

CDIA™ Hemoglobin A1c Immunofluorescence Test Cassette

Cat. No.: DTSJYJ069

Pkg. Size: 25T

Intended use

The CDIA™ Hemoglobin A1c Immunofluorescence Test Cassette is designed for quantitative determination of hemoglobin A1c in human whole blood.

General Description

Glycated hemoglobin is a form of hemoglobin that is measured primarily to identify the three-month average plasma glucose concentration. The test is limited to a three-month average because the lifespan of a red blood cell is four months (120 days). However, since RBCs do not all undergo lysis at the same time, HbA1C is taken as a limited measure of 3 months. It is formed in a non-enzymatic glycation pathway by hemoglobin's exposure to plasma glucose. HbA1c is a measure of the beta-N-1-deoxy fructosyl component of hemoglobin. In diabetes mellitus, higher amounts of glycated hemoglobin, indicating poorer control of blood glucose levels, have been associated with cardiovascular disease, nephropathy, neuropathy, and retinopathy. This kit is intended to use in quantitative detection of HbA1c content in human whole blood.

Principle of the Test

The test uses an anti-human HbA1c monoclonal antibody conjugated with fluorescence latex and another anti-human HbA1c monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human HbA1c monoclonal antibody binds with the HbA1c in sample and forms a marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human HbA1c monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of HbA1c in sample. Then insert test card into the Fluorescent Immunoassay Analyzer FIA7100. According to the ratio of the fluorescence intensity of control region and test region, the concentration of HbA1c in sample will be determined and displayed on the screen.

Reagents and Materials Provides

1. Hemoglobin A1c Test Cassette, 25T
2. Sample diluent buffer

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3. SD card: Calibration curve information card
4. One instruction

Sample preparation

This test can be used for whole blood samples. The test should be completed within 1 hour after blood collection.

1. The sample should be homogeneous by inversion before testing.
2. Deliver 5 µL homogeneous whole blood into the sample diluent buffer and mix well.

Assay operation

1. On the main interface of FIA7100, enter testing interface.
2. Read the SD card information.
3. Enter the sample number and other information.
4. Deliver 90 µL of sample into the sample port on the test card.
5. Insert the test card into FIA7100.
6. Reaction time: 10 minutes. The result will be shown on the screen.

Results

Read the result based on the FIA7100.

Limitation

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. It is possible that technical or procedural errors, as well as other interfering substances in the specimen may cause erroneous results.

Specificity

1. Limit of blank: 3% mg/L.
2. Accuracy: Factory inspection: In the quality control value range.
Type test: The recovery rate should be in the range of 85% to 115%.
3. Precision: Coefficient of Variation CV% ≤15%.
4. Linear range: 3%-15%, R ≥ 0.99.
5. Batch difference: The difference of three batches of the kits is not more than 15%.
6. Stability: After the validity period, the kit can also meet the above 1-4 indicators.

Storage

Store the test device at 4 to 30°C. The kit will be valid in 12 months.

Notice for Operations

1. Please do the assay following the instruction, don not touch the membrane of the strip.
2. This strip is used for only once. Please do not use it repeatedly.
3. Blood sample that can be seen by the naked eyes can interfere with the test and lead to erroneous result.
4. Insert the test card into FIA7100 immediately after delivering sample into the sample port.