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

A. 510(k) Number:

k173127

B. Purpose for Submission:

New Device

C. Measurand:

Whole blood glycosylated hemoglobin (HbA1c)

D. Type of Test:

Quantitative immunoassay with latex agglutination

E. Applicant:

Skyla Corporation H.S.P.B.

F. Proprietary and Established Names:

skyla Hi Hemoglobin A1c System (skyla Hi Analyzer and skyla Hi Hemoglobin A1c Reagent Kit)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LCP	Class II	21 CFR 864.7470 Glycosylated hemoglobin assay	Hematology (81)
JJE	Class I	21 CFR 862.2160 Discrete photometric chemistry analyzer	Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

   The skyla Hi Hemoglobin A1c System, consisting of the skyla Hi Analyzer and skyla Hi Hemoglobin A1c Reagent Kit is an in-vitro diagnostic test for quantitative measurement of the percent concentration (%) of glycated hemoglobin (HbA1c %) in venous and finger-stick capillary whole blood.

   The measurement of % HbA1c is used to monitor long-term glycemic control in persons previously diagnosed with diabetes mellitus.

   This system is intended for clinical laboratory and point-of-care use.

   This test is not for screening or diagnosis of diabetes.

3. Special conditions for use statement(s):
   - For prescription use only
   - This test is not for screening or diagnosis of diabetes or neonatal use
   - Use fresh whole blood only. Do not use plasma and serum.
   - When testing venous whole blood, test only samples collected in K3-EDTA
   - The test is not intended for judging day-to-day glucose control and should not be used to replace daily home testing of urine or blood glucose.
   - 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
   - Hemoglobinopathies may interfere with glycated hemoglobin analysis. The results from the skyla Hi Hemoglobin A1c show that there is no significant interference for Hemoglobin C (≤ 36%), Hemoglobin D (≤ 42%), Hemoglobin E (≤ 26%), Hemoglobin S (≤ 41%). High Hemoglobin F (> 11%) will result in lower than expected HbA1c values. High HbA2 (>5.7%) will result in higher than expected expected HbA1c values.

4. Special instrument requirements:

   skyla Hi Analyzer

I. Device Description:

The skyla Hi Hemoglobin A1c System consists of the skyla Hi Hemoglobin A1c Reagent that is tested using the skyla Hi Analyzer. Each skyla Hi Hemoglobin A1c Reagent Kit includes an analysis cartridge and a reagent pack containing the following components:

- Reagent Pack: Cell Lysis Buffer (surfactant agent dissolved in a buffer), latex solution (latex particles dissolved in a buffer)
- Analysis Cartridge: HbA1c specific mouse monoclonal antibodies and rabbit anti-mouse polyclonal antibodies dissolved in a buffer and then freeze-dried into spherical beads.

The specimen is collected through a capillary tube on the reagent pack before testing. The skyla Hi Analyzer can run up to two skyla Hi Hemoglobin A1c Reagent Kits at the same time. If a single skyla Hi Hemoglobin A1c Reagent Kit will be run, then a dummy balancer (black balancer of similar dimensions to the skyla Hi Hemoglobin A1c Reagent Kit) should be used in the machine.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Afinion AS100 Analyzer
   Afinion HbA1c

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

   k151809

3. Comparison with predicate:

Similarities		
Item	Candidate Device skyla Hi Hemoglobin A1c System System (skyla Hi Analyzer and skyla Hi Hemoglobin A1c Reagent Kit) (k173127)	Predicate Device Afinion HbA1c/ Afinion AS100 Analyzer (k151809)
Intended Use	Intended for the quantitative measurement of the percent concentration (%) of glycated hemoglobin (HbA1c %) in venous and finger-stick capillary whole blood. The measurement of % HbA1c is used to monitor long-term glycemic control in persons previously diagnosed with diabetes mellitus.	Same
Intended users	Laboratory professionals and point-of-care users	Same
Sample type	Whole blood: finger-stick capillary and venous	Same
Method of Sampling	Blood is collected with a capillary tube in the reagent pack, and the sampling device	Same

Similarities		
Item	Candidate Device skyla Hi Hemoglobin A1c System System (skyla Hi Analyzer and skyla Hi Hemoglobin A1c Reagent Kit) (k173127)	Predicate Device Afinion HbA1c/ Afinion AS100 Analyzer (k151809)
	is inserted into the cartridge	
Method Traceability or Standardization	National Glycohemoglobin Standardization Program (NGSP)	Same

Differences		
Item	Candidate Device skyla Hi Hemoglobin A1c System (skyla Hi Analyzer and skyla Hi Hemoglobin A1c Reagent Kit) (k173127)	Predicate Device Afinion HbA1c/ Afinion AS100 Analyzers (k151809)
Test Principle	Immunoassay using latex agglutination	Boronate affinity assay
Sampling Device capillary material	Glass	Plastic
Fill volume of sampling device capillary	0.8 uL	1.5 uL
Time to result	6 minutes	3 minutes
Sample anticoagulant type	K3-EDTA	EDTA, heparin, citrate
Measuring Interval	4-14% HbA1c	4-15% HbA1c

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

IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests

CLSI EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline- Third Edition

CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

CLSI EP07-A2: Interference Testing In Clinical Chemistry; Approved Guideline - Second Edition

CLSI EP17-A2: Evaluation Of Detection Capability For Clinical Laboratory Measurement

Procedures; Approved Guideline -- Second Edition

CLSI EP25-A: Evaluation Of Stability Of In Vitro Diagnostic Reagents; Approved Guideline. (In-Vitro Diagnostics)

L. Test Principle:

The assay principle is based on immunoturbidimetric measurement of a monoclonal antibody agglutination reaction. Through a latex reagent, all hemoglobin can nonspecifically adhere to a latex sphere. Following addition of the HbA1c specific monoclonal antibody, the latex sphere will produce agglutination reaction, and the agglutination causes increased scattering of light, which is measured as an increase in absorbance at 650 nm. The HbA1c concentration is then quantified using a calibration curve of absorbance versus HbA1c concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Internal Precision

The sponsor conducted an internal precision study according to CLSI EP05-A3, using three skyla Hi Analyzers and three lots of skyla Hi Hemoglobin A1c Reagent Kit. Three quality control (QC) samples and eight human venous whole blood (WB) samples (K3-EDTA) were measured over 20 days. The protocol consisted of measuring the sample material in duplicate in two runs per day for 20 days producing n=80 results per sample per lot for a total of 240 results per sample. The within-run, between-run, between-day and total precision were calculated (SD and %CV). The results are summarized below in NGSP units (%HbA1c):

			Within-Run		**Between Run**		**Between Day**		**Total**	
Sample*	**N**	**Mean HbA1c %**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**	**SD**	**CV**
QC 1	240	5.13	0.09	1.8%	0.00	0.0%	0.09	1.7%	0.13	2.5%
QC 2	240	9.72	0.20	2.0%	0.00	0.0%	0.18	1.8%	0.28	2.9%
QC 3	240	13.51	0.16	1.2%	0.03	0.2%	0.18	1.3%	0.33	2.4%
WB 1	240	5.23	0.07	1.4%	0.00	0.0%	0.08	1.5%	0.11	2.1%
WB 2	240	5.51	0.09	1.6%	0.02	0.4%	0.06	1.1%	0.11	2.0%
WB 3	240	7.63	0.15	2.0%	0.05	0.7%	0.07	0.9%	0.18	2.4%
WB 4	240	9.93	0.16	1.6%	0.10	1.0%	0.12	1.2%	0.23	2.3%
WB 5	240	11.98	0.16	1.4%	0.00	0.0%	0.07	0.6%	0.19	1.6%
WB 6	240	5.00	0.08	1.7%	0.01	0.2%	0.06	1.1%	0.10	2.0%
WB 7	240	6.47	0.11	1.8%	0.03	0.4%	0.07	1.0%	0.14	2.1%

WB 8	240	7.99	0.16	2.0%	0.00	0.0%	0.07	0.9%	0.17	2.2%

*WB = Venous Whole Blood (K3-EDTA)
QC = Quality Control Material

External Precision (Point-of-Care)

An external precision study was conducted at three point-of-care (POC) sites. There were three operators at each site, for a total of nine operators. At each site, the samples were measured in duplicate two times a day twice a day for 20 days at three sites. Within run (repeatability), between-run, between day, and total reproducibility (SD and percent CVs) were calculated. Each site had 80 results for a total of 240 results per sample across all three sites.

Each POC site assessed one lot of skyla Hi Hemoglobin A1c Reagent Kit using one skyla Hi HbA1c analyzer, for a total of three lots and three analyzers at three sites. Three quality control (QC) samples and five human venous whole blood (WB) samples (K3-EDTA) were tested.

The within-run, between-run, between-day and total precision were calculated (SD and %CV), for each site and all three sites. The results are summarized below in NGSP units (%HbA1c):

Sample*	Site	Mean HbA1c %	Repeatability (Within-Run)		Between Run		Between Day		Total	
			SD	CV	SD	CV	SD	CV	SD	CV
WB 1	1	5.04	0.097	1.9%	0.000	0.0%	0.032	0.6%	0.103	2.0%
	2	5.06	0.082	1.6%	0.039	0.8%	0.034	0.7%	0.097	1.9%
	3	5.03	0.075	1.5%	0.062	1.2%	0.000	0.0%	0.097	1.9%
	All	5.04	0.085	1.7%	0.038	0.8%	0.014	0.3%	0.095	1.9%
WB 2	1	5.55	0.097	1.7%	0.045	0.8%	0.000	0.0%	0.107	1.9%
	2	5.59	0.095	1.7%	0.032	0.6%	0.000	0.0%	0.100	1.8%
	3	5.56	0.100	1.8%	0.065	1.2%	0.000	0.0%	0.119	2.1%
	All	5.56	0.097	1.7%	0.049	0.9%	0.000	0.0%	0.110	2.0%
WB 3	1	6.57	0.105	1.6%	0.062	0.9%	0.057	0.9%	0.134	2.0%
	2	6.53	0.111	1.7%	0.086	1.3%	0.000	0.0%	0.141	2.2%
	3	6.54	0.110	1.7%	0.057	0.9%	0.040	0.6%	0.130	2.0%
	All	6.54	0.109	1.7%	0.070	1.1%	0.038	0.6%	0.135	2.1%
WB 4	1	7.93	0.126	1.6%	0.099	1.3%	0.067	0.8%	0.174	2.2%
	2	7.95	0.132	1.7%	0.112	1.4%	0.112	1.4%	0.207	2.6%
	3	7.99	0.150	1.9%	0.097	1.2%	0.115	1.4%	0.212	2.7%
	All	7.96	0.137	1.7%	0.103	1.3%	0.100	1.3%	0.198	2.5%
WB 5	1	12.07	0.243	2.0%	0.188	1.6%	0.000	0.0%	0.308	2.5%
	2	12.10	0.250	2.1%	0.189	1.6%	0.000	0.0%	0.313	2.6%
	3	12.13	0.212	1.7%	0.138	1.1%	0.096	0.8%	0.270	2.2%
	All	12.10	0.236	2.0%	0.173	1.4%	0.000	0.0%	0.292	2.4%
QC 1	1	5.24	0.092	1.8%	0.085	1.6%	0.033	0.6%	0.130	2.5%

Sample*	Site	Mean HbA1c %	Repeatability (Within-Run)		Between Run		Between Day		Total	
			SD	CV	SD	CV	SD	CV	SD	CV
	2	5.18	0.115	2.2%	0.000	0.0%	0.055	1.1%	0.128	2.5%
	3	5.20	0.118	2.3%	0.067	1.3%	0.000	0.0%	0.136	2.6%
	All	5.20	0.109	2.1%	0.060	1.2%	0.029	0.6%	0.130	2.5%
QC 2	1	9.70	0.200	2.1%	0.142	1.5%	0.143	1.5%	0.284	2.9%
	2	9.71	0.208	2.1%	0.022	0.2%	0.096	1.0%	0.230	2.4%
	3	9.68	0.228	2.4%	0.000	0.0%	0.171	1.8%	0.285	3.0%
	All	9.69	0.213	2.2%	0.052	0.5%	0.140	1.4%	0.260	2.7%
QC 3	1	13.59	0.085	0.6%	0.100	0.7%	0.000	0.0%	0.131	1.0%
	2	13.57	0.084	0.6%	0.132	1.0%	0.000	0.0%	0.156	1.2%
	3	13.60	0.081	0.6%	0.094	0.7%	0.000	0.0%	0.124	0.9%
	All	13.58	0.083	0.6%	0.110	0.8%	0.000	0.0%	0.138	1.0%

*WB = Venous Whole Blood (K3-EDTA)
QC = Quality Control Material

b. Linearity/assay reportable range:

Linearity was evaluated according to CLSI EP06-A. Test sample pools were prepared by diluting test sample pools of human venous whole blood (WB) samples (K3-EDTA) containing high (15%) and low (4.1%) concentrations of HbA1c to create nine levels of test sample pools. The assigned value of each of the nine (9) levels was determined by a clinical lab. Each test sample pool was tested in quadruplicate with one reagent lot using the skyla Hi Hemoglobin A1c System, and then analyzed using the best-fitting polynomial. The targeted assigned values of each level were measured by a clinical lab. The deviation between polynomial fit and line fit results were determined. The following concentrations of HbA1c were tested.

NGSP Units (% HbA1c)

No.	1	2	3	4	5	6	7	8	9
% HbA1c Conc.	4.1	6.4	7.9	9.4	10.8	12.0	13.0	14.1	15

The linear regression results are in the table below:

NGSP Units (%HbA1c)

Slope	Intercept	Regression Coefficient (R^2)	Claimed Measuring Interval
0.9665	0.3506	0.9939	4-14% HbA1c

The linearity results support the sponsor's claims that the assay is linear across the reportable measuring interval of 4 to 14% HbA1c.

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

Traceability

The skyla Hi Hemoglobin A1c Reagent Kit is traceable to the Diabetes Control and Complications Trial Reference Method. The device is certified with the National Glycohemoglobin Standardization Program (NGSP). The certification expires in one year. See NGSP website for current certification at http://www.ngsp.org.

d. *Detection limit:*

The limit of blank (LoB) and limit of detection (LoD) were determined in accordance with CLSI EP17-A. The LoB and LoD values were determined by measuring 180 blank measurements and 180 low-level HbA1c measurement. To determine LoB and LoD, 5 blank and 5 whole blood low level samples each were tested using 2 reagent lots and 1 instrument system. Testing was performed for 3 days at 4 replicates per day for a total of 60 measurements per reagent lot (120 measurements total per LoB and LoD). The LoB and LoD results are listed below:

Analyte	LoB	LoD
HbA1c (%)	2.5%	2.6%

e. *Analytical specificity:*

Endogenous Interferences

An interference study was performed using the skyla Hi Hemoglobin A1c System to assess the effect of common endogenous interferents. The interference study was conducted according to CLSI guideline EP07-A2. One lot of skyla Hi Hemoglobin A1c Reagent Kit and 1 skyla Hi Analyzer was used in the study. The sample pool material was K3-EDTA venous whole blood with a concentration of approximately 5-6 % HbA1c and approximately 9-10% HbA1c. Two sample pools were prepared for each potential endogenous interferent, with or without interferent (serving as the reference or control sample). The spiked and control pools were mixed in different ratios to yield a dilution series with varying concentrations of the interferent. Each sample was tested in triplicate and the mean value was used for the assessment. The sponsor defined non-significant interference ≤± 6% deviation compared to the result of the control pool. The table below summarizes the results of this study:

Endogenous Substance	Highest Level Tested with no Significant Interference
Conjugated Bilirubin	60.2 mg/dL
Unconjugated Bilirubin	60.2 mg/dL
Lipemia/Intralipid	6110 mg/dL

Endogenous Substance	Highest Level Tested with no Significant Interference
Urea	282 mg/dL
Glucose	2800 mg/dL
Rheumatoid Factor (RF)	1200 IU/mL
Total Protein	22800 mg/dL
Albumin	9500 mg/dL
Glycated albumin	770 mg/dL

Exogenous Interferences

An interference study was performed using the skyla Hi Hemoglobin A1c System to assess the effect of common exogenous interferents. The interference study was conducted according to CLSI guideline EP07-A2. One lot of skyla Hi Hemoglobin A1c Reagent Kit and 1 skyla Hi Analyzer was used in the study. The sample pool material was K3-EDTA venous whole blood with a concentration of approximately 5-6 % HbA1c and approximately 9-10% HbA1c. Two sample pools were prepared for each potential endogenous interferent, with or without interferent (serving as the reference or control sample). The reference or control samples were spiked with equivalent volume of diluent used to prepare the interferent-spiking samples. Each sample was tested in triplicate and the mean value was used for the assessment. The sponsor defined non-significant interference ≤± 6% deviation compared to the result of the reference pool. The table below summarizes the results of this study:

Exogenous Interference	Highest Level Tested with No Significant Interference (≤± 6%)
Aspirin (Acetylsalicylic acid)	100 mg/dL
Acetaminophen	20 mg/dL
Acetylcysteine	166 mg/dL
Ascorbic acid	30 mg/dL
Ampicillin	100 mg/dL
Cefoxitin	250 mg/dL
Cyclosporine A	1 mg/dL
Cyclosporine C	1 mg/dL
Doxcycyline	50 mg/dL
Glyburide	0.2 mg/dL
Heparin	5000 U/dL
Ibuprofen	50 mg/dL
Levodopa (L-dopa)	2 mg/dL
Metformin	40 mg/dL
Methyldopa	20 mg/dL
Metronidazole	20 mg/dL
Phenylbutazone	40 mg/dL
Rifampicin	6.4 mg/dL

Exogenous Interference	Highest Level Tested with No Significant Interference (≤± 6%)
Salicylic acid	60 mg/dL
Theophylline	10 mg/dL

Cross-Reactivity with Hemoglobin Derivatives

A study was performed using the skyla Hi Hemoglobin A1c System to assess the effect of hemoglobin derivatives on measurement of HbA1c. One lot of skyla Hi Hemoglobin A1c Reagent Kit and one skyla Hi Analyzer was used in the study. The sample pool material was K3-EDTA venous whole blood with a concentration of approximately 5-6 % HbA1c and approximately 9-10% HbA1c. Two sample pools were prepared for each potential endogenous interferent, with or without interferent (serving as the reference or control sample). The spiked and control pools were mixed in different ratios to yield a dilution series with varying concentrations of the hemoglobin derivatives. Each sample was tested in triplicate and the mean value was used for the assessment. The sponsor defined non-significant interference ≤± 6% deviation compared to the result of the reference pool. The table below summarizes the results of this study:

Hemoglobin Derivative	Highest Level Tested with No Significant Interference (≤± 6%)
Acetylated hemoglobin	100 mg/dL
Carbamylated hemoglobin	600 mg/dL
Labile hemoglobin	3000 mg/dL
HbA1a+b	16 mg/dL
HbA0	1200 mg/dL

Hemoglobin Variant Interference

A study was performed using the skyla Hi Hemoglobin A1c Sytem to assess the effect of common hemoglobin variants on the measurement of HbA1c. One lot of skyla Hi Hemoglobin A1c Reagent Kit and one skyla Hi Analyzer was used in the study. 55 venous whole blood samples with known target values of HbA1c and variant concentrations (assigned by IFCC and NGSP) were tested in duplicate. The venous whole blood samples (concentrations ranging between 4.1 and 14.0% HbA1c) contained known levels of hemoglobin variants A2, C, D, E, F and S. Between 4 and 11 samples per hemoglobin variant were tested in duplicate using the skyla Hi Hemoglobin A1c System for %HbA1c results. The sponsor defined non-significant interference ≤± 7% deviation compared to the result of the assigned value. The table below summarizes the results of this study:

Hemoglobin Variant	Highest Level Tested with No Significant Interference (≤± 7%)
HbA2	5.7%

Hemoglobin Variant	Highest Level Tested with No Significant Interference (≤± 7%)
HbC	36%
HbD	42%
HbE	26%
HbF	11%
HbS	41%

The sponsor's labeling includes the following limitation:

"Hemoglobinopathies may interfere with glycated hemoglobin analysis. The results from the skyla Hi Hemoglobin A1c System show that there is no significant interference for Hemoglobin C (≤ 36%), Hemoglobin D (≤ 42%), Hemoglobin E (≤ 26%), Hemoglobin S (≤ 41%). High Hemoglobin F (> 11%) will result in lower than expected HbA1c values. High HbA2 (>5.7%) will result in higher than expected expected HbA1c values."

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was conducted at four point of care testing sites. Venous K3-EDTA whole blood and capillary finger-stick blood samples were collected from each patient (n=243 venous whole blood and n=243 capillary finger-stick samples) and tested in singlicate using the skyla Hi Hemoglobin A1c System (five analyzers) and compared to matched venous K3-EDTA venous whole blood measured using the Bio-Rad VARIANT II Turbo System in a clinical laboratory. Each of the four point-of-care sites included between three and five operators, for a total of 16 operators. Between one to four reagent kit lots were used at each site for this study. The range of HbA1c tested was 4.8 to 13.2% HbA1c. The best fit linear regression results are listed in the tables below in NGSP Units (%HbA1c):

HbA1c		N	R^2	Slope	Intercept	Sample Range	
						Low	High
Venous Whole Blood	POC Site 1	62	0.9844	0.9930	0.0794	4.9	13.2
	POC Site 2	62	0.9853	1.0001	0.0733	4.8	12.6
	POC Site 3	64	0.9819	0.9882	0.1013	4.8	13.0
	POC Site 4	55	0.9903	0.9963	0.0636	5.0	9.4

HbA1c		N	R^2	Slope	Intercept	Sample Range	
						Low	High
	Combined	243	0.9858	0.9945	0.0779	4.8	13.2
Finger-stick Capillary Blood	POC Site 1	62	0.9831	1.0010	-0.0075	4.9	13.2
	POC Site 2	62	0.9850	1.0036	0.1193	4.9	12.5
	POC Site 3	64	0.9811	0.9810	0.1871	5.0	13.1
	POC Site 4	55	0.9804	0.9850	0.1111	4.9	9.4
	Combined	243	0.9841	0.9993	0.0589	4.9	13.2

b. Matrix comparison:
Not applicable. The sponsor's only claimed anticoagulant is K3-EDTA.

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 sponsor provides the following expected values in their labeling:

In 2018, 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*".

*American Diabetes Association. Standards of Medical Care in Diabetes-2018. Diabetes Care. 2018 Jan; 41 Suppl. 1: S55-S64.

N. Instrument Name:

skyla Hi Analyzer

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 __x_____ or No _____

   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 _____

3. Specimen Identification:

   Patient information can be entered manually on the device or patient record information can be entered using an optional externally connected barcode scanner, via USB interface.

4. Specimen Sampling and Handling:

   The sample is applied directly from the fingerstick. If using venous whole blood, a drop of blood should be removed from the collection tube, placed on a clean container or slide, and collected using the glass capillary tube on the reagent pack. After application of the sample to the reagent pack capillary, the operator places the reagent pack into the analysis cartridge. The cartridge is then inserted into the instrument. There are no pre-analytical steps needed after the blood sample is taken using the sample capillary.

5. Calibration:

   The analyzer automatically reads in the lot-specific calibration data from the barcode information printed on the analysis cartridge, eliminating the need for calibration by the user

6. Quality Control:

   The recommended quality control material is BIO-RAD Lyphochek Diabetes Control, Level 1 and Level 2. The frequency and criteria of quality control testing should be adapted to each site's individual requirements.

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

Postmarket information for this device and device type was considered during the review of this submission.

Q. Proposed Labeling:

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

R. Conclusion:

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