**Hb Hemoglobin Test Strips (Whole Blood)**

For testing hemoglobin (Hb) in human whole blood.

**Package Insert**

**INTENDED USE**

The Hb Hemoglobin Test Strips (Whole Blood) are firm plastic strips onto which a multilayer dry reagent is affixed and are intended to be read on the Insight® Hb Hemoglobin Meter. The test strips function by lysing erythrocytes and converting the released hemoglobin into methemoglobin. This test is for the quantitative determination of hemoglobin (Hb) and calculated hematocrit (Hct) in capillary and venous whole blood. The test strips are for professional use only.

**SUMMARY**

Hemoglobin is the main component of red blood cells whose main function is to transport oxygen. The determination of hemoglobin concentration in whole blood is useful in the clinical diagnosis of diseases such as anemia and polycythemia. The measurement range of the Insight® Hb Hemoglobin Testing System is 5 – 25.6 g/dL.

**PRINCIPLE AND REFERENCE VALUES**

Erythrocytes in the specimen are lysed to release hemoglobin. The Hb Hemoglobin is converted to methemoglobin. The intensity of the color produced from the reaction is proportional to the hemoglobin concentration. Reference values are listed in the chart below:

<table>
<thead>
<tr>
<th>Gender</th>
<th>Concentration Range (g/dL)</th>
<th>(mM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>13.0 – 17.0</td>
<td>115 – 170</td>
</tr>
<tr>
<td></td>
<td>8.1 – 10.5 (mM)</td>
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<tr>
<td>Women</td>
<td>12.0 – 15.0</td>
<td>100 – 150</td>
</tr>
<tr>
<td></td>
<td>7.4 – 9.3 (mM)</td>
<td></td>
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<tr>
<td>Children</td>
<td>11.0 – 14.0</td>
<td>90 – 140</td>
</tr>
<tr>
<td></td>
<td>6.8 – 8.7 (mM)</td>
<td></td>
</tr>
</tbody>
</table>

**REFERENCES**

Reference ranges may vary between laboratories. Every laboratory should establish its own reference range as needed.

** packages and PRECAUTIONS**

- **For in vitro diagnostic use only.**
- The strip should remain in the closed canister until use.
- Do not use after the expiration date.
- Do not touch the reagent area of the strip.
- Discard any discolored or damaged strips.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used strip 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 strips.
- Insert the code chip into the code chip slot. The code chip slot is on the right side of the meter.

**STORAGE AND STABILITY**

Store as packaged in the closed canister, either at room temperature or refrigerated (2-30°C). Keep out of direct sunlight. Stabilize is performed or whenever a new canister is first opened. Each laboratory should establish its own goals for adequate standards of performance. Contact your local distributor for information on specific controls for this product.

**SPECIMEN COLLECTION AND PREPARATION**

- Acceptable specimens include fresh capillary or venous blood, following NCCLS Guideline H44 for capillary blood specimen collection.
- Fresh capillary or venous blood specimens must be collected and tested immediately.
- Specimens with EDTA or heparin anticoagulants may be used. Preserved specimens may be kept in a closed container and must be used within 8 hours of collection. Mix stored specimens adequately before testing.
- A Capillary Transfer Tube or pipette should be used to collect capillary specimens for accurate results.

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Test strips
- Code chip
- Alcohol swab
- Sterile lancet
- Capillary Transfer Tubes
- Gauze for puncture site
- Materials Provided

**DIRECTIONS FOR USE**

Allow the strip, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Refer to the Hb Hemoglobin Testing System User’s Manual for detailed instructions.

1. Insert the code chip into the meter and code the meter correctly. Refer to Coding the Meter in the User’s Manual for details. Compare the code number on the code chip with the code number printed on the test strip canister label, and ensure the two numbers are identical to avoid inaccurate results.
2. Remove the strip from the closed canister and use it as soon as possible. Immediately close the canister tightly after removing the required number of strips(s).
3. Wait for the meter to flash the strip symbol. Insert the strip completely into the Strip Channel in the same direction as the arrows printed on the test strip until the white edge above the black line on the test strip is no longer visible.
4. Wipe away the first drop of blood. Collect 10 µL of the second drop of capillary blood specimen using a Capillary Transfer Tube or pipette. Refer to the User’s Manual for details. Hold the tube horizontally and touch the tip of the Capillary Transfer Tube to the blood drop. Capillary action will automatically draw the sample to the fill line and stop.

**LIMITATIONS**

- High humidity conditions.
- High concentrations of triglycerides and salicylic acid can lead to low Hb measurements. Anticoagulants, such as heparin and EDTA, are recommended for use with venous whole blood. Do not use anticoagulants such as idoacetate, sodium citrate or those containing fluoride. Do not use plasma or serum with the Hb Hemoglobin Testing System.

**BIBLIOGRAPHY**