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ACCUTURB-100
HbA1c II
Latex-enhanced Turbidimetric Assay

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

For In vitro Diagnostic Use Only

REF	Cont.
HBA 25T	1 x 10 ml
HBA 50T	1 x 20 ml

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 will 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.

KIT CONTENTS

Reagent	25 tests kit	50 tests kit	Major ingredients
Reagent R1	1× 7.5ml	1× 15 ml	antihuman hemoglobin A1c mouse monoclonal antibody-sensitized latex
Reagent R2	1× 2.5ml	1× 5 ml	mouse anti-human HbA1c monoclonal antibody and goat anti-mouse IgG polyclonal antibody in a buffer containing Phosphate
Haemolysing Reagent	1 x 25ml	1 x 50ml	/
Cuvette & Bead	25 no's each	50 no's each	/
Specification	1 copy	1 copy	/
Magnetic card	1 piece	1 piece	/

STORAGE AND STABILITY

Reagents are ready to use and to be stored at 2 - 8^0 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 8^0 C.

SAMPLE PREPARATION

To determine the level of HbA1c, a haemolysate must be prepared for each sample:

1. Dispense 500µl of Hemolysing solution in to a tube
2. Add 10µl of well mixed whole blood sample.
3. Mix thoroughly by gentle vortexing for 30 seconds.
4. Stand for 20 minutes at room temperature until complete lysis
5. Take 10 µl of above lysate for testing.

ASSAY PROCEDURE

1.THE REAGENT DOSE DISPENSING IN THE CUVETTE

Reagent	Dose
Reaction Buffer (R1 Reagent)	300µl
Sample Heamolysate	10 µl
Mix well and incubate the cuvette 4 minutes in incubator slot provided in Accuturb-100 (A,B,C,D)	
HbA1c antibody latex combo (R2 Reagent)	100µl

2.OPERATING STEP

(1). When starting it shows "Read card", Put the corresponding lot magnetic card in the reader slot, reading the card correctly, the screening displays the reagent name and lot number, the instrument status indication light is working (yellow-green). Please check carefully.
(2). Go to test menu and change the Sample type into 'Other'.
(3). After confirm the lot number, dispense 300 µl reaction buffer (R1) to a colorimetric cuvette and 10µl sample lysate and mixing sticker. Do not produce bubbles when dispensing the sample and 4 minutes incubate the tube in incubation slot in Accuturb-100.
(4). Put the colorimetric cuvette in the detection well, gently press the cuvette until it contacts the bottom. The status indication light will be off when the analyzer detects the colorimetric cuvette successfully
(5). When the analyzer shows "Add [R2]", dispense 100µl HbA1c antibody latex combo (R2) in the cuvette. The analyzer will mix automatically and start to detect, it shows: "Testing…" it shows the result automatically and record the value
(6). After detecting, move the cuvette. The status indication light will be working (yellow- green). Return to step (2) to detect next sample.
(7). If moving the cuvette out in the process of detecting, the screen shows "Give up testing".

LINEARITY

Assay is linear between Glycohemoglobin HbA1c concentration of 0 -16.8%, 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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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 Recommendations. Diabetes Care 30 (Suppl. 1): S4-S41 (2007)

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