AGD

# HbA1c

| Code | Pack Size |
|---|---|
| AGDSP-HBA1C20 | R1 - 1x15 mL ,<br>R2 - 1x5 mL ,<br>Calibrator: 5x0.5 mL |

## 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 | 240 µL |
| Incubation Time | 120 secs |
| Reagent Volume R2 | 80 µL |
| Sample Volume | 7 µL |
| Incubation time | 300 secs |
| Mixing Speed | 1 |
| Reaction Time (Delay) | 260 secs |
| Check Time (Read) | 40 secs |
| Unit | % |
| Calibration Type | Non-linear (spline) |
| No. of Calibrators | Calibrator 1 [**] |
| | Calibrator 2 [**] |
| | Calibrator 3 [**] |
| | Calibrator 4 [**] |
| | Calibrator 5 [**] |
| Linearity | 16% |

## PROCEDURE

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

Measurement
(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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ISO 13485:2016 ISO 9001:2015

EU REP


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