AGD

HbA1c

Code	Pack Size
AGDSP-HBA1C40	R1- 1 X 30mL, R2- 1 X 10mL, Calibrator: 5x0.5mL

INTENDED USE

The Hemoglobin A1c (HbA1c) test is a blood test intended for measuring an individual's average blood glucose (sugar) levels over the past 2 to 3 months.

CLINICAL SIGNIFICANCE

HbA1c (glycated hemoglobin) measures average blood glucose over the past 2-3 months, serving as a critical diagnostic and monitoring tool for diabetes. It indicates long-term glycemic control, helping predict and reduce the risk of microvascular complications like retinopathy and nephropathy, and guides personalized treatment adjustments without requiring fasting.

PRINCIPLE

Latex - enhanced Immuno-turbidimetry method utilizes the interaction of antigen and antibody to directly measure HbA1c level in the whole blood. The first reaction, occurring after the sample is mixed with R1, consists of un-specified binding of total hemoglobin and HbA1c to the latex particles at the same rate. The second reaction occurs after the addition of R2 that contains mouse anti-human monoclonal antibody. Agglutination is formed when goat anti mouse IgG polyclonal antibody react with monoclonal antibody.The agglutination can be measured as an absorbance which is proportional to the amount of HbA1c bound to the latex. The % HbA1c in total hemoglobin can be obtained from a calibration curve.

MAIN COMPONENTS

Name	Composition
R1	Latex
R2	Anti-HbA1c cross linked anti-human hemoglobin A1c mouse monoclonal antibody

STORAGE AND STABILITY

1. The test kit should be stored at a temperature between 2-8°C.
2. DO NOT FREEZE.
3. Lyophilized vials of HbA1c Calibrator stored at 2-8°C are stable until the expiration date on the label.
4. Once reconstituted, HbA1c Calibrator is stable at 2-8°C for a week.

WORKING REAGENT

R1 and R2 are supplied as ready to use liquids. Mix gently before use.
Kindly use Deionized water as lysate.

CALIBRATOR PREPARATION

1. Remove the seal and stopper from the vial.
2. Add 500µL of deionized water to the vial.
3. Allow the vials to stand for 30 minutes, then rotate gently until completely dissolved.

HEMOLYSATE PREPARATION

Deionized water	500µL
Sample	10µL

SPECIMEN REQUIREMENTS

The test can be performed with human blood without special preparation of the patient. Follow standard laboratory procedures to collect specimens with EDTA.

PARAMETERS

SHORT NAME	HBA1c
NAME	HEMOGLOBIN A1c
METHOD	TURBILATEX
ASSAY	END POINT (ONE POINT)
MAIN WAVE LENGTH	630nm
SUB WAVE LENGTH	0
DECIMAL	2
UNIT	%
R1 VOLUME	240µL
INCUBATION	120secs
R2 VOLUME	80µL
SAMPLE VOLUME	7.0µL (HEMOLYSATE)
INCUBATION	300secs
MIXING SPEED	1
REACTION TIME (Delay)	260secs
CHECK TIME (Read)	40secs
LINEAR RANGE	16 %
ABSORBANCE RANGE	0-2.5
DETECTION SLOPE	10
DILUTION RATIO	06
SAMPLE VOLUME	50
CALIBRATION	Spline (5 Points)
NO OF STANDARD	5

PROCEDURE

Reagent1 + Incubation + Reagent2 + Sample → Measurement
(240µL) (120sec) (80µL) (7.0µL) (300Sec) (630nm)

Measurement
Measure absorbance (turbidity) of each test sample and respective HbA1c calibrators

REFERENCE VALUES

• Less than 6% for a non-diabetic
• Less than 7 % for glycemic control of a person with diabetes.
Each laboratory should establish its own expected values. In using Hemoglobin A1c to monitor diabetic patients, results should be interpreted individually.

LIMITATIONS

For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.

WARNINGS AND PRECAUTIONS

1.For in vitro diagnostic use only.
2.Operation steps should not be omitted or simplified.
3.Do not use reagent kits beyond the expiration date.
4.Disposal of all waste materials should be in accordance with local guidelines.
5.For professional use only.

REFERENCE

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SYMBOLS

Sr. No.	Symbol	Instruction
1.	AGD	Trademark of AGD Biomedicals P Ltd
2.	Caution	Note : Misoperation may result in injury to the user or property loss.
3.	IVD	In vitro diagnostic medical device
4.		Manufacturer
5.		Date of Manufacture
6.	CE	CE Conformity
7.		Consult the instructions for use
8.	8°C 2°C	Limit of Temperature
9.	REF	Product reference number
10.	EU REP	Authorized representative in the European community
11.	LOT	Lot /Batch number
12.		Expiry

CE | IVD

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EU REP

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