

Quantitative determination of glycated hemoglobin (HbA_{1c})**IVD**

Store 2 - 8°C.

INTENDED USE

This product is for the purpose of calibrating results in the quantitative determination of human hemoglobin A_{1c} (HbA_{1c}) in blood by automated immunoassay

PRODUCT CHARACTERISTICS

The lyophilized hemoglobin A_{1c} calibrators are a hemolysate prepared from packed human erythrocytes. Stabilizers are added to maintain hemoglobin in the reduced state for the accurate calibration of the hemoglobin A_{1c} procedure.

PREPARATION

Reconstitute vials with 1.0mL sample solution. Gently mix for 30 minutes, Observe for undissolved material.

The calibrators should be treated in the same manner as patient specimens regarding 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.

CALIBRATION

The setpoint value of the calibrators was obtained by calibrating with materials referenced to NGSP values using the Audit Diagnostics HbA_{1c} Reagent Set.

MATERIAL REQUIRED AND NOT PROVIDED

Hemoglobin A_{1c} Reagent kit, from Audit Diagnostics

Hemoglobin A_{1c} Control kit, from Audit Diagnostics

STORAGE AND STABILITY

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

PROTECT FROM LIGHT AND HEAT.

2. The reconstituted calibrators should be stored refrigerated (2 - 8°C) and sealed tightly.

The calibrator retains its assigned value for at least 7 days at 2 - 8°C.

PROCEDURE

To be used in enzymatic assays.

Lot No: 911

Test	A1c (μmol/L)	Hb (μmol/L)
HbA _{1c} Calibrator 1	4.50	107.49
HbA _{1c} Calibrator 2	16.63	146.44

