K-*ASSAY*®

Hemoglobin A1c Control

Lot 213601A, Exp. 2025-04-30

Cat. No. K29C-4M

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. FOR *IN VITRO* DIAGNOSTIC USE ONLY.

INTRODUCTION AND SUMMARY

Throughout the circulatory life of the red cell, Hemoglobin A1c is formed continuously by the adduction of glucose to the N-terminal of the hemoglobin beta chain. This process, which is non-enzymatic, reflects the average exposure of hemoglobin to glucose over an extended period. In a classical study, Trivelli et al. showed Hemoglobin A1c in diabetic subjects to be elevated 2-3 fold over the levels found in normal individuals. Several investigators have recommended that Hemoglobin A1c serve as an indicator of metabolic control of the diabetic, since Hemoglobin A1c levels approach normal values for diabetics in metabolic control.

Hemoglobin A1c has been defined operationally as the “fast fraction” hemoglobins (HbA1a, A1b, A1c) that elute first during column chromatography with cation-exchange resins. The non-glycosylated hemoglobin, which consists of the bulk of the hemoglobin has been designated HbAo. The procedure utilizes an antigen and antibody reaction to directly determine the concentration of the HbA1c.

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.

Controls should be included each time patients are assayed for HbA1c to verify that the assay has worked correctly. The mean values of the controls were obtained by assaying representative samples of the entire lot.

CONTROL PREPARATION

Reconstitute vials with 0.5 mL deionized water. Gently mix for 10 minutes. Observe for undissolved material. The reconstituted controls may be dispensed in 0.1 mL aliquots, sealed tightly and frozen at -20°C.

STORAGE AND HANDLING

1. Store controls 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.

WARNINGS AND PRECAUTIONS

1. This product is for *in vitro* diagnostic use only. ℞ 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 HbA1c controls should be assayed in the same manner as blood specimens including the hemolysate procedure. Follow the directions that accompany the instrument, reagent kit used in the assay, and the instrument application instructions for the reagent set.

Materials Supplied

K29C-4M

Normal level control	Level 1, 2 x 0.5 mL
Elevated level control	Level 2, 2 x 0.5 mL

Materials Required But Not Supplied

1. Hemoglobin A1c Reagent.
2. Pipette capable of accurately delivering 0.5 mL.
3. Deionized water

LIMITATIONS

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

EXPECTED VALUES

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 expected range. If they do not, the assay should be repeated, checking closely for the factors mentioned in "LIMITATIONS".

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CONTROL LEVEL	% NGSP Units (RECOMMENDED)		mmol / mol Hb IFCC Units	
	MEAN	RANGE	MEAN	RANGE
Level 1	5.5 %	4.5 - 6.5 %	37	30 - 44
Level 2	11.6 %	10.1 - 13.1 %	103	90 - 116

LABELING SYMBOLS

REF	Catalog Number
	Expiration or "Use By" Date
LOT	Lot Number
CONTROL	Control
	Consult Package Insert for Instructions for Use
IVD	For *In Vitro* Diagnostic Use
CE	CE Mark Registered
℞	For Prescription Use Only
	Potential Human Biohazard
2°C 8°C	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
EC REP	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE

CE

EC REP

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