POINTE SCIENTIFIC, INC.
5449 Research Drive • Canton MI 48188 • USA

Glycohemoglobin Standard

Intended Use
This product is for the purpose of standardizing results obtained from run to run in the quantitative determination of human glycohemoglobin (HbA_1) in blood by cation exchange resin.

Summary
Since cation exchange methods for glycohemoglobin can be influenced by temperature fluctuations, patient specimens should always be assayed with a standard included in the run to eliminate the influence of temperature. The setpoint value of the standard was obtained by assaying representative samples of the entire lot by an HPLC for hemoglobin A_{1C} method.

Reagents
The lyophilized glycohemoglobin standard is a hemolysate prepared from packed human erythrocytes. Stabilizers are added to maintain hemoglobin in the reduced state for the accurate standardization of the glycohemoglobin procedure.

Reagent Preparation
Reconstitute standard vial with 1.0ml deionized water. Gently mix for 10 minutes, or until all material has dissolved.

Reagent Storage and Stability
1. Store at 2-8°C. Stable until expiration date if sealed tightly. PROTECT FROM LIGHT AND HEAT.
2. The reconstituted standard should be stored refrigerated (2-8°C) and sealed tightly. The standard retains it assigned value for at least 30 days at 2-8°C.

Precautions
1. This standard is for *in vitro* diagnostic use only.
2. Although this product has been tested and found non-reactive for Hepatitis B Surface Antigen (HBsAG) and HIV, no known test can offer assurance that products derived from human blood will not transmit disease. Therefore all human serum products and patient specimens should be handled in the same manner as an infectious agent.
3. Do not pipette by mouth. Avoid contact with skin and mucous membranes.

Materials Provided
Glycohemoglobin standard set to approximately 10% glycohemoglobin. Check vial label for the exact setpoint value.

Materials Required But Not Provided
1. Glycohemoglobin test kit
2. 1 ml pipette
3. Deionized water

Procedure
The lyophilized glycohemoglobin standard should be included each time patient specimens are assayed. It should be treated in the same manner as the patient specimens including the hemolysate procedure. Follow the directions which accompany the instrument and reagent kit used in the assay.

Limitations
Things to look for which might cause inaccurate results are improper pipetting, inadequate mixing and poorly calibrated instruments.

Setpoint Value
See setpoint value listed on vial label.

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. 1/10 P803-G7540-05