**Intended Use**

Intended for use as human hemoglobin standard for the cyanmethemoglobin hemoglobin procedure.

**Summary and Explanation**

The lyophilized hemoglobin standard is hemolysate prepared from human erythrocytes. The standard provides a level of hemoglobin concentration within the linearity range of the cyanmethemoglobin hemoglobin procedure. Stabilizers are added to maintain hemoglobin in the reduced state.

**Principle**

The lyophilized hemoglobin standard should be used to calibrate the determination of unknown specimens using the cyanmethemoglobin assay. Controls should be included to validate the calibration of the assay.

**Reagents**


Precautions: For *in vitro* diagnostic use. Handle with the same precautions used for human blood samples. The human blood used in this product has been tested and found to be non-reactive for hepatitis B surface antigen, hepatitis C antigen, and HIV antibody.

Storage and stability: Store at 2-8°C. Stable until expiration date if sealed tightly. Protect from light and heat.

Reconstitution: Add 2.00 ml deionized water. Allow to stand for 15 minutes with occasional gentle mixing. The reconstituted standard is stable for 30 days if stored at 2-8°C and sealed tightly.

Deterioration: The presence of obvious turbidity after reaction with cyanmethemoglobin reagent would indicate deterioration, and the product should not be used.

**Procedure**

The lyophilized human standard should be used to standardize instrument or hemoglobin assay following the directions that accompany the instrument and reagent kit used.

**Materials provided:** lyophilized hemoglobin standard.

**Materials not provided:** cyanmethemoglobin reagent and cyanmethemoglobin controls.

**Limitations:** Among factors that might cause inaccurate results are improper pipetting, inadequate mixing.

**Values:** See table below for assigned setpoints.

**Definitions**

**Standard value:** The value obtained by assaying representative samples of the entire lot using the cyanmethemoglobin hemoglobin procedure.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Setpoint</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pointe 180</td>
<td>11.2</td>
<td>g/dl</td>
</tr>
<tr>
<td>Cobas Mira</td>
<td>11.8</td>
<td>g/dl</td>
</tr>
</tbody>
</table>

**Symbol Key**

- Use by (YYYY-MM-DD)
- LOT Lot and batch code
- Manufacturer
- Consult instructions for use
- In vitro diagnostic medical device

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