GENESIS

Instructions For Use

HbA1c (Turbidimetric Method)

Cat no.	size
6105 101	50 TEST
6105 102	100 TEST
6105 103	200 TEST

INTENDED USE

Hemoglobin A1C reagent is intended for the in vitro Quantitative diagnostic determination of of HbA1c in a human blood.

PRINCIPLE OF THE METHOD

This reagent provides a quantitative assay for measuring concentrations of HbA1c in whole blood or red blood cell.
It is based on latex agglutination.
HbA1c test samples are absorbed onto the surface of latex particles, which react with Anti-HbA1c (antigen-antibody reaction). The turbidity caused by latex agglutination is measured at (620-670) nm, and the HbA1c concentration in whole blood or red blood cell is calculated from supplied table.

CLINICAL SIGNIFICANCE

Diabetes Mellitus is a chronic disease characterized by a hyperglycemia. The consequences are metabolism disorders of carbohydrates, lipids and proteins. The risk of complications associated with diabetes, including nephropathy, retinopathy and cardiovascular diseases, increases in patients with poor metabolic control. In the diabetic patients, where blood glucose levels are elevated, HbA1c is formed as a consequence of the non-enzymatic glycation of the N-terminus of the α-chain of hemoglobin molecule. The level of HbA1c is proportional to the level of glucose in the blood and has been widely accepted as an indicator of the mean daily blood glucose concentration over the preceding (6-8) weeks. It is therefore, a long-term indicator of diabetic control, whereas, the measurement of blood glucose is only a short-term indicator.

REAGENTS

Reagent (R1)	**Water and stabilizers**
Reagent (R2)	**Latex 0,13%, Buffer, stabilizer**
Reagent (R3)	**Mouse anti-human HbA1c monoclonal antibody 0,05mg/ml, goat anti-mouse IgG polyclonal antibody 0,08mg/dl, Buffer, stabilizers**
Cal.	**Calibrator**

PREPARATION

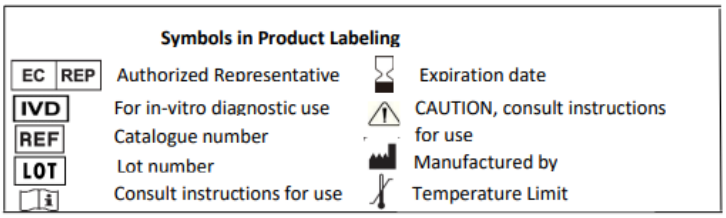
HBA1C Calibrator: Reconstitute (→) with 1.5 mL of distilled water. Mix gently and incubate at room temperature for about 30 minutes before testing.

RECONSTITUTED CALIBRATOR

Stable for 3 weeks at 2-8ºC

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use.
Do not use reagents after the expiration date.



REAGENT DETERIORATION

Presence of particles and turbidity
Do not interchange reagents between different lot numbers.
Do not freeze the reagent**.**

ADDITIONAL EQUIPMENT

Thermostatic water bath at 37ºC
Spectrophotometer or photometer able to read at (620-670) nm filter

SAMPLES

Collect blood samples with EDTA.
Blood samples should be stored at 2-8 and tested within 3 days. Do not freeze blood samples to avoid hemolysis.

PRECAUTIONS AND WARNINGS

1. The reagent is for in vitro diagnostic use only.
2. Reagents are liquid stable, ready-to-use reagents.
3. Mix by inverting at least 10 times before use.
4. Do not mix reagents of different lots.
5. DO NOT FREEZE.

PROCEDURE

1. Bring the reagents and the photometer (cuvette holder) to 37ºC.
2. Mix Well before use
3. Assay conditions:

Mode:…….FIXED TIME
Wavelength:…… 620 nm
Temperature:…….. 37ºC
Cuvette light path:……. ..1 cm
Delay time:…….. 5 sec
Measuring time:……. 300 sec

4. Adjust the instrument to zero with distilled water.

Step (1)

- Preparation of test sample/calibrator (Lysate)

(R1) Dilution buffer	**1.0 ml**
Sample/Calibrator	**10 µL**
Mix and incubate 5-10 minutes (Exactly) at room temperature. Increase incubation time if the mixture not clear,	

Step (2)

Pipette into a cuvette:

(R2) latex reagent	**225 µL**
Lysate (Sample/Calibrator)	**15 µL**
Mix well and incubate 5.0 minutes at 37ºC	
(R3) antibody reagent (µL)	**75 µL**

Mix and read the absorbance immediately (A1) and after 5 minutes (A2) of antibody reagent addition.

CALCULATIONS

$\frac{(A2 - A1)\ sample}{(A2 - A1)\ calibrator}$ × Calibrator concentration = (X) value.

HbA1c concentration value obtained using the supplied table

REFERENCE VALUES

Non-Diabetic	4.0 %—5.8 %	**(NGSP / DCCT)**
Pre-Diabetic	5.9 – 6.4 %	
Diabetic	>=6.5 %	
Controlled Diabetic	<7.0 %	

Each laboratory should establish its own reference range to reflect the age, sex, diet and geographical location of the population.

QUALITY CONTROL

It is recommended to use the Control level I and II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control

METROLOGICAL CHARACTERISTICS

Measuring range: From detection limit of 3% to linearity limit of 16%

Detection limit: 3%

Linearity limit: 16.0 %

Repeatability (within run):

	Level 1	Level 2
n	20	20
Mean (%)	5.5	10.0
SD	0.12	0.15
CV%	2.18	1.5

Reproducibility (run to run):

	Level 1	Level 2
n	20	20
Mean (%)	5.5	10.0
SD	0.22	0.3
CV%	4.0	3.0

INTERFERENCES

No interference below concentration.

1. Free type bilirubin; 40mg/dl
2. Conjugated type bilirubin; 40mg/dl
3. High lipid; 3000 formazin turbidity units
4. Ascorbic acid; 50mg/dl

BIBLIOGRAPHY

Knovich MA et al., Blood Rev. 200923(3):95-104.
Mazza J et al. Can Med Assoc J 1978; 119:884-886
RodriguezPerezJetal.RevistaClinicaEspañola1980:156(1):39-43

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