

HbA1C TEST REAGENT (Turbilatex method)

FOR IN-VITRO DIAGNOSTICS USE ONLY

INTRODUCTION

Glycated Hemoglobin A1c (HbA1c) is intended for Invitro quantitative determination of HbA1c in human whole blood. HemoglobinA1c is a subtype of hemoglobin A that is formed by an enzymatic process that adducts glucose to the N-terminal of the hemoglobin beta chain. This process reflects the average hemoglobin exposure to glucose over an extended period and provides clinical significance in monitoring the blood glucose level. Studies have shown HbA1c in diabetic patient stobe 2-3 times the levels found in normal individuals. HbA1c can be used as an indicator of metabolic control of the diabetic.

Method principle

The kit utilizes latex-enhanced immune turbidimetry to measure the HbA1c level in human whole blood. The Kit utilizes the antibody-antigen reaction to directly measure the HbA1c level in whole blood. The first reaction, occurring after the sample is mixed with R1, consists of unspecified binding of total hemoglobin and HbA1c to the latex particles at the same rate. The second reaction occurs after the addition of R2 that contains mouse anti-human monoclonal antibody and goat anti-mouse IgG polyclonal antibody. Agglutination complexes will be formed from the interaction of the HbA1c bound to the latex particles with the respective antibodies. The agglutination can be measured as an absorbance which is proportional to the amount of HbA1c bound to the latex, and because the total hemoglobin and HbA1c bind to the latex at the same rate, the % HbA1c in total hemoglobin can be obtained from a calibration curve.

Kit contents

R1 – HbA1c Latex	1 x 30 ml
R2– HbA1c Buffer	1 x 10 ml
R3 – Lysing Reagent	1 x 50 ml
HbA1c Calibrator Set	4 vials

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 10 days on board the analyser at 2-8°C. Protect from light and avoid contamination.

The calibrators are lyophilized form contains 4 levels, the concentration and reconstitution instructions to be followed as per the volume mentioned on the calibrator vial labels.



HEME DIAMED LLP

Maharashtra 401208
MFG LIC NO: MFG/IVD/2025/00073



HEME DIAMED LLP

2nd Floor, 4, 1981, Anjikath Lane, near
Vallathol Junction Vazhakala, Thrikkakara,
Edappally, Ernakulam, Kakkanaad, Kerala 682021
MOB: +91 7395966499

General Information—

Method :Turbilatex, Increasing Reaction, End Point Shelf Life : 24 Months

Storage : 2-8°C Wavelength :630nm. Temperature: 37°C

Sample : Serum, Plasma (Heparin or EDTA)

Working reagent preparation and stability

Assay can be performed with use of separate R1-HbA1c and R2- HbA1c reagents or with use of working reagent. For working reagent preparation mix gently 3 parts of R1-HbA1c with 1 part of R2-HbA1c. Avoid foaming.

Concentrations in the test

R1-Latex0.1%; Glycine buffer,pH3.0,	15mmol/L
R2- goatanti-mouse IgG polyclonal antibody	0.8mg/dL Mouse anti-human HbA1c monoclonal antibody
Glycine buffer, pH3.0	0.05mg/ml
R3-H2O2, stabilizers	60mmol/L

Warnings and precautions

- 1 The Kit is for in vitro diagnostic use only. Not for use in humans or animals.
- 2 The instructions must be followed to obtain accurate results.
- 3 Do not use the reagents beyond the expiration date.
- 4 Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

Specimen

The Test can be performed with human blood without special preparation of the patient. Follow standard laboratory procedures to collect specimens with EDTA.

Procedure

These reagents may be used both for manual assay (sample start and reagent start method) and in several automatic analyzers. Applications for the mare available on request.

HEMOSYLATE-Step One: (Only for Blood Sample)

1. Mix 500µl of Hemolysis Reagent with 10µl of well mixed whole blood for Test (T)
 2. Wait for 5 minutes or until completely before using the sample.
 3. If immediate testing is not possible, hemolysates may best upto 10 days at 2-8°C.
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Reagent	Calibrator (C)	Test (T)
R1 HbA1c Latex	750µl	750µl
Lysate Sample from Step 1	-	20µl
Direct Calibrator (No need lysate)	20µl	-
Mix well and incubate for 5 min at 37°C. Then add		
R2 HbA1c Buffer	250µl	250µl

Mix well and incubate for 5 min at 37°C. Measure the absorbance of calibrator & sample against reagent blank.

Calculation

HbA1c concentration = $\Delta A(T)/\Delta A(C) \times$ calibrator concentration

Reference values

HbA1c in whole blood <6% Non-diabetic
 6to7% Glycemic Control
 7 to8% Fair Control
 >8% Poor Control

It is recommended for each laboratory to establish its own reference ranges for local population.

Quality control

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls

Performance characteristics

- Linearity: 2-18%
- Precision: within Run CV <5%

Specificity / Interferences

No interference detected for Bilirubin upto 0.5 g/L
 Ascorbic acid 0.5g/L
 Triglycerides 20g/L and acetylated Hb 5.0mmol/L

Waste management

Please refer to local legal requirements.

System parameters

Method	End Point
Wavelength	630nm
Zero Setting	Reagent Blank
Temperature Setting	37°C
Incubation Temperature	37°C
Delay Time	5 sec
Incubation Time	5 mins + 5 mins
No. of reading	2
Sample Volume	0.02ml(20µl)
Reagent Volume	1.0ml(1000µl)
Standard Concentration	Refer Calibrator Vial
Units	%
Reaction Slope	Increasing
Linearity	18%