CDIA™ C-reactive Protein Immunofluorescence Test Cassette

Cat. No.: DTSJYJ068
Pkg. Size: 25T

Intended use

The CDIA™ C-reactive Protein Immunofluorescence Test Cassette is designed for quantitative determination of C-reactive protein in human whole blood.

General Description

CRP is a protein produced in response to inflammation and excessive deposits of cholesterol and fats in the liver and other tissues. The hs-CRP test accurately measures low levels of C-reactive protein to identify low but persistent levels of inflammation and thus helps predict a person's risk of developing CVD, heart attacks, and strokes. hs-CRP levels indicate an increased propensity for plaque disruption and/ or thrombosis. Levels of hs-CRP greater than 3 mg/l predict recurrent coronary events, thrombotic complications after angioplasty, poor outcome in the setting of unstable angina, and vascular complications after bypass surgery (CABG). It is also useful in determining whether or not more intensive treatment is warranted and in monitoring how well a patient is responding to lifestyle change and statin treatment. Measurement of hs-CRP should be done in patients free of infection or acute illness. This kit is intended to use in quantitative detection of CRP content in human serum, plasma or whole blood.

Principle of the Test

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

Reagents and Materials Provides

1. C-reactive Protein 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 homogeneous serum, plasma (5 μL) or whole blood (7.5 μL) into the sample diluent buffer and mix well.

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 90 μL of sample into the sample port on the test card.
5. Insert the test card into FIA7100.
6. Reaction time: 5 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: 0.5 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%.

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4. Linear range: 0.5-100 mg/L, 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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