

HbA1c Test Kit (Dry Fluorescence Immunoassay) User Manual

[PRODUCT NAME]

HbA1c Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

5 Tests/Kit

25 Tests/Kit

[INTENDED USE]

HbA1c Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of HbA1c in human whole blood and fingertip 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 detects 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. Test strip in a foil pouch with desiccant
2. Sample diluent
3. User manual
4. QR code card for calibration
5. Plastic transfer pipette (Optional).
6. Alcohol pad (Optional).
7. Safety Blood Lancet (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 shelf life of 24 months.

Test strip should be used within 1 hour once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1100 Dry Fluorescence Immunoassay Analyzer
2. LS-2100 Dry Fluorescence Immunoassay Analyzer
3. LS-4000 Dry Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **whole blood** and **fingertip blood**. Other bodily fluids and samples may not get the accurate result.
2. 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. 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 diluent should be recovered to room temperature (22°C-34°C).
The 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

3. According to the temperature, choose the 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)
4. On the main interface of LS-1100, press the "Test" icon to enter the testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. Using a pipette to deliver 5µL of sample (Due to the stickiness of the whole blood and fingertip blood, it is necessary to slowly absorb the sample and the nozzle can be slightly touched by the interface of the whole blood and fingertip blood, the nozzle cannot be completely inserted, so as to avoid excessive blood sample sticking to the nozzle).
7. Deliver 5µL of sample into one tube of sample diluent. Slowly absorb and blow the pipette for 3 times to deliver the sample completely. Mix gently and thoroughly. Let it stand for 60 seconds.
8. Drop 100µL of mixed fluid from the tube into the sample port in the test strip.

9. Reaction Time: 5 minutes

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

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

10. 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.

[REFERENCE INTERVAL]

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]

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.

[LIMITATION]

1. The test is only for human whole blood and fingertip blood.
2. The test results 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. Linearity Range: 3%-14%, $r \geq 0.990$.
2. Limit of Blank: $\leq 3\%$.
3. Accuracy: Verify with comparison experiments, the relative deviation is within $\pm 15\%$.
4. Within-Run Precision: $\leq 15\%$.
5. Between-Run Precision: $\leq 15\%$.
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 $\leq 3\%$, positive specificity result is $\geq 3\%$.


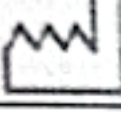



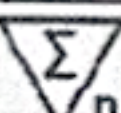




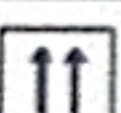
[PRECAUTIONS]

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]

1. Bunn HF. Non enzyme glycosyl compounds in protein: related to diabetes. 1981, 70:331-8.
2. Jovanovic L, Peterson CM. The clinical efficacy of sugar computerized red blood. AM J Med, 1981, 70:331-8.
3. Molnar GD. The management of the metabolism of diabetes in the clinic. Diabetes, 1978, 27:216-25.

[SYMBOL DESCRIPTION]

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

Revision Date: November 15th, 2025

Version Number: 1.7

Production date and expiration see the label.



QR code card (24°C±2°C)



QR code card (28°C±2°C)



QR code card (32°C±2°C)

Batch No.: 0422536



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