HbA1c

15 Tests, 30 Tests
12009025, 12009006

Intended Use
This reagent is intended for *in vitro* quantitative determination of HbA1c in human blood.

-Nephelometry methodology
-Direct measurement of % HbA1c.
-No total Hb determination required
-No calibration required
-Linear up to 13%
-Lower Detection Limit of 3%

Clinical Significance
HbA1c is a glycated form of hemoglobin formed by the attachment of glucose residues in the blood to the hemoglobin molecules. In the diabetic population where blood glucose levels are abnormally elevated, the level of HbA1c also increases. 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 blood glucose concentration in the preceding 6-8 weeks. It is therefore a long-term indicator of diabetic control. For routine use HbA1c levels should be monitored every 3-4 months.

Principle
The whole blood is lysed using haemolysing reagent. The lysed whole blood containing HbA1c along with other haemoglobins compete to adsorb to the unsensitised latex particles in the R1. A mouse antihuman HbA1c monoclonal antibody is added into the reaction that specifically binds to the human HbA1c molecules to form latex HbA1c- mouse antihuman HbA1c antibody complex. Another antibody, goat anti mouse polyclonal antibody that react with the formed complex to give agglutination. The amount of agglutination is proportional to the amount of HbA1c adsorbed on to the surface of latex particles.

Kit Components

Reagent/ Component	Product Code 12009025	Product Code 12009006	Description	
HbA1c R1	1 x 3.25 mL (15T)	1 x 6.2 mL (30T)	Latex Glycine buffer	0.13%(w/v) 20 mmol.L
HbA1c R2	1 x 1.5 mL (15T)	1 x 2.6 mL (30T)	Glycine buffer Mouse anti-human HbA1c Monoclonal antibody Goat anti-mouse IgG Polyclonal antibody	80 mmol/L 10 mmol/L 0.05 mg/dL
HbA1c R3	1 x 8 mL (15T)	1 x 16 mL (30T)	Haemolysis Reagent	

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request.

Reagent Preparation
HbA1c R1, R2 & R3 Reagents are ready to use

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2 - 8^{O}C. **DO NOT FREEZE**

Open Vial Stability
Once opened the reagents are stable for 45 days. .
The validity of the smart card will be up to 45 days from the date of insertion and activation of the card in Mispa *i2*.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe HbA1c control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
Bring the reagents to room temperature (RT) before use. **Allow the reagents to attain temperature between 25^{O}C -30^{O}C before performing the test.**

To avoid contamination, use provided cuvettes and pipette tips for dispensing the reagent & sample. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.
This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Whole blood, collected with EDTA
To determine HbA1c a heamolysate must be prepared for each sample
1. Dispense 0.5 mL hemolysis reagent into a tube.
2. Add 10 µL of well-mixed whole blood and mix.
3. Allow to stand for 2 minutes or until complete lysis is evident.

Note: Don't use Hemolysed sample

Interferences
No interference for

Ascorbic acid up to	50 mg/dL
Bilirubin up to	50 mg/dL
Triglycerides up to	2000 mg/dL
Carbamylated Hb up to	7.5 mmol/L
Acylated Hb up to	5 mmol/dL

It has been reported that results may be inconsistent in patients who have the following conditions: opiate addiction, lead poisoning, alcoholism, and ingestion of large doses of aspirin. Elevated HbF levels may lead to under estimation of HbA1c.

NOTE

For samples having low hemoglobin (<8g/dL), use blood cells for hemolysate preparation for better results.

Materials provided
HbA1c R1, R2 & R3 Reagents
Smart Card, Cuvettes & Pipette Tips

Test Procedure
The test procedure and the calibration data is provided in the smart card along with the kit. Insert the smart card and follow the instructions.

Step 1:
Insert card to card reader slot & display will prompt to add R1+Sample
Step 2:
Pipette 180 µL R1 & 5 µL sample to cuvette & place the cuvette into cuvette holder
Step 3:
After incubation display will prompt to add R2
Step 4:
Pipette 60 µL R2 using attached sensor pipette to the cuvette
Step 5:
The result will show in the display and print out

Calibration
The calibration data is incorporated in the smart card and hence no calibration is required.

Quality Control
It is recommended to use Agappe HbA1c Control (11625002) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range
It is recommended that each laboratory should establish its own reference values. The following value may be used as guide line.
Reference normal value (NGSP): 4.6% -6.2% HbA1c
ADA recommended reference range: 5.7 – 6.4 % HbA1c (High risk group)
Above 6.5% HbA1c (Diabetics)
eAG (estimated average glucose)
eAG = (28.7 x HbA1C) - 46.7

SYMBOLS USED ON THE LABELS

REF PRODUCT NUMBER/ CATALOGE NUMBER
CONTAINS 'N' TEST
IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

AGAPPE DIAGNOSTICS LTD.
Rev.4.200920
CE ISO 9001:2015
EN ISO 13485:2016

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance

1. Linearity

The reagent is linear up to 13%(NGSP).

Sample above the measuring range should not be diluted and retested. These samples should be tested with alternative methods.

2. Comparison

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.9672 and a regression equation of y = 1.0049x.

3. Precision

	Intra Run		Inter Run	
Control	**Level 1**	**Level 2**	**Level 1**	**Level 2**
n	20	20	20	20
Mean (%)	6.45	10.76	6.50	10.82
SD	0.13	0.14	0.03	0.21
CV(%)	1.99	1.31	0.46	1.91

Accuracy (%)		
Control	**Expected Value**	**Measured Value**
Control Level 1	5.33 ± 1.06	5.04
Control Level 2	9.79 ± 1.96	10.4
Agappe Control Level 1	6.4 ± 0.9	6.46
Agappe Control Level 2	10.8 ± 1.8	10.7

4. Sensitivity

Lower detection Limit is 3%

Bibliography

1. Nathan, D.M., Clin, Chem. 29, pp.466-469 (1983)
2. Engbeak, F., *et al*. Clin chem.35 pp. 93-97 (1989)
3. America Diabetes Association : Clinical practice recommendations (position statement). Diabetes care 24 (suppl.1) S33-S55, (2001).
4. Tietz, N.W. Textbook of Clinical Chemistry, W.B. Saunders Company, p.794 - 7795 (1999).

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