

PCT FIA Rapid Test Device

(Whole Blood/Serum/Plasma)

F12-PCT-001

A rapid test for the diagnosis of inflammatory conditions by measuring Procalcitonin (PCT) in whole blood, serum, or plasma with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000). For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda PCT FIA Rapid Test Device is intended for *in vitro* quantitative determination of human Procalcitonin (PCT) 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 Biopanda PCT FIA Rapid Test Device detects PCT based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains PCT, it attaches to the fluorescent microspheres-conjugated anti-PCT 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 product standard curve, the concentration of PCT in the sample can be calculated by the Biopanda Fluorescence Immunoassay Device to show PCT concentration in specimen.

REAGENTS

The test kit includes anti-PCT antibody coated fluorophores and anti-PCT 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 Biopanda PCT FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) by approved medical professionals.

STORAGE AND STABILITY

1. The kit 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 kit from contamination. 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.

KIT COMPONENTS

- 25 x foil wrapped PCT Rapid Test Devices
- 25 x Specimen collection tubes with dilution buffer
- 1 x ID card (PCT)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION

1. Before performing the test, please make sure that all components are brought to room temperature (15-30°C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it. Open the screw cap.

BLOOD SAMPLE COLLECTION

1. Collect the specimen according to standard procedures.
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 1 day, 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 run within half-day 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 K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

SAMPLE DILUTION / SAMPLE STABILITY

1. The specimen (75 µl of whole blood/50 µl serum or plasma) can be added directly with the micro pipette into the buffer.
2. Close the tube and shake the sample by hand vigorously for approximately 10 seconds to mix the sample and dilution buffer.
3. Let the diluted sample rest for approximately 1 minute.
4. The sample can then be used immediately or stored at 2-8°C for up to 8 hours.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the Test. The test should be conducted at room temperature.

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

1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. **Serum/plasma:** Transfer 50 µl of serum/plasma into the buffer tube, mix the specimen and the buffer well.
Whole blood: Transfer 75 µl of whole blood into the buffer tube with pipette; mix the specimen and the buffer thoroughly.
4. **Add diluted specimen with a Pipette:** Pipette 75 µl of diluted specimen into the sample well of the test Device. Start the timer at the same time.
5. There are two test modes for the Biopanda Fluorescence Immunoassay Device; Standard Test mode and Quick Test mode. Please refer to the user manual of the Biopanda Fluorescence Immunoassay Device for details.

"Quick test" mode: Insert the test device into the Analyser at 15 minutes after sample application and click "New Test", the Analyser will automatically give the test result after a few seconds.

"Standard test" mode: Insert the test device into the Analyser immediately after sample application, click "New Test" at the same time, the Analyser will automatically count down the 15 minutes. After the countdown, the Analyser will give the result at once.

INTERPRETATION OF RESULTS

The result of tests for PCT is calculated by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) and displays the result on the screen. For

additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Device.

Linearity range of the Biopanda PCT FIA Rapid Test Device is 0.1-50 ng/ml.
Reference range: <0.1ng/ml

QUALITY CONTROL

Each Biopanda PCT FIA Rapid Test Device contains an 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 device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an error message on the Biopanda Fluorescence Immunoassay Device indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on the Biopanda Fluorescence Immunoassay Device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Biopanda PCT FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of PCT.
2. The Biopanda PCT FIA Rapid Test Device will only indicate the presence of PCT antigen in the specimen and should not be used as the sole criterion 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 produce a dose hook effect, resulting in incorrect interpretation of PCT levels.
5. The results of the Biopanda PCT FIA Tests are based on measuring the levels of PCT 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	Clinical Reference
<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 $\leq \pm 15\%$.
2. **SENSITIVITY:** The Biopanda PCT FIA Test Device can detect levels of PCT as low as 0.1 ng/ml in whole blood, serum or plasma.
3. **DETECTION RANGE:** 0.1~50 ng/ml
4. **LINEARITY RANGE:** 0.1~50 ng/ml, $R \geq 0.990$
5. **PRECISION**
C.V. is $\leq 15\%$.

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 $\leq 15\%$.

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 $\leq 15\%$.

6. METHOD COMPARISON











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

REFERENCES

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.
3. Meisner M and Reinhart K (2001) Is procalcitonin really a marker of sepsis? Int J Intensive Care 8(1), 15-25.
4. Sponholz C, et al. (2006) Diagnostic value and prognostic implications of serum procalcitonin after cardiac surgery: a systematic review of the literature. Critical Care 10, R145.
5. Meisner M, (2002) Pathobiochemistry and clinical use of procalcitonin. Clin Chim Acta 323, 17-29.

Index of Symbols

	Manufacturer		Tests per kit		Do not reuse test
	<i>In vitro</i> diagnostic medical device		Expiration date		Catalogue number
	Store between 4-30°C		Lot Number		Consult instructions for use
	Do not use if package is damaged				

Thank you for purchasing Biopanda's PCT FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.



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