HbA1C Direct Witout calibrator
(Latex Turbidimetric Method)

BEACON

Code	Product name	Pack size
SE002A	HbA1C Direct Without calibrator	40 ml
SE002B	HbA1C Direct Without calibrator	80 ml

Intended use
For the Quantitative determination of Hemoglobin A1c (HbA1c) in human blood.

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 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 latex 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.

contents

Composition	Main ingredients
R1: Latex reagent	Glycine buffer pH7.4 100mmol/L, Latex 15%
R2: Antibody reagent	Sheep anti mouse IgG antibody, mouse anti human HbA1c monoclonal antibody, Glycine
R3: Hemolysis	Pure water, Stabilizer 0.5%

Reagents Preparation
R1, R2 and Hemolysis reagents are supplied as ready to use liquids, Mix gently before use.

Storage and Stability
1. All reagents are stable to the expiration date stated on the labels. Do not use the reagents past their expiration date.
2. Hemoglobin A1c in whole blood collected with EDTA is stable for one week at 2-8°C.

Specimen preparation
Pretreatment
Mix 10 µl of the whole blood sample with 500 µl of Hemolysis reagent .
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

	Calibrator	Sample/control
Latex reagent	300 µl	300 µl
Calibrator	8 µl	-
Hemolysate sample	-	8 µl
Mix & incubator for 5 min at 37℃		
Antibody Reagent	100 µl	100 µl
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	30 mg/dl
Trigs	1600 mg/dl
RF	2000 IU/ml
Acetylsalicylic acid	60 mg/dl
Sodium cyanate	50 mg/dl
Urea	500 mg/dl

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.

Assay parameters for photometers

Test Name	HbA1C
Pri Wave	630 nm
Sec Wave	None
Assay/point	Fixed time
Incubation time	60
Testing time	300
Aspiration volume	350 µl
Unit	%
Linearity Range Low	3.8
Linearity Range High	14.5
Sample Volume	8.0 µl
Reagent 1 (R1) Volume	300 µl
Reagent 1 (R2) Volume	100 µl
Substrate Depleted/Abs.limit	-
Linearity	14.5%
Out Of Linearity Range	-
Calibration Type	Spline
Points	5

Symbols Used On Labels