

# HbA1C SYSTEM PACK

## (Latex Turbidimetric Method)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic Chem 400 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
UNI20	HbA1c SYSTEM PACK	1 x 30 +1 x 10 ML
UNI20A	HbA1c SYSTEM PACK	2 x 30 +2 x 10 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 that HbA1C is formed by the nonenzymatic glycation of the N-terminus of the  $\beta$ -chain of haemoglobin A.

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 buffer pH8.0
R3: Hemolysis Reagent	Pure water, Stabilizer 0.5%
R4: Calibrator (5 level lyophilized 5x1.0 ml)	PBS buffer 50mM, Sucrose 5%, BSA 8%, HBA1C.



# BEACON

### Reagents Preparation

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

**Calibrator:** Reconstitute the Calibrator with 1.0 ml distilled water. Stable for 30 days at +2-+8°C. **Do not freeze.**

### 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 20 $\mu$ l of the whole blood sample with 1.0 ml 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°C, if stored in a sealed container.

### 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  $r \geq 0.990$ , within the range of (3.8%-6.2%), the absolute deviation of the measurement does not exceed  $\pm 0.5\%$ , within the range (6.2%-14.5%), the relative deviation of the measurement does not exceed  $\pm 10\%$ .

#### 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

## 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.

Parameter For B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic Chem 400  
(Fully Auto Biochemistry Analyzer)

Test Name	HbA1C
Full Name	HbA1C
PRI Wave	630 nm
Sec Wave	None
Assay/point	1 Point End
Start	-
End	33
Decimal	2
Unit	%
Linearity Range Low	3.8
Linearity Range High	14.5
Sample Volume	5.0 µl
Reagent 1 (R1) Volume	180 µl
Reagent 1 (R2) Volume	60 µl
Substrate Depleted/Abs.limit	-
Linearity	14.5%
Out Of Linearity Range	-
Calibration Type	Spline
Points	5
Blank Type	Reagent
Concentration Blank	0.00
Concentration STD	Refer calibrator value From calibrator vial

## Symbols Used On Labels



Catalogue  
Number



Manufacturer



See Instruction  
for Use



Lot Number



Content



Storage Temperature



Expiry Date



In Vitro Diagnostics

BEA/24/HBA/UN/IFU Ver-05  
25/07/2025

