### INTENDED USE
The Mission® Plus Hemoglobin (Hb) Testing System is for the quantitative determination of hemoglobin in non-anticoagulated capillary whole blood or 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 specimens 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:

<table>
<thead>
<tr>
<th>Hb (g/dL)</th>
<th>Hb from 5 to 17.5</th>
<th>Hb from 17.5 to 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-12</td>
<td>0.99-1.00</td>
<td>0.99-1.00</td>
</tr>
<tr>
<td>13-16</td>
<td>0.99-1.00</td>
<td>0.99-1.00</td>
</tr>
<tr>
<td>17-21</td>
<td>0.99-1.00</td>
<td>0.99-1.00</td>
</tr>
</tbody>
</table>

### REAGENTS
The concentrations given may vary within manufacturing tolerances.

- **Sodium deoxycholate** 7% w/w
- **Sodium chloride** 35.5% w/w

### PRECAUTIONS
- Use only Mission® Plus Hemoglobin (Hb) Test System with a Mission® Plus Hemoglobin (Hb) meter.
- Keep the test cartridges in the closed canister until use.
- Check the expiration date of the test cartridge before use.
- Discard any damaged or discolored test cartridges.
- All specimens should be considered potentially hazardous. Handle in the same manner as an infectious agent.
- 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 38-86°F (3-23°C). Avoid direct sunlight. Remove only enough test cartridges for immediate testing. Do NOT shake test cartridge or discard immediately after use. Do not use test cartridges past the expiration date.

### SPECIMEN COLLECTION AND PREPARATION
- Useable 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.
- To get accurate results, use a capillary transfer tube to collect capillary blood.

### MATERIALS
- **Test Cartridges**
  - **Code Chip**
  - **Package Insert**
- **Safety Lancets**
- **Hb Meter**
- **Alcohol Swab**
- **Gauze for Puncture Site**
- **Capillary Transfer Tubes**

### DIRECTIONS FOR USE

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 number on the code chip on the test cartridge.

2. 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 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 drop of blood. Blood will automatically be drawn into the tube to the fill line and stop. 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 results to show the test is in progress.

6. Read the results on the screen after 15 seconds.

Note: Do not squeeze the tube while collecting the blood. Make sure that the blood covers the air vent of the tube. If it does not, it will be hard to squeeze the blood out.

### INTERPRETATION OF RESULTS
If you get unexpected or questionable results, follow the steps below:

- **Quality Control**
  - The quality control test should be used to check that the meter and test cartridges are working properly. Follow the test procedure in your User’s Manual for detailed instructions. 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.

### BIBLIOGRAPHY

### PERFORMANCE CHARACTERISTICS

#### Linearity
Mission® Plus Hemoglobin (Hb) Control Solutions with 3 Hb levels were blinded with 10 ID numbers. All specimens should be considered potentially hazardous. Handle in the same manner as an infectious agent.

### LIMITATIONS
The following substances do not affect the test results:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>200 mg/d (1734 µmol/L)</td>
</tr>
<tr>
<td>Aminobenzoic acid</td>
<td>30 mg/d (424 µmol/L)</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>60 mg/d (342 µmol/L)</td>
</tr>
<tr>
<td>Calcium</td>
<td>50 mg/d (4420 µmol/L)</td>
</tr>
<tr>
<td>Creatinine</td>
<td>10 mg/d (147 µmol/L)</td>
</tr>
<tr>
<td>Creatinine kinase</td>
<td>15 µg/d (171 µmol/L)</td>
</tr>
<tr>
<td>Magnesium</td>
<td>10 mg/d (250 µmol/L)</td>
</tr>
<tr>
<td>Phosphate</td>
<td>10 mg/d (450 µmol/L)</td>
</tr>
<tr>
<td>Sodium</td>
<td>150 mg/d (6.6 mmol/L)</td>
</tr>
<tr>
<td>Uric acid</td>
<td>5 mg/d (470 µmol/L)</td>
</tr>
</tbody>
</table>

High concentrations of TRO and SAA can lead to false Hb values.