510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k141944

B. Purpose for Submission:

New Device

C. Measurand:

Glycosylated Hemoglobin (HbA1c)

D. Type of Test:

Quantitative, latex agglutination inhibition method

E. Applicant:

Home Access Health Corp.

F. Proprietary and Established Names:
Home Access®A1C Test
Home Access® Collection Cassette

G. Regulatory Information:

1. Regulation section:
   21 CFR§864.7470
   21CFR§ 862.1675

2. Classification:

   II, II

3. Product code:

   LCP, JKA

4. Panel:

   Hematology (81), Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) 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.

3. Special conditions for use statement(s):

   - For prescription use and over-the counter use
   - 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.
   - This test is not for screening or diagnosis of diabetes
   - This test should not be used in monitoring daily glucose control or to replace daily home testing of urine and blood glucose levels
   - Should not be used for analyzing samples from patients with conditions causing shortened red blood cell survival, such as hemolytic diseases, pregnancy and significant acute or chronic blood loss.
   - Not for use on neonates.

4. Special instrument requirements:

   Beckman Coulter AU640e Chemistry Analyzer in the clinical laboratory located at Home Access Health Corporation.

I. Device Description:

The Home Access® A1C Test includes the use of the Home Access Collection Cassette collection kit, which is sold as part of the test kit and the Beckman Hemoglobin A1c Test method (k031380) which is used in the Home Access laboratory. The Home Access A1c

Test® is intended to facilitate in vitro laboratory testing of finger stick blood samples for the determination of HbA1c using a dried micro-blood sample.

The collection kit includes components needed to self-collect, package and mail a dried micro-blood sample to the Home Access facility 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
- Patient Information Card
- Prepaid Return Mailer (for mailing blood sample to testing lab)

The testing services are performed in the clinical laboratory located at Home Access Health Corporation using the Beckman Coulter AU640e Chemistry analyzer. Once the dried blood sample, which is referred to as Micro-blood sample (MBS) is received in the laboratory, it is punched off and eluted to re-solubilize the hemoglobin components using the Hemoglobin Denaturant (k031380) and assayed. All testing is performed using the Beckman AU640e analyzer (k961274) and the Beckman Coulter Hemoglobin A1c Test (k031380) for measurement of HbA1c.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   HemoChek A1c Sample Collection Kit

2. Predicate 510(k) number(s):

   k990899

3. Comparison with predicate:

Similarities and Differences		
Item	Candidate Device The Home Access® A1C Test	Predicate HemoChek A1c Sample Collection Kit k990899
Indication for Use/ Intended Use	The Home Access A1C Test is an in vitro test method for the quantitative measurement of Hemoglobin A1c using	The HemoChek-A1c Samples collection kit is indicated for over-the

Similarities and Differences		
Item	Candidate Device The Home Access® A1C Test	Predicate HemoChek A1c Sample Collection Kit k990899
	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 patients 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.	counter sale for use in the measurement of HbA1c on blood specimen 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. Sample Pouch with desiccant for specimen packaging 2 Sterile Safety lancets Gauze Pad 2 Bandages Instructions for Use/Things You Should Know About A1C Prepaid Return Mailer for specimen mailing Patient Info Card for specimen labeling and consent Outer packaging	Collection Instructions A1c Test Authorization & Collection Form Sterile Lancet Alcohol Pad Gauze Pad Adhesive Bandage Postage Paid Return Envelope
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).
Location of collection	Sample is collected at Home	Same
Location of analysis	Laboratory	Same
Distribution	Prescription and Over-the-counter	Over-the-Counter

Similarities and Differences		
Item	Candidate Device The Home Access® A1C Test	Predicate HemoChek A1c Sample Collection Kit k990899
Analysis	Mail in to laboratory	Same
Report	Mailed to user	Same
Measuring Range	4.5-14.5% HbA1c	4.7-15.5% HbA1c

K. Standard/Guidance Document Referenced (if applicable):

- CLSI EP5-A2- Evaluation of Precision Performance of Quantitative measurement Methods; Approved Guideline-Second Edition.
- CLSI-EP6-A-Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach-Approved Guideline
- CLSI-EP7-A2- Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition
- CLSI-EP9-A2-IR-Method Comparison and Bias Estimation using Patient Samples; Approved Guideline-Second Edition (Interim Revision)
- CLSI-EP17-A2- Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approve Guideline-Second Edition
- CLSI- EP25-A- Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline
- CLSI-C44-A-Harmonization of Glycohemoglobin Measurements. Approved Guideline

L. Test Principle:

Users of the Home Access A1C Test kit will collect a capillary blood samples by pricking their fingertip using the sterile safety lancet included in the kit packaging. The user will place several drops (30-500µl) of blood into the Home Access Collection Cassette that houses a strip of glass fiber filter paper, until the cassette window indicator turns red. Once the capillary blood sample is collected, the user is instructed to allow the sample to dry for 15 minutes and seal the blood sample in the Sample Pouch that has been labeled using the peel-off label on the Patient Information card. The user mails the sample to Home Access Health Corporation. Once the dried sample is received in the laboratory, it is punched and eluted. Once eluted, the sample is assayed using FDA-cleared reagents. All testing is done using the Beckman Coulter AU640e Chemistry analyzer.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were performed according to CLSI EP5-A2 guideline. Precision was evaluated by testing venous whole blood samples obtained from volunteers at three levels of HbA1c (~5.9, ~6.8 and ~8.9%). A total of 240 samples (80 samples per level) were spotted to the Home Access A1C Test cassettes and allowed to dry following the Home Access A1C Test instructions for use. Micro-Blood Samples (MBS) were eluted and measured using the Beckman Hemoglobin A1c Test method on the Beckman Coulter AU640e Chemistry analyzer for a total of three levels of HbA1c x 2 samples per level per run x 2 runs a day x 20 days (n=80).

The results of the precision study are shown below:

		Within-run		Total	
Samples	HbA1c% Mean	SD	CV%	SD	%CV
1	5.9	0.1	1.1	0.2	2.7
2	6.8	0.1	1.6	0.3	3.9
3	8.9	0.1	1.8	0.3	3.0

An additional Precision study was conducted by testing a whole blood specimen from a volunteer at a level of 12.5% HbA1c. A total of 50 Home Access A1C Test cassettes were spotted and allowed to dry following the Home Access A1C Test Instructions for use. MBS were eluted and measured using the Beckman Hemoglobin A1c Test method on the Beckman Coulter AU640e Chemistry analyzer for a total of 5 samples x 2 runs x 5 days (n=50).

		Within-run		Total	
Samples	HbA1c% Mean	SD	CV%	SD	%CV
4	12.5	0.1	1.4	0.2	1.5

b. Linearity/assay reportable range:

A linearity study was conducted to validate the linear range of the Home Access A1C Test. Linearity was assessed following CLSI EP6-A guideline. Paired venous and capillary samples collected onto Home Access collection cassettes were collected at 19 levels to cover a range of 4.5-15.9% HbA1c. The micro-blood samples were eluted and measured and the results were compared to the expected values (venous samples).

Nineteen 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).

The expected values were plotted versus the observed values. The results using standard linear regression analysis was as follows:

Y = 1.02x - 0.0553; r=0.995

The assay was determined to be linear over the assay range of 4.5%-14.5% HbA1c.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The Home Access HbA1c test system assay is traceable to the IFCC reference calibrators.

The Home Access A1C Test System is certified with the National Glycohemoglobin Standardization Program (NGSP), with an expiration date of February 1, 2016. The NGSP certification expires one year from the certification date. See NGSP website for current certification at http://www.ngsp.org.

Shelf-life of the Home Access A1C Test Kit was determined by real-time studies consisting of patient samples collected from venous whole blood and compared to capillary samples collected with the Home Access A1C Test kit which were stored up to 39 months. Study protocols and acceptance criteria were reviewed and found to be acceptable. The Collection Cassette and Sample Pouch are stable for 36 months when stored at room temperature (15-25°C). The outer box labeling of the kit indicates "Store at Room Temperature (15-25°C, 59-77°F). Avoid exposure to direct Sunlight."

In addition, a real-time shipping study was conducted using spotted dry samples shipped in presumably worst-case shipping conditions, during hot and cold months from the east south-central region (Kentucky) and southwest (California) locations of the continental USA. Study protocols were reviewed and found to be acceptable.

Furthermore, an additional sample stability study that challenged extreme temperatures (45°C and -20°C) was conducted to simulate the worst case scenario. The study consisted of samples stressed at 45°C, then thawed and frozen at -20°C for 3 days. Study protocols were reviewed and found acceptable. Based on the real-time sample stability study, patient samples are stable for up to 21 days at temperatures ranging from -20°C - 45°C and humidity levels of 15-100%.

d. Detection limit:

The claimed measuring range of 4.5%-14.5% for the Home Access HbA1c Test, is based on linearity. See 1b. above.

e. Analytical specificity:

i.) Interference of the Home Access A1C Test was assessed following EP07-A2 guideline. Studies were conducted to assess common or known exogenous substances that may interfere with the Home Access A1C Test. Two levels of HbA1c (5.8% and 8.3%) were tested. Venous whole blood samples were drawn from volunteers and split into two pools. One pool was used as the control pool and the other pool was used to spike with different levels of the potential interfering substance. Stock solution of the exogenous interferents (acetaminophen, acetylsalicylic acid, ibuprofen, L-ascorbic acid, glybenclamide and metformin) were prepared and spiked into the pooled test samples. Control and test specimens were spotted onto Home Access collection cassettes, dried, and packaged in desiccated sample pouches following product instructions. Significant interference was defined by the sponsor as % recovery +/- 10%. The sponsor claims there was no significant interference by the following exogenous substances:

- Acetaminophen up to 20 mg/dL
- Acetylsalicylic acid up to 65 mg/dL
- Ibuprofen up to 50 mg/dL
- L-ascorbic acid up to 4 mg/dL
- Metformin up to 4 mg/dL
- Glyburide up to 0.2 mg/dL

ii.) Endogenous interference was also assessed by using two levels of HbA1c (~5.2% and ~8.3%). Venous whole blood samples were drawn from volunteers and split into two pools. One pool was used as the control pool and the other pool was used to spike with different levels of interfering substance. Significant interference was defined by the sponsor as % recovery +/- 10%. The sponsor claims there was no significant interference by the following exogenous substances:

- Bilirubin (conjugated and unconjugated) up to 30 mg/dL
- Triglycerides up to 1640 mg/dL
- Hemolysis up to 14000 mg/dL
- Rheumatoid Factor up to 600 IU/ml

iii.) Interference from Hemoglobin Variants was tested by using whole blood samples obtained from a commercial reference laboratory. The whole blood samples contained three HbA1c levels (5.7, 6.4 and 7.4)% A1c for each variant (Hemoglobin C, Hemoglobin D, Hemoglobin E, Hemoglobin F, Hemoglobin S). Interference from each hemoglobin variant was evaluated by spotting blood with the respective Hemoglobin variant onto Home Access collection cassettes and comparing MBS HbA1c with the baseline whole blood measurements obtained from the Home Access A1C test and actual HbA1c concentrations obtained by the commercial reference laboratory. Significant interference was defined as +/- 10% difference between the

values obtained from the reference samples and those obtained from the Home Access HbA1c Test kit.

The testing results show there is no significant interference for Hemoglobin D (≤ 36%), and Hemoglobin E (≤ 39%).

The sponsor indicates the following in the labeling: "With this Test, Hemoglobin S and Hemoglobin C may increase HbA1c results by as much as 40%; a blood sample containing >10% of Hemoglobin F may yield a lower than expected result."

The sponsor has the following limitation on the front box and package insert 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."

Additional Studies:

Flex Studies- Flex studies were conducted to assess any potential pre-analytical error that could be introduced to the sample. These studies evaluated blood sample acceptability in terms of:

(a) **A Blood Volume** study was conducted with 3 HbA1c levels across the measuring range of the test 5.6, 7.2 and 12.4% HbA1c to assess the effect of the minimum and maximum blood volume collected in the collection cassette on device performance. Fourteen (14) blood volume levels were tested. Home Access Collection cassettes were spotted with 10, 20, 30, 40 50, 60, 70, 80, 90, 100, 200, 300, 400 and 500 µl of blood. A total of 420 cassettes were tested (10 cassettes x 3 HbA1c levels x 14 separate volumes of blood). Samples were punched, eluted and tested. Results of the MBS volumes were compared with expected (known) values for HbA1c as determined from testing venipuncture blood. Results of the blood volume study demonstrated acceptable performance with capillary sample volumes of 30 µl to 500 µl.

(b) **A Timing** (interruption) study, included professional and venous samples which were collected at the same time. A control group and two variable test groups were established. The control group complete finger stick blood specimen was collected within 5 minutes. The two test groups were spotted with the interval of 30 minutes and of 24 hours. A total of 90 Home Access Collection cassettes were tested (Three levels x 10 cassettes per group x 3 groups (the control and the two test groups). Samples were punched, eluted and tested. The study demonstrated that interruption of specimen collection could be as long as 24 hours and the sample would be acceptable.

(c) **A Hematocrit interference study** used 39 HbA1c levels which were obtained from volunteers with HbA1c values ranging from 4.8% to 12.4%. K^{2-}EDTA venous whole blood samples were collected by phlebotomists and shipped overnight to Home Access Health Corporation. A Control sample, High Hematocrit Test sample and

Low Hematocrit Test sample were created. After drying, Home Access cassettes with venous spotted samples were packaged and stored for processing. MBS were then punched, eluted and tested. Results of this study were found to be acceptable. The results of the study demonstrated that varying hematocrit levels (34-54%) do not interfere with the Home Access A1C Test.

(d) **Interference from coating solution** study 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%. The study included the eluting and measuring of 106 samples (53 x 2) which were collected professionally as finger stick capillary specimens from 53 volunteers. This study tested 53 analyte levels, each with 2 individual capillary Home Access cassettes with coated strips and one Home Access cassette on uncoated strips. One lot of Home Access A1C test kits and one lot of uncoated glass fiber filter paper were used for the study. To evaluate the differences between samples on coated strips and samples on uncoated strips, the measurements for each sample was calculated and samples on coated strips was compared to the samples on uncoated strips. The study determined that the coating solution does not interfere with the testing and the results of HbA1c when using the Home Access HbA1c Test.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was conducted following CLSI EP09-A2-IR guideline. A total of 256 patient samples (128 self-collected capillary samples and 128 professionally-collected venous and capillary samples) with a range of 4.8-13.9% HbA1c were collected. The study was performed to compare test results obtained by the lay user's finger-stick samples via the Home Access collection cassette with the results by the venous samples using the Beckman Coulter Hemoglobin A1c Test (k031380) in the clinical laboratory of the Home Access Health Corporation (HAHC). Blood samples were collected by the lay user at two separate clinic sites following the Home Access A1C Test kit instructions and mailed to HAHC for analysis. The professionally collected finger-stick and venous blood samples were also collected at these two separate sites. All samples (venous and capillary) were mailed at the same time. One sample resulted in HbA1c result higher than the claimed measuring range of the device (>14.5%) and was removed from the analysis. The results of the 127 samples tested across the claimed measuring range of the test using simple linear regression analysis are as follows:

Comparison	Number of Samples	Linear Regression	R^2	Sample Range
Self-collected Capillary vs. Professional Collected Venous Blood at Site 1	107	-0.032x +0.997	0.984	4.8-13.9
Self-collected Capillary vs. Professional Collected Venous Blood at Site 2	20	0.053x + 0.993	0.97	5.9-13.1
Self-collected Capillary vs. Professional Collected Venous Blood (combined sites)	127	-0.043x +0.999	0.983	4.8-13.9

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

Results of the lay user study indicated 100% of the 128 participants successfully self-collected a finger stick blood sample of sufficient quality by following the directions included with the Home Access A1C Test. Participants showed an understanding of the labeling included within the Home Access A1C Test. Study subjects also demonstrated an understanding of their laboratory results as well as correctly identified the appropriate course of action based on their laboratory report. The readability of the labeling was assessed using a Flesch-Kincaid analysis. The Flesch Kincaid score revealed a reading grade level of less than 7.

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Reference Range[1]

	NGSP
Increased risk for diabetes	≥6.5%

[1]Executive Summary of the 2014 American Diabetes Association Clinical Practice Recommendations (Diabetes Care 2014; 37 suppl.1: S5-13)

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.