

Ana-Chek® HbA1c - TURBILATEX

METHOD – IMMUNOTURBIDIMETRY

PRODUCT CODE – LH03



INSTRUCTIONS FOR USE

INTENDED USE: Test for Quantitative determination of Glycohemoglobin in human whole blood by Turbidimetric method.

SUMMARY

Glycosylated Haemoglobin (GHb) is formed continuously by the addition of glucose by covalent bonding to the amino-terminal valine of the haemoglobin 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 haemoglobin A0 (HbA1c), the predominant form of haemoglobin 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

Ana-Chek® HbA1c-Turbilalex is a quantitative turbidimetric test for the measurement of Glycohemoglobin A1c percent in human whole blood. In first reaction HbA1c interacts with antihuman haemoglobin A1c mouse monoclonal antibody-sensitized latex and in the second reaction, it will further interact with anti-human haemoglobin A1c mouse monoclonal antibody labelled-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

KIT COMPONENTS

Diluent (R1)	1 x 15 ml.
Latex Reagent (R2)	1 x 5 ml.
Hemolysing reagent (R3)	1 x 50 ml.

STORAGE & 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.

TEST PARAMETERS

Name	HbA1c	Reagent Volume - R1	300 µl
Reaction Type	Fixed Time Kinetic (↑)	Reagent Volume – R2	100 µl
Wavelength Primary	630 nm	Sample Volume	10 µl
Flow Cell Temp.	37 °C	Incubation Temperature	37 °C
Blank setting	D.W.	Delay Time	10 sec
Blank Abs Limit	< 0.300	Read Time	300 sec
Linearity	16 %		

SPECIMEN COLLECTION & PRESERVATION

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

ASSAY PROCEDURE

1. LYSING OF WHOLE BLOOD - Dispense 1.0 mL of Hemolysing reagent (R3) in a microcentrifuge tube, add 20 µL of whole blood, mix and wait for 10-15 mins.

2. Pipette into clean dry test tubes labelled Test (T).

	Reagent Blank	Calibrator	Test
Reagent 1	300 µl	300 µl	300 µl
Calibrator	-	10 µl	-
Sample	-	-	10 µl
1st Incubation: Mix the reagent and sample/calibrator in the above-mentioned ratio and incubate for 5 mins at 37 °C.			
Reagent 2	100 µl	100 µl	100 µl
2nd Incubation: Add Reagent 2 & aspirate the reaction mixture in the flow cell and measure abs.			

CALCULATION

Plot the calibration curve using ΔOD of multi levels of calibrators against their respective concentration. Locate the sample ΔOD from this graph to find out concentration of HbA1c.

REFERENCE VALUES FOR NORMAL PEOPLE

Non-diabetic individuals	: 4 - 5.9 %
Controlled diabetic individuals	: 6 - 7 %
Uncontrolled diabetic individuals	: Over 7 %

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

REFERENCES

1. Trivell, L.A., Ranney, H.M. and Lai, H.T., (1971) New Eng. J. Med. 284, 353.
2. Nathan, D.M. et al, Clin. Chem. (1983), 29, 466-469.
3. Goldstein, D.E., et al, Clin. Chem. (1986) 32, B64-B70.
4. American Diabetes Association: Clinical Practice
5. Recommendations. Diabetes Care 30 (Suppl. 1): S4-S41 (2007)

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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