PCT/CRP
Fast Test Kit
(Immunofluorescence Assay)

IF2015 for Getein 1600
IF1015 for Getein 1100
IF4015 for Getein 1200
IF3015 for Getein 1180
IF5015 for Getein 1160

REF

Instructions for Use

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

PCT/CRP Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After the sample has been applied to the test strip, the fluorescence latex-labelled PCT and CRP monoclonal antibody binds with the PCT and CRP in sample and forms a marked antigen-antibody complex. The complexes move to the test card detection zone by capillary action and are captured on the test line by another PCT and CRP polyclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of PCT and CRP in sample. Fluorescent signals intensity can be analyzed by applicable device thus the PCT and CRP in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
PCT/CRPtest card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10*0.14 mL/tube	25*0.14 mL/tube	1 bottle	1 bottle
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*PCT/CRP test card
A test card consists of: Fluorescence latex-labelled PCT and CRP monoclonal antibody, PCT polyclonal antibody, CRP polyclonal antibody and polyclonal IgG antibody.
** Sample diluent
(1) Sample diluent for Getein 1100/ Getein 1160/ Getein 1180 is 0.14mL contained in each tube consists of:
--Sample diluent main contains phosphate buffer (20 mmol/L), NaN_3 (＜0.1%).
(2) Sample diluent for Getein 1200/ Getein 1600 is an independent packing box consists of:
-Sample diluent main contains phosphate buffer (20 mmol/L), NaN3 (＜0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),
-Box with pipette tips (96 tips/box),
-Mixing plate (1 piece/box).

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.
Use the test card for Getein 1100/1160/1180 within 1 hour once the foil pouch is opened.
For test card of Getein 1600/1200: 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.

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 instructions for use 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. 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).
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME (for Getein 1100/1160/1180): ***20 μL***

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

<u>For Getein 1100:</u>

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.

2. Select the corresponding “Sample” on the analyzer according to the sample type (see the instructions of analyzer for details).
3. Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4. Use disposable pipet or pipette, deliver 20 μL of sample into one tube of sample diluent, mix thoroughly. Then drop 100 μL of sample mixture into the sample well on the test card.
5. ***Reaction time: 15 minutes***. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button or click on “Start” icon. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

1. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
2. Select the corresponding “Sample” on the analyzer according to the sample type (see the instructions of analyzer for details).
3. Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4. Use disposable pipet or pipette, deliver 20 μL of sample into one tube of sample diluent, mix thoroughly. Then drop 100 μL of sample mixture into the sample well on the test card.
5. Insert the test card into Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (***15 minutes***) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein1200/Getein1600:

1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position in Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/Getein 1600 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 Getein 1100/1180/1160.
2. It is suggested to calibrate once for one batch of kits for Getein 1100/1180/1160.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the instructions for use of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

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		

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. Interferents in samples 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 ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *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/ European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

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

Please read this instructions for use carefully before operating to ensure proper use.

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