Finecare™ PCT (Procalcitonin) Rapid Quantitative Test

Catalog No. W210

INTENDED USE

The Finecare™ PCT (Procalcitonin) Rapid Quantitative Test along with Finecare™ FIA Meter is a fluorescence immunoassay for quantitative measurement of Procalcitonin (PCT) in human whole blood, serum or plasma.

-Fluorescence immunoassay
-Diagnosis and control the treatment of 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.

Normal Reference Value: ＜0.5 ng/mL

Concentrations	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

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 to the sample well of the test, the fluorescence-labeled detector anti-PCT antibody binds to PCT antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and PCT are captured to anti-PCT antibody that has been immobilized on test strip. Thus the more PCT antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of PCT captured and Finecare™ FIA Meter shows PCT concentrations in blood specimen. The default results unit of Finecare™ PCT Rapid Quantitative Test is displayed as XXX ng/mL from Finecare™ FIA Meter. The working range and the detection limit of the PCT Test system are 0.1～100 ng/mL and 0.1 ng/mL, respectively.

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 Meter. 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 Meter 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 detector buffer vials for different specimens. The pipette tips and detector 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 detector 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 congestive heart failure. 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

Test Cartridge	25
Test Cartridge ID Chip	1
Detector buffer	25

Leaflet with instructions for use

Material Required But Not Provided

1. Finecare™ FIA Meter
2. Transfer Pipette Set (100 μL size)
3. Alcohol Pads
4. Centrifuge (for Plasma/Serum only)
5. Timer

STORAGE AND STABILITY

1. Store the detector buffer at 4～30℃. The buffer is stable up to 24 months.
2. Store Finecare™ PCT Rapid Quantitative Test Cartridge at 4～30℃, shelf life is up to 24 months.
3. Test Cartridge should be used within 1 hour after opening the pack.

SPECIMEN COLLECTION AND PREPARATION

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

For Whole Blood Collected by Venipuncture:
1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (EDTA recommended)
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2℃～8℃.
3. It’s not suitable to test the whole blood samples which have been stored at 2℃～8℃ for more than 2 days.

For Serum and Plasma:
1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
3. Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2℃～8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

TEST PROCEDURE

Refer to Finecare™ FIA Meter Operation Manual for the complete instructions on use of the Test. The test should be operated in room temperature.
Step1: Preparation
Check/insert ID Chip into the equipment.
Step2: Sampling
Draw 75μL of whole blood or 50μL of plasma/serum with a transfer pipette and

add it to the buffer tube.

Step3: Mixing

Mix well the specimen with buffer for 1 minute by tapping or inverting the tube.

Step4: Loading

Take 75μL of sample mixture and load it onto the sample well of the Test Cartridge.

Step5: Testing

1.Finecare™ FIA meter:

Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click “Test”. 15 minutes later, the result will show in the display and print out when click “Print”.

Quick test: Put the Test Cartridge on the operation platform. 15 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click “Test”. The result will show in the display and print out when click “Print”.

2.Finecare™ multi-channel FIA meter:

Insert the Test Cartridge onto the Test Cartridge Holder. 15 minutes later, the result will show in the display and print out when click “Print”.

Please refer to the **Operation** in user manual of Finecare™ FIA Meter for details.

QUALITY CONTROL

Each Finecare™ PCT Rapid Quantitative Test Cartridge contains internal control that satisfies routing 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 Meter. An invalid result from the internal control causes an error message on Finecare™ FIA Meter 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 results of Finecare™ PCT Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If PCT test results do not agree with the clinical evaluation, additional tests should be performed.
3. 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.
4. 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. Plasma using anticoagulants (e.g. heparin or citrate) other than EDTA has not been evaluated in Finecare™ PCT Rapid Quantitative Test and thus should not be used.
6. 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 comparison study using 201 human blood samples, PCT concentrations ranging from 0.00 ng/mL to 36.79 ng/mL, demonstrated good correlation with a commercially available kit.

Comparison between the Finecare™ PCT Rapid Quantitative Test and the VIDAS® B•R•A•H•M•S PCT (PCT) for the 201 clinical samples, the Correlation Coefficient is 0.997.

Assay Range and Detection Limit

- **Assay Range:** 0.1～100 ng/mL
- **Detection Limit:** 0.1 ng/mL

Cross-Reactivity

Do not interfere for:

bilirubin	≤2 mg/mL
cholesterol	≤15 mg/mL
triglycerides	≤30 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 replicates of specimen containing 5.0 ng/mL PCT. C.V. is ≤ 15%.

Inter-Lot Precision

Between-run precision has been determined by using 3 replicates for each of three lots using PCT specimen levels at 5.0 ng/mL PCT. 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 trea™ent on antibiotic use and outcome in lower respiratory tract infections : cluster-randomised singleblinded intervention trial, LANCET 2004 363(9409) 600- 607.

IVD	in vitro Diagnostic Use		See Instruction for Use		Expiry Date
Σ 25	Tests per Kit		Manufacturing Date		Keep Dry
LOT	Batch Number	EC REP	Authorized Representative		Keep away from Sunlight
4°C 30°C	Store between 4～30℃				