HbA1c Assay Kits (Lateral Flow Immunoassay)

User Manual

【Product Name】

HbA1c Assay Kits (Lateral Flow Immunoassay)

【Intended Use】

The HbA1c Assay Kits is used to quantitatively test the level of HbA1c in whole blood.

HbA1c reflects average blood glucose level in past 120 days.

【Principle】

Lateral Flow Immunoassay : Adopt method of double mono-cloned antibody. Hb and HbA1c Monoclonal antibody (T line) and rabbit anti-mouse IgG were coated on the NC membrane, and the fluorescein labeled Hb and HbA1c monoclonal antibodies were coated on the conjugate pad. After the sample was added to the sample pad, the Hb and HbA1c react with the antibodies to form immune complexes. The concentration of immune complexes have positive correlation to the concentration of Hb and HbA1c in the sample. Through the standard curve achieved by scanning the RFID card with the FA-160 analyzer, the concentration of the HbA1c in the sample can be calculated.

【Packing Specification and Components】

Component	Packing Specification			
	10Tests / Kit	25Tests / Kit	50Tests / Kit	100Tests / Kit
Test Cartridge (contains a plastic straw, a desiccant, a test cartridge: Hb and HbA1c Monoclonal antibody, Rabbit anti- mouse IgG, Hb and HbA1c Monoclonal antibody labeled fluorescein)	10pcs	25pcs	50pcs	100pcs
Sample diluent (1.0ml/bottle, optional, not supported)	10 bottles	25 bottles	50 bottles	100 bottles
RFID Card	1pc	1pc	1pc	1pc
User Manual	1pc	1pc	1pc	1pc

【Storage and Shelf Life】

Stored the reagent kits at 4~30°C, in sealed aluminium foil bag .

Shelf life is 18 months, and open-bag shelf life is 1 hour; especially under condition of high temp or high humidity, it should be used immediately after opening the package.

Use the reagent kit before expiration date marked on the box.

【Sample Requirements】

1. Whole blood.
2. Adopt common method of clinical laboratory to collect blood samples, it should be tested within 72 hours (Stored under condition of 2~8°C), or it needs to stored for 7 days at 2~8°C, keep in dark place. DO NOT frozen-thawed over and over again.
3. Samples should be recovered to room temperature before test.
4. Samples should not be severe hemolysis, severe lipidemia or jaundice samples.

【Applicable Instrument】

FA series Lateral Flow Immunoassay Analyzer.

【Operation Step】

1. Sample assay

- Recover sample to the room temperature at first;
- After power on, take out the RFID card and put it on the Lateral Flow Immunoassay Analyzer, which will read the information from RFID card. Both the test item and lot number information should match the assay kits;
- Take out the test strip, add 10 μL sample into sample diluent. After mixing for 1min, Use pipette to add 100 μL mixing sample diluent to the load hole;
- Place the reagent test card with the sample added to any idle incubation channel, select the item to be tested.After the reagent test card were incubated at 37°C for 15 minutes, the corresponding incubation "Done" will appear on the channel display. Remove the reagent test card to the detection channel immediately, and press the "Test" button to perform sample test analysis.

2. Quality Control

There is no QC material in reagent kit of the product. It's suggested to use third party QC material. It's allowed that the testing results are in the range of reference range of the third party QC.

【Reference Range】

Reference range of HbA1c level in normal adult group is 4.0%-6.5%.

Reference range is established on testing the HbA1c level of 240 cases normal adult(including 120 cases between 1 and 49 years old and 120 cases over 50 years old. In both groups, half women and half man). It's recommended that laboratory establishes its own reference range according the patient group.

【Limitation of Test Method】

1. Test result is used to auxiliary diagnosis; Appropriate clinical treatment should be taken in combination with clinical manifestations, medical history and other diagnostic results.
2. Severe hemolysis, severe lipidemia or jaundice of the sample will cause inaccurate results.Samples with severe hemolysis (hemoglobin≥600 mg/dL), severe lipidemia (triglyceride≥4000 mg/dL), severe jaundice (bilirubin≥20 mg/dL), please do not use them for detection.
3. Samples with high concentration of heterophilic antibodies or rheumatoid factor may lead to false positive results. Therefore,other clinical symptoms should be take into consideration to make a conclusion.

【Performance Indicators】

1. Limit: the lowest limit ≤ 4.0%;
2. Measurement Range: 4.0%-16.0%; Correlation coefficient (r)≥0.9900;
3. Accuracy: bias between real concentration and standard concentration is ±15％;
4. Intra-assay precision: low level CV≤15%, high level CV≤10%;
5. Inter-assay precision: low level CV≤15%, high level CV≤10%.

【Precautions】

1. Only for In-Vitro Diagnostic.
2. Please follow the instructions in use manual strictly. Test strip should be used within 1 hour once removed package, tested strip should be read timely after 15 minutes incubation finished, or the result will be invalid.
3. The resource material of test strip has been inactivated at 60°C, and HBsAg, anti-HCV, anti-HIV(1&2), anti-TP has been tested negative which was approved by CFDA; But there is no test method to be absolute safe. Since all the samples that are taken from human blood, the samples and test strips should be treated as potentially infectious source and disposed according to local regulation.
4. Different lot number of reagents and RFID cards can not be mixed.
5. The test strip and pipette are for one-time disposable use only.
6. The instrument cannot be used to tumor diagnosis.

【Literature References】

[1] Shuxiang Bai. Relationship of glycated hemoglobin with diabetes and its complications[J]. *Basic medical BBS*, 2011,15(2): 144-145.

[2] Guohua T, XuganJiang,et al. Establishment and evaluation of test of glycated hemoglobin with HPLC method[J]. *Journal of jiangsu university (medical edition)*,2011,21(2):147-150.

【Symbol explanation】

Symbol	Interpretation of symbols
	manufacturer
	Authorized representative in the European Community
	Date of manufacture
	Expiration date
	Lot number
	Temperature limit
	Consult instructions for use
	For In Vitro Diagnostic Use
	Contains sufficient for <n> tests
	Catalog number
	CE marking of conformity

【Manufacturer's information】

Shenzhen Lifotronic Technology Co., Ltd.
Unit A, 4th Floor, Building 15, Yijing Estate, No.1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R.China
Mail：service@lifotronic.com;

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel.+49-40-2513175 Fax.+49-40-255726

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