hemochroma PLUS Microcuvettes

INTENDED 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 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/L) 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.

SUMMARY

"The normal Hb level for males is 14 to 18 g/dL; that for females is 12 to 16 g/dL. When the hemoglobin level is low, the patient has anemia. An erythrocytosis is the consequence of too many red cells; this results in hemoglobin levels above normal."[1]

The hemochroma PLUS Microcuvettes are used for measurement of hemoglobin concentration in human whole blood along with the hemochroma PLUS Analyzer. The hemochroma PLUS Microcuvette is inserted into a holder of hemochroma PLUS Analyzer for quantification of hemoglobin in blood.

PRINCIPLE

The hemochroma PLUS Analyzer uses dual wavelength as the light source. The hemoglobin absorbance is detected and converted into an electrical signal. The signal is directly proportional to the amount of hemoglobin present. The concentration of hemoglobin is calculated based on 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. The blood-filled microcuvette is inserted onto the microcuvette holder.
The hemochroma PLUS Analyzer measures the degree of light absorption with a spectrophotometer using LED as the light source. 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.

REAGENTS

The inner walls of hemochroma PLUS Microcuvettes are coated with 0.05% of Tween 20 (surfactant) and < 0.05% of sodium azide.

MATERIALS SUPPLIED

Components of **hemochroma PLUS Microcuvettes**

- Microcuvettes
- ID Chip
- Instructions For Use

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

- **hemochroma PLUS Analyzer** REF 100-101
- **hemochroma PLUS Controls** REF 100-303
- **hemochroma PLUS Optical System Check** REF 100-404

STORAGE AND STABILITY

- The hemochroma PLUS Microcuvettes are to be stored at 15 - 35°C (59 - 95°F) and stable for 24 months.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this 'Instruction for use'.
- The reagents which coat the inner walls of the hemochroma PLUS Microcuvettes are harmful.
- DO NOT consume. Do not use contaminated hemochroma PLUS Microcuvettes.
- Do not reuse. The microcuvette should be used for processing one sample only.
- Lot numbers of all the test components (hemochroma PLUS Microcuvette and ID Chip) must match each other.
- Please keep the lid of the hemochroma PLUS Microcuvette container closed at all times.
- Do not use the test components after the expiration date.
- All the sample to be at room temperature before the measurement takes place.
- Used microcuvettes, capillary, and sample collection tools should be handled carefully and discarded in accordance with relevant local regulations.

SAMPLE COLLECTION AND PROCESSING

The hemochroma PLUS Microcuvette can be used with capillary or venous blood. Use EDTA (K_2 and K_3), Heparin (sodium or lithium), or sodium citrate as anticoagulants. Venous blood samples should be used within 24 hours upon collection and have been stored at 2 - 8 °C (35.6 - 46.4 °F).

1. Remove sample tube from the refrigerator and bring to the room temperature.
2. Mix the sample tube well prior to sampling. (Mix by gentle inversion at least 10 times or by tube rotator)

For capillary blood, it is recommended to wipe away three drops of blood with dry-gauze or lint-free tissue to avoid any contaminants from tissue fluid or debris. Do not milk (strong and repetitive squeezing) the finger to get sufficient blood.

TEST PROCEDURE

1) For capillary blood, draw finger-prick blood into a hemochroma PLUS Microcuvette by bringing it in contact with the blood drop.
2) For venous blood, place a drop of blood on a hydrophobic surface such as parafilm **or** apply 15 µL of whole blood sample into the opening of the hemochroma PLUS Microcuvette if micropipette or pipette is available.
3) Insert the blood-filled microcuvette onto the microcuvette holder of the hemochroma PLUS Analyzer.
   (Wipe off excess blood from the surface of the hemochroma PLUS Microcuvette by using soft gauze.)
4) Close the holder completely and the hemochroma PLUS Analyzer will run the test automatically.
5) Read the test result on the display screen of hemochroma PLUS Analyzer.

INTERPRETATION OF RESULTS

- The hemochroma PLUS Analyzer calculates the test result automatically and displays hemoglobin concentration in terms of g/dL.
- Expected values:[4,5]
  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
  * Due to a wide range of conditions which affect normal values, it is recommended that each laboratory establishes its own normal range.
- The reportable range of the hemochroma PLUS Analyzer is **5.0 - 25.6** g/dL.

QUALITY CONTROL

hemochroma PLUS Controls are recommended to be used when:

- A new analyzer is taken out of the box.
- Once for each untrained operator
- After opening a new lot of hemochroma PLUS Microcuvettes
- The test results do not match patient's symptoms
- It is to be operated in a different environment than usual.
- In accordance with local, state, and/or federal regulations or accreditation requirements

Only the hemochroma PLUS Controls should be used with hemochroma PLUS Microcuvettes since we cannot guarantee the compatibility with the hemoglobin controls from other brands.

PERFORMANCE CHARACTERISTICS

- **Analytical Limits / Measuring Range**
  LoB was found to be 0.23 g/dL using the parametric analysis.
  LoD was found to be 1.66 g/dL using the parametric analysis.
  LoQ was determined to be 4.5 g/dL.

- **Linearity**
  The study showed that it was linear throughout the claimed range (5.0 - 25.6 g/dL)

- **Precision**
  The results are listed as follow:

[Repeatability]

Sample Level	N	Mean (g/dL)	Within-Run (SD, %CV)	Between-Run (SD, %CV)	Between-Lot (SD, %CV)	Between-Instrument (SD, %CV)	Between-Operator (SD, %CV)	Total (SD, %CV)
1	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
2	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
3	84	14.6	0.09.0.61	0.09,0.61	0.09,0.59	0.09,0.62	0.10,0.66	0.21,1.38
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
5	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]

Site 1.

Sample Level	N	Mean (g/dL)	Within-Run (SD, %CV)	Between-Run (SD, %CV)	Between-Operator (SD, %CV)	Between-Day (SD, %CV)	Total (SD, %CV)
1	160	8.5	0.09,1.01	0.09,1.01	0.08,0.94	0.09,1.01	0.18,1.99
2	160	12.5	0.09,0.70	0.90,0.69	0.09,0.70	0.08,0.68	0.18,1.39
3	160	15.8	0.08,0.54	0.08,0.54	0.08,0.53	0.09,0.55	0.17,1.08

Site 2.

Sample Level	N	Mean (g/dL)	Within-Run (SD, %CV)	Between-Run (SD, %CV)	Between-Operator (SD, %CV)	Between-Day (SD, %CV)	Total (SD, %CV)
1	160	8.5	0.09,1.03	0.09,1.03	0.09,1.03	0.09,1.03	0.18,2.16
2	160	12.5	0.09,0.66	0.09,0.71	0.09,0.71	0.09,0.71	0.18,1.40
3	160	15.8	0.08,0.54	0.08,0.54	0.09,0.54	0.09,0.54	0.17,1.08

Site 3.

Sample Level	N	Mean (g/dL)	Within-Run (SD, %CV)	Between-Run (SD, %CV)	Between-Operator (SD, %CV)	Between-Day (SD, %CV)	Total (SD, %CV)
1	160	8.5	0.09,1.06	0.09,1.06	0.09,1.06	0.09,1.01	0.18,2.10
2	160	12.5	0.09,0.75	0.09,0.73	0.09,0.74	0.09,0.71	0.18,1.47
3	160	15.8	0.09,0.57	0.09,0.57	0.09,0.57	0.09,0.56	0.18,1.14

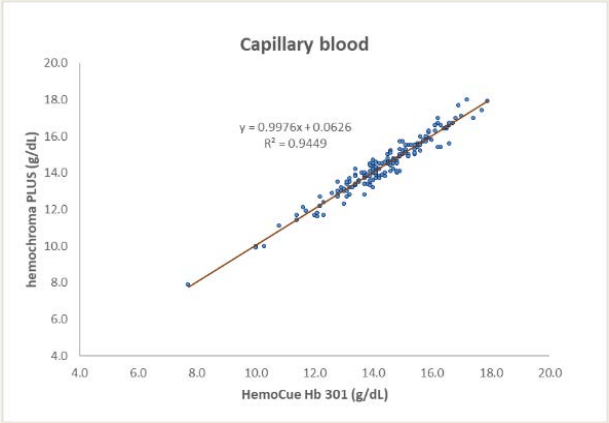
- **Specificity**
  An interference study was performed by adding exogenous and endogenous substances in the test samples at concentrations according to EP07-A2. hemochroma PLUS Analyzer test results did not show any significant interference with these materials.

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		

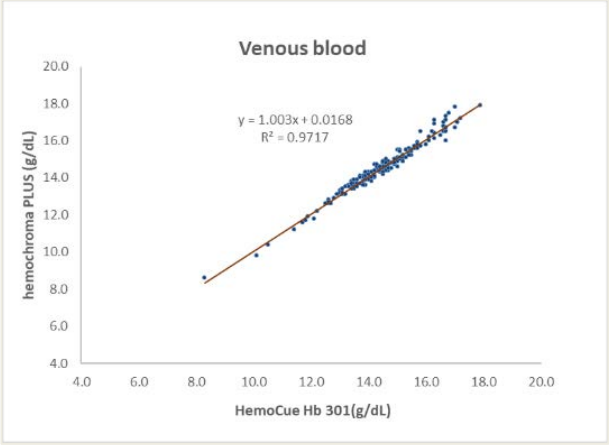
  Another study was conducted to evaluate the potential effect of certain disease conditions on the performance of the hemochroma PLUS System.
  Disease conditions include: polycythemia, hypochromia, high WBC count, and sickle cell anemia. The study showed that there was no interference observed in each disease condition.

- **Matrix Comparison**
  A specimen matrix comparison study was performed to evaluate the effect of anticoagulants on the performance of the hemochroma PLUS System. The anticoagulants tested included sodium heparin, lithium heparin, K_2-EDTA, K_3-EDTA, and sodium citrate tubes and no significant interference was observed.

- **Method Comparison**
  A method comparison study was performed at 3 POC sites to determine the correlation between the hemochroma PLUS System and HemoCue Hb 301. A total of 180 venous blood samples and 180 finger-stick capillary blood samples were obtained.
  The results for capillary blood between the 2 analyzers is as shown below. It satisfied the acceptance criteria, $R^2 > 0.89$.



  The results for venous blood with spiked samples between the 2 analyzers is as shown below. It satisfied the acceptance criteria, $R^2 > 0.97$.



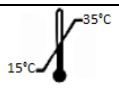
LIMITATION OF THE TEST SYSTEM

- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.
- A limited number of samples from individuals with sickle cell anemia, polycythemia, hypochromia, and high WBC count have been tested.
- The hemochroma PLUS System was not evaluated in patient < 6 months of age.

BIBLIOGRAPHY

1. International Committee for Standardization in Haematology. Recommendations for reference method for haemoglobinometry in human blood (ICSH standard EP 6/2: 1977) and specifications for international haemiglobincyanide reference preparation (ICSH standard EP 6/3: 1977). (1978). Journal of Clinical Pathology, 31(2), 139–143.
2. NCCLS, Evaluation of Precision Performance of Clinical Chemistry Devices; Document EP5-A, Vol 19 No.2, February 1999.
3. NCCLS, Reference and selected procedures for the quantitative determination of hemoglobin blood-second edition; approved standard, NCCLS Document H15-A3, 2000.
4. Billett, HH. Hemoglobin and Hematocrit. Clinical Methods: The History, Physical, and Laboratory Examinations. Boston: Butterworths, 3rd edition, 1990: chapter 151.
5. Andropoulos, Dean B., and George A. Gregory. Gregory's Pediatric Anesthesia. 5th ed., Wiley-Blackwell, 2012.

SYMBOLS USED

Symbol	Used for
	Contains sufficient for 200 tests
	Consult Instructions for Use
	Use by
	Batch code
	Catalog number
	Caution, consult accompanying documents
	*In vitro* diagnostic medical device
	Temperature limitation
	Do not reuse
Rx only	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner
CLIA Waived	CLIA complexity for measurement of hemoglobin in whole blood is CLIA Waived

TECHNICAL SUPPORT

For further information or technical assistance, please contact:
Immunostics Inc.
Tel: (732) 918-0770 / Toll Free: (800) 722-7505
E-mail: technical@immunostics.com

Immunostics, Inc.
38 Industrial Way East Ste. 1
Eatontown, NJ 07724 USA
Tel: (732) 918-0770 / Toll Free: (800) 722-7505
Fax: (732) 918-0618
E-Mail: sales@immunostics.com

Made in Korea

PS-1519 Rev02 04/2019