DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

HOME ACCESS HEALTH CORP.
C/O SANDRA WHITE
ICON CLINICAL RESEARCH LLC.
62 FOREST STREET SUITE 300
MARLBOROUGH MA 01752

March 13, 2015

Re: K141944
Trade/Device Name: Home Access® A1C Test
Home Access® Collection Cassette
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: II
Product Code: LCP, JKA
Dated: February 6, 2015
Received: February 9, 2015

Dear Ms. Sandra White:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Katherine Serrano -A

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141944

Device Name
Home Access® A1C Test
Home Access® Collection Cassette

Indications for Use *(Describe)*
The Home Access® A1C Test is an in vitro test method for the quantitative measurement of Hemoglobin A1c using capillary blood collected from the fingertip, collected onto filter paper via the Home Access collection cassette. The Home Access A1C Test is for measurement of HbA1c on blood specimens which can be collected at the patient's home or in a healthcare professional setting and delivered to the laboratory by mail. Measurements obtained through this method can be used for monitoring the long-term control of blood sugar (glucose) in people with diabetes.

This test is not to be used to diagnose or screen for diabetes. Not for use on neonates.

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

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

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

**FOR FDA USE ONLY**

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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## 5. 510(K) SUMMARY

# Home Access Health Corporation
# Home Access® A1C Test
**(per 21CFR 807.92)**

### 1. SUBMITTER/510(K) HOLDER

Home Access Health Corporation
2401 West Hassell Road, Suite 1510
Hoffman Estates, IL 60169

Contact Person: Mary Vogt
Telephone: (847) 781-2503
Date Prepared: March 12, 2015

### 2. DEVICE NAME

| | |
|---|---|
| Proprietary Name: | Home Access® A1C Test |
| Common Name: | Glycosylated hemoglobin assay |
| Classification Name: | Assay, glycosylated hemoglobin |
| Regulation Number: | 21 CFR §864.7470 |
| Product Code: | LCP |
| Device Class: | II |
| Panel: | Hematology (81) |

| | |
|---|---|
| Proprietary Name: | Home Access® Collection Cassette |
| Common Name: | Blood specimen collection device |
| Classification Name: | Tubes, vials, systems, serum separators, blood collection |
| Regulation Number: | 21 CFR §862.1675 |
| Product Code: | JKA |
| Device Class: | II |
| Panel: | Chemistry (75) |

### 3. PREDICATE DEVICES

| | |
|---|---|
| Proprietary Name: | HemoChek-A1c Sample Collection Kit (sold under the brand ReliOn A1c Test) |
| 510(k) Number: | K990899 |
| Classification Name: | Assay, glycosylated hemoglobin |
| Regulation Number: | 21 CFR §864.7470 |
| Product Code: | LCP |
| Device Class: | II |
| Panel: | Hematology (81) |

## 4. DEVICE DESCRIPTION

The Home Access® A1C Test includes a micro-blood specimen collection kit. The collection kit is intended to facilitate *in vitro* laboratory testing of finger stick blood samples for a variety of clinical chemistry assays.

This collection kit includes components needed to self-collect, package and mail a dried micro-blood sample to the certified clinical laboratory for testing. The collection kit is comprised of:

- *Blood Sample Collection Cassette
- *Sample Pouch
- *Sterile Safety Lancets (2)
- *Gauze Pad
- *Bandage (2)
- Instructions for use
- Prepaid Return Mailer
- Patient Info Card
- Outer Packaging

***** The Blood Sample Collection Cassette, Sample Pouch, Sterile Safety Lancets, Gauze Pad, and Bandages are identical to those submitted in 510(k) under K063852, Accessa Cholesterol Panel.

## 5. TESTING SERVICE DESCRIPTION

The patient/customer follows the directions to self-collect a capillary blood sample, package and mail the sample to a certified clinical laboratory for analysis. Once the cassette is received in the clinical laboratory, the dried blood sample is punched, eluted and tested using FDA-cleared laboratory reagent and analysis systems, specifically the Beckman Coulter (formerly known as Olympus) AU640e (K961274) and Beckman Coulter A1c reagents (K031380). The clinical laboratory is located at the Home Access Health Corporation facility.

## 6. INTENDED USE/INDICATIONS FOR USE

The Home Access® A1C Test is an *in vitro* test method for the quantitative measurement of Hemoglobin A1c using capillary blood collected from the fingertip, collected onto filter paper via the Home Access collection cassette. The Home Access A1C Test is for measurement of HbA1c on blood specimens which can be collected at the patient's home or in a healthcare professional setting and delivered to the laboratory by mail. Measurements obtained through this method can be used for monitoring the long-term control of blood sugar (glucose) in people with diabetes.

This test is not to be used to diagnose or screen for diabetes. Not for use on neonates.

## 7. COMPARISON TO PREDICATE DEVICES

The Home Access® A1C Test has technological characteristics that are substantially equivalent to the predicate device identified in the table below. Both the proposed device and the predicate device provide the patient a method to collect a capillary blood sample at home, mail the sample to a clinical laboratory, and later receive a report showing measured Hemoglobin A1c.

Among the components included with the Home Access® A1C Test is the collection cassette, comprised of two pieces of plastic housing that snap together and contain a strip of filter paper. Once the cassette is received in the clinical laboratory, the dried blood sample is punched, eluted, and tested using FDA-cleared laboratory reagent and analysis systems, specifically the Beckman Coulter (formerly known as Olympus) AU640e (K961274) and Beckman Coulter A1c reagents (K031380). The technological characteristics and intended use are substantially equivalent to the predicate device as summarized in the following table:

| **Device Features** | **Home Access® A1C Test** | **K990899 HemoChek A1c Sample Collection Kit** |
|---|---|---|
| Indication for Use | The Home Access® A1C Test is an *in vitro* test method for the quantitative measurement of Hemoglobin A1c using capillary blood collected from the fingertip, collected onto filter paper via the Home Access collection cassette. The Home Access A1C Test is for measurement of HbA1c on blood specimens which can be collected at the patient's home or in a healthcare professional setting and delivered to the laboratory by mail. Measurements obtained through this method can be used for monitoring the long-term control of blood sugar (glucose) in people with diabetes.<br><br>This test is not to be used to diagnose or screen for diabetes. Not for use on neonates. | The HemoChek-A1c Sample collection Kit is indicated for over-the-counter sale for use in the measurement of HbA1c on blood specimens which can be collected at the patient's home or at a physician's office on filter paper and delivered to the laboratory by mail. The HbA1c test is used in the assessment of the average blood glucose over a 10-12 week period. The results are to be evaluated by the patient and their physician. The product is not indicated for diagnosis of diabetes mellitus. |
| Kit Components | Blood Sample Collection Cassette containing filter paper for specimen collection<br>Sample Pouch with desiccant for specimen packaging<br>2 Sterile Safety lancets<br>Gauze Pad<br>2 Bandages<br>Instructions for Use/Things You Should Know About A1C<br>Prepaid Return Mailer for specimen mailing<br>Patient Info Card for specimen labeling and consent<br>Outer Packaging | Collection Instructions<br>A1c Test Authorization & Collection Form<br>Sterile Lancet<br>Alcohol Pad<br>Gauze Pad<br>Adhesive Bandage<br>Postage Paid Return Envelope |

| Device Features | Home Access® A1C Test | K990899 HemoChek A1c Sample Collection Kit |
|---|---|---|
| Sample Preparation | Lay user independent. Finger stick blood collected on a filter paper within the cassette. | Lay user independent. Finger stick blood collected on Collection Form (filter paper card). |

## 8. PERFORMANCE TESTING

The following standards/guidance documents were used in the design and testing of the Home Access® A1C Test.

| Standards No. | Standards Organization | Standards title |
|---|---|---|
| EP05-A2 | CLSI | Evaluation of Precision Performance of Quantitative measurement Methods; Approved Guideline-Second Edition. August 2004 |
| EP6-A | CLSI | Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. April 2003. |
| EP07-A2 | CLSI | Interference Testing In Clinical Chemistry; Approved Guideline-Second Edition. |
| EP09-A2-IR | CLSI | Method Comparison and Bias Estimation using Patient Samples; Approved Guideline – Second Edition (Interim Revision) |
| EP17-A2 | CLSI | Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline- Second Edition. |
| EP25-A | CLSI | Evaluation of Stability of *in vitro* Diagnostic Reagents; Approved Guideline. |
| C44-A | CLSI | Harmonization of Glycohemoglobin Measurements. Approved Guideline. December 2002. |
| N/A | FDA Guidance | Review Criteria for Assessment of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin *in vitro* Diagnostic Devices |

### a. Precision

A Precision study was performed following *CLSI EP05-A2, Evaluation of Precision Performance of Clinical Chemistry Devices*. Three (3) levels of HbA1c, eluted from dried blood spots (referred to as Micro-blood samples or "MBS") were tested, 2 replicates per level per run, 2 runs per day for at least 20 days. The results are shown below.

**Precision Summary**

| Sample (MBS) N=80 | HbA1c Mean (HbA1c%) | Within-Run Imprecision, or Repeatability | | Total Imprecision | |
|---|---|---|---|---|---|
| | | SD | CV% | SD | CV% |
| Abnormal High | 12.52 | 0.18 | 1.40% | 0.19 | 1.50% |
| High | 8.92 | 0.16 | 1.81% | 0.27 | 3.00% |
| Diabetic in control | 6.83 | 0.11 | 1.64% | 0.27 | 3.93% |
| Normal | 5.85 | 0.06 | 1.09% | 0.16 | 2.69% |

### b. Linearity

Linearity was assessed following *CLSI EP6-A, Evaluation of the Linearity of*

*Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*.

Nineteen (19) levels of HbA1c ranging from 4.5 to 15.9 %A1c were tested in this study, with 4 individual samples at each level, or 76 individually prepared dry blood samples (19 levels of HbA1c x 4 samples per level). Out of these 76 samples, 52 (13 x 4) samples were collected as capillary specimens from 13 volunteers.

These capillary samples were supplemented with six commercially available venous whole blood specimens. Each whole blood specimen was spotted onto four MBS Collection Cassettes.

The linear fit for HbA1c was: y = -0.0553x + 1.02, r=0.995. The assay was determined to be linear over the assay range of 4.5% - 14.5% A1c.

**c. Interference**

Interference was assessed following *EP07-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline- Second Edition*. Studies were performed to assess common or known exogenous and endogenous substances that could interfere with the Home Access® A1C Test. The exogenous substances tested were Acetaminophen, Acetylsalicylic Acid, Glyburide, Ibuprofen, L-Ascorbic Acid, and Metformin, and the endogenous substances were: Rheumatoid Factors, Triglycerides, Bilirubin (conjugated and unconjugated) and Hemoglobin variants (HbC, HbD, HbE, HbF and HbS).

Interference was calculated as the difference between (a) measurement of blood specimens with interferent as compared to (b) measurement of control group specimens without interferent. Interference is claimed when the difference is equal to or exceeds 0.75 HbA1c (%) and/or 10%, whichever is smaller.

Based on the results of this study, the Home Access® A1C Test does not show interference, all levels tested showed < 10% bias from the following *exogenous* substances:

- Acetaminophen up to 20 mg/dL
- Acetylsalicylic Acid up to 65 mg/dL
- Glyburide up to 0.2 mg/dL
- Ibuprofen up to 50 mg/dL
- L-Ascorbic Acid up to 3 mg/dL
- Metformin up to 4 mg/dL

and *endogenous* substances:

- Rheumatoid Factors up to 600 IU/ml
- Triglycerides up to 1640 mg/dL
- Conjugated and unconjugated Bilirubin up to 30 mg/dL
- Hemoglobin variants (HbD and HbE)

The Home Access® A1C Test is suitable for adoption in the laboratory, with the appropriate disclosure in the labeling that Hemoglobin Variants HbS, HbC and elevated HbF have been known to interfere with test results.

The following limitation will be placed in the Home Access® A1C Test labeling (package insert and front of box labeling):

"A1C tests are not reliable for monitoring blood sugar in people with hemoglobin variants. Ask your Doctor if you have Hemoglobin S, Hemoglobin C or elevated Hemoglobin F. These variants have been shown to interfere with this A1c Test. Do not use this test if you have these variants."

**d. Limits of Detection**

Limits of detection were assessed following *CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline-Second Edition*.

The test has a reportable range of 4.5% to 14.5 % A1c.

**e. Product Stability**

Using CLSI EP 25-A, Evaluation of Stability of *in vitro* Diagnostic Reagents; Approved Guideline and CLSI EP09-A2-IR Method Comparison and Bias Estimation using Patient Samples; Approved Guideline – Second Edition (Interim Revision), the difference in test results using aged Collection Cassettes and Sample Pouches was evaluated. Fifty-three (53) levels of HbA1c covering the measuring range were evaluated. This study demonstrated the acceptable shelf-life for the Collection Cassette and Sample Pouch of 36 months.

***Mailed Sample Stability*** was assessed following the format of *CLSI EP 25-A, Evaluation of Stability of in vitro Diagnostic Reagents; Approved Guideline* and *CLSI EP09-A2-IR Method Comparison and Bias Estimation using Patient Samples; Approved Guideline – Second Edition (Interim Revision).*

One hundred twenty eight (128) self-collected capillary blood samples were compared to venous blood. Samples covered the HbA1c measuring range. Patient

capillary blood samples were shown to be stable for 21 days of shipping in extreme conditions.

**f. Flex Studies**

Flex studies were conducted to assess any potential pre-analytical error that could be obtained from blood samples by the testing laboratory. These studies evaluated blood sample acceptability in terms of:

(a) the minimum and maximum blood volume collected in the Collection Cassette,
(b) interruption in collection of blood drops in the Collection Cassette
(c) an evaluation of potential interference of Hematocrit with the Home Access® A1C Test and
(d) whether coating solution on the filter paper interfered with HbA1c testing in capillary micro-blood samples

***Results of Flex Studies.*** For minimum and maximum blood sample acceptability, three (3) HbA1c levels were tested with fourteen (14) blood volumes per level. There were 10 cassettes per volume of blood, 420 cassettes in total. This study demonstrated that as little as 30µl and as much as 500µl could be collected and the sample would still be acceptable.

For the timing (interruption) study, three (3) HbA1c levels were tested using 90 cassettes (total) spread evenly over control group, and two time interval groups. This study demonstrated that interruption of specimen collection could be as long as 24 hours and the sample would still be acceptable.

The Hematocrit interference study used 39 HbA1c levels ranging from 4.8% to 12.4% of the Home Access® A1C Test, six specimens per level: two each of control, or "normal" hematocrit, specimens, high hematocrit and low hematocrit. The study demonstrated that varying hematocrit levels do not interfere with the Home Access® A1C Test.

The Study to evaluate whether using coating solution on filter paper interfered with HbA1c testing in capillary micro-blood samples included specimens collected using coated filter paper, and specimens collected using uncoated filter paper. The study used 53 levels of HbA1c covering the range of 4.8% to 12.4% (approximating the measuring range of the Home Access® A1C Test). The study determined that the coating solution does not interfere with the testing and the results of HbA1c in micro-blood samples.

**g. Traceability and Expected Values (Controls, Calibrators, or Methods):**

The Home Access® A1C Test standardization is traceable to the IFCC reference calibrators. The Home Access® A1C Test is certified with the National Glycohemoglobin Standardization Program (NGSP). The NGSP certification expires in one year. See NGSP website for current certification at http://www.ngsp.org.

The derived result of the ratio (%) from the NGSP correlation is calculated from the individual quantitative results for total hemoglobin (THb) and Hemoglobin A1c. The International Federation of Clinical Chemistry (IFCC) units of mmol/mol are calculated using the Master Equation:

**IFCC= (NGSP-2.15)/0.092**

**h. Human Factors Studies**

Human factor studies demonstrated that lay-users were able to easily (a) interpret instructions, (b) determine if the product was appropriate for their purchase and use, (c) understand the relevance of cautions and warnings included in the product labeling, and (d) understand their results.

**i. Method Comparison**

Method comparison was assessed following *CLSI EP09-A2-IR, Method Comparison and Bias Estimation using Patient Samples; Approved Guideline – Second Edition (Interim Revision),* using 256 patient samples (128 self-collected and 128 professionally-collected) spanning the assay measuring range of 4.5 – 14.5% HbA1c and compared to expected, or whole blood samples from venous blood draw, measured with the predicate device - Beckman Coulter Hemoglobin A1c Test (K031380).

The study demonstrated the new Home Access A1C Test was acceptable for measuring HbA1c. All 128 patients were able to self-collect enough blood to have an adequate sample. Consequently, 128 (or 100%) of self-collected capillary blood samples provided reportable results: the sample adequacy for self-collected samples was 100% (0.95 CI $\geq$ 97.1%). One (1) single specimen result was outside of the measuring range.

An average absolute bias and related confidence interval were well below the acceptable limits of $\pm$ 7%. The results are presented below.

**A comparison of Self-collected Capillary Blood vs. Venous Blood:**

| Comparison | Number of Samples | Linear Regression | R2 | Sample Range Tested |
|---|---|---|---|---|
| Self-collected Capillary vs. Venous Blood at Site 1 | 107 | -0.032 + 0.997 * X | 0.984 | 4.8-13.9 |
| Self-collected Capillary vs. Venous Blood at Site 2 | 20 | 0.053 + 0.993 8 X | 0.97 | 5.9-13.1 |
| Self-collected Capillary vs. Venous Blood (combined sites) | 127 | -0.043 + 0.999 * X | 0.983 | 4.8-13.9 |

**A comparison of Professionally-collected Capillary Blood vs. Venous Blood:**

| Comparison | Number of Samples | Linear Regression | R2 | Sample Range Tested |
|---|---|---|---|---|
| Professional Capillary vs. Venous Blood at Site 1 | 107 | 0.100 + 0.976 * X | 0.984 | 4.8-13.9 |
| Professional Capillary vs. Venous Blood at Site 2 | 20 | -0.196 + 1.032 * X | 0.992 | 5.9-13.1 |
| Professional Capillary vs. Venous Blood (combined sites) | 127 | -0.042 + 0.999 * X | 0.986 | 4.8-13.9 |

## 9. CONCLUSIONS DRAWN

Based on the comparison of technological features and intended use, and as a result of the performance testing completed on the Home Access® A1C Test, the proposed device does not raise new questions of safety and effectiveness and supports the conclusion that the proposed device is substantially equivalent to the predicate device.