SyRe

TBA-120FR

AG A1c

AGAPPE

HbA1c DIRECT

1 x 71/1 x 26.5/4 x 63 mL
12011042

Intended Use
This reagent is intended for *in vitro* quantitative determination of % HbA1c in human blood.
- Latex enhanced Immunoturbidimetry.
- No need to measure total Hb.
- Direct result (% HbA1c) from analyzer

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. It is measured at 660 nm which is used to calculate the HbA1c % from a calibration curve.

Kit Components

Reagent/ Component	Product Code 12011042	Description
HbA1c Direct R1	1 x 71 mL	Latex
HbA1c Direct R2	1 x 26.5 mL	Anti-human HbA1c mousemonoclonal antibody Anti-mouseIgG goat antibody
HbA1c Direct R3	4 x 63 mL	Hemolysis 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 expiry date stated on the label, when stored at 2-8^{o}C.

Open Vial Stability
Once opened the reagents are stable up to 90 days if contamination is avoided.

On-board Calibration Stability
Calibration is stable for 20 days.

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
To avoid contamination, use clean laboratory wares. 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
EDTA-Whole Blood. Do not use haemolysed samples.

To determine HbA1c, a haemolysate must be prepared for each sample
Haemolysis
1. Dispense 0.5 mL of haemolysing reagent (R3) in to a tube
2. Add 10 µL of well mixed whole blood, control or calibrator
3. Mix the reactants
4. Allow to stand for 5 minutes at room temperature for complete lysis

***Follow the same procedure with controls and calibrator

Interferences
No interference for
Ascorbic acid up to : 50 mg/dL
Bilirubin up to : 40 mg/dL
Intra lipid up to : 3000 mg/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.

Materials provided
HbA1c R1, R2 & R3 Reagent

Reagents required but not provided
Agappe HbA1c Control (Product Code: 11625002)
Agappe HbA1c Direct Multicalibrator (Product Code: 11604001)

Calibration
Agappe HbA1c Direct Multicalibrator (Product Code: 11604001) is recommended for calibration of the assay.

Preparation of Calibration Curve
Prepare a calibration curve using 4 level calibrator provided in the kit.
HbA1c % in the sample is calculated by interpolation of Abs of sample on the calibration curve. For calculation of results according to IFCC, use IFCC calibrator values (see calibrator insert), or use following equation.
NGSP = (0.915 x IFCC) + 2.15.

Limitations
Low total hemoglobin samples (< 8 g/dL) may show low HbA1c results.

Quality Control
It is recommended to use HbA1c Control (Product Code: 11625002) to verify the performance of the assay.
Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

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

Performance
1. Linearity
This reagent is linear upto 13% HbA1c(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= 0.9884 and a regression equation of y = 1.0014x.

3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (%)	6.16	9.53	6.17	9.56
SD	0.07	0.10	0.07	0.11
CV(%)	1.10	1.03	1.06	1.10

Accuracy (%)		
Control	Expected Value	Measured Value
Control Level 1	5.33 (4.27 - 6.4)	5.1
Control Level 2	9.79 (7.83 - 11.7)	10.2
Agappe Control Level 1	6.1 (5.5 - 6.7)	6.2
Agappe Control Level 1	9.5 (8.5 - 10.5)	9.7

4. Sensitivity
Lower detection limit (or analytical sensitivity) of the assay is 3 %

Bibliography

1. Engbeak, F., et al. Clin chem.35 pp. 93-97 (1989)
2. American Diabetes Association : Clinical practice recommendations (position statement). Diabetes care 24 (suppl.1) S33-S55, (2001).
3. Tietz, N.W. Textbook of Clinical Chemistry, W.B. Saunders Company, p.794 - 7795 (1999).

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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CE ISO 9001:2015
EN ISO 13485:2016