

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

Reactive ingredients: Hemoglobin prepared from human erythrocytes. Preservatives added. Consult vial label for assigned setpoint for the standard.

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.

Lot # 509204 Exp: 2018 / 03

Instrument	Setpoint	Units
Pointe 180	11.7	g/dl
Cobas Mira	11.9	g/dl

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



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