

Quantitative determination of glycated hemoglobin (HbA1c)**IVD**

Store 2 - 8°C.

INTENDED USE

This product is for the purpose of monitoring accuracy and precision in the quantitative determination of human hemoglobin A1c (HbA1c) in blood by automated immunoassay.

PRODUCT CHARACTERISTICS

The lyophilized HbA1c controls are hemolysates prepared from packed human erythrocytes.

The controls provide two levels of HbA1c one level in the normal range and the other level in the elevated range.

Stabilizers are added to maintain hemoglobin in the reduced state providing complete control of the HbA1c procedure.

PREPARATION

Reconstitute vials with 1.0 mL sample solution. Gently mix for 30 minutes.

Observe for undissolved material.

The lyophilized HbA1c controls should be assayed in the same manner as blood specimens including the hemolysate procedure.

PRECAUTIONS

Components from human origin have been tested and found negative for the presence of HBsAg, HCV and antibody to HIV (1/2). However handle cautiously as potentially infectious.

Avoid contact with skin and mucous membranes.

MATERIAL REQUIRED AND NOT PROVIDED

Hemoglobin A1c Reagent kit, from Audit Diagnostics

Hemoglobin A1c Calibrator kit, from Audit Diagnostics

STORAGE AND STABILITY

1. Store controls at 2-8°C. Stable until expiration date if sealed tightly.

PROTECT FROM LIGHT AND HEAT.

2. The reconstituted controls are stable at least 7 days if stored at 2-8°C and sealed tightly.

PROCEDURE

To be used in enzymatic assays.

Lot No: 209

HbA1c Control Level 1	6.0 (4.68 - 7.32) %
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