



hs-CRP Fast Test Kit

(Immunofluorescence Assay)

Getein1100: Cat.# IF1003

Getein1600: Cat.# IF2003

User Manual

INTENDED USE

hs-CRP Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of C-reactive protein (CRP) in serum, plasma whole blood, or fingertip blood. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury and inflammatory disorders. Measurement of high sensitivity CRP (hs-CRP), when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes (ACS), may be useful as an independent marker of prognosis for recurrent events in patients with stable coronary disease or ACS.

SUMMARY

C-reactive protein is an acute-phase reactant that precipitated with Pneumococcal C-polysaccharide, and is a non-specific immune response component. CRP has wide distribution in our body, and is an acute-phase protein produced in the liver in response to microbic infection or tissue injury, and the hs-CRP can be used to detect lower concentrations of CRP in serum or plasma. Studies revealed hs-CRP levels seem to be correlated with Atherosclerosis and Acute Myocardial Infarction. And the hs-CRP is an inflammation "marker" for ACS patient and is helpful for primary prevention and risk assessment of cardiovascular disease. Its combination with the ratio of total cholesterol to HDL-C is more accurate than other risk factor in predicting cardiovascular disease.

The American Heart Association and US Centers for Disease Control and Prevention have advocated hs-CRP as a predictor of cardiovascular disease (CVD) to define risk groups: less than 1.0 mg/L indicates low risk, 1.0 to 3.0 mg/L means moderate risk, and the amount above 3.0 mg/L (lower than 10 mg/L) strongly suggests a high risk of CVD. Moreover, higher CRP levels are found in late pregnant women, mild inflammation and viral infections (10~40 mg/L), active inflammation, bacterial infection (40~200 mg/L), severe bacterial infections and burns

(>200 mg/L).

PRINCIPLE

The test uses an anti-human hs-CRP monoclonal antibody conjugated with fluorescence latex and another anti-human hs-CRP monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human hs-CRP monoclonal antibody binds with the hs-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 hs-CRP monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of hs-CRP in sample. Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of hs-CRP in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

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1. A kit for Getein1100 contains:

Getein hs-CRP test card in a sealed pouch with desiccant	25
Disposable pipet	25
Sample diluent	25
SD card	1
User manual	1

2. A kit for Getein1600 contains:

Sealed cartridge with 24/48 Getein hs-CRP test cards ..	2
User manual	1
<u>Package specifications:</u>	
2×24 tests/kit, 2×48 tests/kit	
<u>Materials required for Getein1600:</u>	
Sample diluent	1
Box with pipette tips	1
Mixing plate	1

3. Sample diluent composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

4. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human hs-CRP monoclonal antibody, the test line is coated

with another anti-human hs-CRP monoclonal antibody and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer

Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

Store the sample diluent/whole blood buffer at 0~30°C with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8°C for better results.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch or the cartridge is damaged.
5. Do not open pouches or the cartridge until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for *serum, plasma, whole blood and fingertip blood samples*. *Heparin, sodium citrate and EDTA* can be used as the anticoagulant for plasma, whole blood and fingertip blood. Samples should be free of hemolysis.

 Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.bio-GP.com.cn