CDIA™ Creatine Kinase MB Immunofluorescence Test Cassette

Cat. No.: DTSJYJ063
Pkg. Size: 25T

Intended use

The CDIA™ Creatine Kinase MB Immunofluorescence Test Cassette is designed for quantitative determination of creatine kinase MB in human serum, whole blood or plasma.

General Description

Creatine kinase is a dimer existing in three isoenzymic forms, depending on the particular combination of its subunits: BB(brain type);MM(skeletal type); and MB(hybrid type). Creatine kinase-MB isoenzyme is released into circulation later than myoglubin, reaching abnormal levels within 4 to 6 hours after onset of symptoms. It reaches its highest level after about 18 to 24 hours, and returns to normal in about 2 to 3 days. CK-MB is widely recognized as the traditional marker for the diagnosis of acute myocardial infarction (AMI). This kit is intended to use in quantitative detection of CK-MB content in human serum, plasma or whole blood.

Principle of the Test

The test uses an anti-human CK-MB monoclonal antibody conjugated with fluorescence latex and another anti-human CK-MB monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human CK-MB monoclonal antibody binds with the CK-MB 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 CK-MB monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of CK-MB 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 CK-MB in sample will be determined and displayed on the screen.

Reagents and Materials Provides

1. Creatine Kinase MB Test Cassette, 25T
2. Sample diluent buffer
3. SD card: Calibration curve information card
4. One instruction

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Sample preparation

This test can be used for serum, plasma and 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 130 μL homogeneous whole blood into the sample diluent buffer and mix well.
   Serum and plasma can be used directly.
3. Sample volume: Serum & plasma: 90 μL
   Whole blood: 130 μL

Note: Increase the amount of sample if extreme samples make it flow hard.

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 serum, plasma (90 μL) or whole blood (130 μL) 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: 0.32 ng/mL.
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%.

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4. Linear range: 0.32-80 ng/mL, 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.

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