510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k142664

B. Purpose for Submission:

New Device

C. Measurand:

Whole blood Glycosylated hemoglobin (HbA1c)

D. Type of Test:

Quantitative, Immuno-turbidimetric assay

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names

URight Hemoglobin A1c system
FORA A1c System

G. Regulatory Information:

1. Regulation section:

Product Code	Classification	Regulation Section	Panel
LCP	Class II	21CFR 864.7470 Glycosylated hemoglobin assay	Hematology (81)
JJE	Class I	21CFR 862.2160 Discrete photometric chemistry analyzer	Chemistry (75)
JJX	Class I	21CFR 862.1660 Quality control material (assayed and unassayed)	Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indications for use below.

2. Indication(s) for use:

The URight Hemoglobin A1c System is intended to quantitatively measure the percent of hemoglobin A1c in capillary finger-stick or venous whole blood collected in EDTA (K2 and K3) or sodium heparin for clinical laboratory and point of care use. The measurement of hemoglobin A1c concentration is for use in monitoring long-term glucose control of persons with diabetes. The system is for in vitro diagnostic use and is not for use in diagnosis or screening of diabetes or for neonatal use.

The URight Hemoglobin A1c Control Solution is intended for use as quality control material for the URight Hemoglobin A1c System.

The FORA A1c System is intended to quantitatively measure the percent of hemoglobin A1c in capillary finger-stick or venous whole blood collected in EDTA (K2 and K3) or sodium heparin for clinical laboratory and point of care use. The measurement of hemoglobin A1c concentration is for use in monitoring long-term glucose control of persons with diabetes. The system is for in vitro diagnostic use and is not for use in diagnosis or screening of diabetes or for neonatal use.

The FORA A1c Control Solution is intended for use as quality control material for the FORA A1c System.

3. Special conditions for use statement(s):

- This test is not for screening or diagnosis of diabetes or neonatal use
- For clinical laboratory and point-of care use
- For prescription 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, pregnancy and significant acute or chronic blood loss
- HbF and HbS levels tested with this assay show interference and samples containing HbF or HbS will show a lower than expected HbA1c result

4. Special instrument requirements:

URight Hemoglobin A1c Analyzer
FORA Hemoglobin A1c Analyzer

I. Device Description:

This 510(k) submission consists of one device that will be marketed under two names; the URight Hemoglobin A1c system and FORA A1c system. The devices are exactly the same except for their names. All performance studies described below apply to the URight Hemoglobin A1c system and the FORA A1c system. Throughout the discussion of the performance studies, the device will be termed the URight Hemoglobin A1c system.

The URight Hemoglobin A1c system and FORA A1c system are each comprised of a fully automated desktop electric spectrophotometer (analyzer) that measures HbA1c in capillary or venous whole blood samples collected in EDTA (K2 and K3) or sodium heparin using a dedicated cartridge, which is pre-filled with the reagent; latex (reagent R1), antibody and sample dilute solution (reagent 2). The hemoglobin A1c system shines a 655 nm light through the test material and measures the quantity of hemoglobin A1c in the total hemoglobin (HbA1c %) based on the lot-specific reagent parameters and changes in light absorbency caused by antigen-antibody reactions. The R1 Reagent contains: 0.13% latex, buffer, stabilizers. The R2 Reagent contains: 0.05mg/ml Mouse anti-human HbA1c monoclonal antibody, 0.08mg/ml Goat anti-mouse IgG polyclonal antibody, buffer, and stabilizers. The reagent kit contains test cartridge, capillary holder, desiccant bag, cartridge instruction and calibration card.

Two levels of URight Hemoglobin A1c controls will be included as part of the URight Hemoglobin A1c System. Two levels of FORA A1c controls will be included as part of the FORA A1c system. The controls are exactly the same except for their names. All performance studies described below apply to the URight Hemoglobin A1c controls and the FORA A1c controls. Throughout the discussion of the performance studies, the device will be termed the URight Hemoglobin A1c controls. URight Hemoglobin A1c controls and FORA A1c controls are provided for routine quality checks - level 1 in the normal HbA1c range and level 2 in the elevated HbA1c range. The HbA1c controls are lyophilized hemolysates prepared from packed human erythrocytes.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Siemens DCA Vantage
   Hemoglobin A1c Reagent Set

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

   k071466
   k031539

3. Comparison with predicate:

URight Hemoglobin A1c System:

Similarities		
Item	Candidate Device URight Hemoglobin A1c system k142664	Predicate Device Siemens DCA Vantage k071466
Intended Use	Quantitative measurement of the percent Hemoglobin A1c in human whole blood for use in monitoring long-term glucose control of persons with diabetes.	Same
Methodology	Immuno-turbidimetric	Same
Sample Type	Whole blood samples, venous (using K2 or K3 EDTA and sodium heparin) or capillary whole blood from the fingertips.	Same
Recommended Testing Environment	Professional and Point of Care Use	Same
Reagent stability	12 months unopened when stored at 2-8°C	Same
Differences		
Item	Candidate Device URight Hemoglobin A1c system k142664	Predicate Device Siemens DCA Vantage k071466
Analytical Range	4.0-16.0%	2.5 – 14.0%

URight Hemoglobin A1c Controls:

Similarities		
Item	Candidate Device URight Hemoglobin A1c control k142664	Predicate Device Hemoglobin A1c Reagent Set k031539
Intended Use	Intended for use as quality control materials	Same
Format (Material)	Lyophilized hemolysates	Same
Levels	Level 1, Level 2	Same

Differences		
Item	Candidate Device URight Hemoglobin A1c control k142664	Predicate Device Hemoglobin A1c Reagent Set k031539
Stability	18 months unopened when stored at 2-8°C 3 weeks after reconstitution when stored at 2-8°C	Expires 4 weeks after reconstitution

FOR A1c System:

Similarities		
Item	Candidate Device FORA A1c system k142664	Predicate Device Siemens DCA Vantage k071466
Intended Use	Quantitative measurement of the percent Hemoglobin A1c in human whole blood for use in monitoring long-term glucose control of persons with diabetes.	Same
Methodology	Immuno-turbidimetric	Same
Sample Type	Whole blood samples, venous (using K2 or K3 EDTA and sodium heparin) or capillary whole blood from the fingertips.	Same
Recommended Testing Environment	Professional and Point of Care Use	Same
Reagent stability	12 months unopened when stored at 2-8°C	Same
Differences		
Item	Candidate Device FORA A1c system k142664	Predicate Device Siemens DCA Vantage k071466
Analytical Range	4.0-16.0%	2.5 – 14.0%

FORA A1c Controls:

Similarities		
Item	Candidate Device FORA A1c control k142664	Predicate Device Hemoglobin A1c Reagent Set k031539
Intended Use	Intended for use as quality control materials	Same
Format (Material)	Lyophilized hemolysates	Same
Levels	Level 1, Level 2	Same
Differences		
Item	Candidate Device FORA A1c control k142664	Predicate Device Hemoglobin A1c Reagent Set k031539
Stability	18 months unopened when stored at 2-8°C 3 weeks after reconstitution when stored at 2-8°C	Expires 4 weeks after reconstitution

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

CLSI-EP06-A: Evaluation of the Linearity of Quantitative Measurement procedures: A Statistical Approach

CLSI-EP09-A2 Method Comparison and Bias Estimation Using Patient Samples

CLSI-EP05-A2- Evaluation of Precision Performance of Quantitative Measurement Methods

L. Test Principle:

The URight Hemoglobin A1c system and the FORA A1c System are an immuno-turbidimetric method enhanced by latex particles using a two-reagent sequence. Hemolysate is mixed with the R1 reagent. Addition of the R2 reagent leads to agglutination complexes, formed by the interaction between latex-bound HbA1c and the corresponding antibodies. Turbidity created by these aggregates is proportional to the amount of latex-bound HbA1c therefore is proportional to the % of HbA1c in the total hemoglobin.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

This 510(k) submission consists of one device that will be marketed under two names; the URight Hemoglobin A1c system and FORA A1c system. The devices are exactly the same except for their names. All performance studies described below apply to the URight Hemoglobin A1c system and the FORA A1c system. Throughout the discussion of the performance studies, the device will be termed the URight Hemoglobin A1c system.

a. Precision/Reproducibility:

Internal Precision Study

An internal precision study was performed according to CLSI-EP5 using the URight Hemoglobin A1c system. Within-run precision, between-run precision, between-day precision and total precision were determined. Two levels of HbA1c control solutions, low whole blood control (5.9% HbA1c), high whole blood control (10.8% HbA1c), and three levels of EDTA venous blood (low level: 5.1%, middle level: 7.4%, high level: 10.5%) and 3 lots of reagent cartridge were used for this evaluation. The expected values were determined by using the Tosoh Bioscience G8 HPLC Analyzer. Within run precision samples were run 20 times (n=60). Between run and between days precision samples were run in duplicate twice a day for 20 days (n=80). The results are summarized below:

Internal Precision Study (combined lots)

	Within run			Between run			Between Day		
Sample	Mean (mmol/L)	SD	%CV	Mean (mmol/L)	SD	%CV	Mean (mmol/L)	SD	%CV
Control solution Low level	5.9	0.25	4.22	5.9	0.12	2.10	5.9	0.25	4.30
Control solution High level	10.8	0.39	3.60	10.8	0.21	1.96	10.8	0.37	3.45
Venous blood Low level	5.1	0.20	3.97	5.1	0.11	2.09	5.1	0.20	3.96
Venous blood Middle level	7.4	0.26	3.47	7.4	0.12	1.59	7.4	0.25	3.34
Venous blood High level	10.6	0.41	3.89	10.5	0.20	1.89	10.5	0.38	3.64

An external precision study was performed at three Point of Care sites by trained professionals using the URight Hemoglobin A1C System. Two levels of HbA1c control solutions, Low whole blood control (5.7% HbA1c), High whole blood control (11.3% HbA1c) and three levels of EDTA (K2 or K3) venous blood (low level: 5.5%, middle level: 7.7%, high level: 10.3%) were analyzed using 3 lots of URight A1c Reagent cartridge (1 lot per site) and 30 URight Hemoglobin A1c Analyzers. Within run precision samples were run 20 times at 3 POC sites. Between run and between days precision samples were run in duplicate twice a day for 20 days at 3 POC sites. The results are summarized below:

POC Precision Study

Sample	Site	Expected value	Within run			Between run			Between day		
			Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
Control solution Low level	1	5.7	5.9	0.22	3.75	5.8	0.10	1.79	5.8	0.20	3.48
	2		5.7	0.24	4.24	5.7	0.13	2.19	5.7	0.20	3.47
	3		5.8	0.25	4.32	5.7	0.11	1.99	5.7	0.22	3.82
	Combined		5.8	0.25	4.35	5.7	0.12	2.02	5.7	0.21	3.61
Control solution High level	1	11.3	11.4	0.44	3.88	11.3	0.24	2.11	11.3	0.43	3.78
	2		11.4	0.44	3.85	11.2	0.25	2.22	11.2	0.44	3.89
	3		11.2	0.40	3.55	11.3	0.25	2.24	11.2	0.46	4.12
	Combined		11.3	0.43	3.77	11.3	0.24	2.16	11.2	0.44	3.92
Blood sample Low level	1	5.5	5.3	0.15	2.87	5.3	0.10	1.88	5.3	0.20	3.79
	2		5.3	0.22	4.14	5.3	0.11	2.01	5.3	0.21	4.04
	3		5.3	0.17	3.18	5.3	0.13	2.54	5.3	0.20	3.70
	Combined		5.3	0.18	3.46	5.3	0.12	2.18	5.3	0.20	3.87
Blood sample Middle level	1	7.7	7.9	0.33	4.18	7.8	0.13	1.62	7.8	0.30	3.91
	2		7.7	0.38	4.95	7.7	0.10	1.36	7.6	0.29	3.85
	3		7.6	0.27	3.58	7.7	0.16	2.08	7.7	0.30	3.90
	Combined		7.7	0.35	4.50	7.7	0.14	1.79	7.7	0.30	3.92
Blood sample High level	1	10.3	10.4	0.34	3.26	10.4	0.17	1.66	10.4	0.36	3.43
	2		10.4	0.37	3.60	10.5	0.18	1.67	10.5	0.36	3.39
	3		10.4	0.35	3.43	10.5	0.17	1.63	10.5	0.37	3.49
	Combined		10.4	0.35	3.38	10.5	0.18	1.70	10.5	0.36	3.46

b. Linearity/assay reportable range:

Linearity was evaluated according to CLSI-06A. The linearity of the hemoglobin A1c system was verified using a low level (4.3%) and a high level (13%) of K2 EDTA whole blood donor samples. The normal and high samples were intermixed to create eleven samples. Two additional samples, 14.3% and 15.5% HbA1c, were created by spiking in order to cover the assay range of 4-16%. The following sample concentrations were tested;

No.	1	2	3	4	5	6	7	8	9	10	11	12	13
% HbA1c Conc.	4.3	5.1	6.0	6.8	7.9	8.9	9.4	10.4	11.3	12.3	13.0	14.3	15.5

All samples were analyzed using three lots of reagent cartridges. The observed % HbA1c value was determined for each intermediate dilution and plotted versus the relative analyte concentration obtained on the Tosoh Bioscience G8 HPLC analyzer. The linear regression is as follows:

Slope	Intercept	R2	Recovery (%)
1.0037	0.0355	0.9913	95-104

The linearity study was reviewed and found acceptable. Based on linearity results, the sponsor claims the assay is linear across the reportable measuring range of 4 to 16% HbA1c.

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

Traceability:

The URight Hemoglobin A1c Reagent Cartridge uses the Tosoh Bioscience G8 HPLC analyzer to confirm the analyte concentrations used for calibration. The Tosoh Hemoglobin A1c Calibrator Set is used to calibrate the Tosoh Bioscience G8 HPLC analyzer and is produced by the Tosoh Corporation. The assigned values of Tosoh Hemoglobin A1c Calibrator Set are traceable to the Diabetes Control and Compilation Trial (DCCT) Reference method.
The URight Hemoglobin A1c system 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.

Value Assignment: The control value assignment is performed using two levels of URight HbA1c control solutions, one lot of URight Hemoglobin A1c Reagent Cartridges and one URight Hemoglobin A1c Analyzer. Each control level is run 15 times and the mean, SD and CV% is calculated and are lot specific and must meet the sponsor's pre-determined acceptance criteria.

Calibration:

The values for calibration curve for each reagent lot are contained within the barcode and encoded onto the Master Calibration card. A calibration card is provided in the reagent kit and should be used to calibrate the analyzer every time before using each new box of reagent cartridges.

Stability:

The URight Hemoglobin A1c Reagent Cartridge can be stored at temperatures from 2°C - 8°C (35.6°F to 46.4°F) for 12 months and can be used at temperatures from 15°C to 32°C (59°F to 89.6°F) at a relative humidity from 10% to 90%. The stability studies were found to be acceptable and support the claimed stability and operating temperature conditions.

The URight Hemoglobin A1c Control can be stored unopened at 2°C - 8°C for 18 months and 3 weeks at 2°C - 8°C after opening.

d. Detection limit:

Please see linearity study above in M1b.

e. Analytical specificity:

An interference study was performed according to EP7-A2 guidance to assess common or known endogenous and exogenous substances that could interfere with the hemoglobin A1c system. The limiting level of interference was determined by the dose response testing results. Three lots of URight Hemoglobin A1c Reagent Cartridge and 10 URight Hemoglobin A1c Analyzers were used in the study. The potential interferents acetaminophen, ibuprofen, glibenclamide, metformin, L-ascorbic acid and bilirubin (unconjugated) were spiked into K2EDTA whole blood samples from volunteers containing low level (4-6%) and high level (8-9%) of HbA1c. The %HbA1c values of the spiked samples were compared to reference samples (sample containing no interferent). Samples were tested once and the sponsor defined non-significant interference as the % recovery ± 6%. If bias >6%, the substance is a potential interferent at the tested concentration. The interferent study results are summarized in the table below:

Non-Interfering Substances and Test Concentrations

Substance	Test Concentration
Acetaminophen	20 mg/dL
Glibenclamide	0.19 mg/dL
Ibuprofen	50 mg/dL
Metformin	4 mg/dL
Triglycerides	>3000 mg/dL
Bilirubin (unconjugated)	20 mg/dL
Ascorbic acid	3 mg/dL
Rheumatoid Factor	26 IU/mL
Acetylated Hb	5mmol/L
Carbamylated Hb	5mmol/L

Labile A1c study was performed using three lots of URight Hemoglobin A1c Reagent Cartridge and 10 URight Hemoglobin A1c Analyzers and K2EDTA whole blood samples from volunteers containing low level (4-6%) and high level (8-9%) of HbA1c. Samples spiked with a high glucose solution (approx. 20,000 mg/dL) to a concentration of 1400 mg/dL) were incubated for 3 hours at 37°C and control samples prepared to ensure that the dilutions of the spiked and control samples were identical were tested. Samples were tested in once and test samples were compared to the control samples. The sponsor defined non-significant interference as the % recovery ± 6%. The results showed that no significant interferences (± 6%) are observed in this study.

A hemoglobin variant study was performed using high level Hb variant samples to include Hemoglobin C, Hemoglobin D, Hemoglobin E, Hemoglobin A2, Hemoglobin F and Hemoglobin S. Two HbA1c concentrations (low and high) were tested for each variant. The samples were tested in singlicate using three lots of URight Hemoglobin A1c Reagent Cartridge and 10 URight Hemoglobin A1c Analyzers. The sponsor defined non-significant interference as the % recovery ± 6%. The testing results indicate there is no significant interference for HbC ≤37.4%, HbD ≤48.5%, HbE ≤21.4% and HbA2 ≤7.0%. HbF shows interference at 21.2% and HbS shows interference at 20.3%.

The sponsor has the following limitations in the labeling:
HbF and HbS levels tested with this assay show interference and samples containing HbF or HbS will show a lower than expected HbA1c result.

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison:

A POC method comparison study was performed with 149 (146 natural and 3 spiked) venous whole blood samples and 146 capillary blood patient samples in three point of care (POC) sites. Capillary blood was collected from patients and analyzed once using the URight Hemoglobin A1c Reagent Cartridge on the URight Hemoglobin A1c analyzer. Venous blood samples were collected from the same patients using an EDTA collection tube and analyzed once using the URight Hemoglobin A1c Reagent Cartridge on the URight Hemoglobin A1c analyzer and once on the Tosoh Bioscience G8 HPLC analyzer. The range tested was 4.0 to 15.8% HbA1c. Site 1 tested 49 samples (48 natural and 1 spiked venous blood), Site 2 tested 50 samples (48 natural and 2 spiked venous blood) and Site 3 tested 50 samples (49 natural and 1 spiked venous blood). In the capillary blood study, Site 1 tested 49 samples, Site 2 tested 48 samples and Site 3 tested 49 samples.

The linear regression of EDTA venous whole blood and capillary blood between the URight Hemoglobin A1c Reagent Cartridge and Tosoh G8 (the comparator in each study) is as follows:

Site No.	Sample type	N	regression line	R2
1	Capillary	49	y = 1.002x - 0.016	0.9834
1	K2EDTA venous blood	49	y = 1.018x - 0.101	0.9807
2	Capillary	48	y = 1.015x - 0.044	0.9846
2	K2EDTA venous blood	50	y = 1.022x - 0.076	0.9885
3	Capillary	49	y = 0.958x + 0.280	0.9849
3	K3EDTA venous blood	50	y = 0.968x + 0.160	0.9861

b. Matrix comparison:

A matrix comparison study was performed using capillary blood, K2 EDTA venous blood, K3 EDTA venous blood and sodium heparin venous blood. 120 total donor samples were collected from 3 POC sites and analyzed using the URIGHT Hemoglobin A1c Reagent Cartridge on the URight Hemoglobin A1c analyzer. 40 donor samples were collected from site 1 using capillary fingerstick blood, K2 EDTA venous blood and sodium heparin venous blood, 40 donor samples were collected from site 2 using capillary fingerstick blood, K2EDTA venous blood and sodium heparin venous blood and 40 donor samples were collected from site 3 using capillary fingerstick blood, K3EDTA venous blood and sodium heparin venous blood. 9 venous blood samples were spiked to 13-16% HbA1c samples. Each sample was tested once using the URight Hemoglobin A1c Reagent Cartridge on the URight Hemoglobin A1c analyzer. Samples tested ranged from 4.5-16% HbA1c. The linear regression analyses are as follows:

Matrices	N	Slope	Intercept	R2
EDTA vs. Capillary	135	0.978 (0.961-0.995)	0.301 (0.162-0.441)	0.9896
Sodium Heparin vs. Capillary	135	0.982 (0.964-1.000)	0.227 (0.079-0.374)	0.9885
Sodium Heparin vs. EDTA	135	0.999 (0.980-1.018)	-0.033 (-0.189-0.123)	0.9879

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:

   The American Diabetes Association's (ADA) most recent Clinical Practice Recommendation for diabetes specified a treatment goal of less than 7% and suggests additional action when HbA1c level is above 8%.

HbA1c Value	Glycemic Goal
<8% HbA1c	Less Stringent
<7% HbA1c	General (Non-Pregnant Adult)
<6.5%HbA1c	More Stringent

   As recommended by the ADA, patients in the range of 5.7-6.4% HbA1c would be in the category of increased risk for diabetes.
   Source: American Diabetes Association. Diabetes Care 38 (2015): Suppl. 1. S8-S40

N. Instrument Name:

   URight Hemoglobin A1c System
   FORA A1c System

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes _____ or No ____X____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ____X___

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes X or No

   The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

3. Specimen Identification:

   A barcode reader or keyboard may be used to enter patient information. Patient information can only be entered during measurement. Entering the information will not interrupt the processing. Both letters and numbers can be entered. When the test is finished, the test result will display, the result will be automatically recorded and may be printed by the operator

4. Specimen Sampling and Handling:

   Sample is obtained via a capillary tube (from fingerstick collection or from venous whole blood sample collection tube) within a holder that is inserted into a sampling cartridge. The sampling cartridge includes a flexible pull tab. The sampling cartridge which contains the capillary tube and holder is inserted into the cartridge compartment of the analyzer until a gentle snap is heard or felt. Samples must be tested immediately. Using a smooth, slow, continuous motion, pull the flexible pull-tab completely out of the reagent cartridge. Press "Enter" to select measure mode, press "Confirm" to confirm cartridge insertion, close the cover, and start measurement. Reaction is completed in 8 minutes.

5. Calibration:

   The values for calibration curve for each reagent lot are contained within the barcode and encoded onto the Master Calibration card. A calibration card is provided in the reagent kit and should be used to calibrate the analyzer every time before using each new box of reagent cartridges.

6. Quality Control:

   Two levels of URight Hemoglobin A1c controls will be included as part of the URight Hemoglobin A1c System and two levels of FORA A1c controls will be included as part of the FORA A1c System. URight Hemoglobin A1c controls and FOR A A1c controls are provided for routine quality checks - level 1 in the normal HbA1c range and level 2 in the elevated HbA1c range. Both HbA1c controls are lyophilized hemolysates prepared from packed human erythrocytes.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Sample volume studies were performed using 5.2 % HbA1c K2 EDTA whole blood samples and three lots of cartridge tested 10 times at different sample volumes (0.1, 0.15 and 0.2 uL). Test results support the sample volume claim of at least 0.15 uL.

Altitude studies were performed using a glove box system which simulates different altitude conditions with varying atmospheric pressure and pO2 in blood. The HbA1c level tested ranged from 4.3 -15.5%. The altitude study protocol and results were reviewed and found to be acceptable to support an operating altitude claim of up to 2000 meters (6000 feet).

Q. Proposed Labeling:

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

R. Conclusion:

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