

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

k183230

**B. Purpose for Submission:**

New device

**C. Measurand:**

Glycosylated Hemoglobin (HbA1c) with a capillary blood collection device

**D. Type of Test:**

Quantitative, latex agglutination inhibition method

**E. Applicant:**

Drawbridge Health, Inc.

**F. Proprietary and Established Names:**

OneDraw™ A1C Test System

**G. Regulatory Information:**

Regulation	Product Code	Regulation Name	Class	Panel
21 CFR 864.7470	LCP	Glycosylated hemoglobin assay	II	Hematology (84)
21 CFR 862.1675	PRJ	Blood specimen collection device	II	Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

See Indication(s) for use below.

2. Indication(s) for 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 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.

3. Special conditions for use statement(s):

For prescription use only.

For in vitro diagnostic use only.

This test should not be used in monitoring daily glucose control.

This test should not be used to replace daily home testing of urine and blood glucose levels.

This test should not be used for analyzing samples from patients with conditions causing shortened red blood cell survival, such as hemolytic diseases, homozygous sickle cell trait, pregnancy and significant acute or chronic blood loss.

4. Special instrument requirements:

Beckman Coulter AU480 Chemistry Analyzer at a designated single laboratory (InSource Diagnostics).

**I. 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, stabilization and transportation system that uses a combination of two mechanisms, capillary action, and vacuum extraction. The device incorporates lancets to make two small incisions in the skin of the upper arm and a vacuum to draw 150 µL blood at the surface of the skin and through channels to deposit the blood onto two collection and stabilization matrix strips. The base of the device includes a release liner that covers a ring of hydrogel adhesive. The adhesive seals to the skin and holds the device in place during use. A vacuum is created when the user pushes button I, then the user releases the spring that activates two lancets by pushing button II. The OneDraw Blood Collection Device includes a collection device loaded with a sample collection cartridge, a transport sleeve, accessories (alcohol prep pad, gauze pad, bandage), and instructions needed to collect, package, and mail the sample collection cartridge to the designated certified clinical laboratory for HbA1c testing.

The healthcare professional follows the directions in the OneDraw Blood Collection Device instructions for use to collect a blood sample, then packages and mails the sample to a

designated clinical laboratory for analysis. Once the cassette is received in the designated clinical laboratory, one of the sample matrix strips is removed from the OneDraw Blood Collection Device, eluted with the Beckman HbA1c Hemolyzing Reagent, and tested using FDA-cleared A1c reagents on the Beckman Coulter AU480 Chemistry Analyzer (k120199) according to the OneDraw A1C Test instructions for use.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Home Access A1C Test

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

k141944

3. Comparison with predicate:

<b>Similarities and Differences</b>		
<b>Item</b>	<b>Candidate Device Drawbridge Health, Inc. OneDraw A1C Test System k183230</b>	<b>Predicate Device Home Access A1C k141944</b>
Intended Use	Same	<i>In vitro</i> test method for quantitative measurement of Hemoglobin A1c using capillary blood collected onto filter paper. Measurements obtained through this method can be used for long-term control of blood sugar (glucose) in people with diabetes.
Sample Collection	By health care professionals in clinical laboratories	By health care professionals in clinical laboratories or by lay users at patient's home
Sample Type	Capillary blood from the upper arm collected on a collection and stabilizing matrix in the OneDraw Blood Collection Device	Capillary blood from the fingertip on filter paper in a collection cassette
Test Method in Laboratory	Beckman Coulter AU480 Chemistry Analyzer and HbA1c reagents	Beckman Coulter AU640e Chemistry Analyzer and HbA1c reagents
Kit Components	• Blood sample collection cartridge containing filter	• Blood sample collection cassette containing filter paper

<b>Similarities and Differences</b>		
<b>Item</b>	<b>Candidate Device Drawbridge Health, Inc. OneDraw A1C Test System k183230</b>	<b>Predicate Device Home Access A1C k141944</b>
	paper for specimen collection <ul style="list-style-type: none"> <li>• Sample pouch containing desiccant for specimen packaging</li> <li>• 2 sterile lancets within the assembly</li> <li>• Alcohol prep pad</li> <li>• Gauze pad</li> <li>• Bandage</li> <li>• Instructions for Use</li> <li>• Return Mailer (Chipboard) for specimen mailing</li> <li>• Outer Carton</li> </ul>	for specimen collection <ul style="list-style-type: none"> <li>• Sample pouch with desiccant for specimen packaging</li> <li>• 2 sterile safety lancets</li> <li>• Gauze Pad</li> <li>• 2 Bandages</li> <li>• Instructions for Use/Things You Should Know About A1C</li> <li>• Prepaid Return Mailer for specimen mailing</li> <li>• Patient Info Card for specimen labeling and consent</li> <li>• Outer Packaging</li> </ul>
Analysis Method	Mail to laboratory	Same
Report	Mailed to the laboratory that collected the sample	Mailed to laboratory or to the patient identified on the sample pouch label.
Measuring range	4.7-14.3% HbA1c	4.5-14.5% HbA1c

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

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-EP17-A2, 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved 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 <i>in vitro</i> 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

**L. Test Principle:**

The OneDraw Blood A1C Test System is intended to collect capillary blood from the upper arm of adults (18 years of age and older) by a healthcare worker for HbA1c testing in a designated laboratory. The OneDraw Blood Collection Device has a mechanism for skin puncture, a mechanism for drawing blood, a mechanism for stabilizing the blood sample, and can be used for temporary storage and shipping of blood. The OneDraw Blood Collection Device uses two stainless steel lancets to create skin punctures for the collection of capillary blood. When actuated, the device collects the blood sample (150µL) via vacuum draw onto two collection and stabilization matrix strips, and provides an indicator to confirm that collection is complete. The user removes the cartridge from the collection device and inserts it into the transport sleeve prior to shipping of the sample. The OneDraw Blood Collection Device is designed for one-time sample extraction. Once the dried blood sample is received by the designated laboratory, one matrix strip is removed from the sample cartridge by trained professionals using forceps and eluted with Beckman HbA1c Hemolyzing Reagent (k120199). Once eluted, the sample is assayed using FDA-cleared A1c reagents on the Beckman Coulter AU480 Chemistry analyzer.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision studies were performed based on CLSI EP05-A3. Four levels of K2 EDTA venous blood samples (5%, 6.5%, 8%, 12%) were spotted onto OneDraw Blood Collection Device matrix strips, then processed and analyzed at the designated laboratory according to the OneDraw A1C Test instructions for use. Samples were run by one operator in duplicate for 20 days (21 days for the low sample), two runs per day, on one Beckman AU480 analyzer for a total of 80-84 measurements per sample. One lot of Hemolyzing Reagent and two lots of HbA1c Reagent were used. Results are shown below:

Sample	N	Mean %HbA1c	Repeatability (within-run)		Repeatability (within-day)		Total Within-Lab	
			SD	%CV	SD	%CV	SD	%CV
Low	81*	5.10	0.073	1.44%	0.030	0.58%	0.119	2.33%
Threshold	80	6.46	0.091	1.40%	0.033	0.51%	0.135	2.09%
Medium	80	7.87	0.082	1.05%	0.025	0.32%	0.114	1.45%
High	80	11.44	0.119	1.04%	0.071	0.62%	0.161	1.40%

\*No result for three replicates due to measurements below the cleared measuring range of the Beckman Coulter A1c reagents

Lot-to-lot precision

The sponsor evaluated lot-to-lot reproducibility of the sample collection method for the OneDraw A1C Test System at two sites. Representative data for one site is shown below. One healthcare provider collected two to three upper arm capillary blood samples from each of 23 participants using OneDraw Blood Collection Devices from three different lots for a total of 66 collections. Samples were shipped to the designated laboratory where they were eluted and tested according to the OneDraw A1C Test instructions for use. %HbA1c values tested ranged from 4.84% to 10.06%.

Results:

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

Operator-to-operator precision

The sponsor evaluated operator-to-operator reproducibility of the sample collection method for the OneDraw A1C Test System at two sites. Representative data for one

site is shown below. Three healthcare providers collected two to three upper arm capillary blood samples from each of 25 participants using OneDraw Blood Collection Devices from a single lot for each participant (three collection device lots total) for a total of 71 collections. Samples were shipped to the designated laboratory where they were eluted and tested according to the OneDraw A1C Test instructions for use. %HbA1c values tested ranged from 4.66% to 14.38%.

Results:

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

*b. Linearity/assay reportable range:*

A linearity study was conducted to establish the linear range of the OneDraw HbA1c Test System. The sponsor evaluated 107 capillary blood samples collected with the OneDraw Blood Collection Device as well as seven additional K2 EDTA venous blood samples obtained commercially and spotted onto the matrix strips. The sponsor provided data to support that venous blood samples did not behave differently from capillary blood samples from the upper arm in this study. The samples covered a range of 4.76 – 14.7% HbA1c. Samples were eluted and measured in singlicate on the Beckman Coulter AU480 analyzer at the designated laboratory according to the OneDraw A1C Test instructions for use and the results were compared to results from matched liquid K2 EDTA venous blood samples measured using A1c reagents on the Beckman Coulter AU480 analyzer (k120199). A Deming regression was calculated with the following results:  $Y = 1.01x + 0.06$ ;  $R^2=0.99$ .

The study supports the sponsor’s claimed measuring range of 4.7 – 14.3%.

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

Traceability

The OneDraw A1C Test System has been certified by the National Glycohemoglobin Standardization Program (NGSP) and the Diabetes Control and Complications Trial (DCCT). The NGSP certification expires in one year. See NGSP website for current certification at <http://www.ngsp.org>. The OneDraw HbA1c Test System is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Reference Method for Measurement of HbA1c.

Sample stability

Sample stability study at room temperature of sterilized OneDraw Blood Collection Devices was conducted. The matrix strips were spotted with K2 EDTA venous blood

from four donors (5.3, 6.4, 7.9, 11.5% HbA1c) and extracted/tested within 30 minutes and at various time points after storage at room temperature up to 21 days. At each time point, samples were compared to test results obtained with fresh samples. The results of the study support the labeling claim of 21 days of room temperature stability for blood samples collected with the OneDraw Blood Collection Device.

### Shelf Life

1. Real-time shelf life stability studies of upper arm capillary blood collection, storage, and HbA1c analysis using aged OneDraw Blood Collection Devices are ongoing. Stability protocols and acceptance criteria for these studies were reviewed and found acceptable to support an initial shelf life claim of 18 months when stored at the recommended storage temperatures of 15°C-25°C (59°F-77°F).
2. OneDraw Blood Collection Devices (packaged and sterilized) were subjected to accelerated and ongoing real time stability studies. Stability protocols and acceptance criteria for these studies were reviewed and found acceptable to support a shelf life claim of 18 months when stored at the recommended storage temperatures of 15°C-25°C (59°F-77°F).
3. The sponsor evaluated the impact of holding the spring that deploys the lancets in a compressed state over time. New (i.e., never installed) and aged springs were subjected to compression testing. The results of this study support the claimed shelf life of 18 months when stored at the recommended storage temperatures of 15°C-25°C (59°F-77°F).

### Shipping

Several stability studies were conducted to assess the performance of the OneDraw A1C Test System to collect and measure quality samples after undergoing simulated extreme shipping and distribution conditions (extreme cold, extreme heat, extreme humidity). Real-time shipping studies are ongoing. The shipping stability study protocols and acceptance criteria of the OneDraw A1C Test System were reviewed and found to be acceptable. The study results support the manufacturer's claim that the OneDraw A1C Test System can perform as indicated following shipping of the packaged OneDraw Blood Collection Devices.

### Additional bench testing evaluated on the candidate device:

The sponsor conducted additional studies to assess the OneDraw Blood Collection Device malfunction rate as well as the effect of draw volume, sample collection time, hematocrit interference, and equivalence of the two matrix strips on OneDraw A1C Test System performance. Results for these studies were reviewed and found to be acceptable.



d. *Detection limit:*

The limit of detection for the OneDraw HbA1c assay is based on the Beckman HbA1c reagents on the AU480 analyzer (cleared in k120199).

e. *Analytical specificity:*

Endogenous and exogenous interference was evaluated using K2 EDTA venous whole blood at two %HbA1c levels (~5%) and high (~10%) spiked with the potentially interfering substances. Each sample and an un-spiked control was spotted onto OneDraw Blood Collection Device matrix strips and then eluted and tested per the OneDraw A1C Test instructions for use. Six replicates were tested. Results for spiked samples were compared to the results from control samples. The sponsor defined significant interference as > 10% difference between spiked and control samples.

<b>Substance</b>	<b>Highest Concentration Without Significant Interference</b>
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	65 mg/dL
Ibuprofen	50 mg/dL
L-ascorbic acid	3 mg/dL
Metformin	4 mg/dL
Glyburide	0.2 mg/dL
Bilirubin, conjugated	33.2 mg/dL
Bilirubin, unconjugated	30 mg/dL
Triglycerides	3400 mg/dL
Rheumatoid Factor	600 IU/mL

Hemoglobin Variant Interference

Interference from common hemoglobin variants (HbA2, HbC, HbD, HbE, HbS, HbF) was evaluated based on CLSI EP07-A2, Interference Testing in Clinical Chemistry. Four to ten K2 EDTA samples with varying levels of %HbA1c and hemoglobin variants were spotted onto OneDraw Blood Collection Device matrix strips and eluted and measured in replicates of five or six per the OneDraw A1C Test instructions for use. Test results were compared to %HbA1c values obtained with an FDA cleared comparator method free of interference from the respective hemoglobin variant. The sponsor defined significant interference as bias > ±10%. The results of the study support the sponsor's claim that there is no significant interference from hemoglobin variants 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 HbA1c Test System.

The labeling contains the following statement:

*Hemoglobinopathies may interfere with glycated hemoglobin analysis. Studies show that there is no significant interference for HbA2 ( $\leq 5.8\%$ ), HbC ( $\leq 40.1\%$ ), HbD ( $\leq 41.2\%$ ), HbE ( $\leq 22\%$ ), and HbS ( $\leq 34.8\%$ ). 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.*

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

A method comparison study was conducted at the designated laboratory. Two to four healthcare professionals at two clinical sites collected 107 capillary blood samples (4.76 – 14.7% HbA1c) with four lots of the OneDraw Blood Collection device. Results obtained with capillary blood with the OneDraw A1C Test System were compared to results from matched K2 EDTA venous blood samples using the same Beckman Coulter HbA1c reagents on the Beckman Coulter AU480 analyzer (k120199). All samples were tested in singlicate.

Study enrollment was as follows:

<b>%HbA1c Interval</b>	<b>Site 1</b>	<b>Site 2</b>	<b>Total</b>	<b>Total %</b>
< 5.5	8	8	16	14.55%
5.5 – 7.0	14	18	32	29.09%
7.0 - 8.5	24	18	42	38.18%
> 8.5	6	8	14	12.73%
$\geq 11.0$	3	3	6	5.45%
All	55	55	110	100.00%

Passing-Bablok regression results are shown below:

$$y = 1.00x - 0.11, R^2 = 0.99$$

b. *Matrix comparison:*

Not applicable. The OneDraw A1C Test System is intended for use with capillary blood from the upper arm only.

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:

In 2019, the American Diabetes Association (ADA) recommended a reasonable A1c goal for many non-pregnant adults is < 7 % (53 mmol/mol). Providers might reasonably suggest more stringent A1C goals (such as 6.5 % [48 mmol/mol]) for selected individual patients if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Less stringent A1C goals (such as <8% [64 mmol/mol]) may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions, or long-standing diabetes in whom the goal is difficult to achieve despite diabetes self-management education, appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin.<sup>1</sup>

<sup>1</sup>American Diabetes Association, Standards of Medical Care in Diabetes – 2019 (Volume 42, Supplement 1)

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

**O. Conclusion:**

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