HbA1c Test Kit User Manual (Dry Fluorescence Immunoassay)

[PRODUCT NAME]

HbA1c Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

HbA1c Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of HbA1c in human whole blood. This test is used as an aid for monitoring glycemic control in diabetics.

[TEST PRINCIPLE]

HbA1c Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will migrate forward due to capillary action, then the HbA1c of the sample will combine with antibody which is attached to fluorescence microspheres. This marked complex is attached to the detection area of immobilized antibody, and the other fluorescence microspheres are attached to the control area. When the test strip is inserted into the analyzer, the analyzer automatically scans two ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. HbA1c test strip in a sealed pouch with desiccant.....25 tests
2. Sample diluent .....25 pieces
3. User Manual .....1 piece
4. QR code card for calibration.....3 pieces
5. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months. Test strip should be used within 1 hour once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1000 Dry Fluorescence Immunoassay Analyzer
2. LS-2000 Dry Fluorescence Immunoassay Analyzer
3. LS-1100 Dry Fluorescence Immunoassay Analyzer
4. LS-2100 Dry Fluorescence Immunoassay Analyzer
5. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
6. LS-7000 Dry Fluorescence Immunoassay Analyzer
7. LS-7100 Microfluidic and Dry Fluorescence Immunoassay Analyzer
8. LS-7800 Automatic Microfluidic and Dry Fluorescence Immunoassay Analyzer
9. LS-3000 Automatic Fluorescence Immunoassay Analyzer
10. LS-3100 Automatic Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **whole blood**. Other bodily fluids and samples may not get the accurate result.
2. Whole blood sample can be anticoagulant with EDTA under aseptic conditions.
3. At room temperature, the test should be performed within 4 hours after the sample collection.
4. Whole blood sample can be stored at 2°C-8°C for 7 days at most, and must avoid hemolysis, otherwise the result is not accurate.
5. The sample before testing should be recovered to room temperature (22°C-34°C).
6. **Sample Volume: 5μL**

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample, test strip and sample dilute should be recovered to room temperature (22°C-34°C).

Whole blood sample should be gently mixed upside down for 5 times, so that it is in the state of mixing. Avoid violent mixing and blood cells will be broken.

For LS-1100

1. According the temperature, choose matched QR code card (24°C±2°C, 28°C±2°C, 32°C±2°C) to perform calibration when necessary. (Details refer to LS-1100 User Manual)
2. On the main interface of LS-1100, press “Test” icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
3. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
4. Using pipette to deliver 5μL of sample (Due to the stickiness of the whole blood, it is necessary to slowly absorb the sample and the nozzle can be slightly touched by the interface of the whole blood, nozzle cannot be completely inserted, so as to avoid excessive blood sample sticking to the nozzle).
5. Deliver 5μL of sample into one tube of sample diluent. Slowly absorb and blow the pipette for 3 times for delivering sample completely. Mix gently and thoroughly. Let it stand for 60 seconds.
6. Drop 100μL of mixed fluid from the tube into the sample port in the test strip.
7. **Reaction Time: 5 minutes**

For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click “Test”.

For panel outside: After reaction time 5 minutes is elapsed, insert the test strip into the analyzer and then click “Test”.

8. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

Reference Range: 4%-6.5%

HbA1c concentration is determined using samples obtained from 180 apparently healthy individuals.

It is recommended that each laboratory establish its own reference range for the population it serves.

[INTERPRETATION OF RESULT]

1. If the test result of the sample is more than 14%, the analyzer displays ">14%", and if the result is less than 3%, the analyzer displays "<3%". Specific data can be exported through related software as needed.
2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 3 times when the sample is diluted with calf serum or negative sample.

[LIMITATION]

1. This kit is only for human whole blood.
2. The test result of this kit are only one of the diagnostic aids for the clinicians.
3. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.

[PRODUCT PERFORMANCE]

1. Measuring Range: 3%-14%.
2. Lower Detection Limit: ≤3%.
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.
6. Hook Test: No hook effect with high concentration sample.
7. Specificity: Take substances that are easily cross-reactive with HbA1c to test. Test after dilution as required, the negative specificity result is≤3%, positive specificity result is≥3%.

[PRECAUTIONS]

1. IVD Only used for in vitro diagnostics.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix the components of different kits.

[REFERENCES]

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3. Molnar GD. The management of the metabolism of diabetes in theclinic. Diabetes, 1978, 27:216-25.

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Production date and expiration see the label.

IVD	For in vitro diagnostic use only
REF	Catalog number
	Manufacturer
LOT	Lot number
EC REP	European Authorized Representative
	Date of Manufacture
	Use by date
	Consult instructions for use
	Store at 4-30°C
	Contents Sufficient for < n > Tests
	Do not reuse
	Keep away from sunlight
	Fragile handle with care
	Keep dry
	Forbidden to inversion