The OneDraw™ A1C Test System: An innovative blood sampling technology that provides convenient, comfortable, and accurate monitoring of HbA1c

We conducted two sequential clinical studies between September 2018 and June 2019 assessing the performance of our blood sampling device in collecting and stabilizing blood for HbA1c monitoring. Blood collected with the single-use OneDraw Blood Collection Device does not require refrigeration and may be shipped via standard mail. The first study enrolled 153 eligible participants at three independent clinical sites; the second study enrolled 110 eligible participants at two independent clinical sites. The results presented here are combined from both studies.

Our research found that blood collected and tested using the OneDraw A1C Test System, consisting of the OneDraw Blood Collection Device and the OneDraw HbA1c Test, provides accurate HbA1c results when compared with venipuncture. Device precision studies showed that the OneDraw A1C Test System performs consistently when used by multiple healthcare professionals and using multiple manufacturing lots of OneDraw Blood Collection Devices. Study participants found the OneDraw Blood Collection Device to be less painful than venipuncture and fingerstick and the participants strongly preferred the OneDraw Blood Collection Device over the other blood sampling methodologies.

The OneDraw A1C Test System received FDA clearance on August 15, 2019.

Future studies will assess the performance of samples collected using the OneDraw Blood Collection Device testing other analytes.

Introduction

Monitoring hemoglobin A1C (HbA1c) levels in individuals affected by diabetes remains the standard of care for ensuring proper management of the condition.[1] Typically, HbA1c is measured at regular intervals by venipuncture or fingerstick blood collection methods. For nearly all diabetic patients, monitoring HbA1c is a lifelong endeavor.

Many people consider both venipuncture and fingerstick to be inconvenient and painful. Patient surveys have shown that venipuncture induces fear (needle phobia) in more than 20% of adults and 60% of children.[2]

We have designed, developed and validated the OneDraw A1C Test System to improve the blood draw experience and make it more accessible to patients worldwide. The system consists of two elements: the OneDraw Blood Collection Device, intended for the collection and stabilization of capillary blood by a healthcare professional (HCP), and the OneDraw A1C Test, intended for monitoring the long-term control of blood sugar (glucose) in people with diabetes.

Blood collection begins with the application of the OneDraw Blood Collection Device to the patient's upper arm, just below the shoulder, where the device attaches to the skin via an adhesive ring. The HCP presses the first of two buttons to engage a gentle vacuum. Next, the second button is pressed to release the lancets which make two small incisions on the surface of the patient's skin. The vacuum draws capillary blood into the device, where it is deposited into a cartridge containing two paper matrices that absorb and stabilize the blood. The cartridge containing the sample is then removed from the device and placed into a transport sleeve.

Significantly, the sample does not require refrigeration and can be sent via standard mail to a designated clinical laboratory. There, the OneDraw A1C Test, a quantitative measurement of HbA1c using the Beckman Coulter HbA1c (Hemoglobin A1C) reagents and AU480 Chemistry Analyzer, is performed.

1. OneDraw attaches to the upper arm with a hydrogel adhesive and vacuum. Sample is collected with the push of a button.
2. Blood is stabilized within removable cartridge.
3. Removable cartridge is placed in transport sleeve and mailed to lab for HbA1c testing.

High-Quality Blood Samples, the Easy Way

- No tourniquets or visible blood.
- No cumbersome cold chain.
- Just a comfortable process that delivers reliable results.

FDA-Cleared

OneDraw is FDA cleared for the collection of capillary blood for quantitative measurement of HbA1c.

High-Quality Samples

HbA1c levels in blood collected by OneDraw were comparable to those in blood collected with standard venipuncture.

Patient-Friendly

Study participants preferred OneDraw to both venipuncture and fingerstick blood collection methods for HbA1c testing.

Research Methodology

We conducted two sequential clinical studies across three clinical sites in the US (sites 01, 02, and 03). The studies enrolled a total of 263 eligible participants.

The first study aimed to show the equivalence of HbA1c values between the A1C Test System and standard venipuncture, as well as to demonstrate the OneDraw Blood Collection Device precision (using multiple operators and device lots). The second study was conducted specifically to designate a clinical laboratory for HbA1c testing and to obtain additional precision data related to the OneDraw Blood Collection Device across multiple clinical study sites.

The study protocols had identical endpoints, inclusion/exclusion criteria, and study conduct principles, but a different number of clinical sites. For this reason, the results presented in this white paper are based on data combined from both studies.

Participant Demographics

Study participants were pre-selected based on their historical HbA1c values. The participants ranged in age from 18 to 82, with an average age of 45. Approximately 44 percent were male and 56 percent female (Table 1). Because of the need to measure the OneDraw A1C Test System's performance across the range of HbA1c values, approximately 75 percent of study participants were diabetic (Type 1 and Type 2) and 25 percent were not.

	Site 1	Site 2	Site 3	All Sites
N	108	50	105	263
Mean	37	56.1	47.2	44.7
Std Dev	15	15.4	14	16.3
Min	18	23	19	18
Median	33	61.5	48	43
Max	74	80	82	82

Table 1. Age of Enrolled and Eligible Participants by Site (N=263)

Method Comparison

The primary objective of the studies was method comparison: specifically, to compare %HbA1c results from samples collected by the OneDraw Blood Collection Device with those collected by standard venipuncture.

In the first study, all OneDraw Blood Collection Device- and venipuncture-collected blood samples were sent to the Drawbridge Health (DBH) laboratory for testing. In the second study, samples were sent to and analyzed by an independent clinical laboratory.

To analyze the findings, we conducted a linear regression analysis of the test results from venipuncture samples compared to the OneDraw Blood Collection Device samples, using the Passing-Bablok method.

Linearity

To verify the linearity of the OneDraw A1C Test, 253 capillary blood samples from the method comparison were used. In addition, 20 frozen blood samples obtained from a biobank were spotted onto OneDraw matrix strips and tested using the same methodology. The frozen samples were added to ensure a more robust linearity assessment.

Device Performance

We also evaluated the precision of the OneDraw Blood Collection Device with regard to various manufacturing lots (lot-to-lot precision) and across multiple healthcare professionals (HCP-to-HCP precision). Moreover, we evaluated the other characteristics associated with the performance of the OneDraw Blood Collection Device, such as pain, preference, and draw time.

Lot-to-Lot Precision

This portion of the research was carried out at two clinical sites, 01 and 03. To determine lot-to-lot precision, we used OneDraw Blood Collection Devices from a total of six manufacturing lots. The range of HbA1c results was 4.84% to 10.06%. At each site, a single HCP used OneDraw Blood Collection Devices from three different lots to collect samples from each participant. There were 25 participants at site 01 and 23 participants at site 03. Some samples were tested at the DBH lab and some at the independent clinical lab.

As in other analytical precision studies, the lot-to-lot acceptance criterion was based on the performance results obtained by Beckman Coulter's testing on AU480 analyzers with HbA1c reagents. According to the manufacturer's Instructions for Use, correctly operating AU Systems should exhibit precision values of less than or equal to 4% CV.

HCP-to-HCP Precision

This portion of the research was done at two clinical sites, 01 and 02. Three HCPs collected blood samples using OneDraw Blood Collection Devices from a single lot for each participant. The range of HbA1c results was 4.66% to 14.38%. There were 24 participants at site 02 and 25 participants at site 01. Some samples were tested at the DBH lab and some at the independent clinical lab.

As in other analytical precision studies, the operator-to-operator (HCP-to-HCP) acceptance criterion was based on the performance results obtained by Beckman Coulter's testing on AU480 analyzers running HbA1c reagents. According to the manufacturer's Instructions for Use, correctly operating AU480 Systems should exhibit precision values of less than or equal to 4% CV.

Pain Rating and Device Preference

Our studies also assessed the pain associated with the OneDraw Blood Collection Device, as compared with both venipuncture and with fingerstick. Immediately after the completion of each procedure, participants were asked to rate the pain of each of the three blood collection procedures on a scale of 0 (no pain) to 10 (the worst pain imaginable). They also were asked which of the three blood draw methods they preferred.

Draw Time

To determine how long it takes to draw blood using the OneDraw Blood Collection Device, each healthcare professional was instructed to start the timer once the blood collection process began and to stop the timer when the device was removed from the participant's skin.

Study Results

Method Comparison

The linear regression results showed a slope close to 1.00 and a minimal intercept, with a high correlation coefficient. The 95% confidence interval for the slope estimate contains the value 1.00, supporting the conclusion that there is no difference between the methods (Table 2). The pooled results of the combined clinical studies and HbA1c analysis at the two laboratories demonstrate that the OneDraw device performs accurately.

Linearity

We used Deming regression to verify the linearity of the HbA1c test. The R^2 of the fit is 0.99. The fitted line has an intercept of +0.06 (95% Bootstrap CI -0.11, 0.24) and a slope of 1.01 (95%CI 0.98, 1.03) (Figure 1). This indicates a high level of linearity, demonstrating that the assay can precisely distinguish HbA1c levels across a wide range of values.

Passing-Bablok Regression (N=253)				
Intercept	**Slope**	**LowerCL**	**UpperCL**	**Tau**
-0.021	0.99438	0.98039	1.00785	0.9326

Table 2. Passing-Bablok estimates for the linear regression analysis

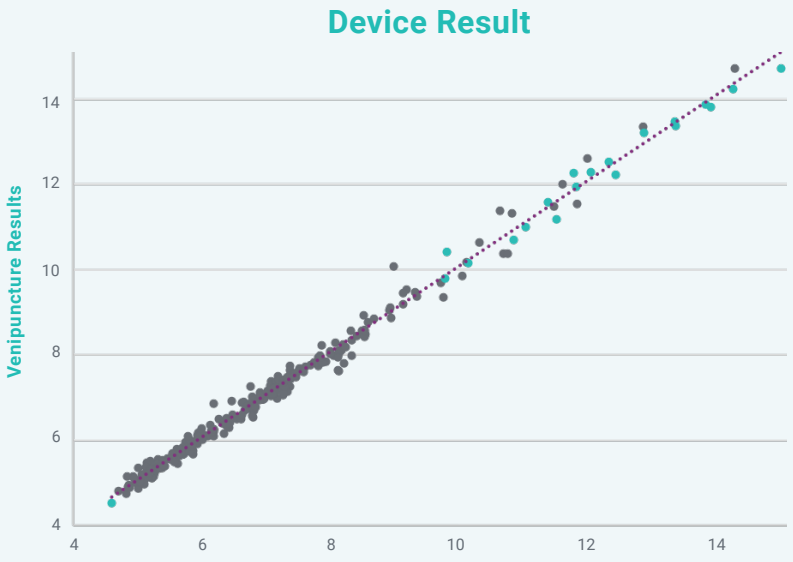

Figure 1. Deming Regression of OneDraw Blood Collection Device vs. venipuncture. Results from frozen supplemental samples are shown in teal.

Device Performance Studies

Lot-to-Lot

For device lot-to-lot precision, the pooled average %CV is 1.1% (range: 0–3.6%), well within the pre-established acceptance criterion. The range of HbA1c was 4.84% to 10.06%. This indicates that OneDraw Blood Collection Devices manufactured in different lots perform consistently.

HCP-to-HCP

For device operator-to-operator precision, the pooled average %CV is 1.2% (range: 0.1–4.8%), well within the pre-established acceptance criterion. The range of HbA1c results was 4.66% to 14.38%. This indicates that multiple healthcare professionals achieve consistent results when using the OneDraw Blood Collection Device.

Pain Rating

Generally, participants reported OneDraw to be equal to or less painful than fingerstick (91%) or venipuncture (93%). A sub-analysis was conducted to evaluate any difference in pain rating in participants with and without diabetes (Table 3). Pain score distributions show the lower pain ratings for OneDraw (Figure 2).

	All Participants			Participants without Diabetes			Participants with Diabetes		
Procedure	**N**	**Mean**	**Median**	**N**	**Mean**	**Median**	**N**	**Mean**	**Median**
Device	263	1.02	1	67	0.96	1	196	1.05	1
Fingerstick	260	2.60	2	67	3.00	3	193	2.47	2
Venipuncture	259	2.68	2	67	2.73	2	192	2.66	2

Table 3. Pain rating analysis including sub-analysis of participants with and without diabetes.

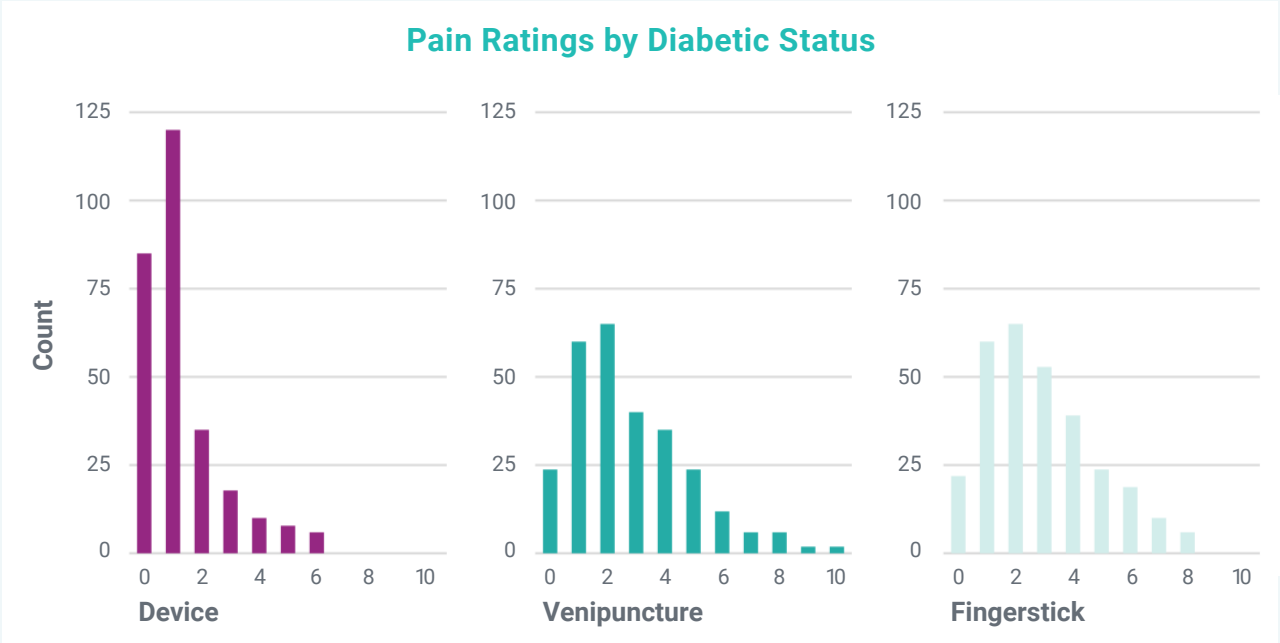

Figure 2. Counts of pain rating for each procedure (all participants).

Device Preference

Generally, the OneDraw Blood Collection Device was strongly preferred over both venipuncture and fingerstick (80%). A sub-analysis was conducted to evaluate any difference in the procedure preference in participants with and without diabetes (Figure 3).

Draw Time

Based on a total of 485 draws, the mean draw time was 4 minutes and 52 seconds (median: 3 minutes and 58 seconds). It is important to note that draw times can vary depending on the device as well as on the physical characteristics of the person whose blood is being drawn, such as the individual's hydration status and capillary bed physiology, among other factors.

Conclusion

Study data shows that the innovative OneDraw A1C Test System provides accurate, comfortable, and convenient blood sampling for HbA1c monitoring. We believe the OneDraw Blood Collection Device offers substantial advantages over current methods of blood sampling and stabilization and has the potential for widespread adoption. In future studies we plan to assess the performance of other analytes in blood samples collected with the OneDraw Blood Collection Device.

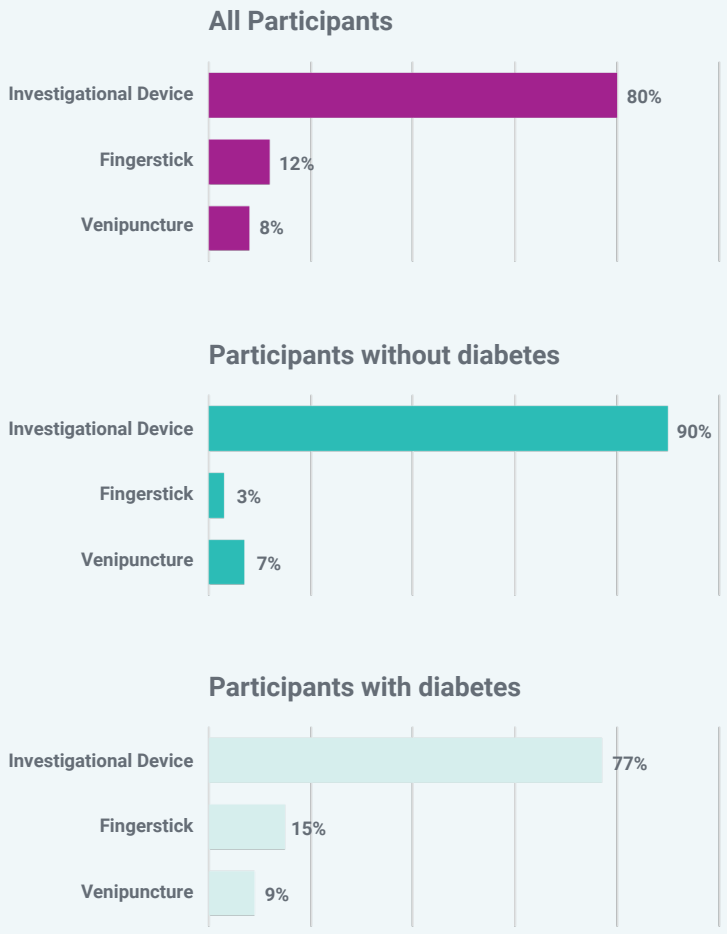

Figure 3. Blood draw procedure preference, for all participants and for the subgroups

References

1. American Diabetes Association. Diabetes Care, vol. 42, supplement 1, Jan. 2019. "Standards of Medical Care in Diabetes."
2. www.needlephobia.com/prevalence.html.