PCT/CRP
Fast Test Kit
(Immunofluorescence Assay)

User Manual

REF IF1015 for Getein1100
IF2015 for Getein1600

INTENDED USE

PCT/CRP Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Procalcitonin (PCT) and C-reactive protein (CRP) in human serum, plasma or whole blood samples. The combination of CRP and PCT will be more accurately to determine the degree of infection and inflammation. It helps to identify systemic or local infection, bacterial infection or virus infection, determine the severity of infection and instruct clinical use of antibiotics. Therefore, the combination of PCT and CRP, when using a wider range of applications, more convenient and more accurate diagnosis.

SUMMARY

PCT is a peptide precursor of the hormone calcitonin, the latter being involved with calcium homeostasis. It is composed of 116 amino acids and is produced by parafollicular cells (C cells) of the thyroid and by the neuroendocrine cells of the lung and the intestine. Measurement of PCT can be used as a marker of severe sepsis and generally grades well with the degree of sepsis, although levels of PCT in the blood are very low. PCT has the greatest sensitivity and specificity for differentiating patients with systemic inflammatory response syndrome (SIRS) from those with sepsis.

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.

PCT compared with CRP, within 3-6 hours infection stimulation can be observed under the PCT continues to rise. In addition, CRP can occur in viral and bacterial diseases, while the PCT only in bacterial infections disease to appear. Thus, PCT is a diagnostic marker with fast and strong and specific characteristics. The combination of CRP and PCT, will be more accurately to determine the degree of infection and inflammation.

PRINCIPLE

Mixed anti-human PCT monoclonal antibody I and anti-human CRP monoclonal antibody I were conjugated with fluorescence latex and another set of anti-human PCT monoclonal antibody II , PCT polyclonal antibody, anti-human CRP monoclonal antibody II were coated on different test lines respectively. After the sample has been applied to the test strip, the fluorescence latex-labeled monoclonal antibodies binds with the PCT or 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 anti-human PCT monoclonal antibody II, PCT polyclonal antibody or anti-human CRP monoclonal antibody II. The fluorescence intensity of the test line increases in proportion to the amount of PCT/CRP in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100 and Getein1600), the concentration of PCT/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.

CONTENTS

1. A kit for Getein1100 contains:

Package specifications: 25 tests/box, 10 tests/box
1) PCT/CRP test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/box
4) SD card: 1 piece/box
5) Whole blood buffer: 1 bottle/box

2. A kit for Getein1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein PCT/CRP test cards
2) User manual: 1 piece/box

Materials required for Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box

3. Sample diluent/Whole blood buffer 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, fluorescence latex pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human PCT/CRP monoclonal antibodies, the test line is coated with other anti-human PCT/CRP monoclonal antibodies or anti-human PCT polyclonal 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. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow the manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma and whole blood*** samples. Heparin, sodium citrate and EDTA can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. ***SAMPLE VOLUME (for Getein1100): 100 µl***

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
4. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver ***100 µl*** of sample into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).
7. ***Reaction time: 15 minutes.*** Insert the test card into Getein1100 and press "ENT" button or click on “Start” icon (for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

8. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
9. Place the sample diluent at the correct position in Getein1600.
10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits for Getein1100.
2. It is suggested to calibrate once for one batch of kits for Getein1100.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/ Getein1600.

EXPECTED VALUE

The expected normal value for PCT was determined by testing samples from 318 apparently healthy individuals. The 99th percentile of the concentration for PCT is 0.10 ng/ml.

The table below comes from the research of ACCP/SCCM (American College of Chest Physicians /Society of Critical Care Medicine), showing the PCT value and its clinical meaning:

PCT concentration	Clinical significance
< 0.50 ng/ml	Local bacterial infection is possible, systemic infection (sepsis) is not likely.
≥ 0.50 and < 2.00 ng/ml	Systemic infection (sepsis) is possible, a moderate risk of severe sepsis and/or septic shock.
≥ 2.00 ng/ml	Systemic infection (sepsis) is likely, a high risk of severe sepsis and/or septic shock.

The expected normal value for CRP was determined by testing samples from 308 apparently healthy individuals. The 95th percentile of the concentration for CRP is 3.0 mg/L.

Research has shown that, CRP can assist diagnosis of cardiovascular disease, normal infection, tissue injury and inflammatory disease:

CRP concentration	Clinical significance
<1.0mg/L	Low risk of cardiovascular disease.
1.0~3.0mg/L	moderate risk of cardiovascular disease.
3.0~10.0mg/L	high risk of cardiovascular disease.
10.0~20.0mg/L	Viral or bacterial infection
20.0~50.0mg/L	General bacterial infection
>50.0mg/L	serious bacterial infection

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

	Measuring Range	Lower Detection Limit	Within-Run Precision	Between-Run Precision
PCT	0.10ng/ml~50.00ng/ml	≤0.10ng/ml	≤ 10%	≤ 15%
CRP	0.5mg/L~200.0mg/L	≤0.5mg/L		

Method Comparison:

The assay was compared with Roche E170 automatic immunoassay system and its matching PCT test kits with 200 serum samples. The correlation coefficient (r) for PCT is 0.984.

The assay was compared with Olympus AU5400 and Nanopia CRP of Sekisui Medical with 200 serum samples. The correlation coefficient (r) for CRP is 0.985.

LIMITATIONS

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. Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5.0 g/L	25.0 g/L	0.1 g/L

REFERENCES

1. Simon P, Milbrandt EB, Emlet LL. Procalcitonin-guided antibiotics in severe sepsis. Crit Care. 2008, 12(6): 309.
2. Simon L, Gauvin F, Amre DK et al. Serum procalcitonin and C-reactive protein levels as markers of bacterial infection: a systematic review and meta-analysis. Clin Infect Dis. 2004, 39(2): 206-217.
3. Schuetz P, Albrich W, Mueller B. Procalcitonin for diagnosis of infection and guide to antibiotic decisions: past, present and future. BMC Med. 2011, 9: 107.
4. Paul M Ridker. C-Reactive Protein: A Simple Test to Help Predict Risk of Heart Attack and Stroke. Circulation [J]. 2003, 108: e81-e85
5. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
6. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on PCT/CRP Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2016/ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged
REF	Catalogue number		

Thank you for purchasing PCT/CRP Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

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