**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>11.4</td>
<td>g/dl</td>
</tr>
</tbody>
</table>

Manufactured for Pointe Scientific, Inc.
5449 Research Drive, Canton, MI 48188

European Authorized Representative:
Obelis s.a.
Boulevard Général Wahis 53
1030 Brussels, BELGIUM
Tel: (32)2.732.59.54 Fax:(32)2.732.60.03 email: mail@obelis.net

**Rev. 4/12 P803-H7506-05**