diagnosticare

PCT Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF FI-PCT-402	English

A test for the diagnosis of inflammatory condition by measuring Procalcitonin (PCT) in whole blood, serum or plasma with the use of Fluorescence Immunoassay Analyzer.

【INTENDED USE】

The PCT Test Cassette (Whole Blood/Serum/Plasma) is based on Fluorescence immunoassay for the quantitative detection of human Procalcitonin in whole blood, serum or plasma as an aid in the diagnosis of inflammatory conditions.

【SUMMARY】

Procalcitonin (PCT) is a small protein that comprises 116 amino acid residues with a molecular weight of approximately 13 kDa which was first described by Moullec et al. in 1984. PCT is produced normally in C-cells of the thyroid glands. In 1993, the elevated level of PCT in patients with systemic infection of bacterial origin was reported and PCT is now considered to be the main marker of disorders accompanied by systemic inflammation and sepsis. 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.

【PRINCIPLE】

The PCT Test Cassette (Whole Blood/Serum/Plasma) detects PCT based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains Procalcitonin, it attaches to the fluorescent microspheres-conjugated anti-procalcitonin antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of PCT in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of PCT in the sample can be calculated by Analyzer to show PCT concentration in specimen.

【REAGENTS】

The test includes anti-Procalcitonin antibody coated fluorphores and anti-Procalcitonin antibody coated on the membrane.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse..
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The PCT Test Cassette should only be used with the Analyzer by approved medical professionals.

【STORAGE AND STABILITY】

1. The test should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the test from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

【SPECIMEN COLLECTION AND PREPARATION】

Blood Sample Taking

1. Collect the specimen according to standard procedures.
   - To collect Fingerstick Whole Blood specimens:
     - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
     - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
     - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
     - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
2. Do not leave specimens at room temperature for prolonged periods. Serum and Plasma specimens may be stored at 2-8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be used within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA, Heparin sodium can be used as the anticoagulant tube for collecting the blood specimen.

Sample Dilution / Sample Stability

1. Transfer 75 µL of serum/plasma/whole blood to the buffer tube with the micro pipette.
2. Close the tube and shake the sample by hand vigorously for approximately **10seconds** to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately **1 minute**. The sample can then be used immediately or stored for up to 8 hours.

【MATERIALS】

Materials Provided

•Test Cassettes	• Specimen collection tubes with buffer
•ID Card	• Package Insert
• Droppers	• Lancets

Materials Required But Not Provided

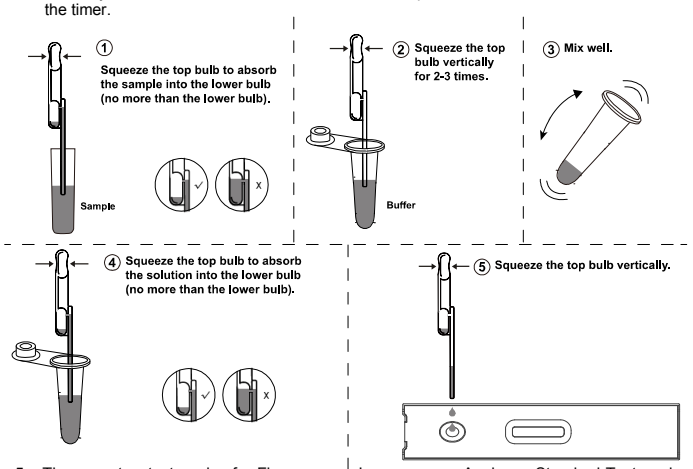
•Timer	•Centrifuge	• Fluorescence Immunoassay Analyzer
• Pipette	•Specimen Collection Containers	

【DIRECTIONS FOR USE】

Refer to Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the analyzer. The test should be in room temperature.

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyzer power. Then according to the need, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyzer ID Card Slot.
3. **To use a pipette**: Pipette **75µL of sample** into the buffer tube; mix the specimen and the buffer well.
   To use a dropper: Immerse the tube end into the sample; squeeze the top bulb to absorb the sample into the lower bulb (no more than the lower bulb). Then release the sample into the buffer tube by squeezing the bulb at the top end of the dropper vertically. Wash the tube 2-3 times by squeezing the top bulb. Mix the sample and the buffer well.
4. **To use a pipette**: Pipette **75 µL of diluted specimen** into the sample well of the cassette. Start the timer at the same time.
   To use a dropper: Immerse the tube end into the diluted sample; squeeze the top bulb to absorb the solution into the lower bulb (no more than the lower bulb). Squeeze the top bulb vertically to release the diluted solution into the sample well of the test cassette and start the timer.



5. There are two test modes for Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of Fluorescence Immunoassay Analyzer for details.

"Quick test" mode : After **15 minutes** of adding sample , Insert the test cassette into the Analyzer and click "**QUICK TEST**", fill the test information and click "**NEW TEST**" immediately. The Analyzer will automatically give the test result after a few seconds.

"Standard test" mode : Insert the test cassette into the Analyzer immediately after adding specimen, click "**STANDARD TEST**", fill the test information and click **"NEW TEST"** at the same time. The Analyzer will automatically countdown **15 minutes**. After the countdown, the Analyzer will give the result at once.

【INTERPRETATION OF RESULTS】

Results read by Fluorescence Immunoassay Analyzer.

The result of tests for PCT is calculated by Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyze.

Linearity range of PCT is 0.1-50 ng/mL.

Reference range: ＜0.1ng/mL.

【QUALITY CONTROL】

Each PCT Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was inserted and read properly by Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on Fluorescence Immunoassay Analyzer indicating that the test should be repeated.

【LIMITATIONS】

1. The PCT Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of procalcitonin.
2. The PCT Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of PCT antigen in the specimen and should not be used as the sole criteria for evaluating inflammatory conditions.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of PCT may lead to hook effects, resulting in incorrect interpretation of PCT levels.
5. The results of PCT Tests are based on measuring the levels of Procalcitonin in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

【EXPECTED RESULTS】

Concentrations	Expected Clinical Conditions
＜0.1 ng/mL	Normal Condition
0.1-0.5 ng/mL	Local inflammation or infection is possible but a low risk for progression to systemic inflammation response
0.5-2.0 ng/mL	High possibility of Systemic inflammatory response
2.0-10 ng/mL	Systemic inflammatory response associated with infection
>10 ng/mL	Progressing on severe sepsis or septic shock

【PERFORMANCE CHARACTERISTICS】

1. Accuracy

The test deviation is≤±15%.

2. Assay Range and Detection Limit

- Assay Range: 0.1 – 50 ng/mL
- Minimum Detection Limit (Analytical Sensitivity): 0.1 ng/mL

3. Linearity range

0.1~50 ng/mL , R≥0.990

4. Precision

CV≤15%

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 0.5 ng/mL, 2.0 ng/mL of PCT. C.V. is ≤15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 0.5 ng/mL, 2.0 ng/mL of PCT. C.V. is ≤15%.

5. Method comparison

The assay was compared with PCT Test of ET healthcare Co.,Ltd with 110 samples. The correlation coefficient(r) is 0.981.

【BIBLIOGRAPHY】

1. Le Moullec JM, et al. (1984) The complete sequence of human procalcitonin. FEBS Letters 167(1), 93-97.
2. Assicot M, et al. (1993) High serum procalcitonin concentrations in patients with sepsis and infection. Lancet 341(8844), 515-518.
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5. Meisner M, (2002) Pathobiochemistry and clinical use of procalcitonin. Clin Chim Acta 323, 17-29.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	4°C 30°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		

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Statement: Information about manufacturer of Lancet is placed on the label.
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Number: F145107500
Revision date: 2022-09-23