510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K163465

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Hemoglobin

D. Type of Test:

Quantitative determination of hemoglobin

E. Applicant:

Immunostics, Inc.

F. Proprietary and Established Names:

hemochroma PLUS System
hemochroma PLUS Controls

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:

Hematology (81)

H. Intended Use:

1. Intended use(s):

   The hemochroma PLUS System is for the quantitative determination of hemoglobin concentration in non-anticoagulated capillary (finger-stick) whole blood or venous whole blood (K_2EDTA, K_3EDTA, sodium citrate, lithium heparin, or sodium heparin) of adults. The testing system is designed for point-of-care use in primary care settings, hospitals, and medical lab facilities. Estimation of hematocrit, as a function, is only for normal hemoglobin values from 12.0 to 18.0 g/dL (120 to 180 g/L).

   The hemochroma PLUS Controls are intended for use as quality control material to assure the validity and performance of the hemochroma PLUS system in measuring the human hemoglobin concentration.

   The hemochroma PLUS Microcuvettes are only used with hemochroma PLUS Analyzer. This device has not been evaluated for pediatric samples. The device has been evaluated for individuals ranging in age from 18 to 96 years old. The hemochroma PLUS System is for in vitro diagnostic 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:

   hemochroma PLUS Analyzer

I. Device Description:

The hemochroma PLUS Analyzer is a battery powered, hand-held device to measure the concentration of total hemoglobin in blood in 3 seconds with 15µL of whole blood. Whole blood may be collected by fingerstick (capillary) or venipuncture and analyzed without pre-processing. The hemochroma PLUS Analyzer uses hemochroma PLUS Microcuvettes with dual ports where the user applies samples either through capillary action or direct volume pipetting.

The hemochroma PLUS Analyzer determines hemoglobin concentration in whole blood samples using a dual wavelength photo-absorption method and measures the degree of light absorption with a spectrophotometer. The optical distance between the hemochroma PLUS

Microcuvette walls is fixed and permits photometric determination of hemoglobin in undiluted blood samples. The computed end result is displayed on a LCD display and can be printed on an external printer (optional).

The hemochroma PLUS System consists of a hemochroma PLUS Analyzer, single-use hemochroma PLUS Microcuvettes, hemochroma PLUS ID Chip, optical System Check Microcuvette and hemochroma PLUS Controls.

1. hemochroma PLUS Microcuvette

   The hemochroma PLUS Microcuvettes are specially designed for use with the hemochroma PLUS Analyzer. The microcuvettes function as measuring devices specifically holding 15 µL of blood and are inserted into the hemochroma PLUS Analyzer.

2. hemochroma PLUS ID Chip

   The hemochroma PLUS ID chip contains encoded memory with the calibration data/information. With the ID chip inserted in the designated port, the hemochroma PLUS Analyzer reads and utilizes the calibration data regarding the lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

3. hemochroma PLUS Optical System Check Microcuvette

   hemochroma PLUS Optical System Check Microcuvette is designed for use with the hemochroma PLUS Analyzer only. The Optical System Check Microcuvette is a special glass filter used to measure the degree of light absorption with the spectrophotometric method. If the result is between 11.7–12.3 g/dL, the optic system is working properly according to specification.

4. hemochroma PLUS Controls

   The hemochroma PLUS Controls: Level 1 (Low), Level 2 (Middle), and Level 3 (High), are external quality controls designed for use with hemochroma PLUS Analyzer only.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   HemoCue Hb 301 System

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

   K061047

2. Comparison with predicate:

Similarities		
Item	Device hemochroma PLUS System K163465	Predicate HemoCue Hb 301 System K061047
Intended Use/Indications for Use	The hemochroma PLUS System is for the quantitative determination of hemoglobin concentration in non-anticoagulated capillary (finger-stick) whole blood or venous whole blood (K_2EDTA, K_3EDTA, sodium citrate, lithium heparin, or sodium heparin) of adults. The testing system is designed for point-of-care use in primary care settings, hospitals, and medical lab facilities. Estimation of hematocrit, as a function, is only for normal hemoglobin values from 12.0 to 18.0 g/dL (120 to 180 g/L). The hemochroma PLUS Controls are intended for use as quality control material to assure the validity and performance of the hemochroma PLUS System in measuring the human hemoglobin concentration. The hemochroma PLUS Microcuvettes are only used with hemochroma PLUS Analyzer. This device has not been evaluated for pediatric samples. The device has been evaluated for individuals ranging in age from 18 to 96 years old. The hemochroma PLUS System is for in vitro diagnostic only.	The HemoCue Hb 301 System is designed for quantitative point-of-care whole blood hemoglobin determination in primary care using a specially designed analyzer, the HemoCue Hb 301 Analyzer, and specially designed microcuvettes, the HemoCue Hb 301 Microcuvettes. The HemoCue Hb 301 system is for in vitro diagnostic use only. The HemoCue Hb 301 Analyzer is only to be used with HemoCue Hb 301 Microcuvettes.
Parameter(s)	Hemoglobin (Hgb)	Same

Differences		
Item	Device hemochroma PLUS System K163465	Predicate HemoCue Hb 301 System K061047
Test Principle	Dual wavelengths for Hgb measurement and reference	Dual wavelengths for Hgb measurement and turbidity

Differences		
Item	Device hemochroma PLUS System K163465	Predicate HemoCue Hb 301 System K061047
	absorption.	compensation.
Wavelength	Dual wavelengths 530 and 850 nm	Dual wavelengths 506 and 880 nm
Measuring Range	5.0–25.6 g/dL	0–25.6 g/dL
Sample Type	Capillary and venous whole blood	Capillary, venous, and arterial whole blood
Test Time	3 seconds	10 seconds
Sample Volume	15µL	10µL

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

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

CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline

CLSI EP09-A3: Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third 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 - Second Edition

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

CLSI EP14-A3: Evaluation of Commutability of Processed Samples; Approved Guideline-Third Edition

L. Test Principle:

The hemochroma PLUS Analyzer utilizes a dual wavelength LED light source by which the hemoglobin absorbance is detected and converted into an electrical signal. The signal is directly proportional to the amount of hemoglobin present in the sample. The concentration of hemoglobin is calculated based on a pre-programmed calibration. The hemochroma PLUS Microcuvette is specifically designed for the hemochroma PLUS Analyzer. Approximately 15 µL of capillary or venous blood is taken up by capillary action using the tip of the hemochroma PLUS Microcuvette or by direct volume pipetting of the sample. The blood filled Microcuvette is inserted onto the microcuvette holder, and the hemochroma PLUS Analyzer measures the degree of light absorption with a spectrophotometer. The absorbance of the light from the hemochroma PLUS Microcuvette is converted into an electrical signal. The optical distance between the hemochroma PLUS Microcuvette walls is fixed and permits

photometric determination of the hemoglobin in undiluted blood samples.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

   Repeatability

   Repeatability was assessed in-house using three hemochroma PLUS Microcuvette test lots, three hemochroma PLUS Analyzers, three operators and one lot of hemochroma PLUS Controls (low, middle, and high hemoglobin). Five test samples collected in K_2EDTA tubes with hemoglobin concentrations evenly distributed throughout the lower and upper limits and medical decision levels of the analytical measuring range of the hemochroma PLUS Analyzer were tested. Each hemochroma PLUS Analyzer was tested seven times in duplicate (duplicate runs in the morning and duplicate runs in the evening) for a total of 84 tests results for each hemoglobin concentration. Sample Level 1 (5.6 g/dL) and Sample Level 5 (23.7 g/dL) were prepared by spiking natural human whole blood samples. Sample Levels 2 (11.3 g/dL), 3 (14.6 g/dL), and 4 (18.4 g/dL) were sourced from unmodified natural samples. Repeatability results were within the defined acceptance criteria.

   Three additional repeatability studies was accessed in-house using five test samples collected in K_2EDTA tubes with hemoglobin concentrations evenly distributed throughout the lower and upper limits and medical decision levels of the analytical measuring range of the hemochroma PLUS Analyzer.

   Between Operator: In order to evaluate the performance for repeatability between operators, three operators conducted the testing with five hemoglobin levels of test samples using the same lot of the hemochroma PLUS Microcuvette and the same instrument. Each operator repeated the test seven times in duplicate runs (duplicate runs in the morning and duplicate runs in the evening).

   Between Lot: In order to evaluate the performance for repeatability between the hemochroma PLUS Microcuvette lots, one operator conducted the testing with five hemoglobin levels of test samples using three different lots of hemochroma PLUS Microcuvette and the same instrument. Each Microcuvette lot was tested seven times in duplicate runs (duplicate runs in the morning and duplicate runs in the evening).

   Between Instrument: In order to evaluate the performance for repeatability between instruments, one operator conducted the testing with five hemoglobin levels of test samples using one lot of hemochroma PLUS Microcuvette and three different hemochroma PLUS instruments.

   Results calculated from the repeatability studies including the three additional are represented in table (1) below.

Table 1. Repeatability Studies Summary

Repeatability Studies				Within Run		Between Run		Between Lot		Between Instrument		Between Operator		Total	
Sample Level		N	Mean (g/dL)	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Hgb	5.6	84	5.6	0.09	1.68	0.09	1.68	0.09	1.60	0.09	1.69	0.09	1.56	0.20	3.67
	11.3	84	11.3	0.10	0.84	0.10	0.85	0.11	0.93	0.10	0.92	0.10	0.87	0.23	1.97
	14.6	84	14.6	0.09	0.84	0.09	0.61	0.09	0.59	0.09	0.62	0.10	0.66	0.21	1.38
	18.4	84	18.4	0.09	0.49	0.09	0.49	0.09	0.51	0.09	0.47	0.10	0.53	0.21	1.11
	23.7	84	23.7	0.11	0.47	0.11	0.47	0.11	0.45	0.11	0.48	0.12	0.50	0.25	1.06

Reproducibility

Reproducibility was conducted at three intended use sites over 20 operating days using three hemochroma PLUS Microcuvette lots (one lot per site), three hemochroma PLUS Analyzers (one instrument per site), and one lot of hemochroma PLUS Controls (levels 1, 2 and 3) tested across the three sites. Testing was performed twice daily using the same set of controls for 20 days. Each control set was run in duplicate (two runs in the morning and two runs in the afternoon), independently, by two operators at each site. A total of 160 test results were generated for each control level at each site. SD and %CV for within-run, between-run, between-day, between-operator, and between-site were calculated for each site and all sites combined. Reproducibility results at all test sites were within the defined acceptance criteria.

Table 2. Reproducibility Study Summary: Site 1

Site 1				Within-Run		Between-Run		Between-Day		Between-Operator		Total	
Control Level		N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Hgb	Low	160	8.5	0.9	1.01	0.9	1.01	0.9	1.01	0.08	0.94	0.18	1.99
	Middle	160	12.5	0.9	0.70	0.9	0.69	0.8	0.68	0.09	0.70	0.18	1.39
	High	160	15.8	0.8	0.54	0.8	0.54	0.9	0.55	0.08	0.53	0.17	1.08

Table 3. Reproducibility Study Summary: Site 2

Site 2				Within-Run		Between-Run		Between-Day		Between-Operator		Total	
Control Level		N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Hgb	Low	160	8.5	0.9	1.03	0.9	1.03	0.9	1.03	0.09	1.03	0.18	2.16
	Middle	160	12.5	0.9	0.66	0.9	0.71	0.9	0.71	0.09	0.71	0.18	1.40
	High	160	15.8	0.8	0.54	0.8	0.54	0.9	0.54	0.09	0.54	0.17	1.08

Table 4. Reproducibility Study Summary: Site 3

Site 3				Within-Run		Between-Run		Between-Day		Between-Operator		Total	
Control Level		N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Hgb	Low	160	8.5	0.9	1.06	0.9	1.06	0.9	1.01	0.09	1.06	0.18	2.10
	Middle	160	12.5	0.9	0.75	0.9	0.73	0.9	0.71	0.09	0.74	0.18	1.47
	High	160	15.8	0.9	0.57	0.8	0.57	0.9	0.56	0.09	0.57	0.18	1.14

Table 5. Reproducibility Summary: All sites combined

All sites				Within-Run		Between-Run		Between-Day		Between-Site		Between-Operator		Total	
Control Level		N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Hgb	Low	480	8.4	0.09	1.02	0.09	1.03	0.09	1.02	0.09	1.03	0.09	1.03	0.20	2.30%
	Middle	480	12.5	0.09	0.70	0.09	0.71	0.09	0.70	0.09	0.72	0.09	0.72	0.20	1.59%
	High	480	15.8	0.09	0.55	0.09	0.55	0.09	0.55	0.09	0.55	0.09	0.55	0.20	1.23%

b. Linearity/assay reportable range:

The linearity study was conducted using low and high-level hemoglobin concentrations prepared from a venous blood sample. A total of 11 hemoglobin concentration levels (2.5, 4.8, 7.1, 9.4, 11.7, 14.1, 16.4, 18.7, 21.0, 23.3, and 25.6 g/dL) spanning the claimed measuring range of the hemochroma PLUS Analyzer (5.0–25.6 g/dL) were tested in triplicate and analyzed using one hemochroma PLUS Analyzer and one lot of hemochroma PLUS Microcuvettes. The hemochroma PLUS Controls (low, middle, and high) were tested to ensure and confirm the validity of the test results obtained with the hemochroma PLUS Analyzer. The mean result for each concentration was plotted against the expected value. Linear regression was performed and based on the data analysis, the hemochroma PLUS System demonstrated linearity over the claimed measuring range of 5.0–25.6 g/dL.

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

<u>hemochroma PLUS Controls (low, middle, and high) Value Assignment</u>

The hemochroma PLUS Controls were produced into three levels (low, middle, high). Each control level was tested in 15 replicates using the same lot of hemochroma PLUS Microcuvettes on the hemochroma PLUS Analyzer. The percent difference between the expected value and the mean value of the 15 replicates was calculated. The average of the 15 replicates was set as the mean value: 8.5 g/dL (low control),

12.5 g/dL (middle control), and 16.2 g/dL (high control). Value assignment was conducted using three hemochroma PLUS Analyzers with three lots of hemochroma PLUS Microcuvettes and one lot of each control level. Each control level was tested in 10 replicates on each hemochroma PLUS Analyzer. All data points for the hemochroma PLUS Analyzers were within the acceptance criteria.

hemochroma PLUS Controls Stability

Closed-vial stability was determined by using three lots of hemochroma PLUS Controls (low, middle, and high) stored at refrigerated temperature (2–8°C) and tested one day every month in triplicate for 10 months. Controls should be brought to room temperature (15–30°C) before testing. The hemochroma PLUS Controls (low, middle, and high) closed-vial stability study supports a stability claim of 6 months when stored at 2–8°C.

Open-vial stability was determined by using three lots of hemochroma PLUS Controls (low, middle, and high) stored at 2–8°C after opening. The controls were tested every day in triplicate for 17 days. After one hour of leaving the controls outside of the refrigerator, the controls were tested and then placed back in the refrigerator at 2–8°C. The open-vial stability claim was established at 14 days after opening when stored at 2–8°C after each use.

hemochroma PLUS Microcuvettes Stability

hemochroma PLUS Microcuvettes shelf-life stability was determined by using three lots of hemochroma PLUS Microcuvettes stored at 15–35°C. Testing was performed one day per month in triplicate for 27 months. The hemochroma PLUS Controls (low, middle, and high hemoglobin) were tested during the hemochroma PLUS Microcuvettes shelf life stability to ensure and confirm the validity of the test results obtained with the hemochroma PLUS Analyzer. The study data support a shelf-life stability claim of 24 months when stored at 15–35°C.

hemochroma PLUS Microcuvettes open container (in-use) stability was determined by using three lots of hemochroma PLUS Microcuvettes stored at 15–35°C. Testing was performed one day per month in triplicate for 27 months. Every month, three lots of hemochroma PLUS Microcuvettes were removed from the container and tested with fresh hemochroma PLUS Controls (low, middle, and high hemoglobin) in triplicate with the hemochroma PLUS Analyzer and each replicate was tested in 1-hour intervals (total of nine test results each month). The study data support a stability claim of 24 months when stored at 15–35°C after the seal is broken.

Sample Stability

The sample stability study was assessed using one lot of hemochroma PLUS Microcuvettes and one hemochroma PLUS Analyzer. Thirty-seven fresh venous blood samples were collected in K_2-EDTA tubes and measured immediately with the hemochroma PLUS Analyzer. The venous blood test samples were then stored in the

refrigerator (2–8ºC) and tested at various time intervals (3, 6, 12 hours, and 1, 2, 3, 6, 7 days). The venous blood test samples were inverted gently 10 times to ensure mixing of anticoagulant with blood prior to testing. The venous blood test samples stored in the refrigerator were brought to room temperature before testing. Percent recovery was calculated for each venous blood test sample after each time point from the fresh venous blood sample test results. The study data support a stability claim of 24 hours when stored at 2–8°C.

d. Detection limit:

Limit of Blank (LoB) was determined by testing five blank hemoglobin (depleted human plasma) samples measured in five replicates and tested over a period of three days with three different lots of hemochroma PLUS Microcuvettes and three hemochroma PLUS Analyzers for a total of 75 test results per lot of hemochroma PLUS Microcuvettes. LoB was calculated by parametric analysis and was determined to be 0.23 g/dL.

Limit of Detection (LoD) was determined by testing six low Hgb samples prepared by spiking plasma with red blood cells. Each sample was tested in five replicates over a period of three days with three different lots of hemochroma PLUS Microcuvettes using one hemochroma PLUS Analyzer for a total of 90 test results per lot of hemochroma PLUS Microcuvettes. LoD was calculated by parametric analysis and was determined to be 1.66 g/dL.

Limit of Quantitation (LoQ) was determined by testing six low Hgb samples prepared by spiking plasma with red blood cells. Each sample was tested in five replicates over a period of three days with three different lots of hemochroma PLUS Microcuvettes using one hemochroma PLUS Analyzer for a total of 90 test results per lot of hemochroma PLUS Microcuvettes. The LoQ data are considered acceptable when the %Total-error is smaller than the desired total error for the measurand. LoQ of the hemochroma PLUS System was determined to be 4.5 g/dL.

e. Analytical specificity:

An interference study was conducted to evaluate the potential of various endogenous and exogenous substances. Three hemoglobin levels of human whole blood were spiked with various potential interfering substances listed in Table 6 below. Control samples (no interfering substances) and test samples (with interfering substances) were tested in five replicates with the hemochroma PLUS Analyzer and HemoCue Hb 301 Analyzer. All tested interference substances (endogenous and exogenous) showed non-significant interference up to the concentrations given in Table 6 below.

Table 6. Potential Interfering substances (Endogenous and Exogenous)

Exogenous Substances	Test Concentration	Endogenous Substances	Test Concentration
Acetaminophen	1324 µmol/L	Bilirubin (conj.)	342 µmol/L
Ammonium Ferric citrate	300 mg/L	Cholesterol	13 µmol/L
Ascorbic Acid	342 µmol/L	Creatinine	442 µmol/L
Ferrous Sulfate	222 mg/L	Protein (Total)	120 g/L
Ferrous Fumarate	300 mg/L	Triglycerides	37 mmol/L
Folic Acid	7.5 mg/L	Urea	42.9 mmol/L
Ibuprofen	2425 µmol/L	Uric acid	1.4 mmol/L
Iron Dextran	2838 mg/L		
Salicylic Acid	4.34 mmol/L		
Tetracycline	34 µmol/L		
Vitamin B12	1000 pg/mL		

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison study was performed at three point-of-care clinical sites in the United States to assess the performance of the hemochroma PLUS System compared to the predicate device (HemoCue Hb 301 System) utilizing a total of 60 capillary fingerstick blood samples and 60 venous blood samples collected in K_2EDTA tubes at each site. An additional 10 spiked venous samples in the extreme hemoglobin ranges were tested to assess the performance at the lower and upper ends of the measurement range. Testing was performed using three hemochroma PLUS Analyzers (one at each site), three operators (one at each site), and three lots of the hemochroma PLUS Microcuvettes (one at each site). The hemochroma PLUS Controls (low, middle, and high) were run prior to testing. Linear regression analyses demonstrate comparable performance between the hemochroma PLUS System and HemoCue Hb 301 System across the analytical measuring range. The method comparison study demonstrated that the analytical performance of the hemochroma PLUS System test is substantially equivalent to the predicate device.

Table 7. Summary of Method Comparison Study

Site #	Sample Type	N	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient (r)
1	Capillary	60	0.9942 (-0.650, 0.892)	0.1214 (0.941, 1.048)	0.980
1	Venous	70	1.0140 (-0.468, 0.083)	-0.1924 0.995, 1.033	0.997
2	Capillary	60	1.0007 (-1.016, 0.998)	-0.0089 0.932, 1.070	0.967
2	Venous	70	0.9971 (-0.136, 0.437)	0.1506 0.978, 1.016	0.997
3	Capillary	60	0.9994 (-0.872, 0.980)	0.0542 0.935, 1.064	0.971
3	Venous	70	1.0042 (-0.263, 0.289)	0.0129 0.985, 1.023	0.997

b. Matrix comparison:

A matrix comparison study was performed to demonstrate comparability between venous whole blood samples and capillary whole blood samples using the hemochroma PLUS Analyzer. The matrix comparison was performed using whole blood (venous and capillary) from 80 study participants with one hemochroma PLUS Microcuvette lot and one hemochroma PLUS Analyzer. The hemochroma PLUS Controls (low, middle, and high) were run prior to testing. The percent difference between capillary blood and venous blood (K_2EDTA) was calculated. A Bland-Altman plot was used to analyze the agreement between capillary blood and venous blood. The results of the Bland-Altman plot analysis and % difference between venous whole blood samples and capillary whole blood samples on the hemochroma PLUS Analyzer met the acceptance criteria.

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):

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

   The reference ranges were based on the existing medically accepted published reference ranges[1].
   Table 10. Reference Range

Group	Cited Reference Range
Adult Male	14.0-18.0 g/dL
Adult Female	12.0-16.0 g/dL

[1] Billett, HH. Hemoglobin and Hematocrit. Clinical Methods: The History, Physical, and Laboratory Examinations. Boston: Butterworths, 3rd edition, 1990: Chapter 151.

N. Instrument Name:

hemochroma PLUS 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 _____ 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 _____

3. Specimen Identification:

   There is no sample identification function for the hemochroma PLUS Analyzer. Samples are applied directly to the microcuvettes as they are collected. The end user must develop a manual system to identify patients that are tested with the hemochroma PLUS Analyzer.

4. Specimen Sampling and Handling:

   Capillary or venous whole blood is directly applied from the finger or blood tube (using a disposable pipette) to the Microcuvette. Wipe off excess blood from the surface of the microcuvette using a piece of soft gauze. The blood-filled Microcuvette is then inserted into the hemochroma PLUS Analyzer.

5. Calibration:

   The hemochroma PLUS ID chip contains encoded memory with the calibration data/information.

6. Quality Control:

   The hemochroma PLUS Controls (low, middle, and high) are intended for use as quality control material to assure the validity and performance of the hemochroma PLUS System in measuring human hemoglobin concentrations. The hemochroma PLUS Controls should be assayed according to the manufacturer's instructions and following the local and state guidelines. If controls do not perform as expected, the test results should not be reported.

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

1. Comparison of hemochroma PLUS Analyzer and HemoCue Hb 301 Analyzer for Disease Conditions:

   A study was conducted to determine the hemochroma PLUS Analyzer and HemoCue Hb 301 Analyzer performance when testing certain disease conditions. Venous blood specimens were collected from diseased donors: 3 specimens from donors with Polycythemia, 2 specimens from the donors with hypochromia, 3 specimens from the donors with high WBC count, and 2 specimens from sickle cell donors. Each test specimen was tested 5 times with the HemoCue Hb 301 Analyzer and 5 times with the hemochroma PLUS Analyzer. These results indicate that hemochroma PLUS System hemoglobin assay meets the expected performance criteria therefore, no interference was observed in these disease conditions.

2. Anticoagulant Comparison (K_2EDTA vs K_3EDTA, Lithium Heparin, Sodium Heparin, and Sodium Citrate):

   To evaluate the effect of anticoagulants (K_2EDTA, K_3EDTA, Lithium Heparin, Sodium Heparin, and Sodium Citrate) on the performance of the hemochroma PLUS Analyzer, venous blood was collected in each of 2.0 mL anticoagulant tubes (K_2EDTA, K_3EDTA, Lithium Heparin, Sodium Heparin, and Sodium Citrate) from 50 study participants. Spiked plasma samples were used for hemoglobin concentrations in the extreme hemoglobin (low and high) measuring ranges. The % difference between K_2EDTA and

four different anticoagulants (K_3EDTA, Lithium heparin, Sodium heparin, and Sodium Citrate) was calculated. A Bland-Altman plot was used to analyze the agreement between the K_2EDTA tube and the four other anticoagulant tubes. The results of the Bland-Altman plot analysis and % difference on the hemochroma PLUS Analyzer were within the defined acceptance criteria.

3. Cleaning Disinfection and Robustness Testing:

   To perform the hemochroma PLUS Analyzer cleaning step, the operator should use a Micro-Kill Bleach Germicidal Bleach Wipe to wipe all surface areas of the analyzer to remove all blood and other body fluids. During the hemochroma PLUS Analyzer disinfection step, the operator uses Micro-Kill Bleach Germicidal Bleach Wipes to thoroughly wet all surface areas of the analyzer. The operator also carefully disinfects the entire surface of the hemochroma PLUS Instrument and the holder for microcuvettes with the Micro-Kill Bleach Germicidal Bleach Wipes. There was a minimum 5-minute rest period between each the cleaning.

   The hemochroma PLUS Analyzer lifespan claim is 27375 cleaning cycles which is equivalent to 3 years of analyzer life.

   One (1) cycle = One (1) wipe for cleaning + One (1) wipe for disinfecting 25 cleaning cycles per day x 365 days x (3) years = 27375 cleaning cycles.

   The lifespan of the analyzer will vary depending on actual usage.

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.