ImmunoScience INDIA

ImmunoTurbi

HbA1c

QUANTITATIVE TURBIDIMETRIC TEST FOR DETERMINATION OF HbA1c

For *In-Vitro* Diagnostic Use Only **Store at 2°C to 8°C**

OVERVIEW

High A1C levels are a sign of high blood glucose from diabetes. Diabetes can cause serious health problems, including heart disease, kidney disease, and nerve damage. But with treatment and lifestyle changes, you can control your blood glucose levels. What is the difference between HbA1c and glucose test? A glucose test estimates the amount of glucose currently in the blood i.e., Blood sugar levels may vary throughout the day. At the same time, the HbA1c test measures the amount of blood sugar (glucose) attached to the hemoglobin.

INTENDED USE

Quantitative turbidimetric test for determination of HbA1c in human whole blood. This test is for in vitro diagnostic use only.

PRINCIPLE

The HbA1c Assay is based on antigen antibody rection. The Blood sample lysate is made in hemolysis reagent then, the lysate is added in latex solution. The total HbA1c is attached to latex particles. It further reacts with anti-human HbA1c added in reaction to form a complex which results in agglutination. The amount of agglutination is directly proportional to concentration of HbA1c in the sample. This amount can be calibrated and measured photometrically.

CONTENTS OF KIT

1. Anti-human HbA1c solution (R1)
2. Latex Reagent (R2)
3. Pack inserts

OPTIONAL MATERIAL REQUIRED

1. Semi-automatic or Fully Automated Biochemistry Analyzer
2. PPEs (Disposable Gloves, Mask, Safety Goggles, Apron)
3. Biohazard Dust Bin.
4. Test Tubes
5. Micropipettes

PRECAUTIONS /KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test.
2. Do not use after the expiration date.
3. Store in between temperature 2°C to 8°C.
4. Do not use if damaged or leaked.
5. Do not open until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the tested reagent.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose the leftover and used reagents and samples hygienically in biohazard waste.
5. Treat samples and reagent reaction volume as potentially infectious. Avoid contact with skin.
6. For in vitro diagnostic use. Not to be taken internally.
7. Do not mix the specimen sample or interchange the different specimen.
8. Do not use the reagents of other lots in combination with the kit.
9. Discard the remaining reagent in the kit.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether director cons sequential rising out for related to an incorrect diagnosis.

SPECIMEN COLLECTION

1. Fresh serum or plasma shall be used.
2. Serum shall be separated from freshly collected blood in plain tube or clot activator tube.
3. Freshly collected EDTA blood can be used to separate plasma for testing.
4. The samples stored at 2-8ºC for 2 to 3 days can also be used.
5. Do not use highly haemolized or lipemic samples.

REAGENT PREPARATION

All reagents are ready to use.

TEST PROCEDURE

	CAL	SAMPLE
Reagent 1 (R1)	400 µl	400 µl
Sample	-	20 µl
Standard	20 µl	-
Incubate at room temperature for 5 minutes		
Reagent	100 µl	100 µl

1. Bring the kit component to room temperature before testing.
2. Take 400 µl of Reagent 1 (R1) in cuvette and add 20 µl of whole blood sample or control or calibrator to be tested.
3. Mix well and incubate the reaction for 5 minutes at room temperature.
4. Add 100 µl latex reagent (R2) in it and mix.
5. Immediately read the absorbance of the reaction & read the absorbance of the reaction.
6. Calculate concentration and interpret the results as per formula.

Wavelength	650 (600-650) nm
Cuvette	1 cm light path
Reaction Temperature	37 °c
Measurement	Against Distilled water
Reaction	End point
Reaction Direction	Increasing
Sample / Reagent Ratio	1: 25
Linearity	15 %

INTERPRETATION OF RESULTS

1. Concentration = $\frac{\text{(A2-A1) Sample}}{\text{(A2-A1) Calibrator}}$ x Concentration of calibrator

Reference Values: -

Normal HbA1c: Less than 6.0 %
Slightly higher HbA1c: 6 to 7 %
Very high HbA1c: more than 7 %

LINEARITY

The method is linear to a concentration of 15 %.

If the concentration exceeds this value, the sample should be diluted 1:3 with 0.9% saline solution and retested. The calculation shall be done with consideration od dilution factor 3.

LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, reference correlation should be considered.
3. Any modification to the above procedure and / or uses of other reagents will invalidate the test procedure.

QUALITY CONTROL

Positive and Negative controls are recommended to monitor the performance of test procedure, as well as a comparative pattern for a better results interpretation.

REFERENCE VALUE

Normal HbA1c: Less than 6.0 %
Slightly higher HbA1c: 6 to 7 %
Very high HbA1c: more than 7 %

Each laboratory should establish its own reference range.

DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

REFERENCES

1. M Fasani et al eur J Lab Med 1994; Vol 2 no 1-67.
2. Todd E W.J exp Med 1932;55:267-280

	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
	Lot Number
	Store at 2°C to 8°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

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