Hipro Biotechnology Co.,Ltd

EN
ENGLISH

# HbA1c

Glycohemoglobin Test Kit
(Nephelometry Immunoassay Method)

## Instructions for Use

Version: A/7

REF HP-HbA1c-25


**Manufacturer**

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## Product Name

General Name：Glycohemoglobin Test Kit（Nephelometry Immunoassay Method）.

## Specification

Package Specification
25 Tests/ Kit

## Intended Use

This product is applicable to the clinical determination of the content of human blood for glycosylated hemoglobin, and specific reagent for the specific protein analyzer, applies only to the clinical in vitro assisted diagnosis.

Glycosylated hemoglobin is the formation of hemoglobin and a combination of sugars by non-enzymatic. The combination of process is slow and relatively irreversible, and the persistence of the life of 120 days in the red blood cells is directly proportional to the concentration of the sugar in the synthesis rate of erythrocyte surroundings. Therefore, the percentage of glycosylated hemoglobin reflects the determination of the average blood sugar levels within 8-12weeks before testing.

## Test Principle

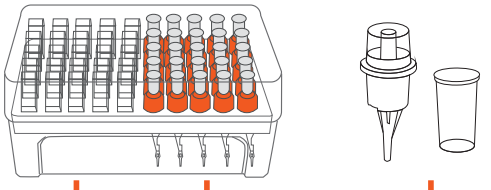
The HbA1c units is the use of antigen-antibody reaction to the direct determination of HbA1c percentage of total Hb. Samples of total Hb, HbA1c and latex in the sample will solidified by the same non-specific adsorption. The latex-HbA1c-mouse anti-human HbA1c monoclonal antibody complexes formed when the HbA1c of specific monoclonal antibody joined in. This composite was agglutinates because of sheep anti-mouse IgG antibodies and will produce the phenomenon of light scattering. Content is proportional to the intensity of scattered light and samples of HbA1c. Specific protein immunoassay to measure the intensity of scattered light, and comparison with the standard curve of HbA1c percentage concentration to get HbA1c percentage of the total Hb content in the sample.

The kits contains all the reactive reagents.

## Component

The HbA1c- test kit consists of two reagents R1 and R2, as shown on Figure 1.

## Figure 1




| Name | Content | Quantity |
|---|---|---|
| Reagent 1 | 15mmol/L glycine buffer | 15mmol/L |
| | latex | 0.1% |
| Reagent 2 | glycine buffer | 60mmol/L |
| | goat anti-rat IgG, rat anti-human HbAlc monoclonal antibody | Appropriate |
| Buffer | Purified water | 0.5ml |
| IC card (optional) | / | 1 |

Do not mix different batches of reagents.

## Storage&stability

Store the test kit at 2°C-8°C until the expiration date indicated on the label. The test kit is stable for one year when unopened.

Use up the test kit within one month after opening the package.

Do not freeze the test kit.

Do not mix different lots of the test kit.

## Special Instrument Requirements

HP-083/4-I POCT Immunoassay System,
HP-083/4-II POCT Immunoassay System,
HP-AFS/1 Automatic Immunoassay System,
HP-AFS/3 Automatic Immunoassay System.

## Specimen type

Whole blood, finger blood or venous blood, anticoagulation including EDTA, heparin, and citrate.

Anticoagulation, mixing 10μL whole blood sample with 0.5mL purity water. The sample store at 4°C in dark place for 10 days, Avoid repeated freezing. Before test, ensure fully mixed.

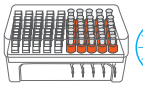
## Procedures

### HP-083/4-I&HP-083/4-II POCT Immunoassay System

Note:

- Please read user manual of HP-083/4-I and HP-083/4-II before use;
- The analyzer will finish self check after start-up;
- Insert the IC card of HbA1c test kit to let analyzer read the parameter;
- The analyzer calibration can be done with app. It is recommended that analyzer calibration should be done for each new lot of test kit.

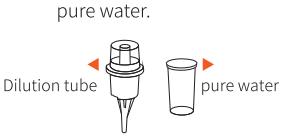
#### Step 1 Sample Preparation

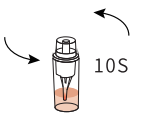



1a Allow the test kit back to room temperature for 30 minutes before use.

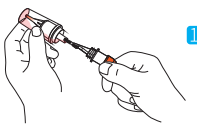
1b Take 10μL whole blood samples( finger blood or venous blood) by sampler.

1c Insert the sampler into dilution tube filled with 0.5mL pure water.




1d Shake 10 seconds to fully mixing.



1e Take 10μL diluted samples by capillary in front of the sample collector, insert the sample collector into the cuvette.

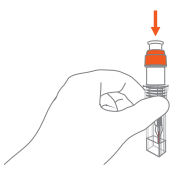
Note:

- The parameter is built in the IC card.
- Please insert the corresponding IC card into analyzer to let the analyzer read the parameter before each assay test.
- The capillary of the R2 should be fully filled.

#### Step 2 Testing

2a Hold the narrow side of R1 and shake from left to right for 12 times to let the sample completely mix with R1.

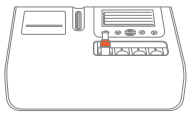
Note: Do not hold the wide sides of R1 .



2b Press the piston on R2.

2c Hold the narrow sides of R1 and shake for 3-5 seconds to let R1 and R2 mix well.

Step 2 Testing



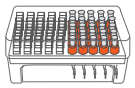
2d Insert the R1 into test channel of HP-083/4-II and the analyzer will finish the test and print out results automatically.

## HP-AFS/1&HP-AFS/3 Automatic Immunoassay System

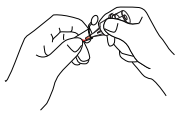
Note:

- Please read user manual of HP-AFS/1 and HP-AFS/3 before use
- The analyzer will finish the self check after start-up;
- It is recommend to do analyzer calibration monthly and for each new lot of test kit.

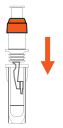
Step 1 Sample Preparation




3a Allow the test kit back to room temperature for 30 minutes before use.



3b Use the R2 with quantitative capillary to collect sample.



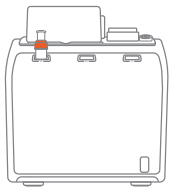
3c Insert the R2 into R1.

Note:

Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.

The capillary of the R2 should be fully filled.

Step 2 Testing



4a Insert the R1 into test channel of analyzer.

4b The analyzer will mix the sample from R2 capillary with R1 automatically.

4c The analyzer will mix the R2 and R1 automatically.

4d The analyzer will test and print the results automatically.

### Calibration

The calibration values for the different lots of the kits are stored on the calibration IC card or the two-dimensional code on the cuvette. Before test the new lot of kits, read the calibration card parameters first. Or the instrument automatically scan the two-dimensional code on the cup to obtain the corresponding calibration curve during testing.

### Quality control

3- level calibration system guarantee the results' reliability for each lot of test kits, including the instrument calibration, remote reagent calibration and the third party calibration.

The third party calibration applicable for:

1. The daily indoor quality control test.
2. New lots of reagent.
3. New operator training.
4. The results can not match the clinical symptoms.
5. The first use of the reagent.

If still can not be calibrated, contact the manufacture for further technical support.

### Reference Value

4%-6%

Recommended that each laboratory establish its own reference range.

### Interpretation

The test result between 6%-7%, the blood glucose in good condition, 7%-8% in general condition,8%-9% is in bad condition, need to strengthen blood sugar control, pay more attention to diet and exercise, and adjust the therapeutic schedule guided by doctor; >9% indicates in dangerous condition, is a risk factor for the development of chronic complications, may lead to diabetic nephropathy, atherosclerosis, cataract and other complications, and there may be ketoacidosis and other acute complications.

The result only for clinical reference, comprehensive consideration should be combined with the clinical management of patients with symptoms / signs, medical history, other laboratory tests and treatment response.

All laboratory tests depend on random errors. If the test results are in doubt, or if they do not match the clinical symptoms, re-test the sample or confirm the results with other methods.

### Limitations

Bilirubin≤648 μmol/L, triglyceride≤9.8mmol/L, NOT effect the test results.

### Performance Characteristics

1. Linearity range: 2% ～ 14%
2. Detection limit: ≤1.2%

   The limit of detection means the lowest detectable analyte level that can distinguish the concentration. Calculate based on the minimum standard above the two standard deviation of the data ( Blank table, 1+2SD, within-run precision,n=21).
3. Precision

   Test the control material by Glycosylated Hemoglobin (HbA1c) Test Kits（Nephelometry immunoassay Method） 2 times per day for 20 days (n=80) according to EP5-A2 of CLSI. The data as below:

a.

| HP-083/4-II POCT Immunoassay System | | | | | |
|---|---|---|---|---|---|
| Sample | Mean % | Within-Run | | Between-Run | |
| | | S.D. | %C.V. | S.D. | %C.V. |
| Control 1 | 5.5 | 0.32 | 5.8 | 0.3 | 5.4 |
| Control 2 | 11.2 | 0.57 | 5.1 | 0.55 | 4.9 |

b.

| HP-AFS/3 Automatic Immunoassay System | | | | | |
|---|---|---|---|---|---|
| Sample | Mean % | Within-Run | | Between-Run | |
| | | S.D. | %C.V. | S.D. | %C.V. |
| Control 1 | 5.7 | 0.35 | 6.1 | 0.31 | 5.4 |
| Control 2 | 11.4 | 0.66 | 5.8 | 0.58 | 5.1 |

c.

| HP-AFS/1 Automatic Immunoassay System | | | | | |
|---|---|---|---|---|---|
| Sample | Mean % | Within-Run | | Between-Run | |
| | | S.D. | %C.V. | S.D. | %C.V. |
| Control 1 | 5.5 | 0.33 | 6.0 | 0.27 | 4.9 |
| Control 2 | 11.0 | 0.62 | 5.6 | 0.51 | 4.6 |

4. Methodology comparison

   Compared to high performance liquid chromatography (HPLC) (x), test the ETDT (EDTA) anticoagulated whole blood samples, the relative data as below:

| HP-AFS/3 Automatic Immunoassay System | | | | |
|---|---|---|---|---|
| Site No. | Sample Type | No.of Assays | Regression Line | Coefficient correlation |
| 1 | Venous | 50 | Y= 0.96X+0.28 | 0.96 |

The concentration of sample is about 4.3%-12.6%.

### Precautions

⚠ Attention:

Only for in vitro diagnostic.

Only for professional use.

All samples and reactive wastes are treated as sources of infection.

Do not use the kits beyond shelf life.

Do not mix different batches of reagents.

⚠ Warning:

To avoid error, do not forced to take out the cuvette from the device. Follow the device operation manual strictly, If the problem cannot be solved, contact the manufacturer for further technical support.

### SYMBOLS USED ON LABELS

| Symbol | Usage | Symbol | Usage |
|---|---|---|---|
| | Use-By date | | Do not freeze |
| LOT | Batch code | | Biological risks |
| | Manufacturer | | Do Not Reuse |
| 2°C 8°C | Temperature Limit | | |
| Σ | Contains sufficient for <n> tests | | |
| | Do not use if package is damaged | | |
| | Consult Instructions for use | | |
| | Keep Away from Sunlight | | |
| IVD | In Vitro Diagnostic Medical device | | |
| EC REP | Authorized Representative in the European Community | | |

### References


1、DCCT Research Group. The effect of intensive trea-tment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus.N.Eng.J.Med.329(1993):977-986.

2、Weykamp,C.W., Miedema,K., de Haan,T., and Doel man, C.J.A. Carbamylated Hemoglobin Interference in Glycohemoglobin Assays.Clin.Chem.45(1999):438-440.


### Approval Date&Revision Date

Approval Date: Sept 9,2015
Revision Date: May 6,2016
Revision Date: May 1, 2017
Revision Date: Oct 9,2019
Revision Date: Jan 1, 2021
Revision Date: Apr 1, 2021
Revision Date: Jan 1, 2023
Revision Date: Dec 22,2023

CE IVD

尺寸：24*25cm展开尺寸，横向三折页再垂直方向两次对折