Hemoglobin A1C

Direct Turbidimetry

INTENDED USE

The HbA1c reagent is used for the *in vitro* measurement of HbA1c in human whole blood.

SUMMARY AND BACKGROUND OF THE CLINICAL UTILITY

HbA1c is formed by the non-enzymatic glycation of free amino groups at the N-terminus of the β-chain of hemoglobin A0. The level of HbA1c is proportional to the level of glucose in the blood. As the glucose remains bound to the red cell throughout its life cycle, measurement of HbA1c provides an indication of the mean daily blood glucose concentration over the preceding two months. Measurement of HbA1c is, therefore, considered to be an important diagnostic tool in the monitoring of dietary control and therapeutic regimes during the treatment of diabetes. Effective control of blood glucose levels is important in the prevention of ketosis and hyperglycemia, and may reduce the prevalence and severity of late diabetic complications such as retinopathy, neuropathy, nephropathy, and cardiac disease.

TEST PRINCIPAL

This method directly determinates the HbA1c in whole blood, using an antigen and antibody reaction. Total hemoglobin and HbA1c compite for the unspecific absortion rate to the latex particles. Mouse ant-human HbA1c monoclonal antibody binds to the coated particles with HbA1c. The presence of goat anti-mouse IgG polyclonal antibody causes the agglutination of the particles (complexes).The amount of agglutination is proportional to the concentration of the HbA1c in the sample and can be measured by turbidimetry.

KIT COMPOSITION

Reagents are ready for use.

R1: Buffer, 20 mmol/L; Latex, < 0.15 %

R2: Buffer pH 6.0, 10 mmol/L; Mouse anti-human HbA1c monoclonal antibody, 5.5 mg/dL; Goat anti-mouse IgG polyclonal antibody, 67 mg/dL

Hemolysing: Buffer and stabilizer.

REAGENT STABILITY

The reagents are stable until the expiry date stated on the labels when stored at 2-8° C and protected from light. Avoid contamination by using clean laboratory material.

SAMPLE

Use whole blood collected with EDTA as specimen.

The red blood cells concentrate or whole blood can be used. The blood should be collected with EDTA or sodium fluoride. The analyte is reportedly stable for about 7 days at 2 - 8 ºC and at least one year at -70 ºC. No known test method can offer complete assurance that human blood samples will not transmit infectious diseases. Therefore, all blood derivatives should be considered potentially infectious. Therefore, follow the established Biosecurity guidelines while handling the samples.

Sample Preparation: 10 µl of well-mixed whole blood sample add to 500 µl of hemolyzing reagent. Mix and allow to stand for 5 - 10 minutes until complete lysis is apparent.

Specimen Stability:

Whole blood 1 week at 2 – 8°C
Hemolysate 10 hours at 15 – 25°C
Hemolysate 10 days at 2 – 8°C

TEST MANUAL PROCEDURE

Wavelength: 660 nm

Temperature: 30°C, 37°C

Cuvette: 1 cm light path

(Measure against Reagent)

	Sample	Calibrator
Sample	5 µL	-
Calibrator	-	5 µL
Reagent R1	180 µL	180 µL
Mix, incubate for 5 min., then add:		
Reagent R2	60 µL	60 µL
Mix, read absorbance after exactly 1 min and read absorbance after a total of exactly 5 min.		

CALIBRATION

The concentration of HbA1c in unknown samples is derived from a calibration curve using an appropriate mathematical model such as e.g. spline. The calibration curve is obtained with 4 calibrators at different levels plus hemolyzing solution for determination of the value 2.5%.

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REFERENCE VALUES

Non-diabetic	4.0 to 6.0 %.
Pre-diabetic	6.0 to 6.5 %.
Diabetic	> 6.5 %.

Note: It is recommended for each laboratory to establish and maintain its own reference values. The given data are only an indication.

SYMBOLS USED

IVD **For in vitro diagnostic medical use**

LOT **Batch Code**

Use by

Temperature limitation

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