Hemoglobin (Hb) Test Cartridges

English

Package Insert

REF CLIA-Hab-ST-5060

For testing Hb in human whole b For in vitro diagnostic use only

INTENDED USE

The CLIAwaived, Inc Hemoglobin (Hb) Testing System is for the quantitative determination of hemoglobin in non-anticoagulated capillary whole blood or anticoagulated venous whole blood in EDTA (K2, K3, Na2) 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). This device has not been evaluated for pediatric subjects

SUMMARY

Hemoglobin is the main transporter of oxygen in red blood cells. Measuring hemoglobin concentrations is useful in the clinical diagnosis of diseases, such as anemia and polycythemia

PRINCIPLE AND REFERENCE VALUES

Red blood cells in the specimen are lysed to release Hb, which is converted into MHb. The shade of the color produced depends on the concentration of Hb. Reference values are listed in the table below .

Men 13.5 - 18 g/dL (135 - 180 g/L, 8.38 - 11.17 mmol/L)

Wome 12 - 16 g/dL (120 - 160 g/L, 7.45 - 9.93 mmol/L)

All results below 5.6 g/dL or above 23.5 g/dL must be confirmed by a suitable laboratory method. Reference ranges for children under the age of 18 have not been validated. Reference ranges may vary between laboratories. Every laboratory should establish its own reference range, as needed.¹² REAGENTS

The concentrations given may vary within manufacturing tolerances

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	Reagent	Composition					
	Sodium deoxycholate	3% w/w					
	Sodium nitrite	1.5% w/w					
	Non-reactive Ingredients	95.5% w/w					
PRECAUTIONS							

• Use only CLIA waived, Inc Hemoglobin (Hb) Test Cartridges with a CLIA waived, Inc Hemoglobin (Hb) meter.

Keep the test cartridges in the closed canister until use

· Discard the test cartridges if they are past the expiration date on the canister label

· Do not touch the test area of the test cartridges.

- Discard any discolored or damaged test carridges.
 All specimens should be considered potentially hazardous. Handle in the same manner as an infectious agent.
- Used test cartridges should be discarded according to local regulations after testing.
- Check the code chip before performing a test. Make sure to use the code chip that is included with the canister of test cartridges. Insert the code chip into the code chip slot.

STORAGE AND STABILITY

Store in the closed canister at the temperature or refrigerate 36-86°F (2-30°C). Avoid direct sunlight, Remove only enough test cartridges for immediate use. Close the canister immediately and tightly. DO NOT FREEZE. Do not use past the expiration date Note: Once the canister has been opened, the test cartridges may be used for up to 3 months. In high humidity conditions, the test cartridges

may expire sooner SPECIMEN COLLECTION AND PREPARATION

· Acceptable specimens include fresh capillary or venous blood.

· Fresh blood specimens must be collected and tested immediately

 Whole blood with EDTA or heparin may be used. Preserved specimens must be kept in a closed container and must be used within 8 hours
 after collection. Mix stored specimens adequately before testing. To get accurate results, use a capillary transfer tube to collect capillary blood

	MATERIALS		
	Materials Provide	d	
 Test Cartridges 	Code Chip	 Package Inst 	sert
	Materials Required But No	t Provided	
 Safety Lancets 	Hb Meter	 Gauze for P 	uncture Site
Latex Gloves	 Alcohol Swab 	 Capillary Transition 	ansfer Tubes
	DIRECTIONS FOR U	ISE	
Please make sure the test	cartridge, specimen, and/or controls reac	h the temperature 59-86°	F (15-30°C) before testing
Refer to the User's Manual f	or detailed instructions.		
 Insert the code chip into the 	meter. Io avoid inaccurate results, please mak	te sure the number on the	San Gran
code chip is the same as the	one printed on the test cartridge canister label.		
 Remove the test cartridge cartridge. 	from the canister. Close the canister immediate	By after removing the test	
When the test cartridge symbol	ool flashes, insert the test cartridge as far as it w	ill go into the meter. Follow	Carlos and
the same direction as the Ins	ert Arrows on the top of the test cartridge. The t	est cartridge arrows should	
be parallel with the two arrow	s on the cartridge holder.		

4. Wipe away the first drop of blood. Collect 10 µL of blood by using a capillary transfer tube. Hold the tube slightly downward. Touch the tip of the tube to the blood drop. Blood will automatically be drawn into the tube to the fill line and stop.

- Note: Never squeeze the capillary transfer tube and/or cover the air vent while collecting the blood sample. Make sure that the blood covers the air vent of the tub, if it does not, it will be hard to squeeze the blood out.
- 5. When the blood drop symbol flashes, apply the blood (10 µL) to the sample well. Three (3) dashed lines will appear on the meter to show the test is in progress.

Read the results on the screen after 15 seconds

Note: The hematocrit value is calculated using the formula Hct=F x Hgb [g/dL], with F= 2.94. A true hematocrit test is not determined with this system. The use of this formula is allowed only within the normal hemoglobin range, means from 12.3 g/dL (7.63 mmol/L) - 17.5 g/dL (10.86 mmol/L)12. If the Hb result is outside this range then the estimated hematocrit result will not be calculated and "--" will appear.

INTERPRETATION OF RESULTS

If you get unexpected or questionable results, take the following steps:

Ensure that the test cartridges are not expired.

 Compare results to controls with known levels. Repeat the test using a new test cartridge. If the problem still exists, discontinue using the test cartridges. Contact Customer Service at 1-888-882-7739.

QUALITY CONTROL

The quality control test should be used to check that the meter and test cartridges are working together properly. Follow the test procedure in your User's Manual to run a quality control test. Three levels CTRL 0, CTRL 1 and CTRL 2 are shown on the control solution bottle label. All three levels of control solutions (CTRL 0, CTRL 1 and CTRL 2) must be tested and all levels must be within the assigned value ranges. CAUTION: If your quality control test result falls outside the control ranges shown on the control solution bottle label, DO NOT use the system to test your blood. This may be a sign that the system is not working properly. If you cannot correct the problem, please call Customer Service at 1-888-882-7739.

PERFORMANCE CHARACTERISTICS

Linearity

8 blood samples with adjusted Hb levels from low to high end of measurement range were tested with CLIAwaived, Inc Hemoglobin (Hb) Test System, Each level of the blood sample was tested in 18 replicates. 3 lots of CLIAwaived, Inc Hemoglobin (Hb) Test Cartridges were tested. The results are present in the table below:

Cartridge Lot	Linearity Equation	R ²	Hb range tested
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	v = 0.9693x + 0.3211	0.9963	56-253

Reproducibility and Precision

CLIA waived. Inc Hemoglobin (Hb) Control Solutions with 3 Hb levels were blind labeled with ID number and provided to 3 clinical study sites. Each level of the control solution was performed with CLIA waived, Inc Hemoglobin (Hb) Test System in separated 2 runs by 2 operators each day for 20 days at each site. Results are present in the tables below: 01.4

N	Mean	Within-Run (SD, %CV)	Between-Operator (SD, %CV)	Between-Day (SD, %CV)	Total (SD, %CV)
80 80 80	9.37 13.70 17.29	0.10, 1.11% 0.22, 1.58% 0.35, 2.03%	0.00, 0.00% 0.00, 0.00% 0.00, 0.00%	0.05, 0.55% 0.09, 0.66% 0.19, 1.09%	0.12, 1.24% 0.23, 1.71% 0.40, 2.30%
N	Mean	Within-Run (SD, %CV)	Between-Operator (SD, %CV)	Between-Day (SD, %CV)	Total (SD, %CV)
80 80	9.42 13.98	0.07, 0.72% 0.12, 0.87%	0.01, 0.12% 0.00, 0.00%	0.08, 0.81% 0.12, 0.85%	0.10, 1.09% 0.17, 1.22%
	N 80 80 80 80 N 80 80	N Mean 80 9.37 80 13.70 80 17.29 N Mean 80 9.42 80 13.98	N Mean Within-Run (SD, %CV) 80 9.37 0.10, 1.11% 80 13.70 0.22, 1.58% 80 17.29 0.35, 2.03% N Mean Within-Run (SD, %CV) 80 9.42 0.07, 0.72% 80 13.98 0.12, 0.87%	N Mean Within-Run (SD, %CV) Between-Operator (SD, %CV) 80 9.37 0.10, 1.11% 0.00, 0.00% 80 13.70 0.22, 1.58% 0.00, 0.00% 80 17.29 0.35, 2.03% 0.00, 0.00% N Mean Within-Run (SD, %CV) Between-Operator (SD, %CV) 80 9.42 0.07, 0.72% 0.01, 0.12% 80 13.98 0.12, 0.87% 0.00, 0.00%	N Mean Within-Run (SD, %CV) Between-Operator (SD, %CV) Between-Day (SD, %CV) 80 9.37 0.10, 1.11% 0.00, 0.00% 0.05, 0.55% 80 13.70 0.22, 1.58% 0.00, 0.00% 0.05, 0.55% 80 17.29 0.35, 2.03% 0.00, 0.00% 0.19, 1.66% N Mean Within-Run (SD, %CV) Between-Operator (SD, %CV) Between-Day (SD, %CV) 80 9.42 0.07, 0.72% 0.01, 0.12% 0.08, 0.81% 80 13.98 0.12, 0.87% 0.00, 0.00% 0.12, 0.85%

Cito 2

Sample Level	N	Mean	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%

Sites Combined

Sample Level	N	Mean	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%

Precision study:

Fresh venous blood samples were collected into the tubes containing EDTA anticoagulant and adjusted Hb levels from low to high end of the measurement range. The Hb value was confirmed with Sysmex hematology analyzer. Each hemoglobin level was performed in 30 replicates. Total three lots of test catridges were tested for this study. The results are present in the table below:

Sample Level	N	Mean	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%

Accuracy Comparison Study: Approximately 375 clinical specimens collected from adult subjects either via finger stick or venous at 3 clinical sites were tested with CLIA waived, Inc Hemoglobin (Hb) Test System and a predicate device.

Total 35 contrived blood specimen with adjusted Hb levels from low to high end of the measurement range were tested at 3 POL sites using CLIAwaived, Inc Hemoglobin (Hb) Test System and predicate device.

The results are present in the table below:

	Method Comparison Data Summary -CLIA waived, Inc 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	
					LIMITATIONS				

The following substances do not affect the test results:

Substance	Amount	Substance	Amount
Acetaminophen	200 mg/dl (1324 µmol/L)	Cholesterol	5 g/l (13 mmol/L)
Ascorbic Acid	60 mg/dl (342 µmol/L)	Tetracycline	15 mg/dl (34 µmol/L)
Conjugated Bilirubin	20 mg/dl (342 µmol/L)	Uric Acid	235 mg/l (1.4 mmol/L)
Creatinine	50 mg/dl (4420 µmol/L)	Methyldopa	15 mg/l (71 µmol/L)
Ibuprofen	500 mg/dl (2425 µmol/L)		
Dopamine	0.9 mg/l (5.87 µmol/L)		

High concentrations of TRIG and SA can lead to low Hb value. For anticoagulants, only use heparin and EDTA-K2, EDTA-K3 and EDTA-Na2. BIBLIOGRAPHY

1. McPherson, R.A. and Pincus, M. R., Henry's Clinical Diagnosis and Management by Laboratory Methods, 22nd Edition, 2011, Page 1494

2. Alan H.B. Wu., TIETZ CLINICAL GUIDE TO LABORATORY TESTS, 4th Edition, 2006, Page 524

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