K-*ASSAY*®

Hemoglobin A1c Calibrator

Lot 123456, Exp. 2026-08-31

Cat. No. KAI-098C

INTENDED USE

This product is for the purpose of calibrating results in the quantitative determination of human hemoglobin A1c (HbA1c) in blood by automated immunoassay. FOR *IN VITRO* DIAGNOSTIC USE.

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*[1] 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.[2,3,4]

Hemoglobin A1c has been defined operationally as the "fast fraction" hemoglobins (HbA_{1a}, A_{1b}, A_{1c}) 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 HbA_0. The **K-*ASSAY*®** procedure utilizes an antigen and antibody reaction to directly determine the concentration of the HbA1c.

The setpoint values of the calibrators were obtained by assaying representative samples of the entire lot against IFCC and NGSP traceable reference materials using the **K-*ASSAY*®** Hemoglobin A1c Reagent.

KIT COMPOSITION

The lyophilized hemoglobin A1c 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 A1c procedure.

WARNINGS AND PRECAUTIONS

1. This calibrator set 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.

CALIBRATOR PREPARATION

Reconstitute each calibrator vial using 0.5 mL of deionized water. Gently mix for 10 minutes, or until all material has dissolved.

STORAGE AND STABILITY

1. Store at 2-8°C. Stable until expiration date if sealed tightly. PROTECT FROM LIGHT AND HEAT.
2. The reconstituted calibrator should be stored refrigerated (2-8°C) and sealed tightly. The calibrator retains its assigned value for at least 30 days at 2-8°C.

PROCEDURE

Materials Supplied

Hemoglobin A1c calibrator with four levels of hemoglobin A1c.

Materials Required But Not Supplied

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

Assay Procedure

The lyophilized hemoglobin A1c calibrator will produce a calibration curve that will be stable for at least 7 days on most analyzers. The calibrators should be treated in the same manner as patient specimens regarding the hemolysate procedure. Follow the directions that accompany the instrument and reagent kit used in the assay for specific instrument calibration procedures.

LIMITATIONS

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

REFERENCES

1. Trivelli, L.A., Ranney, H.M., and Lai, H.T., New Eng. J. Med. 284,353 (1971).
2. Gonen, B., and Rubenstein, A.H., Diabetologia 15, 1 (1978).
3. Gabbay, K.H., Hasty, K., Breslow, J.L., Ellison, R.C., Bunn, H.F., and Gallop, P.M., J. Clin. Endocrinol. Metab. 44, 859 (1977).
4. Bates, H.M., Lab. Mang., Vol 16 (Jan. 1978).

SETPOINT VALUES

The setpoint value of the calibrator was obtained by assaying representative samples of the entire lot against materials referenced to NGSP values using the ***K-ASSAY®*** Hemoglobin A1c Reagent. See setpoint values listed below.

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Instrument	% NGSP Units (RECOMMENDED)				mmol / mol Hb IFCC Units			
	Calibrator 1	Calibrator 2	Calibrator 3	Calibrator 4	Calibrator 1	Calibrator 2	Calibrator 3	Calibrator 4
Tosoh G8 (HPLC)	5.3 %	7.7 %	11.1 %	15.1 %	34	61	96	142
Beckman AU	5.3 %	8.5 %	12.5 %	15.5 %	34	69	113	146
Biolis 24i	5.0 %	7.7 %	11.8 %	15.5 %	31	61	105	146
Cobas Mira	5.1 %	8.1 %	11.8 %	15.0 %	32	65	105	140
Envoy	5.4 %	8.0 %	12.2 %	15.1 %	36	64	110	142
Hitachi 717	5.3 %	8.0 %	12.0 %	15.3 %	34	64	108	144
Mindray BS-200	5.6 %	8.7 %	12.2 %	15.5 %	38	72	110	146
Mindray BS-480	4.5 %	7.3 %	10.9 %	15.1 %	26	56	96	142
Mindray BA-800	5.0 %	7.9 %	11.8 %	15.3 %	31	63	105	144

LABELING SYMBOLS

REF	Catalog Number
	Expiration or “Use By” Date
LOT	Lot Number
	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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