



HbA_{1c} CONTROL

Quantitative determination of HbA_{1c}

IVD
Store at 2 – 8 °C

PRODUCT CHARACTERISTICS

The control is lyophilized, prepared from packed human erythrocytes. Stabilizers have been added to maintain hemoglobin in the reduced state. The control is made up of 2 levels of HbA_{1c}, one level in the normal range and the other in the elevated range.

REAGENTS

HbA _{1c} Control Normal	Human packed erythrocytes with normal/abnormal HbA _{1c} values
HbA _{1c} Control Abnormal	

PRECAUTIONS

Components from human origin have been tested and found negative for the presence for HbsAg and HIV (1/2). However no known test can offer assurance that products derived from human blood will not transmit disease, therefore handle cautiously as potentially infectious.

PREPARATION

1. Open the vial very carefully, avoiding any loss of the lyophilized material.
2. Add exactly 0.5 mL of deionized water (inaccurate reconstitution of the control and error in assay technique can cause erroneous results).
3. Close the vial carefully and gently mix for 10 minutes or until all the material has dissolved avoiding foam formation. Do not shake or vortex!
4. The reconstituted controls must be assayed in the same manner as blood specimens. Refer to the HbA_{1c} insert under "preparation" for the hemolysis procedure.

STORAGE AND STABILITY

This control is stable until the expiration date on the label when stored tightly closed at 2-8 °C. After the reconstitution the control is stable 30 days at 2-8°C or 3 months at –20°C.

PROCEDURE

To be used in turidimetric assays.

COMPONENT	VALUE	RANGE	UNITS
HbA _{1c} Level 1			%
HbA _{1c} Level 2			%

Ref: ACC16-050 Cont: 4x0.5 mL
Lot:
Expiry date:



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