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ACCUCARE
HbA1c
Turbidimetric Method

Quantitative determination of Glycohemoglobin in human whole blood by Latex Turbidimetric method

For In vitro Diagnostic Use Only

CLINICAL SIGNIFICANCE

Glycosylated Hemoglobin (GHb) is formed continuously by the adduction of glucose by co-valent bonding to the amino-terminal valine of the hemoglobin beta chain progressively & irreversibly over a period of time & is stable till the life of the RBC. This process is slow, non enzymatic and is dependent on the average blood glucose concentration over a period of time. HbA1c is a glycated product of hemoglobin A0 (HbA1c), the predominant form of hemoglobin in adults. Measurement of the percentage of HbA1c reflects the mean blood glucose concentration over the preceding one to two months, and is therefore considered to be an important diagnostic marker for monitoring blood glucose levels.

PRINCIPLE

HbA1c-Turbilatex is a quantitative turbidimetric test for the measurement of Glycohemoglobin A1c percent in human whole blood. In first reaction HbA1c interacts with antihuman hemoglobin A1c mouse monoclonal antibody-sensitized latex and in the second reaction, it wil further interact with anti-human hemoglobin A1c mouse monoclonal antibody labeled-anti-mouse. IgG goat polyclonal antibody. Then, measure absorbance of coagulated reaction solution and determine the ratio of Hba1c volume against total Hb amount from concentration of HbA1c and values of calibrator

STORAGE AND STABILITY

Reagents are ready to use and to be stored at 2-8 °C and are stable till the expiry mentioned on the labels. Do not freeze the reagents.

SAMPLE COLLECTION

Whole blood samples (EDTA, NaF-EDTA, heparin) can be used. Glyco HbA1c in samples is stable for 3 days when stored at 2 to 8 °C.

KIT CONTENTS

Reagent 1 : Anti human Hemoglobin A1c Mouse Monoclonal antibody-Sensitized latex

Reagent 2 : Anti human Hemoglobin A1c Mouse Monoclonal antibody-labeled anti mouse IgG goat polyclonal antibody

Calibrator : Lyophilized vial reconstitute with DM water

REAGENT PREPARATION

All reagents are ready to use. Allow reagents to attain room temperature before performing the test. Do not freeze; frozen Latex or Diluent could change the functionality of the test.

SYSTEM PARAMETERS

AUTOMATED PARAMETERS	
Wavelength	630 nm
Measurement	Against DI Water
Reaction Temperature	37°C
Reaction Type	Fixed time
Reaction Direction	Increasing
Reagent Volume	300 µL (R1) + 100 µL (R2)
Sample Volume	10 µL
Incubation	300 Sec.
Delay Time	10 Sec.
Read Time	300 Sec.
Calibrator	As mentioned on vial
Linearity	3-16 %

PROCEDURE

A. LYSING OF WHOLE BLOOD

Dispense 1.0 mL of DI Water in a microcentrifuge tube, add 20 µL of whole blood, mix and wait for 10-15 mins.

B. Pipette into clean dry test tubes labeled Calibrator (C) or Test (T):

C. Use distilled water for C0 Calibrator

	REAGENT BLANK	CALIBRATOR	SAMPLE
REAGENT I	300 µl	300 µl	300 µl
Cali.(C0,C1,C2, C3,C4)	-	10 µl	-
SAMPLE	-	-	10 µl
Mix well and incubate for 5 mins at 37℃ & Immediately Add			
REAGENT II	100 µl	100 µl	100 µl
Mix well, and read the absorbance immediately A1 and after 5 minutes A2 of the sample addition.			

Read the absorbance of calibrator and Test at 630 nm against DI water blank

LINEARITY

Assay is linear between Glycohemoglobin HbA1c concentration of 3-16%, under the described assay conditions.

CLINICAL VALUES

4 - 5.9% non diabetics,
6 - 7% controlled diabetics
Over 7% uncontrolled diabetics

It is recommended that each laboratory establish its own references range to reflect the age, sex, diet and geographical location of the population

REFERENCES

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