

HbA1c Rapid Quantitative Test



INTENDED USE

The HbA1c (Glycosylated Hemoglobin A1c) Rapid Quantitative Test is intended to quantify the percentage of HbA1c in human whole blood on Biotime FIA Analyzer (Semi-automatic / Automatic) by fluorescent immunoassay. The test is used as an aid in management and monitoring of the long-term glycemic status in patients with diabetes mellitus.

-Fluorescent immunoassay

-Glycemic status, diabetes mellitus

For in vitro diagnostic use only. For professional use only.

INTRODUCTION

This product is used to quantify the percentage of the Glycosylated Hemoglobin A1c (HbA1c) in whole blood. HbA1c is a form of hemoglobin that is bound to glucose. It is formed in a non-enzymatic glycation pathway by hemoglobin's exposure to plasma glucose. It is measured primarily to identify the three-month average plasma glucose concentration and thus can be used as a diagnostic test for diabetes and as assessment test for glycemic control in people with diabetes^[1-4].

PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the specimen and the buffer are mixed and applied into the test cartridge, HbA1c in blood and hemoglobin monoclonal antibody labeled with fluorescent microsphere form a reaction intermediate complex (complex 1) while Hb and hemoglobin monoclonal antibody labeled with fluorescent microsphere form different reaction intermediate complexes (complex 2). During lateral flow, complex 1 and 2 move along the nitrocellulose membrane pre-coated with a detection line (T-line: coated with HbA1c specific monoclonal antibodies) and a control line (C-line: coated with Hemoglobin monoclonal antibodies). The complex 1 will be captured by T-line and the complex 2 will be captured by C-line. The fluorescent signal from microsphere of each complex will be detected respectively and calculated according to the calibration curve (in SD card provided with the test kit) to represent the percentage of HbA1c among hemoglobin in blood.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only. Please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for single time use.
4. Once opening, the reagent should be used within the specified time to avoid detection failure due to moisture absorption.
5. While using the test cartridge and instruments, vibration and strong electromagnetic environment shall be avoided.
6. Lot number of buffers and test cartridges must be matched.
7. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. Otherwise, it may cause damages to the instrument.

MATERIAL

Material Provided

The following components are included in the HbA1c Rapid Quantitative Test.

Specification and Component

1. For type A reagent

| Packing specification | | | | |
|-----------------------|----------------|------------------|-------------|----------------------|
| Catalog No. | Test cartridge | Detection buffer | SD card | Instructions for Use |
| BT2501 | 25 tests/kit | 25 tubes/kit | 1 piece/kit | 1 copy/kit |

2. For type B reagent

| Packing specification | | | | |
|-----------------------|----------------|------------------|-------------|----------------------|
| Catalog No. | Test cartridge | Detection buffer | SD card | Instructions for Use |
| BT0203701 | 25 tests/kit | 1 panel/25 tests | 1 piece/kit | 1 copy/kit |

Material Required But Not Provided

1. Biotime FIA Analyzer

| Applied information | Biotime FIA Analyzer | Applicable model |
|---------------------|----------------------|---------------------------------------|
| For type A reagent | Semi-automatic | BIOT-YG-I, FLI-100, FLI-600, FLI-1200 |
| For type B reagent | Automatic | FLI-4000 |

2. Transfer Pipette Set (range 0.5~10μL and 10~100μL size)
3. Specimen Collection Containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-30°C, the shelf life is 24 months.
2. Store the test cartridge at 2-30°C, the shelf life is 24 months.
3. Test Cartridge should be used within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

1. The test specimen should be whole blood.
2. The sample collection container should be EDTA-K2 anti-coagulant tube for whole blood.
3. The collection of the sample: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected in time, it can be stored in refrigerator at 2-8°C for no more than 3 days. Samples should be recovered to the room temperature before test.
4. Do not use hemolyzed sample.

TEST PROCEDURE

Please refer to the operation manual of Biotime FIA analyzers for details.
The test should be operated at room temperature (~25°C).

For Type A reagent

Step 1: Preparation

Check/insert SD card into the equipment.

Take out one tube of buffer from refrigerator and balance it to room temperature.

Step 2: Sampling

Take 5μL of whole blood specimen with a transfer pipette and add it into the buffer tube.

Step 3: Mixing

Mix well the specimen with buffer by tapping or inverting the tube.

Step 4: Loading

Take 80μL of sample mixture and load it into the well of the test cartridge.

Note: Step 2 to step 4 should be completed within 1 minute to ensure the accuracy of the test results.

Step 5: Testing

Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 5 minutes.

For Type B reagent

Step 1: Preparation

Check the lot number. Tear the aluminum foil bag, take out the test cartridge and buffer, and put it into the analyzer card slot.

Step 2: Sampling

For whole blood sample, after put the sample to be tested into the analyzer, the analyzer automatically absorbs 5μL sample;

Step 3: Mixing

The instrument automatically adds the sample into the sample buffer, and then fully mixed.

Step 4: Loading

The instrument automatically absorbs 80μL of the above mixed solution into the detection hole of the test cartridge, and moves it to the incubator;

Step 5: Testing

After sample mixture addition, the test cartridge reacts in the incubation tank for 5min, and the analyzer reads the result;

NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal reference interval: 4%-6.5%.

Note:

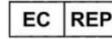
1. Individual reference range is suggested to be established for each laboratory.
2. According to the standards given by the American Diabetes Association, levels between 5.7% and less than 6.5% are in the prediabetes range, and levels of 6.5% or higher indicate diabetes.

LIMITATIONS OF PROCEDURE

1. This test kit is only applicable to human whole blood specimen.
2. Human anti-mouse antibody (HAMA) may be presented in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies^[5-6].
3. Other factors also can induce the false results, including the technology, operational error and other sample factors.



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PERFORMANCE CHARACTERISTICS

Accuracy

HbA1c control materials with two different percentages were tested by every lot of Test Cartridges, and the deviations were within $\pm 15\%$.

Assay Range: 4%-15%

The Lowest Detection Limit: 4%

Linearity

A serial percentages of HbA1c reference materials at 4%-15% were tested, and the correlation coefficient (R) is ≥ 0.9900 .

Precision

Intra-Lot Precision

Intra-lot precision was determined by testing of HbA1c reference materials using 10 test cartridges from the same lot. The C.V. is $\leq 15\%$.

Inter-Lot Precision

Inter-lot precision was determined by testing of HbA1c reference materials using 30 test cartridges from 3 consecutive lots randomly (10 test cartridges from each lot). The C.V. is $\leq 20\%$.

Specificity

Deviation of detection result is not greater than $\pm 10\%$ when the concentration of acetylated hemoglobin is 5mol/L.

Deviation of detection result is not greater than $\pm 10\%$ when the concentration of carbamylated hemoglobin is 10mol/L.

Deviation of detection result is not greater than $\pm 10\%$ when the concentration of glucose is 500mg/dL.

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SYMBOLS

| Symbol | Description | Symbol | Description |
|--------|---------------------|--------|--|
| | Catalogue number | | In vitro diagnostic medical device |
| | Batch code | | Consult instructions for use |
| | Date of manufacture | | Keep dry |
| | Use-by date | | Keep away from sunlight |
| | Manufacturer | | Store at 2-30°C |
| | Do not re-use | | Authorized representative in the European Community/European Union |
| | CE mark | | |

BIBLIOGRAPHY OF SUGGESTED READING

1. Xin Li. The early diagnostic value of hsCRP, UmAlb and HbA1c in diabetic nephropathy patients. [J]. International Journal of Laboratory Medicine, 2011; 32(2):198-199.
2. Jun Yu. Study of the type 2 diabetes mellitus with screening value and level for diagnostic evaluation. [J]. Chinese Journal of Diabetes. 2011; 19(12):910-912.
3. Yaowen Zhou. Study of glycosylated hemoglobin level from patients of coronary artery disease combined with diabetes (CAD-DIA) [J]. China Practical Medical, 2011; 6(21):84-85
4. Hongqing Zhang. The value of hemoglobin A1c test for the hospitalized non-diabetic patients with essential hypertension and coronary heart disease [J]. Journal of National Medical Frontiers of China, 2011; 6(2):68~69.
5. Levinson SS. The Nature of Heterophilic Antibodies and the Role in Immunoassay Interference. [J]. Journal of Clinical Immunoassay, 1992; 15:108-114.
6. Hansen JH, et al. HAMA Interference with murine monoclonal antibody-based immunoassays[J]. Journal of Clinical Immunoassay, 1993; 16: 294-299.