isaw®

# Hemoglobin Test Strips
## HB01

CE 0197 IVD 2℃ 30℃

**IMPORTANT:**
Please read this package insert and the user's manual of the ***isaw***® Multi-Monitoring Meter before hemoglobin concentration testing. Besides the user's manual of Multi-Monitoring Meter contains information to perform test with Hemoglobin Test Strips and obtain accurate and consistent test result.

**Intended Use:**
Hemoglobin Test Strips are used combination with Multi-Monitoring Meter, intended for quantitatively measuring Hemoglobin level of fresh capillary whole blood derived from the human body solely to provide information for anemia, blood loss auxiliary diagnosis purposes. This system used by lay person.

**Ingredients**
Each Test Strip contains potassium ferricyanide: 1.2-2.0 mg; other ingredients (buffer, etc.): 0.16-0.23 mg. The vial contains a drying agent.

**Strips Structure**
The test strip is composed of plastic strip, electrode layer, reagent layer and cover layer (as Figure 1)

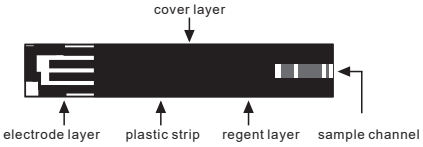



Figure 1

**Test Principle**
Based on biosensor principle. Hemoglobin in the blood sample mixes with special chemicals on the test strip and a small electrical current is produced. This current is measured by the ***isaw***® Multi-Monitoring Meter and displayed as your hemoglobin result. The strength of these current changes with the amount of hemoglobin in the blood sample.

**Also Required for Hemoglobin Testing**
- ***isaw***® Multi-Monitoring Meter and user's manual.
- Lancing device and lancets.

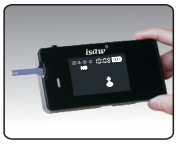
**Storage and Handling**
- Store the test strip package in 2°C-30°C. Keep away from direct sunlight and heat. Do not refrigerate. Write the date opened on the vial label. 3 months of shelf life for test strip after first opening the vial when stored at room temperature. After that test strip need to be discarded.
- Store your test strips in their original vial only; Do not transfer them to a new vial or any other container.
- After taking the ***isaw***® Hemoglobin Test Strip out of the vial. Close cap immediately and tightly.
- Use each test strip immediately after removing it from the vial.
- Avoid getting test strip dirt.
- Do not use Hemoglobin Test Strips beyond the expiration date printed on the package since they may lead to inaccurate results.
- Do not bend, cut or alter an ***isaw***® Hemoglobin Test Strip in any way.
- Use universal blood precautions when handling and disposing of blood hemoglobin monitoring materials. All patient samples and materials with which they come in contact are considered biohazards and should be handled as if capable of transmitting infection. Follow proper precautions in accordance with local regulations when disposing of all materials.
- Transportation Management: Store in a cool, dry environment and keep away from direct sunlight, environment temperature: 2-30°C, humidity: ≤80%. Handle with care, prevent collision and crush.

**WARNING: Keep the test strip vial away from children, the cap is a choking hazard. Furthermore, the vial or cap may contain drying agent that are harmful if inhaled or swallowed and may cause skin or eye irritation.**

**Sample Requirements:** Fresh capillary blood.

**Testing Procedure:**
**Step 1 Preparation**
Wash hands with hand sanitizer or hand soap. Using the alcohol pad to disinfect your finger after get dry. Then let your arm hang vertically for 10-15 seconds to facilitate sampling.

**Step 2 Code number and test item matching**
Take out one Hemoglobin test strip from packaged bottle, and insert it into Multi-Monitoring Meter test port, make sure contact bars of Hemoglobin test strip face you and push the strip to the largest distance.

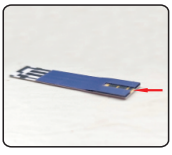



The code number will show on the Multi-Monitoring Meter screen for 3 seconds automatically. Comparing the code number shown on Multi-Monitoring Meter screen and make up on the packaged bottle label, when the numbers are the same, and character 'HB' shown on Multi-Monitoring Meter screen, go to next step.

**Note:** If the Multi-Monitoring Meter don't show 'HB', please repeat step 2 with a new strip.

**Step 3 Specimen Sampling**
Puncture the different positions of finger with a lancet when conduct several times of sampling to avoid festering.

Squeeze your fingertip to get one drop of blood at least 1.5 microliter and contact the sample channel.



**Step 4 Test Result**
After Multi-Monitoring Meter countdown from 5 to 0, the blood hemoglobin concentration will be shown on the display.

**Note:** When Multi-Monitoring Meter count down to "0", the blood should cover all sample channel. If not, please repeat step 3 ~ step 4 to get accurate test result.

**Step 5 Test strip disposal**
Pull test strip out Multi-Monitoring Meter via press the ejection button. Treat used test strips as biohazardous waste.

**WARNING: Pay more attention corner stabbing when pull test strip out. Make sure used test strip disposal follow your local regulations accordingly.**

Hemoglobin Reference Ranges:
Refer to
https://www.gloshospitals.nhs.uk/our-services/services-we-offer/pathology/haematology/haematology-reference-ranges/
Male: 13-18 g/dL.
Female: 11.5-16.5 g/dL.

**Explanation of Test Results**
- The meter displays hemoglobin test results with unit of measurement as g/dL.
- Do not use test strips after the unopened expiration date printed on the vial.
- If your hemoglobin test result fall outside the hemoglobin reference ranges or if you are experiencing symptoms that are not consistent with your test result, should not take any decision of medical relevance without first consulting medical practitioner please repeat a test, if you still get a unexpected test result, please contact your healthcare professional.
- If your hemoglobin test result is lower than 5.0 g/dL, symbol "LO" will appear on the meter display. This indicates severe low hemoglobin. If your hemoglobin test result is higher than 26 g/dL, symbol "HI" will appear on the meter display. This indicates severe high hemoglobin. You should repeat a test, if still get the same result, please contact your healthcare professional.
- The test result refer to hemoglobin reference ranges and should consult with healthcare professional.

**LIMITATIONS**

***isaw***® Hemoglobin Test Strips give accurate results when the following limitations are observed:

- The test strips are for single use only. Do not reuse.
- The test strips are specific to hemoglobin and do not react to other things which may be present in blood.
- Use only fresh capillary whole blood. Do not use serum or plasma.
- In vitro diagnostic use only

**Please Note These Additio nal Limitations**

- Interference might occur when the values of the limiting concentrations of these compounds are greater than those listed below.

Acetylchlorophenol ＞20 mg/dL
Ascorbic acid ＞2.3 mg/dL
Dopamine ＞13 mg/dL
Salicylic acid ＞50 mg/dL
Bilirubin ＞40 mg/dL
Cholesterol ＞500 mg/dL
Creatinine ＞30 mg/dL
Lactic acid ＞100 mg/dL
Pyruvic acid ＞2.0 mg/dL
Urea ＞500 mg/dL
Fructose ＞30 mg/dL
Sucrose ＞50 mg/dL
Gentisic acid ＞50 mg/dL
Ibuprofen ＞40 mg/dL
Ecodextrin ＞4600mg/dL
Methyldopa ＞2.5mg/dL
Toluene sulfonamide ＞100mg/dL
Xylose ＞19 mg/dL

- Patients undergoing oxygen therapy may yield falsely lower results.
- Test results may be falsely low if the patient is severely dehydrated, in shock, or in a hyperosmolar state (with or without ketosis).
- Critically ill patients should not be tested by ***isaw***® Multi-Monitoring Meter.

**Performance Characteristics**

**Measurement range**

The measurement range of the ***isaw***® system is 5-26 g/dL.

**Precision**

Hemoglobin concentration intervals for intermediate measurement precision evaluation

| Hemoglobin concentration | Precision |
|---|---|
| 10.2g/dL | CV=3.85% |
| 14.6g/dL | CV=4.15% |
| 17.6g/dL | CV=4.57% |
| 20.8g/dL | CV=4.24% |

**System Accuracy**

**● Compared to reference system**

The blood samples were from more than 106 participants. Capillary blood samples were taken from fingertip. Fingertip samples from the same subjects were also analyzed with the Auto hematology analyzer model: URIT-2981. The results were compared.

| Hemoglobin concentration ≤8.8 g/dL | | |
|---|---|---|
| Within±0.44g/dL | Within±0.88g/dL | Within ±1.32g/dL |
| 38.5%(7/16) | 69.5% (12/16) | 100%(16/16) |
| Hemoglobin concentration ＞8.8 g/dL | | |
| Within ±5% | Within±10% | Within±15% |
| 34%(31/90) | 75%(68/90) | 100%(90/90) |

**● Consumer Study.**

A consumer study was conducted using one lot of test strip. Participants and a trained technician used the Multi-Monitoring Meter System. This study shows that the patient can run the test as well as a trained technician.

Evaluating Hemoglobin values from fingertip capillary blood samples obtained by 106 persons showed the following results:
96.5 % of the measured hemoglobin values fall within ± 1.17 g/dL of the medical laboratory values at Hemoglobin concentrations ≤ 8.8 g/dL
90.06 % of the measured hemoglobin values fall within ± 10% of the medical laboratory values at Hemoglobin concentrations ＞8.8 g/dL

**References**


1. CherneckyCC, BergerBJ, eds. (2004). Laboratory Tests and Diagnostic Procedures, 4thed. Philadelphia, Saunders. FischbachFT, Dunning MB III, eds. (2004).
2. https://www.gloshospitals.nhs.uk/our-services/services-we-offer/pathology/haematology/ haematology-reference-ranges/


**Notes on Symbols and Marks**

| | |
|---|---|
| STRIP | Hemoglobin Test Strips |
| | Consult instructions for use |
| IVD | In vitro diagnostic medical device |
| | Temperature limit |
| | Keep away from sunlight |
| | Do not re-use |
| | Contains sufficient for < n > tests |
| | Manufacturer |
| | Date of manufacture |
| LOT | Batch code |
| | Use-by date |
| CE 0197 | Conformity with Directive 98/79/EC |
| EC REP | Authorized representative in the European Community / European Union |

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Guilin Royalyze Medical Instrument Co., Ltd.
Registration Address: 18 Li River Road, Qixing District, Guilin 541004 Guangxi P.R. China
Business Address: 13 Lushan Road, Lushan Industrial Park, Xicheng Economic Development Zone, Guilin, 541199 Guagnxi P.R. China

EC REP Caretechion GmbH
Add: Niederrheinstr. 71, 40474 Duesseldorf, Germany
Tel: +49 211 23 98 900