

AGD HbA1c

Code	Pack Size
AGD-HBA1C20	AGD-HBA1C40
R1: 1 x 15mL R2: 1 x 5mL Calibrator : 5 x 0.5mL	R1: 1 x 30mL R2: 1 x 10mL Calibrator : 5 x 0.5mL



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

This test is based on latex immunoagglutination where HbA1c in the test sample is absorbed onto latex particles, and then Cross-linked anti-HbA1c is added to form an Antigen-Antibody reaction. Finally the percentage of HbA1c is obtained from the dose response 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

Reaction Type	Endpoint (Increasing)
Wavelength	630nm (630-800)
Light Path	1cm
Reaction Temperature	37°C
Zero Setting	With deionized water
Reagent Volume R1	375 µL
Reagent Volume R2	125 µL
Sample Volume	15 µL
Incubation Time	5 mins + 5 mins
Standard Concentration	Refer Calibrator Vial
Delay Time	4 sec
Read Time	1 sec
Unit	%
Calibration Type	Non-linear (spline)
No. of Calibrators	Calibrator 1 [**]
	Calibrator 2 [**]
	Calibrator 3 [**]
	Calibrator 4 [**]
	Calibrator 5 [**]
Linearity	16%

PROCEDURE

• Preparation of test samples

Take 500 µL of DI water and add 10 µL of test sample to prepare the hemolysate.

Mix and allow to stand for 5 minutes or until complete lysis is evident.

• Add 375 µL of R-1 Latex to 15 µL of the hemolysed test sample or each HbA1c calibrator, and after mixing the solution, incubate it for five minutes at 37°C.

• Then add 125 µL of R-2 solution and after mixing, incubate for five minutes at 37 °C.

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.		Trademark of AGD Biomedicals P Ltd
2.		Note : Misoperation may result in injury to the user or property loss.
3.		In vitro diagnostic medical device
4.		Manufacturer
5.		Date of Manufacture
6.		CE Conformity
7.		Consult the instructions for use
8.		Limit of Temperature
9.		Product reference number
10.		Authorized representative in the European community
11.		Lot /Batch number
12.		Expiry



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