

### Intended Use

Intended for use as human hemoglobin controls for the cyanmethemoglobin hemoglobin procedure

### Summary and Explanation

The lyophilized Hemoglobin controls are hemolysates prepared from human erythrocytes. The controls provide multiple levels of hemoglobin concentration within the linearity range of the cyanmethemoglobin hemoglobin procedure. Stabilizers are added to maintain hemoglobin in the reduced state providing complete control of the cyanmethemoglobin test.

### Principle

The lyophilized hemoglobin controls should be assayed in the same manner as unknown specimens. The expected range gives the acceptable limits for assay values.

### Reagents

Reactive ingredients: Hemoglobin prepared from human erythrocytes. Preservatives added. The lyophilized hemoglobin controls provide multiple levels of hemoglobin. Consult mean and expected range for acceptable results.

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 controls are stable for 90 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 controls should be assayed in the same manner as unknown blood specimens. Follow the directions that accompany the instrument and reagent kit used in the assay.

### Materials Provided

Lyophilized hemoglobin controls.

### Materials not provided

Cyanmethemoglobin reagent and cyanmethemoglobin standard.

### Limitations

Among factors that might cause inaccurate results are improper pipetting, inadequate mixing and poorly calibrated instruments.


### Definitions

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


Expected range: The acceptable limits to be used as a guide in determining the accuracy of the assay procedure. The assay results for the controls should fall within the stated expected range.

**Lot #: 501601 Exp. Date: 2017-12**

| Analyzer               | Low     | Mid       | High      | Units |
|------------------------|---------|-----------|-----------|-------|
| Pointe 180 / manual    | 7.2-8.0 | 10.9-12.1 | 14.8-16.4 | g/dl  |
| Cobas Mira / automated | 7.3-8.1 | 11.1-12.3 | 15.4-17.0 | g/dl  |














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**EC REP**

### Symbol Key

|   |  |
|---|--|
|  Use by (YYYY-MM)<br> Catalog number<br> <i>In vitro</i> diagnostic medical device<br> Consult instructions for use<br> Caution<br> Authorized representative in the European Community |  Lot and batch code<br> Manufacturer<br> Temperature limitation<br> CE mark<br> Potential Biohazard |
|---|--|

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