

Intended Use

This product is for the purpose of calibrating results in the quantitative determination of human hemoglobin A1c (HbA_{1c}) in blood by automated immunoassay. For *in vitro* diagnostic use only. **Rx Only**

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 al¹ 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 HbA₀. The Pointe Scientific procedure utilizes an antigen and antibody reaction to directly determine the concentration of the HbA1c. The setpoint value of the calibrators were obtained by assaying representative samples of the entire lot against IFCC and NGSP traceable reference materials using the Pointe Scientific Hemoglobin A1c Reagent Set.

Reagents

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.

Reagent Preparation

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

Reagent 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 set 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.

Precautions

1. This calibrator set is for *in vitro* diagnostic use only.
2. Although this product has been tested and found non-reactive for Hepatitis B Surface Antigen (HBsAG), HIV-1, HIV-2 and HCV, 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.

Materials Provided

Hemoglobin A1c calibrator set with four levels of hemoglobin A1c.

Materials Required But Not Provided

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

Procedure

The lyophilized hemoglobin A1c calibrator set 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.

Setpoint Values

The setpoint value of the calibrators were obtained by assaying representative samples of the entire lot against materials referenced to NGSP values using the Pointe Scientific Hemoglobin A1c Reagent Set. See setpoint values listed below.

For Pointe Scientific's Direct Hemoglobin A1c reagent, the following calibrator values should be used:

LOT 111001

2024-02-29

Setpoints in NGSP Units (%)

Instrument	Calibrator 1	Calibrator 2	Calibrator 3	Calibrator 4
Beckman AU	5.2	9.2	13.0	15.6
Biolis 24i	5.0	8.4	11.8	15.4
Cobas Mira	5.1	8.5	11.5	15.3
Hitachi 717	5.4	8.2	12.0	15.3
Mindray BS-200	5.4	9.3	12.3	15.6
Mindray BS-480	5.2	8.3	11.3	15.3
Mindray BA-800	4.8	8.4	12.0	15.3

Setpoints in IFCC Units (mmol / mol Hb)

Instrument	Calibrator 1	Calibrator 2	Calibrator 3	Calibrator 4
Beckman AU	33	77	119	147
Biolis 24i	31	68	105	145
Cobas Mira	32	69	102	144
Hitachi 717	36	66	108	144
Mindray BS-200	36	78	111	147
Mindray BS-480	33	67	100	144
Mindray BA-800	29	68	108	144

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).

Manufactured by MedTest Dx: Pointe Brand
5449 Research Drive, Canton, MI 48188



European Authorized Representative:
Obelis s.a.
Boulevard Général Wahis 53
1030 Brussels, BELGIUM
Tel: (32)2.732.59.54 Fax:(32)2.732.60.03 email: mail@obelis.net

REF H7541-CAL

Manufactured by MedTest Dx: Pointe Brand
5449 Research Drive Canton, MI 48188



Symbol Key

Use by (YYYY-MM-DD)

LOT Lot and batch code

REF Catalog number

Manufacturer

IVD *In vitro* diagnostic medical device

Temperature limitation

Consult instructions for use

Rx Only: Prescription Use Only

CE mark

Authorized representative in the European Community

Certified Performance Guarantee

MedTest Dx certifies that all of our products are manufactured according to specified parameters. Any product not meeting specifications through their listed expiration date will be remedied immediately without charge.

Rev: 05/21

P803-H7541-02