Haemoglobin A_{1c} (HBA1C)Diagnostic Reagent Kit (Latex Enhanced Immunoturbidimetry Method) Product Instruction

Product name

Generic Name: Haemoglobin A1c (HBA1C) Diagnostic Reagent Kit (Latex Enhanced Immunoturbidimetry Method)
Abbreviation: HBA1C

Package Specifications

R1	R2
60ml×1	20ml×1
30ml×1	10ml×1
60ml×2	20ml×2

Calibrator (lyophilized):
Specification 1 (1.0mL×5; 5 levels);
Quality Control (lyophilized):
Specification 1 (1.0mL×1; 2 levels).

Intended use

Haemoglobin A_{1c} (HBA1C) diagnostic reagent is used for quantitative in vitro determination of the percentage of HbA1c in total Hb in human blood on photometric systems.

Clinical significance

Diabetes Mellitus is a disease associated with poor glycaemic control. Numerous clinical studies, including the Diabetes Control and Complications Trial, have shown that diabetes related complications may be reduced by the long term monitoring and tight control of blood glucose levels.
In the diabetic patient where blood glucose levels are abnormally elevated the level of HBA1C also increases, the reason for this is that HBA1C is formed by the nonenzymatic glycation of the N-terminus of the β-chain of haemoglobin A0.
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 daily blood glucose concentration over the preceding 6-8 weeks. It is therefore, a long term indicator of diabetic control, whereas, the measurement of blood glucose is only a short term indicator.

Principle

This kit is to directly measure the percentage of HbA1c in total Hb by using antigen-antibody reaction. The total hemoglobin and glycated hemoglobin in the sample have the same non-specific adsorption with latexand and turn into solid phase. When the specific monoclonal antibody of glycated hemoglobin is added, a complex of latex-glycated hemoglobin-mouse anti human glycated hemoglobin monoclonal antibody is formed. The complex is agglutinated with the help of goat anti mouse IgG antibody, and the amount of agglutination varies depending on the amount of glycated hemoglobin immobilized on the latex surface. By measuring the absorbance and comparing it with the standard curve of the percentage concentration of glycated hemoglobin, the percentage of glycated hemoglobin in the total hemoglobin can be calculated.

Main ingredient

Composition	Main ingredients
R1	Glycine buffer pH7.4 100mmol/L, Latex 15%
R2	Sheep anti mouse IgG antibody, mouse anti human HbA1c monoclonal antibody, Glycine buffer pH8.0
hemolytic agent	Pure water, Stabilizer 0.5%
Calibration	PBS buffer 50mM, Sucrose 5%, BSA 8%, HBA1C.
Quality control	PBS buffer 50mM, Sucrose 5%, BSA 8%, HBA1C.

Storage and stability

This kit stays stable for 18 months when stored in a dark condition at 2-8° C (do not freeze). After being opened for the first time, the kit can be stored at 2-8° C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation

Pretreatment
Mix 10μl of the whole blood sample with 500μl of Denaturant reagent (1: 51 dilution).
Avoid foaming.
Incubate for a minimum of 5 minutes at room temperature prior to testing.
The treated sample may be stored up to 8 hours at room temperature or up to 48 hours at +2 to +8℃, if stored in a sealed container.

Assay procedure

1. Reagent preparation
This reagent is liquid and can be used directly.

Main wavelength	660nm	Sample(S)	4 μ l
Subwavelength	no	Reagent 1	150 μ l
Reation temperature	37℃	Reagent 2	50 μ l
Cuvette light path	1cm	Reaction type	Two Point End

2. Operation steps

Add to the cuvette:	
Sample (S)	4 μ l
R1	150 μ l
Mix well, incubate at 37° C for 5 minutes, then add	
R2	50 μ l
Mix well, incubate at 37℃for 1 minute, absorbance A1; incubate at 37℃for 5 minutes, absorbance A2 △A= A2-A1	

Calculations

A non-linear method (such as Logit-Logit4P, Spline mode or Cubic mode) needs to be used to correct the calibration curve, and the concentration value of the sample is automatically obtained.

Reference interval

4%～6.2%

It is recommended that each laboratory should establish its own reference interval.

Quality control

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics

1. Measuring range

Within the linear range of (3.8%-14.5%), the correlation coefficient of linear regression r≥0.990, within the range of (3.8%-6.2%), the absolute deviation of the measurement does not exceed ± 0.5%, within the range (6.2%-14.5%), the relative deviation of the measurement does not exceed ± 10%.

2. Sensitivity

The assay is sensitive to a level of 0.3 g/dl HbA1c,1.38 g/dl total haemoglobin. The % HbA1c sensitivity was found to be 2.571%. This corresponds to 0.3 g/dl HbA1c and 11.667 g/dl total haemoglobin.

Interference

The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values.

Substances	Concentrations
Bilirubin	50 mg/dl
Chyle	3000 mg/dl

Automation

Special adaptations for automatic analyzers can be made on request.

Precautions and warnings

General precautions

For in vitro diagnostic use only.

Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement

Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.

Reagents with different lot numbers should not be interchanged or mixed.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Material safety data sheet available for professional user on request.

Parameters

HITACHI	
Model	7180
Assay Code	2 Point End
Reaction Time	10
Assay Point	18-34
Wave Length Sec	/
Wave Length Prim	660
ABS. Limit	32000
Sample Volume（uL）	4
R1 Volume（uL）	150
R2 Volume（uL）	0
R3 Volume（uL）	50
Calibration Type	SPLINE
Calibration Point	5
Span Point	3
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume（uL）	4

Sample DIL. VOL.	/
R1 Volume（uL）	150
R2 Volume（uL）	50
Reagent DIL. VOL.	/
Measure Wave 1	660
Measure Wave 2	/
METHOD	END
SLOPE	-
Method Point	11-27
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	
FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Dynamic Range L	0
Dynamic Range H	1000
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	5AB
Formula	spline
STD(1) Conc.#	*
Unit	%

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