Finecare™

PCT Rapid Quantitative Test

Catalog No. W210

INTENDED USE

The Finecare™ PCT Rapid Quantitative Test is a fluorescence immunoassay used along with Finecare™ FIA System (Model No.: FS-112/FS-113/FS-205) for quantitative determination of Procalcitonin (PCT) in human whole blood, serum or plasma.
This test is used as an aid to diagnosis severe, bacterial infection and sepsis.

For in vitro diagnostic use only. For professional use only.

SUMMARY

Procalcitonin (PCT) is a small protein, which comprises 116 amino acid residues with a molecular weight of approximately 13 kDa ,was first described by Moullec et al. in 1984. It is the prohormone of calcitonin. Whereas calcitonin is only produced in the C cells of the thyroid gland as a result of hormonal stimulus, PCT is secreted by different types of cells from numerous organs in response to proinflammatory stimulation, particularly bacterial stimulation. The diagnostic value of PCT is important due to the close correlation between PCT concentration and the severity of inflammation. It was shown that “inflammatory” PCT is not produced in C-cells. Cells of neuroendocrine origin are presumably the source of PCT during inflammation.

Sepsis is an excessive reaction of the immune system and coagulation system to an infection. It has been proven that PCT levels increase precociously, specifically in patients with a bacterial infection. For laboratory diagnosis, PCT is therefore an important marker enabling specific differentiation between a bacterial infection and other causes of inflammatory reactions.

PRINCIPLE

The Finecare™ PCT Rapid Quantitative Test is based on fluorescence immunoassay technology. The Finecare™ PCT Rapid Quantitative Test uses a sandwich immunodetection method. When sample is added into the sample well of the Test Cartridge, the fluorescence-labeled detector PCT antibodies on the sample pad bind to PCT antigens in blood specimen and they form immune complexes. As the complexes migrate on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibodies and PCT are captured to PCT antibodies that have been immobilized on test strip. Thus the more PCT antigens in blood specimen, the more complexes accumulated on test strip. Signal intensity of fluorescence of detector antibodies reflect the amount of captured PCT.

PRECAUTIONS

1. This kit is for *in vitro* diagnostic use only. Do not swallow.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Don’t use Test Cartridge if its lot # does not match with ID Chip # that is inserted onto the instrument.
5. The Finecare™ PCT Rapid Quantitative Test kit is only operational in the Finecare™ FIA system. And tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample(s) is taken by qualified medical personnel.
6. The Test Cartridge should remain in its original sealed pouch until ready to use. Do not use the Test Cartridge if the pouch is punctured or not well sealed. Discard after single use.
7. The Test Cartridge and system should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may introduce minute vibration, which should be regarded normal.
8. Use separate clean pipette tips and detection buffer vials for different specimens. The pipette tips and detection buffer vials should be used for one specimen only. Discard after single use.
9. Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
10. Blood specimens, used Test Cartridges, pipette tips and detection buffer vials are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
11. The Finecare™ PCT Rapid Quantitative Test should not be used as absolute evidence for diagnosis severe, bacterial infection and sepsis . The results should be interpreted by the physician along with clinical findings and other laboratory test results.
12. The test will be applied on a routine basis and not in emergency situations.

MATERIAL

Material Provided

Components of Finecare™ PCT Rapid Quantitative Test:

● Test Cartridge in a sealed pouch with desiccant	25
● ID Chip	1
● Detection Buffer	25
● Pipette Tip	25
● Leaflet with Instructions for Use	1

Material Required But Not Provided

- Finecare™ FIA System
- Transfer Pipette Set (100 µL size)
- Specimen Collection Containers
- Centrifuge (for serum/plasma specimen only)
- Timer

STORAGE AND STABILITY

1. Store the test kit at 4 ºC~30 ºC up to the expiration date printed on package.
2. If removed from refrigerator, allow the test kit for 30 minutes to return to room temperature before testing.
3. Do not remove the Test Cartridge from the pouch until use. The Test Cartridge should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with either serum or plasma or whole blood.

For Whole Blood Collected by Venipuncture:

1. According to standard phlebotomy procedure, collect a venipuncture whole blood specimen with a blood collection tube which contains suitable anticoagulant. (EDTA, Heparin, Sodium Citrate)
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged period. If the specimens are not tested immediately, they should be kept at 2 ºC～8 ºC.
3. It is not suitable to test the whole blood specimen which have been kept at 2 ºC～8 ºC for more than 2 days.

For Serum and Plasma:

1. According to standard phlebotomy procedure, collect a venipuncture whole blood specimen. If you need to collect plasma, use a blood collection tube which contains suitable anticoagulant (EDTA, Heparin, Sodium Citrate).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis. Test should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged period. Specimens should be kept at 2 ºC~8 ºC for up to 7 days. For long time storage, specimens should be kept below -20 ºC.

Note: Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolytic specimens can be used.

TEST PROCEDURE

For complete information and operating procedures, please refer to Finecare™ FIA System Operation Manual. Test should be performed at room temperature.

Step 1: Preparation

Before testing, activate “use” in setting then save it.
Ensure that the lot number of the Test Cartridge matches ID Chip as well as the Detection Buffer. Insert ID Chip into Finecare™ FIA System.

Step 2: Sampling

Draw 75 µL of whole blood or 50 µL serum or plasma with a transfer pipette and add into the Detection Buffer tube.

Step 3: Mixing

Close the lid of Detection Buffer tube and mix the sample mixture thoroughly by shaking it about 10 times.

Step 4: Loading

Pipette 75 µL of sample mixture and load it into the sample well of the Test Cartridge.

Step 5: Testing

There are two test modes for Finecare™ FIA System, Standard Test mode and Quick Test mode. Please refer to the Operation Manual of Finecare™ FIA System

for details.

a) **For Standard Test mode:** Insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA System right after adding sample mixture to the sample well. Press "**Test**" to start testing. (Apply to FS-112, FS-113 and FS-205)

b) **For Quick Test mode:** Set the timer and count down right after adding sample mixture into the sample well and leave it at room temperature for 15 minutes. Then insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA System. Press "**Test**" to start testing. Finecare™ FIA System will start scanning the sample-loaded Test Cartridge immediately. (Apply to FS-112 and FS-113)

Results are displayed on main screen or be printed by press "**Print**".

Discard the used Test Cartridge according to local regulations and procedures after released from Finecare™ FIA System.

INTERPRETATION OF RESULTS

The Finecare™ FIA system calculates PCT test results automatically and displays the exact concentrations of PCT on the screen as form of XXX.XX ng/mL. For further information, refer to the Operation Manual for the Finecare™ FIA system.

Concentration	Clinical Reference
＜0.5 ng/mL	A Partial Bacterial Infection or Viral Infection, except for Systemic Infection.
0.5~2.0 ng/mL	There may be Systemic Infection and moderate risk of Severe Systemic Infection
2.0~10.0 ng/mL	There may be Systemic Infection and high risk of Severe Systemic Infection
＞10 ng/mL	Severe Systemic Infection

Note: Recommend that each laboratory formulates its own reference range according to actual situation.

QUALITY CONTROL

Each Finecare™ PCT Rapid Quantitative Test Cartridge contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the Test Cartridge was inserted and read properly by Finecare™ FIA system. An invalid result from the internal control causes an error message on Finecare™ FIA system indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human whole blood, serum, plasma specimen only.
2. The test procedure, precautions and interpretations of results for this test must be followed when testing.
3. The results of Finecare™ PCT Rapid Quantitative Test should be evaluated with all available clinical and laboratory data.
4. The false positive results include cross-reactions with some components of serum from individual to antibodies; and non-specific adhesion of some components in human blood that have similar epitopes to capture and detector antibodies. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of PCT antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.
5. Other factors may interfere with Finecare™ PCT Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparative study is tested for 81 clinical samples in using Finecare™ PCT Rapid Quantitative Test and Roche PCT reagent kit.
The Correlation Coefficient (R^2) is 0.9644.

Assay Range and Detection Limit

- **Assay Range:** 0.1~100 ng/L
- **Detection Limit (Analytical Sensitivity):** 0.1 ng/mL

Cross-Reactivity

The following substances do not interfere with the test results at the indicated concentrations: bilirubin at 2.0 mg/mL, cholesterol at 15.0 mg/mL and triglycerides at 30.0 mg/mL.

Linearity

A serial concentration of PCT controls at 0.5 ng/mL, 2.0 ng/mL 5.0 ng/mL, 10.0 ng/mL, 50.0 ng/mL, 100.0 ng/mL were each tested for three times, the Correlation Coefficient (R) is ≥ 0.990.

Precision

Intra-Lot Precision
Within-run precision has been determined by using 10 Test Cartridges of same batch to test with PCT controls. C.V. is ≤ 15%.

Inter-Lot Precision
Between-run precision has been determined by using 3 Test Cartridges of 3 random and continuous batches to test with PCT controls. C.V. is ≤15%.

BIBLIOGRAPHY OF SUGGESTED READING

1. Le Moullec JM, et al., The complete sequence of human procalcitonin, FEBS Letters 1984 167(1), 93-97.
2. DANDONA P. et al., Procalcitonin increase after endotoxin injection in normal subjects, JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM 1994 79(6) 1605-1608.
3. American College of Chest Physicians/Society of Critical Care Medicine, Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis, Crit Care Med 1992 20: 864-874.
4. CHRIST-CRAIN M. et al., Effect of procalcitonin-guided treatment on antibiotic use and outcome in lower respiratory tract infections : cluster-randomised singleblinded intervention trial, LANCET 2004 363(9409) 600- 607.

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INDEX OF SYMBOLS

See Instruction for Use	Tests per Kit	Manufacturing Date
In Vitro Diagnostic Use	Expiry Date	Do not reuse
Store between 4～30℃	Batch Number	Catalog #
Keep away from Sunlight	Keep Dry	Authorized Representative
Manufacturer		

Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District,
510663, Guangzhou, P.R. China

Qarad b.v.b.a.
Cipalstraat 3
B-2440 Geel, Belgium

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