Haemoglobin A1c（HbA1c）Rapid Quantitative Test (Fluorescence immunoassay)
User manual

【Product Name】
Haemoglobin A1c（HbA1c）Rapid Quantitative Test (Fluorescence immunoassay)

【Packing Specification】
25 Tests/kit

【Intended Use】
The kit is used for quantitative determination of HbA1c in human whole blood，and is mainly used for diagnosis of diabetes and monitoring of blood glucose level clinically.

【Test principle】
This kit is a one-step chromatographic sandwich immunoassay designed for the quantitative measurement of HbA1c. The HbA1c antigen in the sample was first bound with the conjugated compound of fluorescent labeled HbA1c monoclonal antibody, then moved and combined with Hb monoclonal antibody fixed on the nitrocellulose membrane, and the double antibody sandwich complex was formed at the detection line of the cellulose nitrate membrane. The quantitative detection results were obtained by NIR-1000 dry fluorescence immunoassay.

【Components】

Name	Quantity	Component
Test cards	25	The product consists of fluorescent mat (coated with fluorescently-labeled HbA1c mouse antibody), nitrocellulose membrane (coated with HbA1c mouse antibody and Goat anti mouse IgG antibody), absorbent paper and PVC soleplate, and so on.
Sample diluent	25 (1.0mL/ tube)	Phosphate buffer
ID card	1	With specific stand curve file

The components in different batches of kits cannot be used interchangeably.

【Storage Conditions and Validity】
The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20%～90% relative humidity.
The production date, batch number and expiration date are shown in the outer package of the product.

【Applicable Instrument】
NIR-1000 dry fluorescent immunoassay analyzer produced by WWHS Biotech. Inc.

【Sample Requirements】
1. The whole blood should be collected in a tube containing EDTA as the anticoagulant.
2. Venous blood was collected according to routine laboratory methods to avoid hemolysis.
3. It is highly recommended to use fresh samples instead of keeping the samples at room temperature for a long time. After samples were collected, the detection should be completed within 4 hours at room temperature (15℃~30℃). The whole blood sample can be stored at 2℃~8℃ for 48 hours.
4. Before testing, the sample should return to room temperature (15℃~30℃). The frozen samples should be completely thawed, rewarming and mixed evenly before use. Repeated freeze-thaw cycles should be avoided.

【Test procedure】
1. Before the test, please read the instructions completely. If the test card and sample are stored in cold storage, they should be balanced at room temperature (15-30)℃ for not less than 30min before use.
2. Start NIR-1000 dry fluorescence immunoassay analyzer according to the instruction manual of the instrument, and carry out quality control verification according to the instruction manual of the instrument（Note: the reagent has been calibrated in advance, and the calibration curve parameters of each batch of reagent have been stored in the information card. The information card is inserted before use, so it is not necessary to calibrate again, and the test can be carried out only after the quality control is passed. Otherwise, the cause should be found out before testing.)
3. Remove the test card from the aluminum foil bag and use it within 15 minutes.
4. Place the test card on a clean horizontal table and mark it horizontally.
5. Add 10μL of sample into HbA1c sample diluent (1.00mL). After mixing thoroughly the solution for 1 min, take 100μL of the solution and add it into the well.
6. Insert the test card into NIR-1000 dry fluoroimmunoassay analyser, read and record the results at 10 minutes after addition of samples, then dispose of used test appropriately.

【Reference Interval】
Test and analyze the HbA1c in the whole blood from 269 healthy people aged 17-89, according to 95th percentile method, the result shows that HbA1c reference interval is 4.0%-6.0%. It is strongly recommended that each laboratory should determine its own normal and abnormal values.

【Interpretation of Test Results】
1. The kit can be used for auxiliary test only. If test result is abnormal, retest timely and judge combined with clinical symptoms.
2. For samples whose HbA1c concentration is lower than 4.0% and higher than 14.0%, test result is

"＜4.0%" and "＞14.0%" respectively.

【Limitation of Test Method】

1. The kit is only used to test whole blood specimens of human body.
2. Due to the limitations of immunoassay methods of antigen and antibody reaction, the results cannot be used as the only basis for clinical diagnosis, but should be evaluated with all the existing clinical and experimental data.
3. The content of triglyceride in the sample shall not exceed 10mg/ml, the content of bilirubin shall not exceed 0.2mg/ml, the content of glucose shall not exceed 10mg/ml, and the relative deviation is limited to ±10.0%.
4. When HbA1c concentration of samples reaches 18.0%, there is no hook effect.
5. HAMA effect was not produced when the concentration of human anti rat in the sample was less than 50ng/ml.
6. When RF concentration of samples is less than 2000IU/mL, relative deviation of test result is limited to ±10.0%.
7. For samples exceeding the linearity range, test cannot be conducted after dilution.

【Performance 】

1. Limits of detection

No higher than 4.0%.

2. Accuracy

The relative deviation to the target value is limited to ±10.0%.

3. Repeatability

Coefficient of variations are within 10%.

4. Batch-to-batch difference

The relative range (R) between batches shall not be greater than 15.0%.

5. Linearity range

Within the specified linearity range （4.0%-14.0%）:

a) Linearly dependent coefficient (r) is no less than 0.9900;

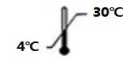
b) Within （4.0%-6.0%）, linear absolute deviation is limited to ±0.6%.

Within （6.0%-14.0%）, linear absolute deviation is limited to ±10.0%.

【Note】

1. The kit can be used for in vitro diagnosis only.
2. Test card and buffer solution are single-use and they cannot be reused.
3. Please check the integrity and validity of the kit package before use, and then open the package. When it is stored at low temperature, it should be restored to room temperature (15℃～30℃) before opening the package for use. The reagents with damaged inner package and beyond the validity period cannot be used.
4. Take the test card out of the aluminum foil bag and carry out experiment in 15min. Do not place it in the air for a long time to avoid dampness.
5. It is required to strictly comply with the requirements for sample collection and storage. If the sample is turbid, please centrifuge and precipitate it before use.
6. The kit used should be disposed of as latent infective material, and all samples, reagents and latent contaminants should be disinfected and disposed of according to relevant local regulations.

【Interpretation of Signs】

	Storage temperature		Single-use
	Keep in dark place	IVD	IVD Reagents
	Dampproof		Refer to the specification

【Reference 】

[1] National Health and Family Planning Commission of the People's Republic of China. Glycosylated Hemoglobin Assay [S]. Sanitary Industry Standard of the People's Republic of China, WS/T461-2015.
[2] Glycosylated Hemoglobin Assay Expert Consensus Commission. Glycosylated Hemoglobin Assay Expert Consensus [J]. Chinese Journal of Diabetes, 2014, 6(12):853-858.

【Essential information】

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