two control levels were tested. It is not clear how this differed from the precision study. Were these samples also performed on another analyzer for comparison? Please provide the protocol, the predetermined acceptance criteria for determining accuracy, and your conclusions.

3. CTD-REP-2009-03: It is still not clear from the protocol you sent and the various descriptions in the study how many lay users and HCPs participated in this study. Table B states that there were 110 subjects (93 diabetics and 17 non-diabetics). In your response from 3/19 you stated that there were 101 subject results obtained from 53 lay users. Also in the response to #1 on 3/19, you presented summarized data for the HCPs compared to the Tosoh and n=97. In an email from 4/14 you state that there were 69 subjects that had a first test result and a HCP result. Please clarify these discrepancies. In addition, please provide the following information:
   a. How many lay users and HCPs participated at each site in the study.
   b. How many discreet whole blood samples were collected and how many first fingersticks were collected and used for the comparison with the HCPs. If this is different from the number of subjects, please explain why.
   c. Provide the testing protocol for the whole blood samples on the Tosoh, state the predetermined acceptance criteria, and your conclusions.
   d. Please clarify how you determined that the first time failure rate was 11.3% in this study.

4. Stability studies: It isn't clear from the information sent on 3/19 what was used as a control for the studies and there were no conclusions presented for the 45 degree stress study. Also in table B you state that cartridges were "exposed to high humidity environments for up to 5 minutes prior to testing". There is no description of this study. Please provide this information.

5. Sample volume sensitivity: There is no description of these studies. Please provide this information.

Can you please let me know if I might expect answers today or tomorrow?

Thanks again for your help,
Chris

Christine King, MS, CLS(NCA)

Scientific Reviewer
FDA/CDRH/OIVD/DCTD
2098 Gaither Road HFZ-440
Rockville, MD 20850
240.276.0384
chris.king@fda.hhs.gov

King, Christine

From: Catherine Peters [catherine.peters.b@bayer.com]
Sent: Friday, May 01, 2009 7:20 PM
To: King, Christine
Subject: Re: Additional questions and clarifications for k097413

Hi Chris,

Please see our reponses below; also, please don't hesitate to let me know if you need further clarification. I am out of the office the beginning of next week but will be periodically checking my e-mail and responding (along with our team) to any further questions.

Sincerely,

Cathy

Q1- This is correct, except the second time, users received instruction only if they requested it.

Q2- For K251, K264 and K265 - 1 test level was used, a BioRad Lyphochek Diabetes control Level 2 that is ~9% A1C (Designated BR2 in the charts). An N of 10 replicates were tested at the initial checkpoint and 5 replicates for the remaining checkpoints. For K266 - Two test levels were tested. The same BioRad Lyphocheck, level 1 and level 2 ~ 5% and ~9% A1C (BR1 and BR2). The same level of replication as above was used.

----- Original Message -----
From: "King, Christine" [Chris.king@fda.hhs.gov]
Sent: 05/01/2009 11:14 AM AST
To: Catherine Peters
Subject: RE: Additional questions and clarifications for k097413

Hi Cathy,
Thank you for your response. Can you please let me know if I am interpreting your response regarding CTD 2008-4(CTD-REP-2009-3)correctly?

The subjects in this study performed two fingersticks and two analyses on the meters on themselves. The first fingerstick and analysis on the device was performed after reviewing the instructions and/or DVD without any assistance or intervention from staff. For the second fingerstick and analysis, each subject received instruction from staff. Is this correct?

I've also looked at your response from 3/19 regarding the stability studies. I appreciate your reference to that response. The response didn't mention what you are using to evaluate the performance at the various time points in the study, ie, controls, patient samples. It also didn't specify if testing was performed at one HA1c level or two levels or more. Please clarify what was used to evaluate performance at the various timepoints.

Thanks,
Chris

-----Original Message-----
From: Catherine Peters [mailto:catherine.peters.b@bayer.com]
Sent: Thursday, April 30, 2009 5:01 PM
To: King, Christine
Subject: Re: Additional questions and clarifications for k097413

Hi Chris,

Please see our answers to your questions below. Per our conversation earlier
today, I'm planning on traveling tomorrow but will be intermittently checking
e-mail and voice mail, so please feel free to follow-up as needed.

Best regards,

Cathy

Cathy Peters, RAC
Regulatory Affairs Manager
Bayer HealthCare Diabetes Care- A1CNow+
510 Oakmead Parkway
Sunnyvale, CA 94085
Phone: 408-524-2255, ext. 236
Cell: 408-220-4086

"King, Christine"
<Chris.king@fda.hhs
.gov>
04/29/2009 12:35 PM

To: catherine.peters.b@bayer.com

cc:

Subject: Additional questions and clarifications for k097413

Hi Cathy,

I left a message for you today. In order to continue the review, I need some additional clarifications and information. Can I please get it by COB on Friday? If not, can you please let me know?

Based on the information sent in response to the hold, please clarify for the user study CTD 2008-4 (CTD-REP-2009-3) if instruction was given to lay users if they failed to understand the labeling or DVD, or if they couldn't obtain a good fingerstick sample. This was done in DVD 07-01-02.

During the first subject test no instruction was given. During the 2nd subject test, all subjects were given instructions for all aspects of the test for which they needed help.

Also, please clarify how many health care providers participated in this study.

There were 8 HCP's across the 2 sites.

From the chart you sent on page 6 of your response of 4/13, it is not clear if the modified sampling device was used in this study. Please clarify if CTD-REP-2009-3 used the modified sampling device.

Yes, the modified sampling device was used with this study.

I will also need a copy of DVR-07-11-002 which was used to evaluate the stability and accuracy of the modified device. It needs to include the predetermined acceptance criteria used for determining increased stability for each parameter measured and a summary of the data and conclusions.

As noted in K097413 (Table B), DVR-07-11-002 shows that testing performed to validate initial performance of the product continues to meet all product release requirements. The acceptance criteria and results of these tests are summarized in this table. In addition, the same table (p. 4-6) notes that studies under DVP 07-11-002 continue to be monitored for long term performance at room temperature. Page 4 of our 3/19/09 response provides further details on protocol, acceptance criteria, and results (to date) of stability studies conducted both at room temperature and higher temperature stress conditions. Graphs on pgs. 5-6 of this 3/19/09 response detail the results of these

studies.

Thanks again for your help.

Best regards,

Chris

Christine King, MS, CLS(NCA)

Scientific Reviewer

FDA/CDRH/OIVD/DCTD

2098 Gaither Road HFZ-440

Rockville, MD 20850

240.276.0384

chris.king@fda.hhs.gov

King, Christine

From: Catherine Peters [catherine.peters.b@bayer.com]
Sent: Friday, March 20, 2009 12:56 PM
To: King, Christine
Subject: Re: Clarification question k090413

Sure, no problem. The antibody:latex striping solution is a mixture that is sprayed onto one of the membranes of the test strip. The test strips are housed in the cartridge.

I am going to be offline for the remainder of the day, but will be able to respond to any further questions Mon.

Best regards,

Cathy

From: "King, Christine" [Chris.king@fda.hhs.gov]
Sent: 03/19/2009 10:52 PM AST
To: Catherine Peters
Subject: Clarification question k090413

Hi Cathy,
Can you please clarify what the antibody latex striping solution is? Is it something on the cartridge or in the hemolysate solution?

Thanks,
Chris

Christine King, MS, CLS(NCA)
Scientific Reviewer
FDA/CDRH/OIVD/DCTD
2098 Gaither Road HFZ-440
Rockville, MD 20850
240.276.0384
chris.king@fda.hhs.gov

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name — Chris King

Subject: 510(k) Number — K090413

To: The Record

Please list CTS decision code TH

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☒ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

v. 7/2/07

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Carol Benson DCHD March 20, 2009
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

MEMO TO FILE: TELEPHONE HOLD

DATE: 3/19/09
TO: File
RE: k090413 (special), Bayer A1CNow, A1CNow Self Check HbA1C
FROM: Christine King, Scientific Reviewer, CDRH/OIVD/DCTD

This submission is being placed on a telephone hold. The review cannot continue until additional information and clarifications are received for the items below:

Items pertaining to your Response dated 3/19/09

1. Follow-up clarifications for Item 1:
   a. You have stated that you will be sending additional clarification for your lay user studies. Please send it electronically when it is available.
   b. You refer to protocol CTD-2008-14. Please define this protocol and clarify how it pertains to the changes made to your device.
   c. You have not specifically stated what your predetermined acceptance criteria are for precision, or accuracy and if your device met the criteria. It is not sufficient to state that the criteria were the same as the predicate.
   d. You state that the six lots of trial product were built and tested under the same lot acceptance requirements as the predicate. Please specify what your lot acceptance requirements are and include your predetermined acceptance criteria. Present a summary of the candidate device results versus the predicate and include your conclusions as to whether your device met your criteria.
   e. Table B: You state that lay users were evaluated for precision and accuracy and total error. Please clarify if this is the same as the NGSP study. If it is not, please provide a table summarizing the results of the lay users against your predetermined precision, accuracy and total error criteria, state your conclusion(s) from the data and if your device met the acceptance criteria. Also provide a detailed study protocol and indicate how many lay users participated, and how many devices and lots were used in the study.

2. Follow-clarifications for Item 4:
   You have stated that there have been no changes to the HbA1c calibration process "beyond the change in the reagents used...." Please clarify if the release criteria for your hemolyzing reagent and reagent disks have changed and if they have had to be broadened or narrowed to accommodate the changes in sucrose and surfactant concentrations. Also state how lots that do not meet your criteria are handled.

3. Additional questions:
   a. You state that you've changed the striping reagent but have not provided an explanation of which part of the device contains this change. Please provide that information.

b. In Table A, for your fault condition of the Device Failing to Display a Clinical Result, please clarify the difference between the two acceptance criteria for the clinical validation study. Please also clarify how these failure rates compared to the predicate device, what your acceptance criteria are for error in-procedure and if your device meets those criteria.

c. Legislation passed last year requires sponsors to fill out FDA form 3674. You can access it online at: http://inside.fda.gov/administrative , then go to FDA forms and select 3674. You may send it in with your response.

King, Christine

From: King, Christine
Sent: Friday, March 20, 2009 12:21 PM
To: 'catherine.peters.b@bayer.com'
Subject: Telephone Hold for k090413 Bayer A1CNow

Good morning Cathy,
I am placing this submission on a "telephone hold" pending receipt of the additional information that you indicated was not yet ready to send, and for additional questions and clarifications that I need to continue the review. This email is your notice of the hold and it will be recorded by DMC. To remove the hold, you will need to put your responses together into one document, as you would do for the Request for Additional Information letter, and send it in to them. In case you are unfamiliar with this process, a telephone hold functions the same as the Request for Additional Information letter but is a less formal way of communicating. The advantage to both of us is that we can let you know of any information or additional studies in more "real time", and you can start working on your responses more quickly. The manufacturer response times and the procedure for requesting an extension through DMC is the same as with the letters.

The following items need additional information or clarification:

Items pertaining to your Response dated 3/19/09

1. Follow-up clarifications for Item 1:
   a. You have stated that you will be sending additional clarification for your lay user studies. Please send it electronically when it is available.
   b. You refer to protocol CTD-2008-14. Please define this protocol and clarify how it pertains to the changes made to your device.
   c. You have not specifically stated what your predetermined acceptance criteria are for precision, or accuracy and if your device met the criteria. It is not sufficient to state that the criteria were the same as the predicate.
   You state that the six lots of trial product were built and tested under the same lot acceptance requirements as the predicate. Please specify what your lot acceptance requirements are and include your predetermined acceptance criteria. Present a summary of the candidate device results versus the predicate and include your conclusions as to whether your device met your criteria.
   e. Table B: You state that lay users were evaluated for precision and accuracy and total error. Please clarify if this is the same as the NGSP study. If it is not, please provide a table summarizing the results of the lay users against your predetermined precision, accuracy and total error criteria, state your conclusion(s) from the data and if your device met the acceptance criteria. Also provide a detailed study protocol and indicate how many lay users participated, and how many devices and lots were used in the study.

2. Follow-clarifications for Item 4:
   You have stated that there have been no changes to the HbA1c calibration process "beyond the change in the reagents used...." Please clarify if the release criteria for your hemolyzing reagent and reagent disks have changed and if they have had to be broadened or narrowed to accommodate the changes in sucrose and surfactant concentrations. Also state how lots that do not meet your criteria are handled.

3. Additional questions:
   a. You state that you've changed the striping reagent but have not provided an explanation of which part of the device contains this change. Please provide that information.
   b. In Table A, for your fault condition of the Device Failing to Display a Clinical Result, please clarify the difference between the two acceptance criteria for the clinical validation study. Please also clarify how these failure rates compared to the predicate device, what your acceptance criteria are for error in-procedure and if your device meets those criteria.
   c. Legislation passed last year requires sponsors to fill out FDA form 3674. You can access it online at: http://inside.fda.gov/administrative , then go to FDA forms and select 3674. You may send it in with your response.

Best Regards,
Chris

Christine King, MS, CLS(NCA)
Scientific Reviewer
FDA/CDRH/OIVD/DCTD
2[illegible] Gaither Road HFZ-440
R[illegible].ville, MD 20850
240.276.0384
chris.king@fda.hhs.gov

Re Questions k090413 with zip.txt

From: Catherine Peters [catherine.peters.b@bayer.com]
Sent: Thursday, March 19, 2009 10:06 PM
To: King, Christine
Subject: Re: Questions k090413

Attachments: K090413_response_3_19_09.pdf.zip; Att_1_NGSP Certificate A1CNow+ 2008.pdf.zip; Att_1_NGSP_Cert_letter.pdf.zip; Att_2_BayerAC1NowCarton.pdf.zip; Att_2_Modified_overview.pdf.zip; Att_2_Modified_QRG.pdf.zip; Att_2_Predicate_overview.pdf.zip; Att_2_Predicate_QRG.pdf.zip

Dear Chris,

Please see the attached response (with documents for attachments 1 and 2). I will also send two copies of this information to the FDA Document Mail Center tomorrow via Fed Ex. If you have any questions/comments, please feel free to contact me via e-mail or phone.

Thank you for your attention to this submission.

Best regards,

(See attached file: K090413_response_3_19_09.pdf.zip)(See attached file: Att_1_NGSP Certificate A1CNow+ 2008.pdf.zip)(See attached file: Att_1_NGSP_Cert_letter.pdf.zip)(See attached file: Att_2_BayerAC1NowCarton.pdf.zip)(See attached file: Att_2_Modified_overview.pdf.zip)
(See attached file: Att_2_Modified_QRG.pdf.zip)(See attached file: Att_2_Predicate_overview.pdf.zip)(See attached file: Att_2_Predicate_QRG.pdf.zip)

Cathy

Cathy Peters, RAC
Regulatory Affairs Manager
Bayer HealthCare Diabetes Care- A1CNow+
510 Oakmead Parkway
Sunnyvale, CA 94085
Phone: 408-524-2255, ext. 236
Cell: 408-220-4086

"King, Christine" <Chris.king@fda.hhs.gov>
03/17/2009 07:34 AM

To: Catherine.peters.b@bayer.com
cc:
Subject: Questions k090413

Hello Ms. Peters,
How are you? I have some questions regarding the special 510k for the A1cNow

Response to Questions re: K090413 3/19/09
Bayer HealthCare

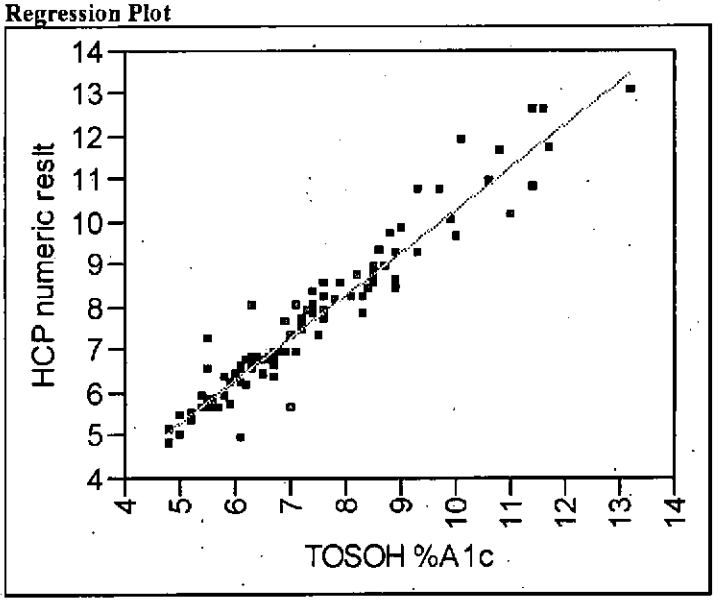
1. You state that you have increased the stability of your device by adding more sucrose and decreasing the surfactant in the striping solution and the sample treatment buffer, respectively. Please provide a more detailed description of the validation and verification activities performed for accuracy, precision, and interference and show the results of the modified device against the predicate. Include the number of samples analyzed, number of replicates and the range of the samples tested in your studies as well as your predetermined acceptance criteria.

The equivalence of accuracy and precision between the modified and predecessor device were established by several means. These included internal design validation following site procedures for design change control and documented under protocol DVP-07-011, testing with lay and professional users at three clinical trial sites under protocol CTD-2008-14, and testing under the NGSP-defined protocol.

For the internal design validation at least six lots of trial product were built and tested under the same lot acceptance requirements as established for the predecessor product. The predetermined acceptance criterion was that all modified lots must meet the same requirements for precision and accuracy as the predecessor product. All trial lots successfully met these requirements. This requires testing of a minimum of 22 replicates at each of two levels of %A1C (normal at 5-6% and elevated at 8.5-9.5%) for precision and 15 replicates at the same levels for accuracy.

The three clinical trial lots also met the same lot acceptance criteria established for the predecessor product. In addition, the clinical results with lay users were evaluated against a predetermined criterion for total error combining both precision and accuracy. This criterion was met and is described in Section 4, Table B of the submission. There were 101 subject results obtained by 53 lay users with HbA1c values ranging from 4.8 to 13.2%. We are unable to extract the data for these 101 results for the relevant labeling condition in the time frame for this response, but below is the data for the results obtained by the health care professionals (HCPs) running single tests on the subjects across both labeling conditions vs. the Tosoh reference method.

Response HCP numeric result CTD 2008-14
Regression Plot



Summary of Fit

RSquare	0.926496
Mean of Response	7.725773
Observations (or Sum Wgts)	97

Parameter Estimates

Term	Estimate	Std Error	t Ratio	Prob>|t|
Intercept	0.2733643	0.221973	1.23	0.2212
Slope	1.0001157	0.028902	34.60	<.0001

Finally, the NGSP accuracy requirements were verified with a modified device lot in a protocol described in the response to question #2. Details of acceptance criteria, replication and sample range are described there.

During the product improvement risk assessment, the potential impact of the proposed formulation changes on interfering substances was determined to be very low. There are three major reasons for this conclusion:

1) No new components are being introduced into the chemistry system.
2) The increase in sucrose in the antibody:latex striping solution is to improve the consistency of the release of the latex from the membrane over time and is unlikely to impact the immunochemical reactions critical to the test, nor will it impact the measurement of the total hemoglobin over time.
3) Surfynol® 485 concentrations both lower and higher than that in the modified device have been used with the product with no change in sensitivity to interfering substances.

Due to this very low assessment of risk, no additional verification of interfering substances was completed.

2. You state that your accuracy studies met NGSP requirements of 95% of the results within +/- 1%. NGSP accuracy requirements are now 0.85% and you need to be sure that your new device still meets NGSP criteria. Please provide validation and verification activities for accuracy which show that your device meets the current NGSP requirements. Please refer to http://www.ngsp.org/.

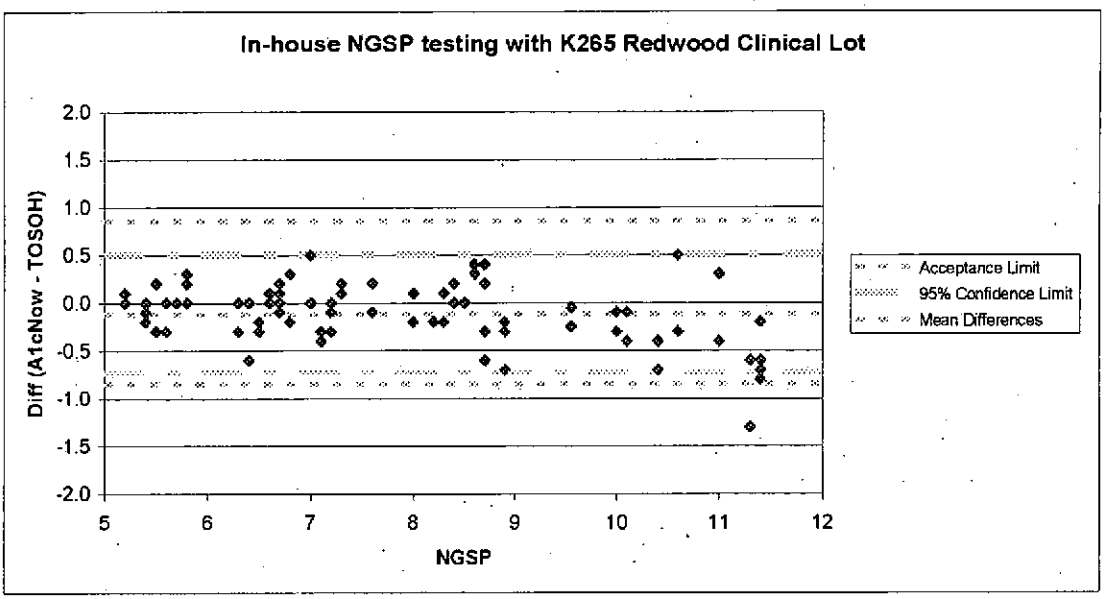
At the time the Sampler studies were conducted, the NGSP requirement was still 95% of the results within +/-1%; the chart in the 510(k) notes the specifications tested at the time. The A1CNow+ device is annually certified, and the A1CNow+ with the new Sampler was part of the NGSP certification conducted in July 2008, under the new requirements of 0.85%. Please see Attachment 1 for the NGSP certificate from July 2008. We will re-certify our product again in July 2009.

In order to evaluate the performance of A1cNow with the modified formulation, the LN A806035 (K265) lot was tested with heparin whole blood samples according a modified NGSP protocol. According to the standard NGSP testing procedure, 40 samples should be tested on a single instrument in 5 different days (test 8 samples per day). In our modified protocol for this study, samples were tested with 16 different instruments (monitors) in a single day. Other than this change, the procedure is the same as the standard NGSP protocol. Venous whole blood samples collected in heparinized tubes were distributed over a clinical range as follows:

- 8 samples from 4-6%A1c
- 12 samples from 6-8%A1c
- 12 samples from 8-10%A1c
- 8 samples from 10-12%A1c

Each specimen was analyzed in duplicate using A1CNow+. Using in-house NGSP-certified TOSOH as the reference method, the results were within the NGSP assessment of agreement criteria for Manufacturer Certification of ± 0.85 %HbA1c.

Mean Difference	sd	Lower 95% CI	Upper 95% CI
-0.12	0.31	-0.73	0.50



3. You state that you have performed accelerated stability studies. Please clarify if real time studies are occurring. If so, what time point are you at now? Please comment on the results-to-date of the real time study.

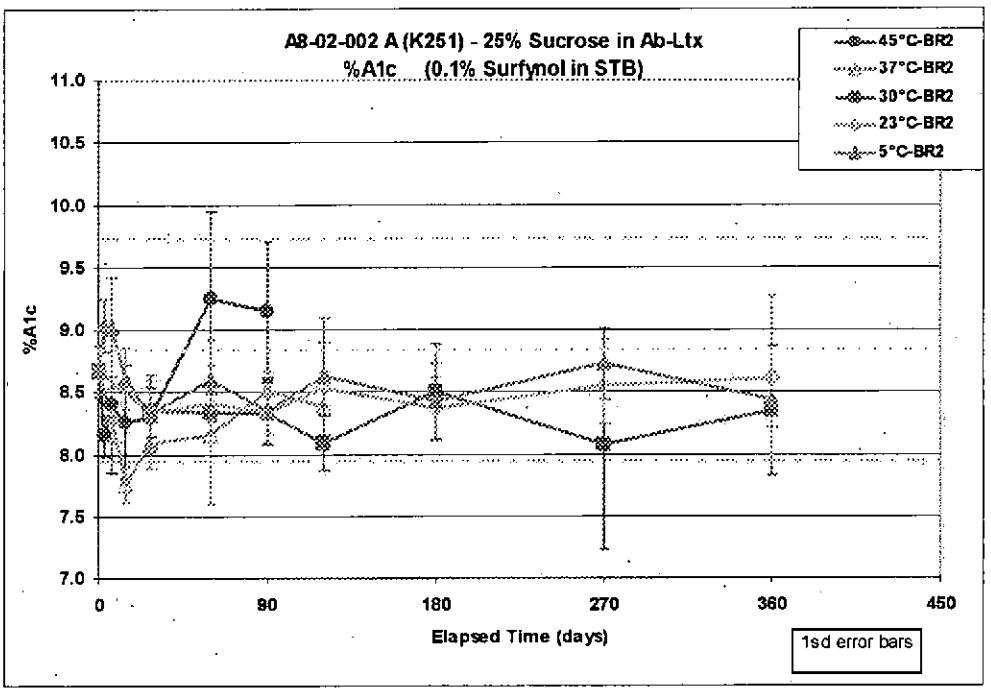
Four lots of A1CNow cartridges are currently under evaluations. Those lots are K251, K264, K265 and K266. The exact testing checkpoints varied slightly between the 4 studies, but generally are scheduled at 1, 2, 4, 8, 13, 20 and 26, 39, 52, 65 and 78 weeks (actual test dates are provided below). Testing of the 45°C stressed samples occurred at each checkpoint through 13 weeks and testing of 37°C stressed samples began at 1 or 4 weeks and continued through 20 weeks.

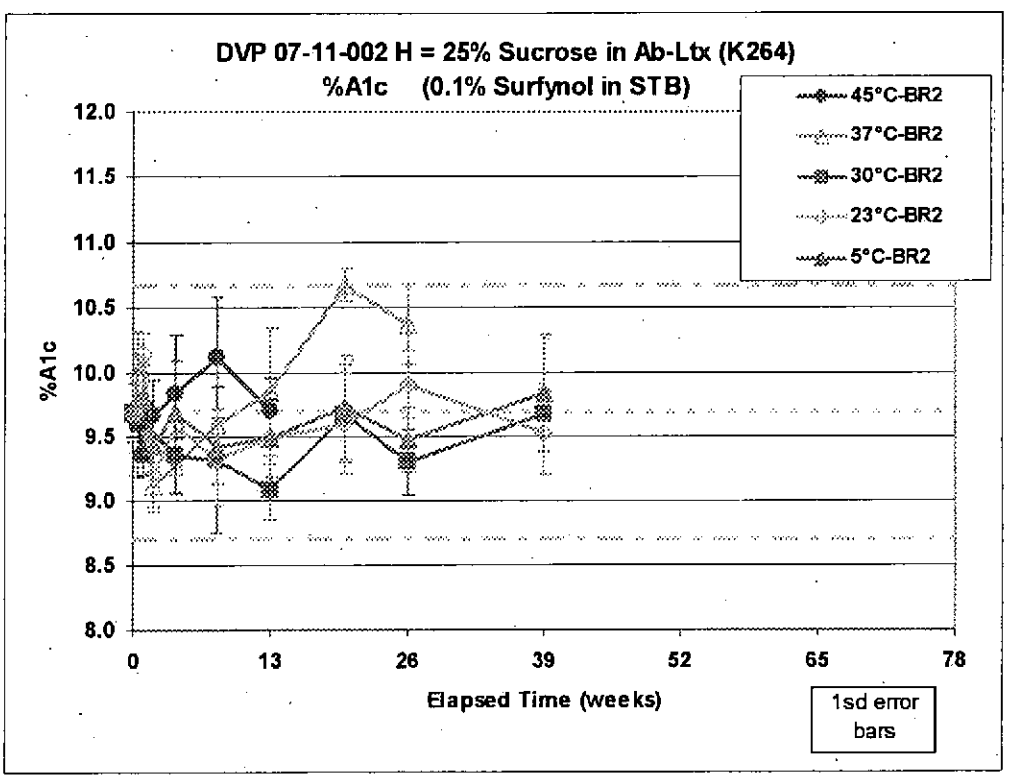
	Initial Stability	3 Days	7 Days	14 Days	30 Days	60 Days	90 Days	120 Days	180 Days	270 Days	360 Days	450 Days	540 Days		
K251	3/13/2008	03/16/08	03/20/08	03/27/08	04/12/08	05/12/08	06/11/08	07/11/08	09/09/08	12/08/08	03/08/09	06/06/09	9/10/2009		
	Initial Stability	1 Day	2 Days	4 Days	7 Days	2 Wks	4 Wks	8 Wks	13 Wks	20 Wks	26 Wks	39 Wks	52 Wks	65 Wks	78 Wks
K264	6/2/2008	06/03/08	06/05/08	06/08/08	06/15/08	06/16/08	06/30/08	07/28/08	09/01/08	10/20/08	12/01/08	03/02/09	06/01/09	08/31/09	11/30/09
K265	6/2/2008	06/03/08	06/05/08	06/08/08	06/15/08	06/16/08	06/30/08	07/28/08	09/01/08	10/20/08	12/01/08	03/02/09	06/01/09	08/31/09	11/30/09
K266	6/2/2008	06/03/08	06/05/08	06/08/08	06/15/08	06/16/08	06/30/08	07/28/08	09/01/08	10/20/08	12/01/08	03/02/09	06/01/09	08/31/09	11/30/09

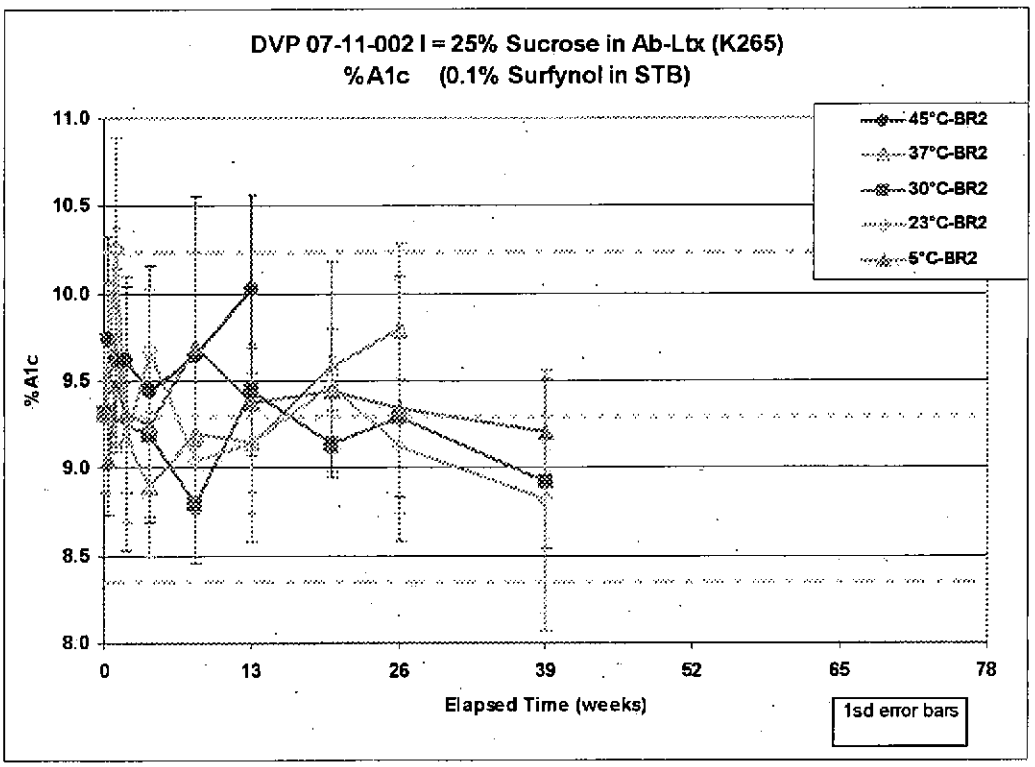
Highlight Indicates Completed testing

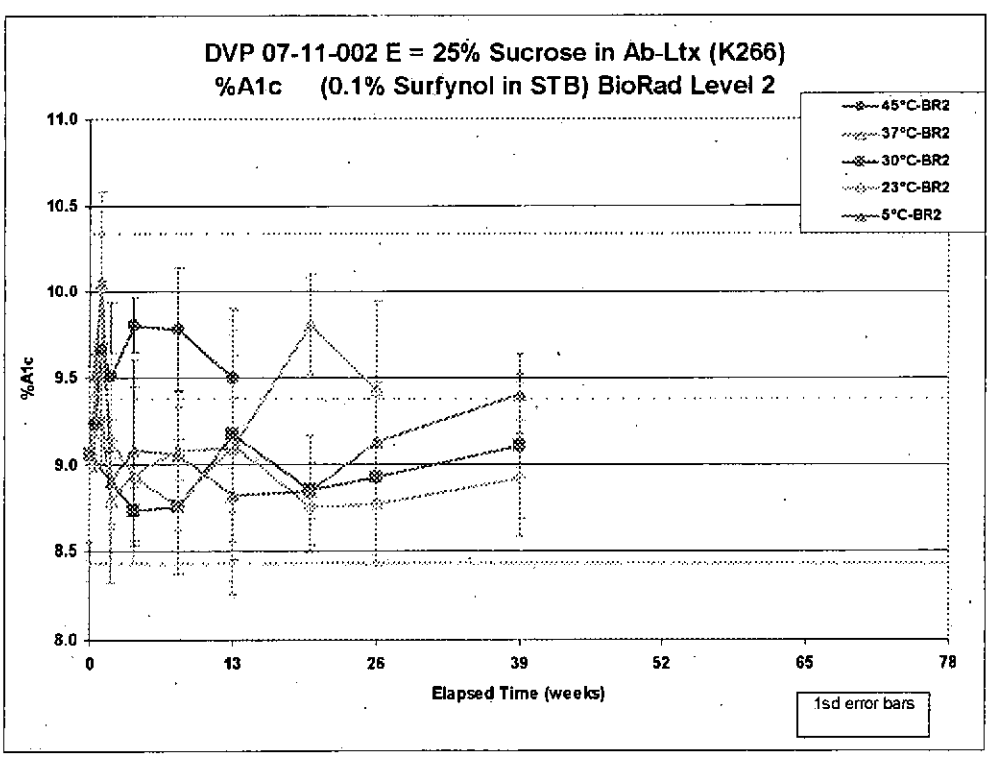
Allowing for statistical uncertainty in each time/temperature measurement, the limits are ±10.14% of the initial value.

The following charts provide a summary of the data collected to date:









4. Please describe how the change in formulation of your reagents impacted the pre-set calibration manufacturing process for your meter. Specify if the changes resulted in how you set your calibration parameters or changed the manufacturing of the meters. Describe those changes and the validation/verification activities.

The change in the reagent formulation did not require any changes to the HbA1c calibration process beyond the change in the reagents used (strip and diluent formulation). Each lot of cartridges and associated meters goes through a calibration process with human whole blood samples to establish the specific calibration coefficients required. These coefficients are then uploaded into the meter to be packaged with that lot of cartridges. Once all the cartridges sold with each meter are consumed, the monitor will not perform additional tests.

5. You state that you performed an ease-of-use study for the modified sample collector but did not include details of your validation or verification activities. Please provide a detailed summary which includes the age, educational background and any other pertinent demographic information.

The validation study (DVR-07-01-002) is summarized in Section 4, Table A, under verification/validation testing for the "Sampler." Further details on this study are provided below.

SUMMARY OF DVR-07-01-002

A1CNow+™ with the integrated sampler, was evaluated at three clinical sites (see chart below for site information) for accuracy with three distinct lots. For precision testing, an abbreviated NGSP (National Glycohemoglobin Standardization Program) protocol was performed in which two frozen samples were tested sixteen times a day for five days. Two lots of A1CNow+ were tested. From these data, precision estimates of percent coefficients of variation (%CVs) were calculated.

For the accuracy phase of the study, approximately 40 subjects at each site performed one A1CNow+ test on themselves solely by following the written instructions after watching a short three-minute video. The subjects were mostly people with diabetes, but some non-diabetics were included in order to evaluate the lower end of the test's dynamic range.

Self-testing was performed first, and then site personnel performed a second A1CNow+ test on the subjects using a new fingerstick sample, a new reagent cartridge (same lot), and the same monitor. After both A1CNow+ tests were performed, one tube of venous blood was collected from each subject, and this sample was processed, transported to Metrika, and tested within five days of collection by the Tosoh A1C 2.2 Plus system (Tosoh Bioscience, South San Francisco, CA). The Tosoh system at Metrika is certified by the NGSP as a Level II A1C method, and lab personnel were blinded to the A1CNow+ results.

As this is a home-use test as well as a professional-use test, subjects were asked to complete quizzes and questionnaires. The quizzes assessed comprehension of the procedural steps and

result interpretation, and the questionnaires allowed the subjects to voice their opinions regarding the simplicity/complexity of the test, and ease-of-use issues.

A1CNow+ CLINICAL SITE INFORMATION

SITE #	LOCATION	# ENROLLED
1	Fairfield, NJ	40
2	Minneapolis, MN	39
3	Concord, CA	38

Subject/Sample Accountability

Site Identification	# Enrolled	Subjects/Samples Excluded from Data Analyses (reasons)	# Evaluated
Fairfield, NJ	40	• ID 1.133 and 1.137 (variant hemoglobin; all data excluded) • ID 1.123, no venous blood drawn	Self vs Ref = 37 Pro vs Ref = 37 Self vs Pro = 38
Minneapolis	39	• ID 2.201 (variant hemoglobin, all data excluded) • ID 2.233, no venous blood drawn	Self vs Ref = 37 Pro vs Ref = 37 Self vs Pro = 37
Concord	38	• ID 3.312 (self test result OR1)	Self vs Ref = 37 Pro vs Ref = 37 Self vs Pro = 37
Total	117	6	Self vs Ref = 111 Pro vs Ref =112 Self vs Pro = 112

Demographic Summary

	Site 1	Site 2	Site 3	Total
Gender				
Males	15	19	22	56
Females	25	20	16	61
Total	40	39	38	117
Age (years)				
Minimum	19	17	19	17
Maximum	77	71	79	79
Median	53	43	51.5	
Ethnicity				
American Indian		2		2
Black	2	3	2	7
Caucasian	35	32	27	94
Hispanic/Latino	3	1	6	10
Asian		1	1	2
Caribbean				
Pacific Islander			1	1
Unknown/Declined			1	1
Total	40	39	38	117
Education				
Grade School	1	1		2
High School	17	4	8	29
Some college, 2-yr degree, vocational	16	18	17	51
4-yr degree, post grad	5	16	13	34
Unknown/Other	1			1
Total	40	39	38	117
Diabetes Status				
Type 1	6	8	11	25
Type 2	31	27	23	81
Non-diabetic	3	4	4	11
Total	40	39	38	117

The study included wide ranges of demographic factors, including educational levels, where no more than 29% attained advanced education defined as a 4-year baccalaureate degree or beyond.

6. I have received on CD the predicate and proposed labeling for the OTC device. You have only provided the proposed professional labeling. Please send an electronic copy of the predicate professional labeling. Please also resend an electronic copy of the proposed professional labeling, OTC labeling and quick user's guides for both highlighting the sections that have been revised.

OTC Labeling
I have included electronic copies of the OTC labeling and quick user guide, with sections highlighted that have been revised, in Attachment 2. Please note the following changes in the OTC labeling (items identified on attached labeling):

Overview and Helpful Hints

Item #	Predicate	Modified
1	Capillary blood	Whole blood
2	Tel # changed	Tel # changed
3	Notes to keep control over blood glucose levels	No note
4	Note to phone/mail results to professional	No note
5	Notes "an" A1C Test	2 tests
6	Kit content- contains test dilution kit	Contains Shaker (AKA Sampler in professional version), also notes DVD included
7	Relationship of A1C to average plasma glucose levels in overview and helpful hints	This information now appears on outside of OTC box*
8	Includes clinical study information	Information not included
9	No temperature label	Includes info on temperature label
10	No DVD	Recommends watching DVD
11	No warning	Warns not to handle white circle area of cartridge
12	10 QC/QR codes noted	13 notes under QC/QR section
13	Sampler information included	Shaker information included
14	Lancet disposal question and answer	Lancet disposal info under general question of what should be done with test when completed

*Copy of OTC box graphics included in Attachment 2 for reference

Quick Reference Guide

Item #	Predicate	Modified
1	Notes to complete test in 15 minutes	Notes that cartridge should be used after opening in 2 minutes
2	Steps for how to prepare sample with test dilution kit	Steps for use of Shaker

Professional Labeling

As noted in my previous e-mail communications, the current professional labeling was reviewed and accepted under the CLIA process last year. The review was triggered by a name change to our product (from "InView" to "A1CNow+"), and was added as Amendment 2 to K051321. Yung Chan from the FDA led the review; the official Bayer correspondent at that time was Witney McKiernan. Witney sent Yung a copy of our updated product insert (PI) to include in the CLIA file at that time. The CLIA record for this change can be found at:

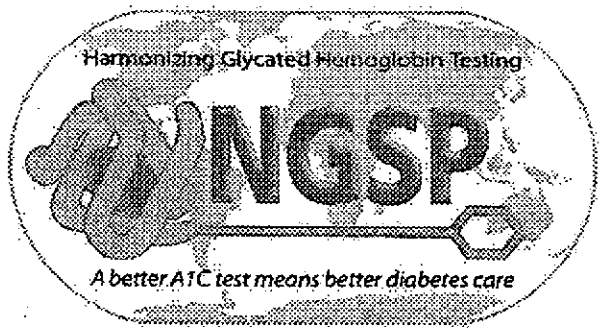
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Detail.cfm?ID=8595

Regarding your point about whether the change in collection tube type warrants a new 510k for the professional use of the A1cNow device- this was addressed during the above CLIA review. After further discussion with the FDA, on 2/15/2008, Yung Chan provided the following response via e-mail: "We decided that you do not need to file a 510(k) submission now since your heparin samples were NGSP certified; however, we think you should put your heparin comparative testing with NGSP method in your package insert since you are recommending heparin sample now."

Accordingly, the heparin comparative testing with NGSP method was added to our package insert to finalize the CLIA review (see "A1CNow+ Venous Comparative Testing" section of the A1CNow+ professional product insert provided in K090413).

7. You have not provided any information on the quality control material used with this device. Please describe if there have been any changes to quality control value assignments or QC shifts due to these changes. Please provide a comparison of the current QC ranges with the proposed QC ranges for the candidate device.

Bayer does not produce quality control material for the device. We recommend and assign ranges for control materials made by three manufacturers: BioRad, Thermo Fisher, and Nova One. We have found that results with these materials using the modified product fall within the same ranges established with the predecessor product and no significant shifts occur. Therefore, it is not necessary to reassign ranges for the modified product.



Certificate of Traceability

Manufacturer Certification

This certifies that ***Bayer HealthCare LLC***, using ***A1CNow+*** has participated in and successfully completed the NGSP certification for manufacturers and is traceable to the **Diabetes Control and Complications Trial** Reference method. The comparison was performed with: **University of Minnesota SRL#8**

The system evaluated was:

Instrument: **A1CNow+**
Reagent Lot: **K250, LN 0804905**

Date of Certification: July 1, 2008 Certification Expires: July 1, 2009

David Sacks
NGSP Steering Committee Chair

Randie R Little PhD.
NGSP Network Coordinator

SRL director/ supervisor

NGSP Administrative Core

University of Missouri School of Medicine
1 Hospital Drive M767 • Columbia, MO 65212 • (573) 882-1257 • Fax (573) 884-8823
E-mail: ngsp@missouri.edu Web site: http://www.ngsp.org

June 23, 2008

Jennifer Knaebel
Bayer HealthCare LLC
510 Oakmead Parkway
Sunnyvale, Ca 94085

Dear Ms. Knaebel,

Congratulations! We are pleased to inform you that Bayer HealthCare LLC has successfully completed the NGSP **Manufacturer** certification for the following methods:

Instrument:
A1CNow+
Reagent Lot:
K250, LN 0804905

The above method is now considered traceable to the Diabetes Control and Complications Trial (DCCT) Reference Method. Enclosed is a certificate of traceability for this method.

Following is a summary of the method comparison results. Detailed method comparison evaluation reports are also enclosed for your information.

Method	Assessment of Agreement CI; lower 95%, upper 95% (limit ±0.85%)
A1CNow+	-0.79, 0.47

Column 2, Assessment of Agreement CI of diff, lower and upper 95%; (limit ±0.85%): 95% Confidence Interval of the differences between methods (test method vs. SRL) must fall within the clinically significant limits of ±0.85% GHB for manufacturer methods and Level II Laboratory methods, ±0.75% for Level I Laboratory methods. **Your method's results were within the NGSP assessment of agreement criteria for Manufacturer Certification.**

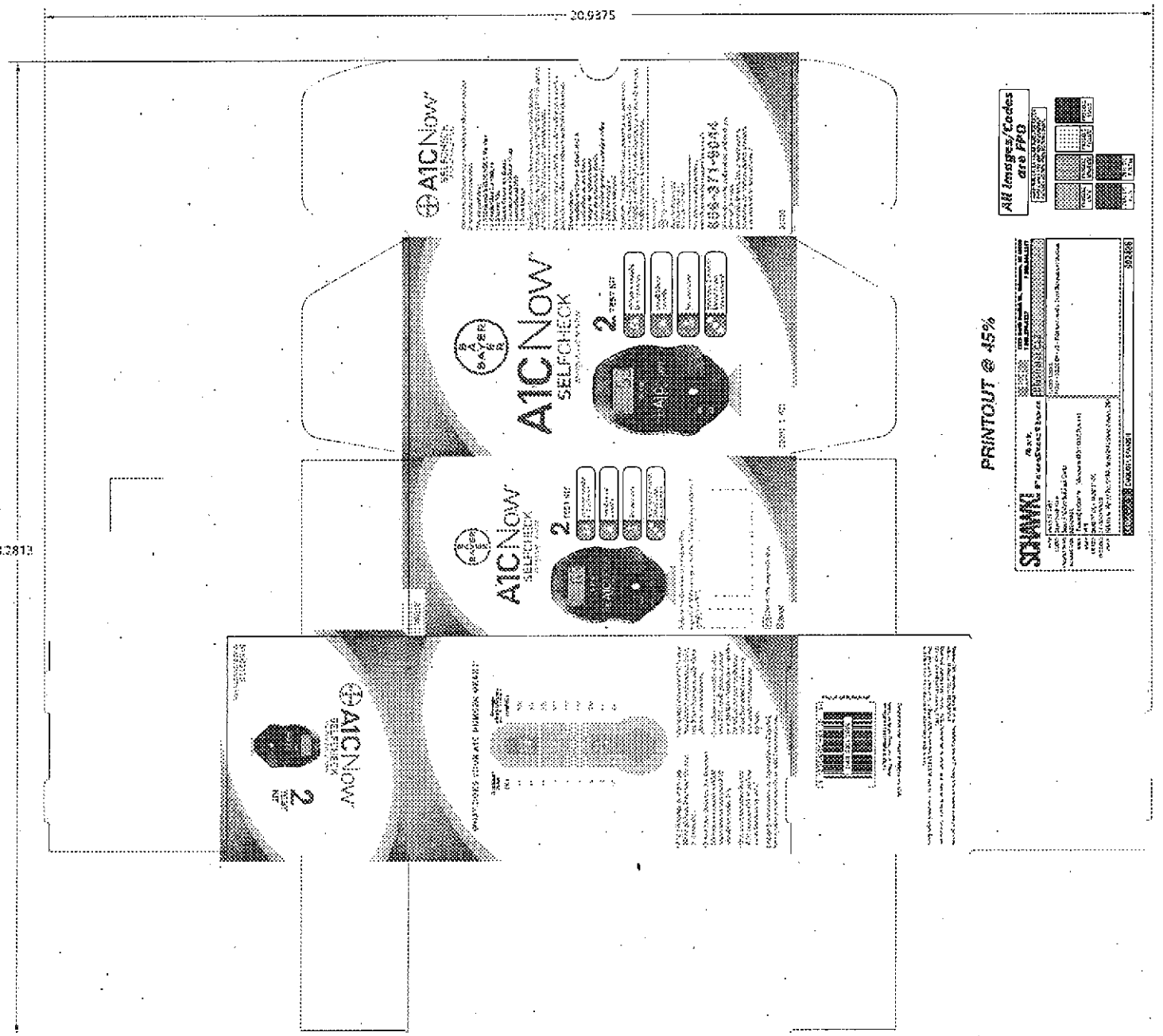
This certification is effective for one year and will expire on July 1, 2009. All data for next year's certification should be received by May, 2009.

If you have any questions about any of the data, please feel free to call. If you or your customers would like updated information about the NGSP (including a list of certified methods and laboratories) they can visit our web site at **www.ngsp.org**

Sincerely,

Randie R Little PhD.

Randie R. Little, Ph.D.,
NGSP Network Coordinator



A1CNow®, SELFCHECK At-Home A1C System
OVERVIEW AND HELPFUL HINTS

INTENDED USE
The A1CNow® SELFCHECK test provides quantitative measurement of the percent of glycated hemoglobin (%A1C) levels in capillary (fingerstick) blood samples. The test is for home use to monitor glycemic control in people with diabetes.

Before using this test, please read all instructions carefully. If you need help, call XXX-XXX-XXXX. We invite you to call and we will walk you through the test.

INTRODUCTION
The percent (%) of A1C in your blood today tells you how well you have been controlling your glucose levels over the past 2-3 months. About 50% of the A1C result is from the past 30 days of glucose levels; about 25% is from the past 30-60 days and about 25% is from the past 60-90 days.[1]

The American Diabetes Association (ADA) recommends that you test your A1C levels at least 2 times per year if your blood sugar target range is stable. If you are taking insulin, your treatment changes or your blood sugar is too high, the ADA recommends that you test at least every 3 months.[2]

The A1CNow SELFCHECK test is an easy-to-use test to measure your A1C levels at home. By measuring your levels at home, you can be better informed prior to your doctor visits and feel more in control of your diabetes.

KIT CONTENT
The box contains materials for two A1C tests. Make sure all of the following parts are in the box. DO NOT open the pouches until ready to use.

- A1CNow SELFCHECK Monitor (1)
- Cartridge Pouch (2)
- Shaker Pouch (2), each containing:
  - Shaker (1)
  - Blood Collector (1)
  - Lancet, disposable (1)
- Extra lancets (1)
- Quick Reference Guide (1)
- Instructional DVD (1)
- Overview and Helpful Hints (1)

PREPARING TO TAKE THE TEST
You may take your fingerstick blood sample and do your A1C test any time of the day. No special diet is necessary (you do not have to be fasting when taking this test). You may want to do this test at the same time as you do a blood glucose test.

Avoid running the test in direct sunlight, on hot or cold surfaces or near sources of hot or cold. If the test has recently been at high temperatures (greater than 82° F or 28° C) or at cold temperatures, allow the kit parts to come to room temperature (64°-82° F or 18°-28° C) for at least one hour before you do your test. Leave the parts in their sealed pouches while waiting.

WHAT TO DO WITH THE RESULT
The Monitor will not store your result in memory, so write down the result and the test date on the log page on your Educational Information as soon as possible to prevent loss of information.

WHAT THE TEST RESULT MEANS
Your A1C result shows your overall glucose control over the last 2-3 months. The ADA recommends a goal of 7% or lower and suggests action when the A1C level is above 8%.[3] Your health care professional will tell you what level is right for you.

HOW DOES THIS TEST COMPARE WITH THE A1C TEST FROM THE DOCTOR'S OFFICE OR THE LABORATORY?
The A1CNow SELFCHECK test is annually certified by the National Glycohemoglobin Standardization Program (NGSP). The American Diabetes Association (ADA) recommends that A1C tests be certified by the NGSP. For information about NGSP certified methods, please visit the website: www.NGSP.org.

STORAGE
- Store at room temperature (below 82° F or 25° C). Do not freeze.
- DO NOT use the test after the expiration date shown on the box.
- If the temperature label, placed on the outside of the kit is exposed to a temperature in excess of

122°F/50°C, the dot on the label will turn red and the product should not be used.

WARNINGS AND PRECAUTIONS

- Leave the Cartridge Pouch sealed until ready for use.
- Carefully read and follow the Quick Reference Guide and watch the DVD to ensure proper test performance.
- DO NOT reuse the Shaker or the Cartridge. Throw these parts away after using them once.
- DO NOT use the test kit if any parts are cracked or broken.
- **DO NOT adjust your medication unless instructed to do so by your doctor or health care professional.**
- DO NOT substitute this test for glucose monitoring.
- DO NOT eat or drink any parts of this kit.
- If the solution from inside the Shaker touches your skin or your eyes, flush with water.
- For use outside of the body only (in-vitro diagnostic use).
- People with hemophilia (bleeding disorder) or on anti-coagulant therapy (blood thinning medicine) should consult their doctor or health care professional before using this kit.
- Keep out of reach of children under the age of 7 years. When children are performing the test, be sure that testing is done under adult supervision.
- DO NOT use any other body fluids or food to perform this test. Use ONLY your fingerstick blood sample.
- DO NOT add your blood directly to the cartridge. Your blood must first be added to the Shaker.
- DO NOT handle the white circle area of the Cartridge.

LIMITATIONS

- This test is NOT for the screening or diagnosis of diabetes.
- This test is to be used at temperatures between 64° and 82° F (18° and 28° C). Using the test outside this temperature range will give you an error code.
- This test is not a substitute for regular visits to your health care professionals or for monitoring your glucose levels.
- If you have high levels of hemoglobin F, S or C (or any other variant hemoglobin) you may get incorrect results.
- If you have hemophilia or are on anticoagulant therapy, talk to your doctor before using this test.

TROUBLESHOOTING

See the table below for a description of A1CNow+ operating and error codes (OR =Out of Range; QC = Quality Control, E= Monitor Error).

Check Code	Description and Recommended Action
OR 1	The blood sample may have too little hemoglobin for the test to work properly. Or you added too little blood. Call customer service.
OR 2	The blood sample may have too much hemoglobin for the test to work properly, or you added too much blood. Call customer service.
OR 3	The blood sample may have too little Hemoglobin A1C for the test to work properly, or you added too little blood. Call customer service.
OR 4	The blood sample may have too much hemoglobin A1C for the test to work properly, or you added too much blood. Call customer service.
OR 5	The Monitor temperature is below 18°C (64°F). The test must be repeated with a new kit at room temperature (18-28°C).
OR 6	The Monitor temperature is above 28°C (82°F). The test must be repeated at room temperature (18-28°C).
<4.0	The %A1C is less than 4%. Call your doctor.
>13.0	The %A1C is greater than 13%. Call your doctor.
QC 2	Occurs when you insert a Cartridge that already has sample added to it. Do not remove and reinsert a Cartridge after adding sample.
QC 6	Sample was added to Cartridge before "SMPL" display. This counts down one test on the Monitor. Remove and discard Cartridge. To avoid this error, do not add sample until the "WAIT" prompt clears and "SMPL" appears.
QC 7	The Cartridge remained in the Monitor without sample addition for 2 minutes after "SMPL" prompt. This counts down one test on the Monitor. Discard the Test Cartridge and insert a fresh one when you are ready to dispense the Shaker.
All other QC Codes	The quality control checks inside the Monitor did not pass. The test will need to be repeated with another kit. Call customer service.
E	The Monitor is not working. This is a fatal error. Call customer service.

Customer Service: XXX-XXX-XXXX

DISPOSAL OF MATERIALS

Throw away all the kit part (except the Lancet) in your daily household waste. The Lancet, Shaker, Blood Collector and Cartridge can be used only once. The Monitor may be used again, if you purchased a 2-test kit.

Since the Lancet has a sharp point it should be disposed of in an appropriate sharps container in the same way you dispose of your glucose testing lancets.

FREQUENTLY ASKED QUESTIONS

When should I do the A1CNow SELFCHECK test?

The A1CNow SELFCHECK test can be performed at any time of day. No fasting is required. You may wish to do the test at the same time you do your glucose test.

My Lancet accidentally went off before I pressed it against my finger. What should I do?

There is one extra Lancet included in the box. You should use that one.

Sometimes I have trouble getting a blood drop that is large enough. What can I do?

Try washing your hands in warm water. Warm water will help increase blood flow for a better fingerstick. You may also massage the finger before the fingerstick.

What is the best way to fill the Blood Collector?

Hold the Blood Collector horizontally relative to the blood drop. Touch the tip gently to the drop of blood and allow the tube to fill. It will stop itself when it is filled completely.

My Blood Collector is not filled completely. What should I do?

Apply pressure to your finger to get more blood. Again, touch the tip gently to the drop of blood and allow the tube to fill. You may have to re-stick your finger to get the necessary blood. If the Blood Collector does not fill, call customer service.

There is extra blood on the tip of the Blood Collector. What should I do?

Carefully wipe the tip of the Blood Collector with a piece of gauze or tissue. If some of the blood comes out while doing this, touch the tip gently to the blood drop to re-fill the Blood Collector.

The Shaker seemed to leak when I pushed the Blood Collector into it. What should I do?

Call customer service.

The Cartridge will not insert into the Monitor. What should I do?

Make sure you are inserting Cartridge right side up with the Shaker well and the Test Code on top. Also, be sure the Cartridge is facing the right way. You should be able to read the Test Code as you insert the Cartridge into the Monitor.

I accidentally opened the Cartridge pouch too early. What should I do?

You can use the second Cartridge in the kit. Do not use the already opened Cartridge. Throw away the Cartridge that has been opened too long.

The Test Codes on the Cartridge and the Monitor do not match. What should I do?

Do not use the Cartridge. Save the packing materials and call customer service.

The Monitor did not turn on after I inserted the Cartridge. What should I do?

Take the Cartridge out. Re-insert in until it 'clicks'. If the Monitor still does not turn on, this means that it may have a problem and can't be used. Call customer service.

I did not see 'RUN' and a countdown after I added the sample using the Shaker. What should I do?

Call customer service.

My result says 'QCOK' and a number. What should I do?

'QCOK' means the Monitor is working correctly. The number you see is your A1C result. Write your result down in the result log in the Quick Reference Guide. Review your result with your Health Care Professional.

The A1CNow SELFCHECK test does not match the result my doctor got from the laboratory. Why is this?

Test results will rarely match exactly. This is true even for tests done in the same lab. The A1CNow SELFCHECK is certified by NGSP. 95% of the time, certified A1C results are expected to be within +/- 0.85% range of the true result. Your difference in

A1C results may be due to: slight differences between labs, normal variation within each test and the time between two tests.

My result is not 'QCOK' and a number. What should I do?

Refer to the troubleshooting section. You can also call customer service.

What should I do with the test after I am done with it?

After you write down your result, you can throw away the used Blood Collector, Shaker and Cartridge in your daily household trash. These items can be used only once. Save the Monitor for your second test. Once you used the second test, you can throw away the Monitor in your daily household trash. Note that the Lancet is also a single-use item and should be disposed of in a sharps container.

QUESTIONS OR COMMENTS
Call customer service at XXX-XXX-XXXX

Bayer HealthCare, LLC
510 Oakmead Parkway
Sunnyvale, CA 94085-4022
tel XXX-XXX-XXXX
fax XXX-XXX-XXXX
www.A1CNow.com

90867-00 TEXT

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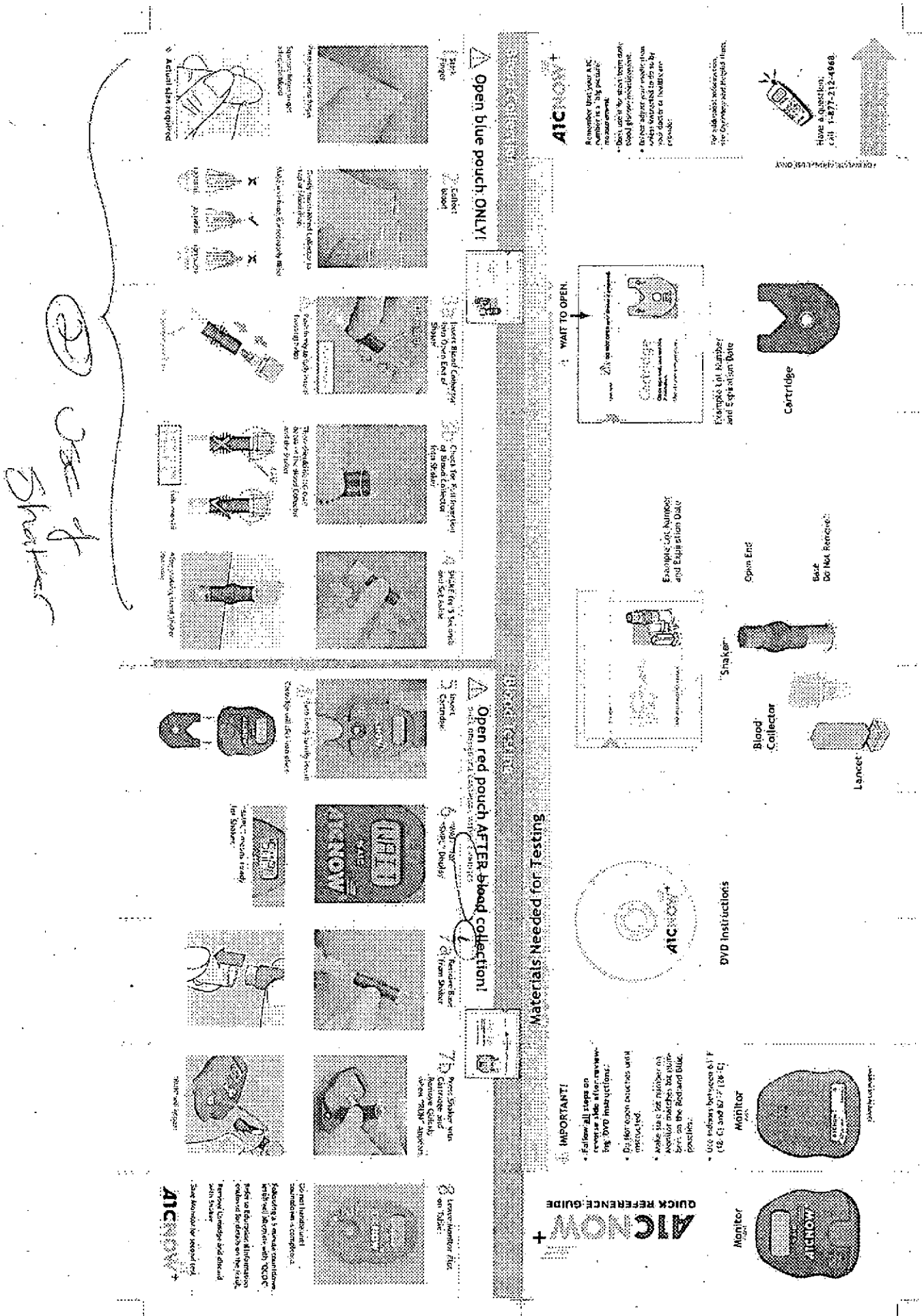
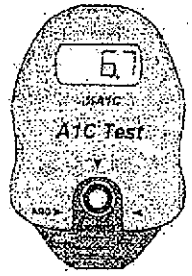
[1] Burtis, C.A., Ashwood, E.R., Tietz Textbook of Clinical Chemistry, 3rd Edition, W.B. Saunders Co., 1999
[2] www.diabetes.org
[3] www.diabetes.org



METRIKA A1cNow

A1C Home Test Overview & Helpful Hints

Supplemental Information



For the Quantitative Measurement of the Percent of Glycated Hemoglobin (%A1C) Levels in Whole Blood. For Home Use by People with Diabetes to Monitor Glycemic Control. Need help? Call 1-877-212-4998.

BEFORE USING THIS KIT, PLEASE READ ALL THE DIRECTIONS CAREFULLY.

INTRODUCTION

The percent (%) of A1C in your blood today tells you how well you have been controlling your glucose levels over the past 2-3 months. About 50% of the A1C result is from the past 30 days of glucose levels; about 25% is from the past 30-60 days; and about 25% is from the past 60-90 days[1]. It is important to keep control over your glucose levels so you lower the risks of getting diabetes-related problems for example, blindness and circulatory problems) in the future.

The American Diabetes Association (ADA) recommends that you test at least 2 times per year if your blood sugar target range is stable. If you are taking insulin, your treatment changes or your blood sugar is too high, the ADA recommends that you test at least every 3 months.

A1C Home Test is an easy-to-use test to measure your A1C levels at home. By measuring your levels at home, you can have this information ready before you have your checkups. Also, you can phone or mail your results to your health care professional.

WARNINGS AND PRECAUTIONS

- *Leave the A1C Test Cartridge (Pouch 2) sealed until ready to use.*
- *DO NOT reuse the Sample Dilution Kit or Test Cartridge. Throw all these parts away after you use them once.*
- *DO NOT use the test kit if any parts are cracked or broken.*
- *DO NOT adjust your medication unless instructed to do so by your doctor.*
- *DO NOT substitute this test kit for glucose monitoring.*
- *DO NOT eat or drink any parts of this kit.*
- *If yellow solution touches eyes, flush with water.*
- *For use outside of the body only (in vitro diagnostic use).*
- *People with hemophilia (blood clotting disease) or on anticoagulant therapy (blood thinning medicine) should consult their doctor or health care professional before using this kit.*
- *Keep out of reach of children under the age of 7 years. When children are performing this test, be sure that testing is done under adult supervision.*
- *DO NOT use any other body fluids or food to perform this test. Use ONLY your fingerstick blood sample.*
- *DO NOT add your blood directly to the Test Cartridge. Your blood must first be added to the tube.*
- *Refer to the enclosed Quick Start Guide for step-by-step directions for using this test kit.*

STORAGE

- *Store at room temperature (below 82°F or 28°C - Do not freeze)*
- *DO NOT use the test after the expiration date shown on the box.*

KIT CONTENTS

This box contains materials for one A1C test. Make sure all of the following parts are in the box. DO NOT open the pouches until ready to use.

- *A1C Home Test Monitor*
- *Quick Start Guide with A1C Result Log*
- *One time use Lancet*
- *Sample Dilution Kit (Pouch 1), containing Tube, Affixed to the other side in a plastic bag are: Blood Collector, Sample Dropper, and Tube Holder.*
- *A1C Home Test Cartridge (Pouch 2)*

PREPARING TO TAKE THE TEST

You may take your fingerstick blood sample and do your A1C test at any time of day. No special diet is necessary (you do not have to be fasting to do this test). You may wish to do this test at the same time you do a glucose test.

Avoid running the test in direct sunlight, on hot or cold surfaces, or near sources of heat or cold. If the test kit has recently been at high temperatures (greater than 82°F or 28°C) or at cold temperatures, allow the kit parts to come to room temperature (64°-82°F or 18°-28°C) for at least one hour before you do your test. Leave the parts in their sealed pouches while doing this.

WHAT TO DO WITH THE RESULT

Write down your result, the test date, and your kit's lot number from the outside of the A1C Home Test box on the Result Log as soon as possible to prevent loss of information.

You and your health care professional should review your test result and discuss your goals.

WHAT THE TEST RESULT MEANS

Your A1C result shows your overall glucose control over the last 2-3 months. The American Diabetes Association recommends a goal of 7% or lower, and suggests action when the A1C level is above 8%. Your health care professional will tell you what level is right for you.

RELATIONSHIP OF A1C TO AVERAGE PLASMA GLUCOSE LEVELS

Studies show a direct relationship between your A1C and your average or mean plasma glucose (MPG) levels. For every 1% change in A1C there's a change of about 35 mg/dL in MPG[2]. Refer to the chart below to find your approximate average plasma glucose value from your A1C result[2]. DO NOT change your diabetes management program without your doctor's approval.

A1C %:	Mean Plasma Glucose (mg/dL)	Interpretation
[illegible]	[illegible]	[illegible]
7	170	ADA Target for Diabetes in Control
[illegible]	[illegible]	[illegible]

OTHER RESULTS/TROUBLESHOOTING

If you get a message on the display of your Monitor with letters and/or symbols, follow "Reasons/What to Do" in the table below. If you get a message like those below, you will NOT get a test result number. The A1C Home Test will have to be repeated with another test kit to get your A1C result. Call 1-877-212-4998.

Message	Reasons/What to do
[illegible]	[illegible]
OR1	[illegible]
OR2	*Your blood sample may have too much hemoglobin for the test to work properly. Or, you added too much blood. Call Metrika for assistance.*
[illegible]	[illegible]
OR4	*Your blood sample may have too much hemoglobin A1C for the test to work properly. Or, you added too much blood. Call Metrika or your doctor.*
[illegible]	[illegible]
OR6	*The Monitor temperature is above 82°F (28°C). The test must be repeated with a new kit at room temperature (64°-82°F or 18°-28°C).*
[illegible]	[illegible]
>13.0	*Your A1C is greater than 13%. Call your doctor.*
[illegible]	[illegible]
E	*The Monitor is not working. This is a fatal error, call Metrika. The Monitor needs to be replaced.*

Over

Information No. 11-2010

METRIKA

A1cNow™

A1C Home Test Overview & Helpful Hints

DISPOSAL OF MATERIALS

Recap the Tube. Throw away all the kit parts (except the Lancet) in your daily household waste. The Sample Dilution Kit and Test Cartridge can be used only once. The Monitor may be used again if you purchased a 2-test kit.

Since the Lancet has a sharp point, it should be disposed of in an appropriate sharps container in the same way that you dispose of your glucose testing lancets.

TEST LIMITATIONS

- This test is NOT for the screening or diagnosis of diabetes.
- A1C Home Test is to be used at temperatures between 64° and 82°F (18° and 28°C). Using the test outside this temperature range will give you an error code.
- This test is not a substitute for regular visits to your diabetes health care professional(s), or for monitoring your glucose levels.
- If you have high levels of Hemoglobin F, S, or C or any other variant hemoglobin), you may get incorrect results.
- If you have hemophilia or are on anticoagulation therapy, talk to your doctor before using this test.

HOW DOES THIS TEST COMPARE WITH THE TEST FROM THE DOCTOR'S OFFICE OR HOSPITAL LABORATORY?

A1C Home Test is NGSP-certified. The American Diabetes Association recommends that A1C tests be certified by the NGSP. For more information about NGSP-certified methods please visit the following website, http://www.ngsp.org

A1C Home Test was compared to an NGSP-certified laboratory method in clinical studies with 189 untrained users. These studies showed that an individual result will fall within -1.2 to +1.1 %A1C from the true result 95% of the time. This study also showed that results obtained by the untrained lay users were the same as results obtained by professionally-trained health care workers.

FREQUENTLY ASKED QUESTIONS

When should I do the A1C Home Test?
The A1C Home Test can be performed at any time of day. You may wish to do the test at the same time you do your glucose test.

My Lancet accidentally went off before I pressed it against my finger. What should I do now?
You may use the lancet that you normally use for glucose testing, or you may call Metrika for a replacement Lancet.

Sometimes I have trouble getting a blood drop that is large enough. What can I do?
Try washing your hands in warm water. Warm water will help increase blood flow for a better fingerstick. You may also massage the finger before the fingerstick.

What is the best way to fill the Blood Collector?
Hold the Blood Collector near the bottom of the Bulb (at the top of the flat part). Hold it horizontal to the blood drop. Touch the Tip gently to the blood drop and allow the Blood Collector to fill by itself without squeezing the Bulb. It will stop by itself when it reaches the line. Fill just to the line. DO NOT squeeze the Bulb until you are ready to add your blood to the Tube.

My Blood Collector is not filled to the line. What should I do?
Apply pressure to the finger to get more blood. Again, touch the tip of the Blood Collector to the blood drop until filled to the black line. You may have to re-stick your finger to get the necessary blood. If the Blood Collector does not fill, please call Metrika for help.

There was excess blood on the outside of the Blood Collector. I wiped the blood off, but some of the blood from inside the Tube also came out. Should I still use this blood sample?
Squeeze the remaining blood out of the Blood Collector onto some gauze or a cotton ball. Then refill the Blood Collector up to the black line. You may have to lance your finger again if it is no longer bleeding.

There was blood left in the Blood Collector after I added the blood to the Red Capped Tube. Is this OK?
All the blood should be washed out of the Blood Collector when you squeezed the bulb 2-3 times. A small amount of diluted sample in the Blood Collector is OK. Any blood still in the Blood Collector should be squeezed into the Tube so that your results are accurate.

The Test Cartridge will not go in the Monitor, what should I do?
Make sure you are inserting the Test Cartridge face up, with the word "SAMPLE" showing on the top. Also, make sure the Test Cartridge is facing the right way; you should be able to read "SAMPLE" as you insert the Test Cartridge into the Monitor.

I accidentally opened the Test Cartridge pouch too early. What do I do?
Call Metrika. If you purchased a two-test kit, you can use the second Test Cartridge that came in the kit. Do not use the previously opened Test Cartridge.

The codes on the Monitor and Test Cartridge do not match. What should I do?
Check the lot number on the pouch of the Test Cartridge to see if it matches the lot number on the back of the Monitor. If it does, continue with the test. If it does not, call Metrika for help.

The Monitor did not turn on after I inserted the Test Cartridge, what should I do?
Take the Test Cartridge out. Reinsert it until it comes to a complete stop. If the Monitor still does not turn on, this may mean it has used up all of its available tests (check the lot numbers of your Test Cartridge and Monitor) or the Monitor has had a fatal error and can't be used anymore. Call Metrika for help.

The Sample Dropper does not look like it is filled correctly. What do I do?
If the Sample Dropper looks like the picture that says "Too Little" you can squeeze the liquid back into the Tube and refill it correctly by following the instructions.

There were some bubbles in the Sample Dropper when I added my diluted sample to the test. Is this OK?
A few (3-4) small bubbles are OK. It's normal to see a few small bubbles float to the top of the barrel of the Sample Dropper. If you see a large number of bubbles, call Metrika for help.

I touched the Sample Well with the Sample Dropper when I added my sample and some liquid splashed out. Is the test OK?
Touching the Sample Well with the Sample Dropper may cause splashing of the diluted sample when you add it to the test or you might accidentally pull some diluted sample back up into the Sample Dropper. If you see "OCOK" and a number, enough sample was added and the result is OK.

I did not see "---" and a countdown after I added my diluted sample. What should I do?
Call Metrika for help.

My result says "OCOK" and a number. What should I do?
This means the test is working correctly. The number you see is your A1C result. Write this number down on the Result Log that is part of the Quick Start Guide. Review your result with your healthcare professional.

The A1C Home Test result does not match the result I got from my laboratory. Why is this?
Test results will rarely match exactly — this is even true for tests done in the same lab. A1C Home Test is certified by the national certification body for A1C (the NGSP), and certified A1C tests can differ from the true results by up to ±1% A1C, 95% of the time. Your difference in A1C results may be due to: slight differences between labs, normal variation within each test system, and the time between the two tests.

My result is not "OCOK" and a number. What should I do?
Refer to "Other Results/Troubleshooting" in the "Overview and Helpful Hints". You may also call Metrika for help.

What should I do with the test after I'm done with it?
After you write down your result, recap the Tube and throw everything except the Monitor away in your daily household trash. These items can only be used once.

How should I dispose of the Lancet that came with my test kit?
Since the Lancet has a sharp point, it should be disposed of in an appropriate sharps container in the same way that you dispose of your glucose testing lancets.

REFERENCES

[1] Burtis, C.A., Ashwood, E. R., Tietz Textbook of Clinical Chemistry, 3rd Edition, W.B. Saunders Co., 1999

[2] Diabetes Care 1999; 22 (Suppl 1): S32-S41

Questions or comments?
Call Metrika 1-877-212-4968

Metrika, Inc.
510 Oakmead Parkway
Sunnyvale, CA 94085

King, Christine

From: King, Christine
Sent: Wednesday, March 18, 2009 8:34 AM
To: 'Catherine Peters'
Subject: RE: Questions k090413

Hi Cathy,
Can you please clarify item 2? Is the sampler that was part of the CLIA labeling the same device you are including in this 510k?

So that I can become more familiar with the device history, can you please include the 510k number that the CLIA update from 1/24/08 referenced and also please send the predicate professional use package insert.

Thanks for your help.

Sincerely,
Chris

-----Original Message-----
From: Catherine Peters [mailto:catherine.peters.b@bayer.com]
Sent: Tuesday, March 17, 2009 8:10 PM
To: King, Christine
Subject: Re: Questions k090413

Hi Christine,

Thank you for your thorough review and timely response below. We have begun working on our responses, and hope to send you all of the requested information by COB this Thursday. I have one question for clarification, however. In regards to the professional labeling- I did not submit proposed professional labeling for our device because our labeling content has not significantly changed (except for format/grammatical changes) since it underwent an extensive CLIA review which ended on 1/24/08 with acceptance by the FDA. During this CLIA review, the FDA reviewed professional use labeling which had been revised 1) for clarity and 2) to include information on use of the Sampler and controls (the latter per the FDA's request). With the introduction of the Sampler, this labeling also was updated to recommend heparinized whole blood vs. EDTA whole blood when testing venous samples and to add a "Limitations" for rheumatoid factor.

The professional use labeling which was submitted in this 510(k) is currently used with our device, and we do not have any additional "proposed labeling" at this time for the professional use version. Is a CLIA review and acceptance considered acceptable, or would you like to review our current labeling (in which case, I will send the predicate PI per your request)? Please let me know so that I can proceed accordingly.

Sincerely,

Cathy

Cathy Peters, RAC
Regulatory Affairs Manager
Bayer HealthCare Diabetes Care- A1CNow+
510 Oakmead Parkway
Sunnyvale, CA 94085
Phone: 408-524-2255, ext. 236
Cell: 408-220-4086

"King, Christine"
<Chris.king@fda.hhs
.gov>

03/17/2009 07:34 AM

To Catherine.peters.b@bayer.com

cc

Subject Questions k090413

Hello Ms. Peters,
How are you? I have some questions regarding the special 510k for the AlcNow Multi-Use device. Although you have included some of the information below in your labeling, I need to see more specifics for the review. Because of the shortened review time for specials, please let me know if you cannot send the information before COB Thursday, 3/19/09.

1. You state that you have increased the stability of your device by adding more sucrose and decreasing the surfactant in the striping solution and the sample treatment buffer, respectively. Please provide a more detailed description of the validation and verification activities performed for accuracy, precision, and interference and show the results of the modified device against the predicate. Include the number of samples analyzed, number of replicates and the range of the samples tested in your studies as well as your predetermined acceptance criteria.

2. You state that your accuracy studies met NGSP requirements of 95% of the results within +/-1%. NGSP accuracy requirements are now 0.85% and you need to be sure that your new device still meets NGSP criteria. Please provide validation and verification activities for accuracy which show that your device meets the current NGSP requirements. Please refer to http://www.ngsp.org/.

3. You state that you have performed accelerated stability studies. Please clarify if real time studies are occurring. If so, what time point are you at now? Please comment on the results-to-date of the real time study.

4. Please describe how the change in formulation of your reagents impacted the pre-set calibration manufacturing process for your meter. Specify if the changes resulted in how you set your calibration parameters or changed the manufacturing of the meters. Describe those changes and the validation/verification activities.

5. You state that you performed an ease-of-use study for the modified sample collector but did not include details of your validation or verification activities. Please provide a detailed summary which includes the age, educational background and any other pertinent demographic information.

6. I have received on CD the predicate and proposed labeling for the OTC device. You have only provided the proposed professional labeling. Please send an electronic copy of the predicate professional labeling. Please also resend an electronic copy of the proposed professional labeling, OTC labeling and quick user's guides for both highlighting the sections that have been revised.

7. You have not provided any information on the quality control material used with this device. Please describe if there have been any changes to quality control value assignments or QC shifts due to these changes. Please provide a

comparison of the current QC ranges with the proposed QC ranges for the candidate device.

I may have additional questions or need more clarification based on your responses to the items above. Please don't hesitate to contact me for questions, concerns, or clarifications. Thanks for your help.

Best Regards,
Chris

Christine King, MS, CLS(NCA)
Scientific Reviewer
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240.276.0384
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From: King, Christine
Sent: Wednesday, March 04, 2009 7:24 AM
To: 'catherine.peters.b@bayer.com'
Subject: k090413 Bayer A1CNow Hemoglobin A1C

Dear Ms. Peters,
I am the reviewer assigned to your special 510k k090413. May I please contact you if I have any questions? I look forward to working with you on this submission.

Best Regards,
Chris King

Christine King, MS, CLS(NCA)
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