CDIA™ Troponin I Immunofluorescence Test Cassette

Cat. No.: DTSJYJ062
Pkg. Size: 25T

Intended use

The CDIA™ Troponin I Immunofluorescence Test Cassette is designed for quantitative determination of cardiac troponin I (cTnI) in human serum, whole blood or plasma.

General Description

Cardiac troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22.5 kilodaltons. Together with troponin T (TnT) and troponin C (TnC), TnI forms a troponin complex in heart to play a fundamental role in the transmission of intracellular calcium signal actin-myosin interaction. The human cTnI has an additional amino acid residues on its N -terminal that are not exist on the skeletal forms thus making cTnI a specific marker for indicating cardiac infarction. cTnI is released rapidly into blood after the onset of acute myocardial infarction (AMI). Its release pattern is similar to CK-MB (4-6 hours after the onset of AMI). However, CK-MB level returns to normal after 36-48 hours, while levels of cTnI remains elevated for up to 6-10 days. The level of cTnI is very low in normal healthy people, and not detected in patients with skeletal muscle injury. Therefore, cTnI is a specific marker for diagnosis of AMI. This kit is intended to use in quantitative detection of cardiac troponin I content in human serum, plasma or whole blood.

Principle of the Test

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

Reagents and Materials Provides

1. Troponin I Test Cassette, 25T

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Tel: 631-624-4882 Fax: 1-631-938-8221
E-mail: info@creative-diagnostics.com
www.cd-diatest.com

2. Sample diluent buffer
3. SD card: Calibration curve information card
4. One instruction

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: 0.16 ng/mL.

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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% ≤10%.
4. Linear range: 0.16-32 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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