November 16, 2018

Immunostics, Inc.
Junghee Kim
Regulatory Affairs Specialist
38 Industrial Way East, Suite1
Eatontown, New Jersey 07724

Re: K182298
Trade/Device Name: hemochroma PLUS System
Regulation Number: 21 CFR 864.5620
Regulation Name: Automated hemoglobin system
Regulatory Class: Class II
Product Code: GKR, GGM
Dated: August 22, 2018
Received: August 24, 2018

Dear Junghee Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology
and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182298

Device Name
hemochroma PLUS System

Indications for Use *(Describe)*

The hemochroma PLUS System is for the quantitative determination of hemoglobin concentration in non-anticoagulated capillary (finger-stick) whole blood or venous whole blood (K2-EDTA, K3-EDTA, sodium citrate, lithium heparin, or sodium heparin). The testing system is designed for point-of-care settings, hospitals, and medical lab facilities.

Estimation of hematocrit, as a function, is only for normal hemoglobin values, 12.0 to 18.0 g/dL (120 to 180 g/dL) and in patients ≥ 6 months old.

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. The hemochroma PLUS System is for in vitro diagnostic only.

The hemochroma PLUS Analyzer calculates the test result automatically and displays hemoglobin concentration in terms of g/dL.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 8: 510(k) Summary

hemochroma PLUS System

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR, Section 807.92.

Sponsor's Information

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Contact: Junghee Kim, RA Specialist
E-mail: jhkim@immunostics.com
Website: www.immunostics.com
Establishment Registration Number: 2244821

Device Information

Trade/Device Name: hemochroma PLUS System, hemochroma PLUS Controls
Regulation Number: 21 CFR § 864.5620, 21 CFR § 864.8625
510(k) Number: K182298
Classification Name: Automated hemoglobin system, Hematology quality control mixture
Regulatory Class: Class II
Panel: Hematology
Product Code: GKR, GGM
Predicate Device: HemoCue Hb 301 System
Predicate 510(k) Number: K061047

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_2-EDTA, K_3-EDTA, sodium citrate, lithium heparin, or sodium heparin). The testing system is designed for point-of-care settings, hospitals, and medical lab facilities.

Estimation of hematocrit, as a function, is only for normal hemoglobin values, 12.0 to 18.0 g/dL (120 to 180 g/dL) and in patients ≥ 6 months old.

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. The hemochroma PLUS System is for *in vitro* diagnostic only.

The hemochroma PLUS Analyzer calculates the test result automatically and displays hemoglobin concentration in terms of g/dL.

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 preprocessing. 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 3 Microcuvette walls is fixed and permits photometric determination of hemoglobin in undiluted blood samples. The computed end result is displayed on the 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

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

Substantial Equivalence Information:

Predicate 510(k) number(s): K061047

Similarities		
Item	Device hemochroma PLUS System K182298	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_2-EDTA, K_3-EDTA, sodium citrate, lithium	The HemoCue Hb 301 System is designed for quantitative point-ofcare 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

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	heparin, or sodium heparin). The testing system is designed for point-of-care settings, hospitals, and medical lab facilities. Estimation of hematocrit, as a function, is only for normal hemoglobin values, 12.0 to 18.0 g/dL (120 to 180 g/dL) and in patients ≥ 6 months old. 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. The hemochroma PLUS System is for *in vitro* diagnostic only. The hemochroma PLUS Analyzer calculates the test result automatically and displays hemoglobin concentration in terms of g/dL.	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 K182298	Predicate HemoCue Hb 301 System K061047

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Test Principle	Dual wavelengths for Hgb measurement and reference absorption.	Dual wavelengths for Hgb measurement and turbidity 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	15 µL	10 µL

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.

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

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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 were 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.

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

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Reproducibility

Reproducibility was conducted at three intended use sites over 20 operating days utilizing three hemochroma PLUS Microcuvette lots (one lot per site), three hemochroma PLUS Analyzers (one instrument per site), and one lot of hemochroma PLUS Controls (low, middle, and high hemoglobin) tested across the three intended use sites. Testing was done twice daily using the same set of controls, for 20 days. Each control set was run, in duplicate (two runs in the morning and 2 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. Reproducibility results at all test sites were within the defined acceptance criteria.

Reproducibility Test Results 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

Reproducibility Test Results 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

Reproducibility Test Results 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

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Combined Sites Reproducibility Test Results

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

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 eleven 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) 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.

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.

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Quality Control 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. hemochroma PLUS Controls (low, middle, and high) closed vial stability study data support 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 once opened at (2–8°C). 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 opened vial stability claim has been 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_2EDTA 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

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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.

Detection limit:

Limit of Blank (LoB) testing was performed using five blank hemoglobin depleted human plasma samples measured in five replicates tested over a period of 3 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 of the study data. LoB of hemochroma PLUS System was found to be 0.23 g/dL.

LoD testing was performed using six Hgb-low samples prepared by spiking plasma with red blood cells. Five replicates of each of the six Hgb-low samples was tested over a period of 3 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 of the study data. LoD of hemochroma PLUS System was found 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.

Analytical specificity:

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

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Potential Interfering substances (Endogenous and Exogenous)

Interference Materials			
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		

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 finger-stick blood samples and 60 venous blood samples in K_2EDTA tubes. An additional 10 hemoglobin samples in extreme hemoglobin ranges were spiked in order to assess performance at the lower and upper ends of the measurement range (for venous blood samples only). 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 hemoglobin) were run prior to testing. Linear regression analyses demonstrate comparable performance between 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.

Summary of Method Comparison Study

Site #	Sample Type	N	Slope (95% CI)	Intercept	95% CI Intercept	Correlation Coefficient (r)
1	Capillary	60	0.9942 (-0.650, 0.892)	0.1214	0.1214 (0.941, 1.048)	0.980

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1	Venous	70	1.0140 (-0.468, 0.083)	-0.1924	-0.1924 (0.995, 1.033)	0.997
2	Capillary	60	1.0007 (-1.016, 0.998)	-0.0089	-0.0089 (0.932, 1.070)	0.967
2	Venous	70	0.9971 (-0.136, 0.437)	0.1506	0.1506 (0.978, 1.016)	0.997
3	Capillary	60	0.9994 (-0.872, 0.980)	0.0542	0.0542 (0.935, 1.064)	0.971
3	Venous	70	1.0042 (-0.263, 0.289)	0.0129	0.0129 (0.985, 1.023)	0.997

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. 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.

Reference Range:

The reference ranges were based on the existing medically accepted published reference ranges.

Reference Range[1,2]

Group	Cited Reference Range
2-6 months	9.5-13.5 g/dL
7 months-2 years	10.5-14.0 g/dL
3-6 years	11.5-14.5 g/dL
7-12 years	11.5-15.5 g/dL
13-18 years Male	13.0-16.0 g/dL
13-18 years Female	12.0-16.0 g/dL
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.

2. Andropoulos, Dean B., and George A. Gregory. Gregory's Pediatric Anesthesia. 5th ed., Wiley-Blackwell, 2012.

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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.

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.

Calibration:
The hemochroma PLUS Optical System Check is used to assure the performance of the Optic System of the hemochroma PLUS.

Quality Control:
The hemochroma PLUS Controls (low, middle, and high hemoglobin) 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 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 used.

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):

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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 4 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 4 other anticoagulant tubes. The results of the Bland-Altman plot analysis and % difference between the K_2EDTA tube and 4 different anticoagulants 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.

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Standard/Guidance Document Referenced (if applicable):

No.	Standard Developing Organization	Title of Standard	Date
1	CLSI Reference Standard	**EP05-A3:** Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition	**08/14/2015**
2	CLSI Reference Standard	**EP6-A:** Evaluation of Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline	**01/30/2014**
3	CLSI Reference Standard	**EP07-A2:** Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition	**05/21/2007**
4	CLSI Reference Standard	**EP09-A3:** Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Third Edition	**01/30/2014**
5	CLSI Reference Standard	**EP14-A3:** Evaluation of Commutability of Processed Samples; Approved Guideline-Third Edition	**08/14/2015**
6	CLSI Reference Standard	**EP17-A2:** Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline-Second Edition	**01/15/2013**
7	CLSI Reference Standard	**EP25-A:** Evaluation of Stability of *In Vitro* Diagnostic Reagents; Approved Guideline	**01/15/2013**
8	CLSI Reference Standard	**EP25-A:** Evaluation of Stability of *In Vitro* Diagnostic Reagents; Approved Guideline	**01/15/2013**
9	CLSI Reference Standard	**EP28-A3C:** Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline-Third Edition	**01/30/2014**

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