August 15, 2019

Drawbridge Health, Inc.
Annie Wright
Associate Director, Regulatory Affairs & Quality Assurance
11535 Sorrento Valley Road, Suite 407
San Diego, CA 92121

Re: K183230
Trade/Device Name: OneDraw™ A1C Test System
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, PRJ
Dated: July 15, 2019
Received: July 15, 2019

Dear Annie Wright:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183230

Device Name
OneDraw™ A1C Test System

Indications for Use *(Describe)*

The OneDraw™ A1C Test System, which consists of the OneDraw Blood Collection Device and the OneDraw A1C Test, is intended to collect capillary blood from the upper arm of individuals 18 years of age or older onto filter (matrix) paper within the collection device by a healthcare professional. Samples are delivered to the laboratory for the quantitative measurement of HbA1c for monitoring the long-term control of blood sugar (glucose) in people with diabetes. Testing performed on samples collected with this device should not be used to diagnose or screen for diabetes. The OneDraw A1C Test System should not be used with 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

OneDraw™ A1C Test System

Applicant Name: Drawbridge Health, Inc.
11535 Sorrento Valley Road, Suite 407
San Diego, CA 92121 USA

Company Contact: Annie Wright
Associate Director, Regulatory Affairs & Quality Assurance
Phone: (408) 421-1510
Email: awright@dbhealth.com

Date Prepared: July 25, 2019

DEVICE IDENTIFICATION

Device Name: OneDraw™ A1C Test System, which consists of the following:

Trade or Proprietary Names:	OneDraw™ A1C Test
Device Classification Name:	Glycosylated hemoglobin assay
Product Codes:	LCP
Regulatory Class:	Class II
Classification Regulation:	21 CFR 864.7470
Panel:	Hematology (81)
Trade or Proprietary Names:	OneDraw™ Blood Collection Device
Device Classification Name:	Blood specimen collection device
Product Codes:	PRJ
Regulatory Class:	Class II
Classification Regulation:	21 CFR 862.1675
Panel:	Chemistry (75)
Predicate Device:	Home Access Health Corp., Home Access® A1C Test and Home Access® Collection Cassette (K141944)

INTENDED USE

The OneDraw™ A1C Test System, which consists of the OneDraw Blood Collection Device and the OneDraw A1C Test, is intended to collect capillary blood from the upper arm of individuals 18 years of age or older onto filter (matrix) paper within the collection device by a healthcare professional. Samples are delivered to the laboratory for the quantitative measurement of HbA1c for monitoring the long-term control of blood sugar (glucose) in people with diabetes. Testing performed on samples collected with this device should not be used to diagnose or screen for diabetes. The OneDraw A1C Test System should not be used with neonates.

DEVICE DESCRIPTION

The OneDraw™ A1C Test System includes the OneDraw Blood Collection Device and the OneDraw A1C Test. The OneDraw Blood Collection Device is a single-use, sterile, capillary blood specimen collection device. The OneDraw Blood Collection Device includes a transport sleeve, accessories, and instructions (OneDraw Blood Collection Device Instructions for Use (IFU)) which are needed to collect, package, and mail the sample to the designated certified clinical laboratory for HbA1c testing, using the OneDraw A1C Test.

The OneDraw Blood Collection Device incorporates lancets to make incisions in the skin and a vacuum to draw blood at the surface of the skin through channels to deposit the blood onto collection and stabilization matrices (matrix strips). The matrix strips are contained within a cartridge which is removed from the device after the draw is complete. The cartridge is then inserted into the transport sleeve which encloses and protects the sample during shipping to the clinical laboratory.

Once the transport sleeve containing the sample is received by the clinical laboratory, one of the dry blood sample matrices is removed. The matrix is then eluted in Beckman Hemolyzing Reagent (BHR) in 2 mL tubes or 2.2 mL deepwell plates using an orbital shaker. Next, the sample is diluted in BHR to its final concentration and tested using FDA-cleared Beckman Coulter AU480 Chemistry Analyzer and A1c reagents, including calibrators, (K120199) per the OneDraw A1C Test IFU.

TECHNOLOGICAL CHARACTERISTICS

The OneDraw A1C Test System has technological characteristics that are substantially equivalent to the predicate device as identified in the table below. Both the subject device and the predicate device provide a method to collect a capillary blood sample to be analyzed in a clinical laboratory for determination of Hemoglobin A1c (HbA1c) using a previously cleared reagents and analysis system.

Attribute	Predicate Device Home Access® A1C Test (K141944)	Candidate Device OneDraw™ A1C Test System
Similarities and Differences		
Intended Use	The Home Access® A1C Test is an *in vitro* test method for 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' home or in a healthcare professional setting and delivered to the laboratory by mail. Measurements obtained through this method can be used for long-term control of blood sugar (glucose) in people with diabetes. This test is not to be used to diagnose or screen for diabete Not for use with neonates.	The OneDraw™ A1C Test System, which consists of the OneDraw Blood Collection Device and the OneDraw A1C Test, is intended to collect capillary blood from the upper arm of individuals 18 years of age or older onto filter (matrix) paper within the collection device by a healthcare professional. Samples are delivered to the laboratory for the quantitative measurement of HbA1c for monitoring the long-term control of blood sugar (glucose) in people with diabetes. Testing performed on samples collected with this device should not be used to diagnose or screen for diabetes. The OneDraw A1C Test System should not be used with neonates.
Sample types	Dry capillary blood	Same
Standardization	Traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and Diabetes Control and Complications Trial (DCTT) reference method. Certified via the National Glycohemoglobin Standardization Program (NGSP).	Same
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	• Blood sample collection cartridge containing filter paper for specimen collection • Sample pouch containing desiccant for specimen packaging • 2 sterile lancets within the assembly • Alcohol prep pad • Gauze pad • Bandage • Instructions for Use • Return Mailer (Chipboard) for specimen mailing • Outer Carton
Sample Preparation	Finger stick blood collected on a filter paper within the cassette	Blood drawn from upper arm and is collected on a filter paper within the cartridge
Location of collection	Sample collected at home or HCP setting	Healthcare Professional (HCP) setting
Location of analysis	Laboratory	Same
Distribution	Prescription and Over the Counter	Prescription
Analysis	Mail to laboratory	Same
Report	Mailed to user	Mailed to healthcare professional
Measuring Range	4.5-14.5% HbA1c	4.7-14.3% HbA1c
Puncture site	Fingertip	Upper arm
Mechanism of blood draw	Fingerstick	Collection device (lancet-stick and vacuum)
Collection method	Blood is collected using the fingerstick method	The blood is drawn into the collection device by puncture of capillaries located near the surface of the skin using lancets or similar small sharp objects

PERFORMANCE TESTING

The following standards/guidance documents were used in the design and testing of OneDraw™ A1C Test System:

Designation/Revision	***Title***
CLSI C44-A, 2002	Harmonization of Glycohemoglobin Measurements; Approved Guideline
CLSI EP05-A3, 2014	Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition
CLSI-EP06-A, 2003	Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
CLSI-EP07-A2, 2005	Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition
CLSI-EP09-A3, 2013	Method Comparison and Bias Estimation using Patient Samples; Approved Guideline – Third Edition
CLSI-EP17-A2, 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approve Guideline-Second Edition
CLSI- EP25-A, 2009	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline
ANSI/AAMI/ISO 11137-1:2006/(R)2015; A1:2013	Sterilization of Health Care Products-Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ANSI/AAMI/ISO 11137-2:2013	Sterilization of Health Care Products-Radiation - Part 2: Establishing the sterilization dose
ANSI/AAMI/ISO 11137-3:2017	Sterilization of Health Care Products-Radiation - Part 3: Guidance on dosimetric aspects.
ISO 10993-1:2009	Biological Evaluation of Medical Devices-Part 1: Evaluation and testing within a risk management process
ISO 10993-3:2014	Biological Evaluation of Medical Devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
ISO 10993-4:2002, A1:2006	Biological Evaluation of Medical Devices-Part 5: Selection of tests for interactions with blood
ISO 10993-5, 2009	Biological Evaluation of Medical Devices-Part 5: Test for *in vitro* cytotoxicity
ISO 10993-10, 2010	Biological Evaluation of Medical Devices-Part 10: Test for Irritation and Skin Sensitization
ISO 10993-11, 2006	Biological Evaluation of Medical Devices-Part 11: Test for Systemic Toxicity
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Medical Device Packages
ASTM-4169-16	Standard Practice for Performance Testing of Shipping Containers and System
Pouch Leak test per ASTM F2096-11	Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)
Pouch Seal Strength test per ASTM F88/F88M-15	Standard Test Method for Seal Strength of Flexible Barrier Materials

1. Precision

A. Precision (Assay) – Repeatability

Repeatability (within-run and within-day) precision was determined according to CLSI Guideline EP05-A3. Blood samples spotted onto matrix strips and tested using different Beckman reagent lot combinations and one Beckman analyzer were analyzed for at least 20 days, two runs per day. A run was defined as running each sample in duplicate.

Table 1a: Repeatability Precision (n=80*)

	Mean	Repeatability (within-run)		Repeatability (within-day)		Total	
Sample	**%HbA1c**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	5.10	0.073	1.44%	0.030	0.58%	0.119	2.33%
2	6.46	0.091	1.40%	0.033	0.51%	0.135	2.09%
3	7.87	0.082	1.05%	0.025	0.32%	0.114	1.45%
4	11.44	0.119	1.04%	0.071	0.62%	0.161	1.40%

*total of 81 data points was collected, an additional data point for Sample 1

B. Precision (Device) – Lot-to-Lot Analysis

A lot-to-lot device precision study was conducted to demonstrate the reproducibility of collecting samples using different lots of manufactured OneDraw Blood Collection Devices across collection sites in accordance with CLSI Guideline EP05-A3. **Figure 1a** shows high agreement between results from the same participant, same operator, but different device lots. The range of %HbA1c was 4.84% to 7.55%. The average CV is 1.6% (range: 0.0% – 3.6%).

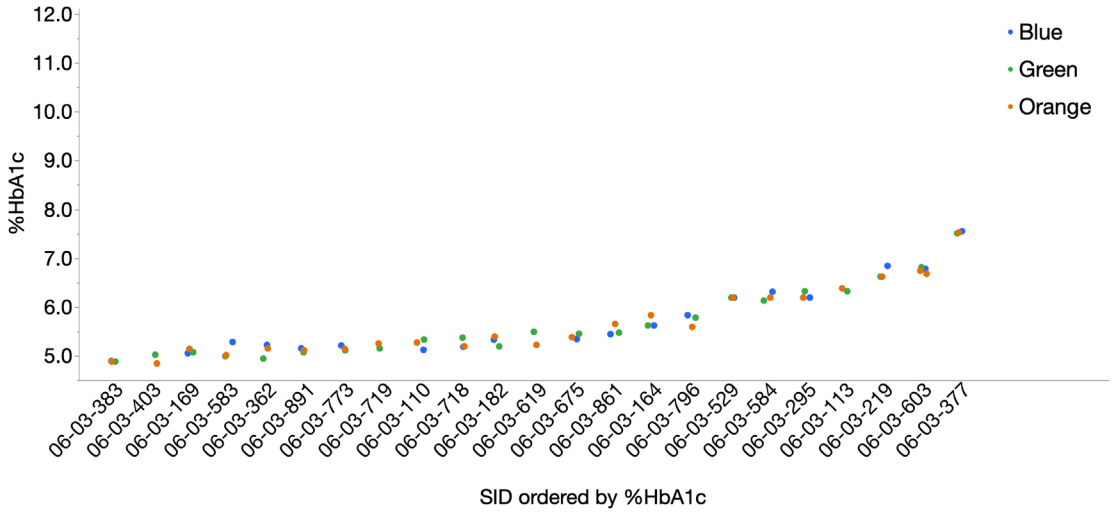

Figure 1a: %HbA1c results for samples collected from two or three device lots across 23 participants

Table 1b: Precision, Within and Between Lots and Total %CV

%HbA1c group	Mean %HbA1c	Within Lot %CV (95% CI)	Between-Lot %CV (95%CI)	Total %CV (95%CI)
< 6	5.23	1.95% (1.53, 2.36)	0.37% (0.29, 0.44)	1.99% (1.57, 2.42)
≥ 6	6.58	1.04% (0.70, 1.34)	0.36% (0.24, 0.48)	1.10% (0.74, 1.45)

C. Precision (Device) - Operator-to-Operator

An inter-operator precision study was conducted to demonstrate the reproducibility of collecting samples by different operators across collection sites using the same lot of manufactured OneDraw Blood Collection Devices in accordance with CLSI Guideline EP05-A3. **Figure 1b** shows high agreement between results from the same participant, same lot of devices, by different operators. The range of %HbA1c was 4.66% - 14.38%. The average CV is 1.5% (range: 0.1% – 4.8%).

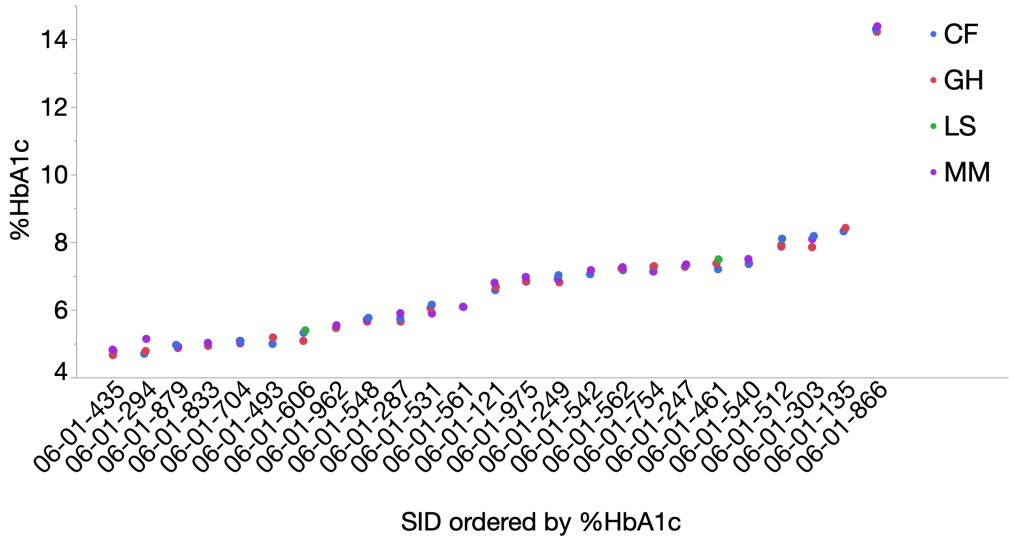

Figure 1b: %HbA1c results for samples collected by two or three operators across 25 participants

Table 1c: Precision, Within and Between Operators and Total %CV

%HbA1c group	Mean %HbA1c	Within Operator %CV (95% CI)	Between-Operator %CV (95%CI)	Total %CV (95%CI)
< 6	5.21	1.97% (1.55, 2.38)	1.06% (0.84, 1.30)	2.24% (1.76, 2.72)
≥ 6	7.74	1.23% (0.83, 1.62)	0.16% (0.11, 0.21)	1.24% (0.84, 1.64)

2. Method Comparison

The method comparison study was conducted to demonstrate the equivalence of HbA1c measurement using blood samples collected and tested using the OneDraw A1C Test System as compared to results using blood samples collected using standard venipuncture (tested using Beckman's NGSP-certified method on the Beckman Coulter AU480 Analyzer). Blood collections were conducted at two different clinical sites and sample analysis was conducted at the designated test laboratory.

Table 2: Regression analysis results (Passing-Bablok)

	Estimate	**95% lower bound**	**95% upper bound**
Slope	1.00	0.97	1.03
Intercept	-0.11		
Pearson correlation coefficient (R)	0.9907	0.9864	0.9937
Number of participants	107		
Range tested (OneDraw A1C Test System results, %HbA1c)	4.70 – 14.3		
Range tested (venipuncture, %HbA1c)	4.76 – 14.7		

3. Linearity

The linearity of the OneDraw A1C Test is established as 4.70-14.3 % HbA1c (DCCT/NGSP) and in accordance with CLSI-EP6-A, determined the following linear fit, $Y = 1.01x + 0.06$; $R^2=0.99$.

4. Interference

Interference was assessed following EP07-A2. Studies were performed to assess common or known exogenous and endogenous substances that could interfere with the OneDraw A1C Test. The exogenous substances were Acetaminophen, Acetylsalicylic Acid, Ibuprofen, L-ascorbic Acid, Metformin, Glyburide; 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 ±10% bias from the following substances:

Substance	Substance description	Highest concentration tested	Interference observed With highest test concentration
Acetaminophen	Analgesic	20 mg/dL	No
Acetylsalicylic acid	Analgesic	65 mg/dL	No
Glyburide	Antidiabetic	0.2 mg/dL	No
Ibuprofen	Anti-inflammatory, analgesic	50 mg/dL	No
Metformin	Antidiabetic	4.0 mg/dL	No
L-ascorbic acid	Antioxidant	3.0 mg/dL	No
Triglycerides	Endogenous	3400 mg/dL	No
Bilirubin – conjugated	Endogenous	33.2mg/dL	No
Bilirubin - unconjugated	Endogenous	30mg/dL	No
Rheumatoid factor	Endogenous	600 IU/mL	No

Whole blood containing hemoglobin variants A2 (≤5.8%), C (≤40.1%), D (≤41.2%), E (≤22%), S (≤34.8%), or low F (≤ 8.5%) do not show significant interference (over 10% absolute bias) when spotted on matrix strips were compared to the reference laboratory liquid blood values.
The OneDraw A1C Test is suitable for adoption in the laboratory with the appropriate disclosure in the labeling that Hemoglobin Variant HbF (elevated) has been known to interfere with test results. The following limitation is presented in the OneDraw A1C Test labeling (OneDraw A1C Test IFU): "Hemoglobinopathies may interfere with glycated hemoglobin analysis. Studies show that there is no significant interference for HbA2 (≤ 5.8%), HbC (≤ 40.1%), HbD (≤ 41.2%), HbE (≤ 22%), and HbS (≤ 34.8%). Samples containing HbF levels > 8.5% show a significant negative bias with the OneDraw A1C Test. Do not use this test if the patient has this variant."

5. Limits of Detection

The claimed measuring range is 4.70%-14.3% for the OneDraw A1C Test, which is based on linearity testing.

6. Product Stability

In accordance with EP25-A and EP09-A3, the difference in test results using aged OneDraw Blood Collection Devices was evaluated. Four levels of HbA1c covering the measuring range were evaluated. The OneDraw Blood Collection Device has an expiry date 12 months after the date of manufacturing.

Sample storage and shipping stability studies were conducted using whole blood spotted on matrix strips. Based on these studies, patient samples are stable for up to 21 days at room temperature. The results also demonstrate that extreme temperature excursions of whole blood spotted onto the matrix strips do not cause a significant difference in the measurement of HbA1c using the OneDraw A1C Test. Overall these studies demonstrate the robustness of the matrices and transport sleeves to ensure that they are able to withstand the stressed conditions experienced during shipping and storage of the sample prior to HbA1c testing.

7. 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 onto the device matrix strips

(b) potential interference of hematocrit with the OneDraw A1C Test

(c) the equivalency between the two matrix strips from the same cartridge for the OneDraw A1C Test

(d) a comparison of HbA1c results for the following:

- Venous whole blood collected in EDTA tubes with venous whole blood spotted on the matrix strips
- Venous whole blood collected in EDTA tubes with capillary blood collected using OneDraw Blood Collection Device
- Venous whole blood spotted on the OneDraw matrix strips with capillary blood collected using OneDraw Blood Collection Device

Results of Flex Studies

(a) For minimum and maximum blood sample acceptability, two (2) HbA1c levels were tested with six (6) blood volumes per level. There were 6 matrix strips per volume of blood, 72 matrix strips

in total. This study demonstrated that spotted volumes ranging between 52.5 µL and 90 µL were within ±10% relative bias when compared to the corresponding 75 µL spotted samples.

(b) The hematocrit interference study used two (2) HbA1c levels tested with the OneDraw A1C Test, six matrix strips per level: six each of control, or "normal" hematocrit, high hematocrit, and low hematocrit specimens. The study demonstrated that varying hematocrit levels do not interfere with the OneDraw A1C Test.

(c) The two matrix strips contained within the same cartridge were analyzed and compared. The data demonstrates that there is not a significant difference in %HbA1c results between the two matrices.

(d) HbA1c results obtained from dried whole blood spotted on matrix strips and from capillary blood collected with the OneDraw Blood Collection Device are comparable to those collected via the standard phlebotomy technique (venous whole blood through venipuncture).

CONCLUSION

The information and data in this 510(k) application demonstrate that the samples collected and tested using the OneDraw A1C Test System result in accurate and precise results that correlate well with current cleared methods. Based on the criteria stated above, this device is found to be substantially equivalent to the predicate device.