CLIA*waived* Inc.

Hemoglobin (Hb) Test Cartridges
Package Insert

REF CLIA-Hgb-ST-5060	English

For testing Hb in human whole blood.
For in vitro diagnostic use only.

INTENDED USE

The CLIA*waived,* 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)
Women	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. [1,2]

REAGENTS

The concentrations given may vary within manufacturing tolerances.

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 cartridges.
- 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 36-86ºF (2-30ºC). 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 Provided

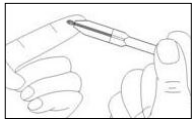
- Test Cartridges
- Code Chip
- Package Insert

Materials Required But Not Provided

- Safety Lancets
- Hb Meter
- Gauze for Puncture Site
- Latex Gloves
- Alcohol Swab
- Capillary Transfer Tubes

DIRECTIONS FOR USE

Please make sure the test cartridge, specimen, and/or controls reach the temperature 59–86ºF (15-30ºC) before testing. Refer to the User's Manual for detailed instructions.



1. Insert the code chip into the meter. To avoid inaccurate results, please make sure the number on the code chip is the same as the one printed on the test cartridge canister label.
2. Remove the test cartridge from the canister. Close the canister immediately after removing the test cartridge.
3. When the test cartridge symbol flashes, insert the test cartridge as far as it will go into the meter. Follow the same direction as the **Insert Arrows** on the top of the test cartridge. The test cartridge arrows should be parallel with the two arrows 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: **Do not squeeze the tube while collecting the blood.** 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.
6. 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)[1,2]. 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 CLIA*waived,* Inc Hemoglobin (Hb) Test System. Each level of the blood sample was tested in 18 replicates. 3 lots of CLIA*waived,* 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	y = 0.9693x + 0.3211	0.9963	5.6 – 25.3

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:

Site 1

Sample Level	*N*	*Mean*	*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%

Site 2

Sample Level	*N*	*Mean*	*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%

Site 3

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 cartridges 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 CLIA*waived,* 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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