510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

k122553

B. Purpose for Submission:

New device

C. Measurand:

Hemoglobin

D. Type of Test:

Quantitative, photometric measurement of hemoglobin and estimation of hematocrit

E. Applicant:

ACON Laboratories, Inc.

F. Proprietary and Established Names:

Mission® Plus Hemoglobin (Hb) Testing System
The Mission® Plus Hemoglobin (Hb) Control Solution

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.5620 – Automated hemoglobin system
   21 CFR 862.1660 – Quality control material (assayed and unassayed)

2. Classification:

   Class II

3. Product code:

   GKR – System, Hemoglobin, Automated
   JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)

4. Panel:

   (81) Hematology

   (75) Chemistry

H. Intended Use:

1. Intended use(s):

   The Mission® Plus Hemoglobin (Hb) Testing System is for the quantitative determination of hemoglobin in non-anticoagulated capillary whole blood or anticoagulated venous whole blood in EDTA (K_2, K_3, Na_2) or sodium heparin. The testing system is designed for point-of-care use in primary care settings. Estimation of hematocrit is only for hemoglobin values from 12.3 to 17.5 g/dL (123 to 175 g/L).

   The Mission® Plus Hemoglobin (Hb) Control Solution is intended to validate hemoglobin testing using the Mission® Plus Hemoglobin (Hb) Testing System.

   The Mission® Plus Hemoglobin (Hb) Testing System is for professional in vitro diagnostic use only.

2. Indication(s) for use:

   Same as intended use

3. Special conditions for use statement(s):

   For Prescription Use only

4. Special instrument requirements:

   Mission® Plus Hemoglobin (Hb) Testing Meter

I. Device Description:

Major components of the Mission® Plus Hemoglobin (Hb) Testing System include the Mission® Hemoglobin (Hb) Testing Meter, Test cartridge, Control Solutions, and Optical Verifier.

The test cartridges are used with the meter for monitoring hemoglobin concentration and for estimation of Hematocrit (Hct) within the normal range of hemoglobin in capillary or venous whole blood. The test cartridge includes a mesh covered sample reaction zone, which contains assay reagents, sodium deoxycholate and sodium nitrite. Erythrocytes in the specimen are lysed by the action of sodium deoxycholate to release hemoglobin. Then the hemoglobin is converted to methemoglobin by the action of sodium nitrite causing a color change in the reagent area. The meter is a portable, battery-powered device that analyzes the intensity and color of light reflected from the reagent area of the test cartridge. A code chip is used to store and transfer calibration information for the test cartridges and is provided with each canister of test cartridges.

The Mission® Plus Hemoglobin (Hb) Testing System contains 3 levels (0, 1, 2,) of control solutions with known concentration of hemoglobin used to confirm that the meter and test cartridges are working together properly.

The optical verifier works with the meter to ensure the optical system of the meter works properly.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   HemoPoint® H2 Hemoglobin Measurement System and HemoPoint® H2 Cuvettes

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

   k032482

3. Comparison with predicate:

Similarities		
Item	Device	Predicate (K032482)
Intended Use	The Mission® Plus Hemoglobin (Hb) Testing System is for the quantitative determination of hemoglobin in non-anticoagulated capillary whole blood or anticoagulated venous whole blood in EDTA (K_2, K_3, Na_2) or sodium heparin. The testing system is designed for point-of-care use in primary care settings. Estimation of hematocrit is only for hemoglobin values from 12.3 to 17.5 g/dL (123 to 175 g/L). The Mission® Plus Hemoglobin (Hb) Control Solution is intended to validate hemoglobin testing using the Mission® Plus Hemoglobin (Hb) Testing System. The Mission® Plus Hemoglobin (Hb) Testing System is for professional in vitro diagnostic use only.	The HemoPoint® H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood. The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste. Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/L or 12.0 to 18.0 g/dL). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values and will not be reported. For In Vitro Diagnostic Use Only
Test Principle	Quantitative photometric measurement of hemoglobin	Same
Visual Display	LCD readout	Same
Calibration	Factory calibrated against CLSI H15-A3 reference method	Same

Similarities		
Item	Device	Predicate (K032482)
Recommend Testing Environment	Doctors' offices	Same
Units of Measure	g/dL, g/L, mmol/L	Same

Differences		
Item	Device	Predicate
Assay Method	Methemoglobin method: Erythrocytes in the specimen are lysed to release hemoglobin by the action of sodium deoxycholate. Then the hemoglobin is converted to methemoglobin by the action of sodium nitrite.	Modified azide methemoglobin method
Specimen Type	Capillary or venous whole blood	Venous, arterial, or capillary blood
Test Time	≤15 seconds	Approximately 30-60 seconds

K. Standard/Guidance Document Referenced:

CLSI H4-A6; Procedures and Devices for the Collection of Diagnostic Blood Specimens; Approved Standard; 6th Edition

CLSI H15-A3; Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard; 3rd Edition

CLSI EP09-A2; Method Comparison and Bias Estimation Using Patient Samples; Approved Standard; 2nd Edition

CLSI EP05-A2; Evaluation of Precision Performance of Qualitative Measurement Methods; Approved Guideline; 2nd Edition

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

CLSI H20-A2; Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard; 2nd Edition

CLSI H26-A2; Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard

CLSI EP07-A2; Interference Testing in Clinical Chemistry; Approved Guideline; 2nd Edition

CLSI EP25-A; Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline

CLSI EP17-A2; Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline; 2nd Edition

CLSI C28-A3; Defining, Establishing, & Verifying Reference Intervals Clinical Laboratory; Approved Guideline; 3rd Edition

EN 11137-1: 2006; Sterilization of Health Care Products – Radiation – Part 1: Requirements

for Development, Validation and Routine Control of a Sterilization Process for Medical Devices

EN 11137-2: 2013; Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose

EN 11137-3: 2006; Sterilization of Health Care Products – Radiation – Part 3: Guidance on Dosimetric Aspects

EN 556-1: 2001; Sterilization of Medical Devices. Requirements for Medical Devices to be Designated "Sterile". Requirements for Terminally Sterilized Medical Devices

EN 11737-1: 2006; Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products

EN 11737-2: 2000; Sterilization of Medical Devices – Microbiological Methods – Part 2: Tests of Sterility Performed in the Validation a Sterilization Process

EN 10993-5: 2009; Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity

EN 10993-10: 2009; Biological Evaluation of Medical Devices – Part 10: Test for Irritation and Delayed-Type Hypersensitivity

EN/ISO 14971: 2009; Application of Risk Management to Medical Devices

EN 61326-1: 2006; Class B Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements– General Requirements

EN 61326-2-6: 2006; Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Particular Requirements – In vitro Diagnostic (IVD) Medical Equipment

IEC/EN 61010-1: 2001; Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements

IEC/EN 61010-2-101: 2002; Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Particular Requirements for In vitro Diagnostic (IVD) Medical Equipment

EN 62366: 2008; Medical Devices – Application of Usability Engineering to Medical Devices

EN 62304: 2006; Medical Device Software – Software Life-Cycle Processes

L. Test Principle:

The Mission® Plus Hemoglobin (Hb) Testing System utilizes quantitative reflectance photometry for measurement of hemoglobin.

The test cartridge includes a mesh covered sample reaction zone. Specimen is applied to the center of the reaction zone and the mesh functions to separate the sample evenly on the entire reaction zone. The reagents on the reaction zone function to hemolyze red blood cells and release the hemoglobin. The hemoglobin is converted to methemoglobin to generate a color change. The meter reads the intensity of the reflected light at 525 nm every second until the

end point of the reaction is detected. The light intensity at the end point is directly proportional to the hemoglobin concentration.

M. Performance Characteristics:

1. Analytical performance:

a. Precision/Reproducibility:

A precision study was conducted using fresh venous blood specimens. Hemoglobin concentration was adjusted to 8 levels. One specimen at each level was tested on 6 meters. Each meter was tested in 5 replicates on each lot of test cartridge by one technician in one day. Three lots of test cartridges were tested in this study. For sample level 1, four readings were below the reportable range of the device. Results are summarized in the following table. The acceptance criterion was SD ≤0.4 g/dL when Hb <10 g/dL or CV ≤3% when Hb ≥10 g/dL.

Precision Data Summary						
Sample Level	N	Mean (g/dL)	Within-Run (SD, %CV)	Between-Run (SD, %CV)	Between-Lot (SD, %CV)	Total (SD, %CV)
1	86	5.12	0.36, 7.1%	0.00, 0.0%	0.07, 1.3%	0.37, 7.2%
2	90	24.25	0.50, 2.0%	0.00, 0.0%	0.19, 0.8%	0.53, 2.2%
3	90	12.29	0.17, 1.4%	0.00, 0.0%	0.33, 2.6%	0.37, 3.0%
4	90	15.34	0.20, 1.3%	0.04, 0.3%	0.16, 1.1%	0.26, 1.7%
5	90	13.26	0.16, 1.2%	0.00, 0.0%	0.23, 1.8%	0.28, 2.1%
6	90	16.94	0.23, 1.4%	0.09, 0.6%	0.29, 1.7%	0.38, 2.2%
7	90	11.48	0.22, 1.9%	0.00, 0.0%	0.25, 2.2%	0.33, 2.9%
8	90	14.33	0.17, 1.2%	0.04, 0.3%	0.29, 2.0%	0.34, 2.3%

A reproducibility study was conducted across three sites using 3 levels of control solutions. Each control solution was tested in 2 runs each day for 20 days. Two operators were involved at each site. A total of 240 readings were generated at each site (2 runs × 20 days × 2 operators × 3 levels). Results are summarized in the following tables. The acceptance criterion was SD ≤0.4 g/dL when Hb <10 g/dL or CV ≤3% when Hb ≥10 g/dL.

Reproducibility Data Summary: Site 1						
Sample Level	N	Mean (g/dL)	Within-Run (SD, %CV)	Between-Operator (SD, %CV)	Between-Day (SD, %CV)	Total (SD, %CV)
1	80	9.37	0.10, 1.11%	0.00, 0.00%	0.05, 0.55%	0.12, 1.24%
2	80	13.70	0.22, 1.58%	0.00, 0.00%	0.09, 0.66%	0.23, 1.71%
3	80	17.29	0.35, 2.03%	0.00, 0.00%	0.19, 1.09%	0.40, 2.30%

Reproducibility Data Summary: Site 2						
Sample Level	N	Mean (g/dL)	Within-Run (SD, %CV)	Between-Operator (SD, %CV)	Between-Day (SD, %CV)	Total (SD, %CV)
1	80	9.42	0.07, 0.72%	0.01, 0.12%	0.08, 0.81%	0.10, 1.09%
2	80	13.98	0.12, 0.87%	0.00, 0.00%	0.12, 0.85%	0.17, 1.22%
3	80	17.68	0.18, 1.03%	0.00, 0.00%	0.31, 1.77%	0.36, 2.05%

Reproducibility Data Summary: Site 3						
Sample Level	N	Mean (g/dL)	Within-Run (SD, %CV)	Between-Operator (SD, %CV)	Between-Day (SD, %CV)	Total (SD, %CV)
1	80	9.41	0.10, 1.06%	0.00, 0.00%	0.08, 0.81%	0.13, 1.33%
2	80	13.89	0.18, 1.32%	0.00, 0.00%	0.00, 0.00%	0.18, 1.32%
3	80	17.42	0.24, 1.38%	0.04, 0.21%	0.09, 0.50%	0.26, 1.48%

Reproducibility Data Summary: 3 Sites Combined							
Sample Level	N	Mean (g/dL)	Within-Run (SD, %CV)	Between-Operator (SD, %CV)	Between-Day (SD, %CV)	Between-Site (SD, %CV)	Total (SD, %CV)
1	240	9.40	0.09, 0.98%	0.00, 0.00%	0.07, 0.73%	0.02, 0.18%	0.12, 1.24%
2	240	13.86	0.18, 1.31%	0.00, 0.00%	0.08, 0.57%	0.14, 1.00%	0.24, 1.74%
3	240	17.46	0.27, 1.53%	0.00, 0.00%	0.22, 1.24%	0.19, 1.09%	0.39, 2.25%

b. Linearity/assay reportable range:

Specimens having 8 hemoglobin levels were prepared from venous whole blood. Each level was tested on 6 meters, 3 replicates on each meter. Average results (y) were plotted against results obtained from a Sysmex pocH-100i Hematology Analyzer (x), which was used as the reference method. Three lots of test cartridges were used in the study. Summarized results are presented in the table below. Correlation coefficients for all three lots of test cartridges were greater than 0.99 and the slopes of the linear equations were within 1.0±0.1 which met acceptance criteria.

Linearity Data Summary			
Cartridge Lot	Linear Regression Equation	R^2	Hb Range Tested (g/dL)
1	y = 0.9716x + 0.3025	0.9966	5.6-25.3
2	y = 0.9768x + 0.1327	0.9951	5.6-25.3
3	y = 0.9693x + 0.3211	0.9963	5.6-25.3

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

Calibration

A calibration process is performed by the manufacturer to build a calibration equation between hemoglobin concentration and light reflection for each lot of test cartridges

using a series of standard solutions. This calibration equation is stored in a code chip, which is provided to the user with each canister of test cartridges. Hemoglobin concentrations of the standard solutions are confirmed by the hemiglobincyanide (HiCN) method.

Kit Stability

An accelerated stability study was conducted at 37°C, 45°C, and 55°C to estimate closed canister stability of the three lots of stored test cartridges. Another accelerated stability study was conducted at 45°C to estimate the stability of the test cartridges stored in an "open/closed" form using three lots of test cartridges. Closed canister stability (shelf life) of the test cartridge was estimated to be 2 years and 3 months in the "open/closed" form. A real time stability study was conducted using 3 lots of test cartridges at 2~8°C and 30±3°C to verify the stability of the test cartridges stored in either the "closed" form or the "open/closed" form. At each testing time point, fresh human blood was collected and hemoglobin concentration was adjusted to three predetermined levels. One specimen at each hemoglobin level was tested in 10 replicates with each lot of test cartridges. Real time stability testing is still in progress and shelf life of the test cartridges will be updated upon completion of this study and meeting the following criteria.

Hb Level	Precision	Bias vs. Target Hb Level
<10 g/dL	SD ≤0.4 g/dL	±0.7 g/dL
≥10 g/dL	CV ≤3%	±7%

Controls

The Mission® Plus Hemoglobin (Hb) Testing System includes 3 levels (0, 1, 2,) of control solutions. A control value assignment study was conducted to determine the value assignment of the control solutions in the Mission® Plus Hemoglobin (Hb) Testing System. Three levels of controls were prepared with target hemoglobin values listed in the table below.

Control Solution	Target Hemoglobin Value (g/dL)
Level 1	8.1-10.2
Level 2	13.2-14.9
Level 3	17.0-18.8

Each level of the controls was tested on 5 meters, 2 replicates on each meter. Each lot of controls was tested with 3 lots of test cartridges. Three lots of controls were tested. The control value assignment was determined to be the total average result ± 9% of the average value.

A control precision study was conducted to examine the precision of the controls tested with the Mission® Plus Hemoglobin (Hb) Testing System. Three bottles of control solutions from the same lot were tested for each level of controls. Each bottle was tested with 5 meters, 4 replicates on each meter. Within-run CV was calculated for each bottle and total CV was calculated for each level of controls. All within-run

CVs and total CVs were less than 3.0%. All individual testing results were within the assigned control value range.

An accelerated stability study was conducted at 37°C and 45°C to estimate the stability of the controls in "closed" form using three lots of control solutions. Another accelerated stability study was conducted at 37°C to estimate the stability in an "open/closed" form using three lots of control solutions. The accelerated stability studies demonstrated that the control solutions have an estimated shelf life of 1 year if stored at 4°C in either the "closed" form or the "open/closed" form. A real time stability was conducted to test product stability using three lots of control solutions stored at 2~8°C in either the "closed" form or the "open/closed" form. Real time stability study demonstrated that when stored at 2~8°C, the control solutions have a shelf life of 6 months in the "closed" form and a shelf life of 30 days after the bottle is opened.

Sample

Sample Volume Flex Study

Multiple sample volumes were evaluated at three hemoglobin levels. Each sample was tested on the Mission® Plus Hemoglobin (Hb) Testing System in 5 replicates using one lot of test cartridges on five meters. Hemoglobin concentration was confirmed with a Sysmex pocH-100i Hematology Analyzer, which was used as the reference method. Test result was determined to be acceptable if the bias against the reference method was less that ±7%. The appropriate sample volume range was determined to be 5-40 µL. The sponsor recommends use of a pipette or the provided capillary blood transfer tube with fixed volume of 10 µL for blood application.

Sample Storage Time Flex Study

The effect of sample storage time was evaluated at various time points using EDTA-K_2 as the anticoagulant. Fresh venous blood collected from a single donor was adjusted to three hemoglobin levels. Samples at each hemoglobin level were divided into four containers and stored at 25°C. Each container was tested at a pre-determined time point. Each sample was tested on the Mission® Plus Hemoglobin (Hb) Testing System in 5 replicates using one lot of test cartridges on five meters. Hemoglobin concentration was confirmed with a Sysmex pocH-100i Hematology Analyzer, which was used as the reference method. A test result was determined to be acceptable if the bias against the reference method was less that ±7%. The sample storage time was determined to be within 8 hours at 25°C.

d. Detection limit:

Please refer to item M.1.a, precision/reproducibility and M.1.b, linearity/assay reportable range, above.

e. Analytical specificity:

A study was performed to assess the effect of potential interferents on the Mission® Plus Hemoglobin (Hb) Testing System according to the CLSI EP7-A guideline.

Specimens with three different hemoglobin levels were spiked with various potential interfering substances. Five replicates were tested for each specimen. Specimens without interfering substance were tested as the control. Biases of the test specimens against the controls were calculated. The acceptance criterion was bias ≤ 7%. Interferents tested are listed in the table below.

Potential Interfering Substances and the Concentrations Tested			
Substance	Test Concentration	Substance	Test Concentration
Bilirubin, conj	342 µmol/L	Ferrous Sulfate	222 mg/L
Cholesterol	13 µmol/L	Ammonium Ferric Citrate	300 mg/L
Creatinine	442 µmol/L	Ferrous Fumarate	300 mg/L
Protein (total)	120 g/L	Iron Dextran	2838 mg/L
Triglyceride	37 mmol/L *	Folic Acid	7.5 mg/L
	18.5 mmol/L *	Vitamin B12	0.025 mg/L
	9.2 mmol/L *	Lithium Carbonate	225 mg/L
	4.6 mmol/L	Methyltestosterone	25 mg/L
Urea	42.9 mmol/L	Immunoglobin	5000 mg/L
Uric Acid	1.4 mmol/L	Methyldopa	71 µmol/L
Acetaminophen	1324 µmol/L	Salicylic Acid	4.34 mmol/L *
Ascorbic Acid	342 µmol/L		2.17 mmol/L *
Dopamine	5.87 µmol/L		1.0 mmol/L
Ibuprofen	2425 µmol/L	Tetracycline	34 µmol/L

All tested substances showed non-significant interference except triglyceride and salicylic acid at concentrations labeled with " * ". The sponsor stated the following limitations in the labeling:

"High concentrations of TRIG and SA can lead to low Hb value."

Interference from Disease Conditions

Studies were conducted to evaluate the potential effect of certain disease conditions on the performance of the Mission® Plus Hemoglobin (Hb) Testing System. Venous blood specimens were collected from diseased donors. Hemoglobin concentration was confirmed with a Sysmex pocH-100i Hematology Analyzer, which was used as the reference method. Each specimen was tested in 5 replicates with the Mission® Plus Hemoglobin (Hb) Testing System. No interference was observed if the bias against the reference method was less than ±7%.

Disease Condition	Number of Specimens	Interference Result
Polycythemia	1	No Interference
Hypochromia	1	No Interference
High WBC Count	3	No Interference
Sickle Cell	1	No Interference

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed at 3 U.S. clinical sites to determine the agreement between the Mission® Plus Hemoglobin (Hb) Testing System and the HemoPoint® H2 Hemoglobin Measurement System. True clinical specimens from total 375 adult subjects, 190 venous blood specimens and 185 fingerstick capillary blood specimens, were collected and tested. An additional 34 specimens with hemoglobin concentration manipulated at the extremes of the measurement range were tested in order to assess performance at the lower and upper ends of the measurement range. The summarized regression statistics are shown below.

Method Comparison Data Summary – Acon vs. HemoPoint, Hb (g/dL)								
Site #	Blood Type	N (Clinical)	N (Contrived)	Slope	95% CI Slope	Intercept	95% CI Intercept	R
1	Venous	59	35	0.978	0.952 to 1.003	0.233	-0.166 to 0.633	0.992
1	Capillary	62	35	0.976	0.947 to 1.005	0.144	-0.305 to 0.593	0.989
2	Venous	62	35	0.977	0.950 to 1.003	0.207	-0.208 to 0.621	0.991
2	Capillary	53	35	0.975	0.940 to 1.010	0.162	-0.371 to 0.696	0.987
3	Venous	69	35	0.988	0.968 to 1.009	0.060	-0.243 to 0.363	0.994
3	Capillary	70	35	0.980	0.958 to 1.001	0.193	-0.121 to 0.507	0.994

b. Matrix comparison:

A specimen matrix comparison study was conducted to compare the performance of the Mission® Plus Hemoglobin (Hb) Testing System on venous blood and on fingerstick capillary blood. A total of 50 participants were enrolled in this study. Venous blood and capillary blood was collected at the same time from each donor. The venous blood specimens were collected using EDTA-K_2 as the anticoagulant and tested within 8 hours after collection. The capillary blood specimens were tested immediately after collection. Difference of hemoglobin concentration between venous blood and capillary blood was within the acceptable range.

Effect of Anticoagulants

A study was conducted to evaluate the effect of anticoagulants on the performance of the Mission® Plus Hemoglobin (Hb) Testing System. Fresh venous blood was collected to tubes contained different anticoagulants: EDTA-K_2, EDTA-K_3, EDTA-Na_2, or sodium heparin. Two tubes were used for each anticoagulant. Hemoglobin concentration in the first tube was kept unadjusted. Hemoglobin concentration in the second tube was adjusted to five target levels: 4.5~5.5 g/dL, 10~11 g/dL, 12~14 g/dL, 17~18 g/dL and 24.6~25.6 g/dL. Hemoglobin concentration, adjusted and unadjusted, in tubes with EDTA-K_2 was tested immediately with a Sysmex pocH-100i Hematology Analyzer, which was used as Control 1. The fresh venous blood was also collected without anticoagulant and tested immediately with the Mission® Plus Hemoglobin (Hb) Testing System, which was used as Control 2 for the

unadjusted blood specimens. Each specimen was tested in 5 replicates with the Mission® Plus Hemoglobin Testing System at different time points. Testing conditions are summarized in the following table. All testing conditions included unadjusted and adjusted specimens.

Testing Condition	Anticoagulant	Testing System	Testing Time (Hour)			
			0	4	8	24
1	EDTA-K_2	Mission Plus	x	x	x	x
2	EDTA-K_3	Mission Plus	x	x	x	x
3	EDTA-Na_2	Mission Plus	x	x	x	x
4	Sodium Heparin	Mission Plus	x	x	x	x
5 (Control 1)	EDTA-K_2	Sysmex	x			
6 (Control 2)	No Anticoagulant	Mission Plus	x			

Biases of testing results under the testing conditions were calculated against both Control 1 and Control 2 for unadjusted specimens and against Control 1 for adjusted specimens. The acceptance criterion was defined as all applicable biases ≤ 7%. No significant interference was observed from EDTA-K_2, EDTA-K_2, EDTA-Na_2, and sodium heparin.

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 following reference ranges were cited from literature. These reference ranges were verified by testing blood specimens from healthy donors using the Mission® Plus Hemoglobin (Hb) Testing System.

Group	Cited Reference Range	Number of Specimens Tested
Adult Men	13.5 – 18 g/dL	240
Adult Women	12 – 16 g/dL	240

N. Instrument Name:

Mission® Plus Hemoglobin (Hb) Testing Meter

O. System Descriptions:

1. Modes of Operation:

   Automated, one-at-a-time analysis.

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:

   There is no specimen identification function with this device. Specimens are identified manually.

4. Specimen Sampling and Handling:

   Fingerstick, capillary whole blood, or venous whole blood is applied to the test cartridge using pipette or provided capillary blood transfer tube. The test cartridge is then inserted into the meter.

5. Calibration:

   The Mission® Plus Hemoglobin (Hb) Testing System is factory calibrated and is not user adjustable. Calibration information for the test cartridges is stored in the code chip, which is provided with each canister of testing cartridges and is required to run the test.

6. Quality Control:

   The Mission® Plus Hemoglobin (Hb) Testing System includes 3 levels of control solutions with known hemoglobin concentration. Controls are prepared from bovine hemoglobin with added preservatives and stabilizers. The Mission® Plus Hemoglobin (Hb) Testing System also includes an optical verifier that verifies the proper operation of the meter's optical detection system. Users are directed to perform optical verification testing and control testing on each day of testing, when a new canister of test cartridge is opened, or when test results seem inaccurate.

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

Operating Temperature and Humidity Study

Test cartridges and meters were stored in chambers at different temperatures and humidity for 2 hours. Tests were performed in the same chamber using samples at three hemoglobin levels. Each sample was tested on 2 meters, 5 replicates on each meter. One lot of test cartridges was used. Testing result at 20±3°C and 40~60% relative humidity was used as the control. A test result was determined to be acceptable if the bias against the control was less that ±7%. Studies demonstrated that the Mission® Plus Hemoglobin (Hb) Testing System can be operated over a temperature range of 10-40°C and relative humidity <90%.

Meter Storage Study

Meters were stored in chambers at different temperature and humidity for a pre-determined period. The meters were then removed from the chambers and left at ambient condition for a pre-determined period. Tests were performed at ambient condition using samples at three hemoglobin levels. Each sample was tested on 2 meters, 5 replicates on each meter. One lot of test cartridges was used. Testing result from the meters stored at 20±3°C and 40~60% relative humidity was used as the control. A test result was determined to be acceptable if the bias against the control was less that ±7%. Studies demonstrated that the test meter can be stored over a temperature range of 0-50°C and relative humidity <90%.

Control Temperature Flex Study

One lot of test cartridges, one lot of control solutions and one meter were stored at different temperature for 30 minutes. Each level of control solution was tested on the meter in 5 replicates at each temperature. Result at 25°C was used as the control. Test results were determined to be acceptable if the bias against the control was less that ±7%. It was demonstrated that the control solutions can be used a temperature range of 2~8°C to 37°C.

Meter Battery Limit Test

A meter battery limit test was conducted to verify that the Mission® Plus Hemoglobin (Hb) Testing System meets the requirements of the design goal at battery limit. The Mission® Hemoglobin (Hb) Testing Meter displays battery symbol when battery voltage discharged to 3.7 volt. Twenty more accurate tests are allowed after meter display battery symbol. After 20 tests, meter will displays E-4. When the battery voltage discharged to 3.6 volt, the meter will displays E-4 directly.

Cleaning and Disinfecting Validation Study

A virucidal efficacy validation study was conducted to validate the virucidal efficacy using the selected disinfectant with the recommended disinfection protocol. In the presence of a 5% fetal bovine serum organic soil load, OXIVIR® Tb Wipes (EPA

Registration No. 70627-60), a ready to use pre-saturated towelette, demonstrated complete inactivation of Hepatitis B virus for all tested materials, following one minute exposure at 21.0°C. The sponsor also demonstrated that there was no significant change in appearance, function, and performance of the meter after 10950 disinfection and cleaning cycles designed to simulate a 3-year life of the meter.

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.