Glycosylated Hemoglobin (HbA1c) Quantitative Test Cassette (Quantum Dot Fluorescence Immunochromatography) Instruction For Use

CE IVD REF

In Vitro Diagnosis
For Professional Use

【Product Name】

Glycosylated Hemoglobin (HbA1c) Quantitative Test Cassette (Quantum Dot Fluorescence Immunochromatography)

【Package Specification】

25 tests/kit

【Intended Use】

This kit is used for the detection of Glycosylated Hemoglobin (HbA1c) levels in human whole blood, samples in vitro quantitatively.

For Professional Use Only.

【Test Principle】

The HbA1c Test Cassette is a fluorescent lateral flow immunoassay, which adopts a double antibody sandwich method to quantitatively detect the concentration of HbA1c in human whole blood,. The test consists of: 1) a probe conjugate pad containing anti-HbA1c monoclonal antibody conjugated with fluorescent microspheres (antibody probe conjugate) and a control antibody (goat anti-chicken IgY) conjugated with fluorescence microspheres, 2) a nitrocellulose membrane with immobilized antibodies in the test area (T line) and a control area (C line). The T line is pre-coated with another anti-HBA1C antibody, and the C line is pre-coated with a control line antibody (chicken IgY). The specimen to be tested is added to the sampling hole of the test card, as the liquid flows, specimen to be tested first passes through the sample pad and forms a fluorescent complex with the probe pad fixed with quantum dot-labeled antibodies. The complex passes through the detection line and quality control lines, specifically immunobind with the antibodies in the detection line and quality control line respectively, and are captured by the coating antibodies on the nitrocellulose membrane to present fluorescent bands.

Intensity of the fluorescence signal reflects the amount of captured HbA1c. The higher the concentration of HbA1c in the sample, the more accumulated complexes on the detection line, the higher signal intensity will be tested out. Use a fluorescence immunoassay analyzer to analyze the photoelectric values of the quality control line and detection line, then the analyzer calculates the concentration of HbA1c based on the calibration curve that has been preset inside the analyzer and displays the result in %.

【Main Material】

Main Material as below:

25 Test cassettes
25 Deliver pipettes
1 Bottle of diluent
25 Empty centrifuge tubes
1 ID Card
1 User Manual

Material Required but not Provided:

1. Timer, thermometer, hygrometer;

Note: Components of different batches of reagent kits cannot be used interchangeably to avoid incorrect results.

【Storage Conditions and Validity Period】

1. The test kit should be stored at 2~30°C, protected from light, and has a shelf life of 18 months.
2. The test cassette should be used within 1 hour after opening at a temperature of 10°C to 30°C and a humidity of 35% to 65%.

【Applicable Analyzer】

Dry fluorescence immunoassay analyzer GKYG-500 produced by Dezhou Guoke Medical Technology Co.，ltd.

【Specimen Requirement】

1. Applicable to human whole blood samples, samples shall be tested within the same day after collection; if the assay cannot be completed on the same day, the samples can be stored for 3 days under 2-8℃, freezing is prohibited.Before the experiment, the sample must be returned to room temperature (10℃~30℃) and mixed well before use. All specimens should be treated as infectious agents.
2. Whole blood samples can be anticoagulated with heparin, sodium citrate or EDTA
3. whole blood, specimens should be tested immediately, if not use, need to be stored at 2-8°C for no more than 4 hours. Repeated freezing and thawing should not occur more than 3 times. Frozen specimens should be thoroughly mixed after thawing.
4. If the sample contains particulate matter, it will affect the test results. Samples containing visible particles should be centrifuged and the supernatant should be taken for experiments.
5. Do not test samples from patients with hemolysis, lipemia and jaundice.
6. The specimen must be restored to 10~30℃ before testing. Frozen and preserved specimens must be completely thawed, rewarmed, and mixed evenly before use.

【Test Procedure】

1. When stored at low temperature, the test kit and diluent should be restored to 10~30℃ before use.
2. Turn on the analyzer according to the analyzer instruction manual.
3. Take out the ID card from the kit and read the ID card information at the card reading position of the fluorescence immunoassay analyzer.
4. Tear open the outer packaging, take out the test cassette, and place it flat on the operating table. The removed test cassette should be used within 1 hour.
5. Pipette 10 μL of sample, add to a tube of sample dilution, mix thoroughly, let stand for 3 min, take 100 μL of the mixture and add it vertically dropwise to the spiking hole of the test card.
6. Immediately insert the test cassette into the fluorescence immunoassay quantitative analyzer at 15 minutes of reaction, click the "Detect" button, the test results will automatically be displayed on the instrument screen, and the results can be saved and printed.
7. Used test cassettes should be treated as potentially biohazardous items.
8. Quality control:

1) C line is used as an indicator of the effectiveness of the test cassette, C line should appear in any cases.

2) The company's internal quality control products or other approved and applicable quality control products can be used to conduct quality control on the product. The test results should be within the specified quality control range.

Note: Test should be completed at a temperature of 10°C to 30°C and a humidity of 35% to 65%.

【Positive Judgment Value or Reference Interval】

Positive ≥6%, a positive result.
Negative <6%, a negative result.

The recommended reference interval for this cassette is 4.0% to 6.0%.

6%-8%, controllable level blood glucose > 8% poorly controlled blood glucose level.

The reference value is verified with reference to similar products on the market. Due to racial and regional differences, each laboratory can establish its own reference interval based on actual conditions.

【Interpretation of Test Results】

1. The accuracy of the sample amount will directly affect the accuracy of the test results.
2. Please check the integrity and expiration date of the kit package before use, then open the package. Low-temperature storage should be restored to 10~30℃ before opening the package for use. Direct use at low temperatures

will affect the test results.

【Limitations of Detection Method】

This kit is a fluorescence immunochromatography diagnostic kit and has inherent methodological limitations:

1. The test results can only be used as an auxiliary for doctors or other diagnoses and need to be combined with other clinical and laboratory data. If the test results are inconsistent with the clinical assessment, further examination is required.
2. Bilirubin ≤0.5mg/ml, triglycerides ≤10mg/ml, hemoglobin ≤5mg/ml would affect the test result, and the deviations are within ±10%.
3. The HOOK effect will not occur when the HbA1c concentration content in the sample is ≤20%.
4. If the sample test result shows more than 14%, it is recommended to dilute the sample with saline (the maximum dilution should not exceed 1:5), and the concentration value of the test obtained after the dilution should be calculated in accordance to the dilution ratio.

【Product Performance Indicator】

1. Appearance inspection: The product and outer packaging should be clean and smooth, with clear markings, complete components, and strong material attachment.
2. Migration speed: The liquid migration speed should not be less than 10mm/minute.
3. Linear range:
In the range of 3%～15%, the Correlation Coefficient(R) value should be ≥0.990.
4. Accuracy
Use company's internal control accuracy reference products (C1, C2) to test, and the test results should be within the following range:
1) Using company's internal control accuracy reference product C1:
concentration of 6.4% for testing, the analyzer's measurement range is concentration of 6.4%±15% at 15 minutes;
2) Using company's internal control accuracy reference product C2:
concentration of 8.4% for detection, the analyzer's measurement range is concentration of 8.4%±15% at 15 minutes;
5. Intra-Lot precision
Use the company's internal control precision reference materials (C9: concentration of 6.4%, C10: concentration of 8.4%) for 10 parallel tests each, and measure with the analyzer at 15 minutes. The concentration value variation coefficient CV ≤ 15%.
6. Inter-Lot precision
For the three batches of kits, the company's internal control precision reference materials (C9: concentration of 6.4%, C10: concentration of 8.4%) were tested 10 times in parallel. The analyzer measured the concentration value at 15 minutes, and the concentration value variation coefficient CV ≤ 15%.
7. Detection limit
Use the company's internal control detection limit reference product L1 to test, and measure with the analyzer at 15 minutes. The result should be ≤3%.
8. Specificity
Using the company's internal control specific reference materials (C3, C4, C5, C6, C7, C8) to detect, the measured values of the analyzer should be < 3% at 15 minutes.

【Precautions】

1. This kit is only for in vitro diagnosis, one-time use, please do not re-use.
2. The test kit should be treated as contain infectious material.
3. Please check the integrity and expiration date of the kit packaging before use.
4. Please read the instructions for use of this reagent and instrument carefully before any operation.
5. Please strictly follow the instructions. After the test starts, it cannot be stopped in halfway. If it is stopped halfway, the test cannot be resumed. If a retest is needed, use new reagents and retested.
6. Each batch of reagents has corresponding parameters in the supporting analyzer, and the manufacturer regularly updates the parameters in the analyzer. If the new batch of product reagents is not recognized by the analyzer, please contact the manufacturer in time to update the parameters.
7. The test cassette shall not be used after more than 1 hour after opening.
8. Reagents with different batch numbers cannot be mixed, and ID cards and test cassettes must not be used with mixed batch numbers.
9. The experimental environment should be avoided from being too high. Test cassettes stored at low temperature need to be returned to room temperature before opening to avoid moisture absorption.

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【Index of Symbols】

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Manufacturer:
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