

Intended Use

Controls for use in the quantitative determination of human glycohemoglobin (HbA_{1c}) in blood by cation exchange resin.

Summary and Principle

Controls should be included each time patients are assayed for glycohemoglobin to verify that the assay has worked correctly. The mean value of the controls were obtained by assaying representative samples of the entire lot.

Reagents

The lyophilized glycohemoglobin controls are hemolysates prepared from packed human erythrocytes. The controls provide two levels of glycohemoglobin in the normal and elevated range. Stabilizers are added to maintain hemoglobin in the reduced state providing complete control of the glycohemoglobin procedure.

Reagent Preparation

Reconstitute vials with 1.0ml deionized water. Gently mix for 10 minutes. Observe for undissolved material. The reconstituted controls should be dispensed in 0.1ml aliquots, sealed tightly and frozen at -20°C.

Reagent Storage

1. Store reagent at 2-8°C. Stable until expiration date if sealed tightly. PROTECT FROM LIGHT AND HEAT.
2. Reconstituted controls retain their assigned values for at least three months if frozen. If not frozen, the reconstituted controls are stable at least one month if stored at (2-8°C) and sealed tightly.
3. Do not freeze and thaw more than once.
4. Do not store in a self-defrosting freezer.

Precautions

1. This reagent 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.

Procedure

The lyophilized glycohemoglobin controls should be assayed in the same manner as blood specimens including the hemolysate procedure. Follow the directions that accompany the instrument and reagent kit used in the assay.

Materials Provided

1. Normal level control
2. Elevated level control

Materials Required but not Provided

1. Glycohemoglobin test kit.
2. 1 ml Pipette
3. Deionized water

Limitations

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

Expected Values

See values listed on vial label. The assayed limits are 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. If they do not, the assay should be repeated, checking closely for the factors mentioned in "Limitations".

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