



INSTRUCTION FOR USE

Procalcitonin TEST, WB/S/P

Procalcitonin Detection in
(Whole Blood/Serum/Plasma)

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: TPCT02

BACKGROUND INFORMATION

Procalcitonin 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. Procalcitonin is produced normally in C-cells of the thyroid glands. In 1993, the elevated level of Procalcitonin in patients with a system infection of bacterial origin was reported and Procalcitonin is now considered to be the main marker of disorders accompanied by systemic inflammation and sepsis. The diagnostic value of Procalcitonin is important due to the close correlation between Procalcitonin concentration and the severity of inflammation. It was shown that "inflammatory" Procalcitonin is not produced in C-cells. Cells of neuroendocrine origin are presumably the source of Procalcitonin during inflammation.

INTENDED USE

The Procalcitonin Test (Whole Blood / Serum / Plasma) is a rapid chromatographic immunoassay for the semi-quantitative detection of Procalcitonin in whole blood, serum or plasma.

REAGENTS

The test cassette contains gold particles conjugated with anti-Procalcitonin antibody, and anti-Procalcitonin antibody coated on the membrane.

METHOD

The Procalcitonin (Whole Blood/Serum/Plasma) is a semi-quantitative, lateral flow immunoassay for the detection of Procalcitonin in Whole Blood, serum or plasma. The membrane is pre-coated with anti-Procalcitonin antibody on the test line region. During testing, the Whole Blood, serum or plasma specimen reacts with the particle coated with anti-Procalcitonin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-Procalcitonin antibody on the membrane and generates colored lines. The presence of colored lines in the test region indicates a positive result, while its absence indicates a negative result. Depending on the Procalcitonin concentration, different patterns of test lines appear. The presence of only Test Line 1 (T1) corresponds to a PCT level of 0.5–2.0 ng/ml. The appearance of Test Lines 1 and 2 (T1 and T2) together indicates a PCT level of 2.0–10.0 ng/ml. When Test Lines 1, 2, and 3 (T1, T2, T3) are all visible, it demonstrates that the PCT level exceeds 10.0 ng/ml. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Read this insert completely and carefully prior to use of the test. Test must be performed in strict accordance with these instructions to obtain accurate results.
3. The test is designed for whole blood / serum / plasma samples. Using other types of samples may cause invalid or false results.
4. Do not use test kit beyond the indicated expiry date. The test device is single use. Do not reuse.
5. PCT values near the cut-off level Test line 1 (T1: 0.5ng/ml), Test line 2 (T2: 2.0ng/ml), and Test line 3 (T3: 10.0ng/ml) should be reported with caution as with all quantitative assays there exists some level of variation. Therefore, a T line with slightly higher intensity than T3 can also represent a value slightly below 10.0ng/ml. Similar observations may occur with values near 2.0ng/ml and 0.5ng/ml. A repeat test or further quantitative test is recommended.
6. Do not eat, drink or smoke in the area where the specimen or kits are handled.
7. Handle all the specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
9. Humidity and temperature can adversely affect results.
10. As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.
11. In some instances elevated Procalcitonin levels in due to noninfectious reasons can be observed:
 - During the first days after trauma or surgical intervention burns, release of proinflammatory cytokines, lung cancer (oat cell carcinoma), Medullary Thyroid Carcinoma (C-Cell Carcinoma).
 - New born children, < 48hours.
 - Severe cardiogenic shock.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze.

The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.

Kit components: Test cassettes, pipettes, diluents and instructions for use.

Additional materials required but not provided: Sample collection tube, centrifuge and timer, for fingerstick whole blood: sterile lancet and capillary tubes.

Additional materials recommended but not provided: Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

SAMPLE COLLECTION AND PREPARATION

The PCT Test (Whole Blood/Serum/Plasma) can be performed using whole blood (venous blood and capillary blood), serum or plasma.

Plasma and venous blood can be collected with the following anticoagulants: K3EDTA, K2EDTA, sodium citrate (3.2%), sodium citrate (3.8%), lithium heparin, sodium heparin.

Serum Samples: Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum (Centrifugation time & speed: 2300-2880 x g for ~ 10 min).

Plasma Samples: Collect blood into a collection tube with anticoagulants to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma (Centrifugation time & speed: 2300-2880 x g for ~ 10 min).

For Venous Whole Blood Specimens: Collect anti-coagulated blood specimen (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures.

For Finger-stick Whole Blood Samples: 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. Add the Fingerstick Whole Blood specimen to the test by using a capillary tube. Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles. Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (S) of the Test Cassette.

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens. Testing should be performed immediately after specimen collection. Do not leave the 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 run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

1. Bring the tests and whole blood / serum / plasma samples to room temperature. Take the test out of its pouch.

2. **For Serum / Plasma Samples:** Draw serum / plasma into pipette and put 2 drops (80 µL) into the sample well of the cassette. Immediately after, 1 drop of diluent (40µL) added into the sample well and allowed to soak in.

For Whole Blood Samples: Draw whole blood into pipette and put 3 drops (120 µL) into the sample well of the cassette. Immediately after, 2 drops of diluent added (80µL) into the sample well and allowed to soak in.

For Fingerstick Whole Blood Samples:

To use a capillary tube: Fill the capillary tube and transfer approximately 120 µL of fingerstick whole blood sample to the sample well (S) of the Test Cassette, then add 2 drops of diluent (approximately 80 µL) and start the timer. See illustration below.

Avoid the formation of any air bubbles.

3. Wait for the colored line is appeared. The result should be read at 5 minutes. Do not interpret the results after 8 minutes.

INTERPRETATION OF RESULTS

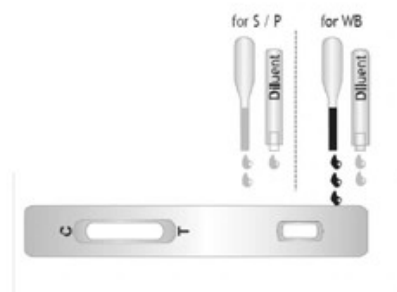
(Please refer to the illustration below)

Negative: Only one colored line is visible in "C" area. No apparent purple line appears in the test region (T).

Test line (T)	Semi quantitative result	Recommended interpretation
No line	PCT level is lower than 0.5ng/ml	Local inflammation or infection is possible with a low risk for progression to systemic inflammation response

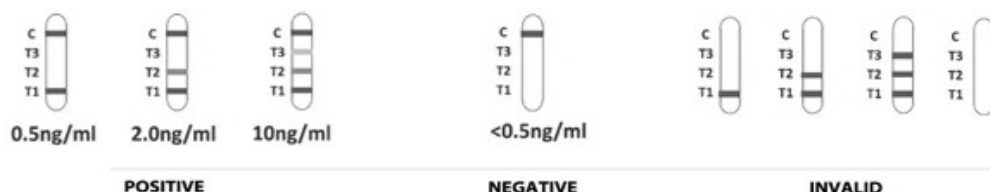
Positive: One colored line is visible in control area "C" and one or more colored lines are visible in test "T" area.

Test line (T)	Semi quantitative result	Recommended interpretation
Only T1 appears	PCT level is between 0.5-2.0ng/ml	High possibility of Systemic inflammatory response
Only T1 and T2 appear	PCT level is between 2.0-10.0ng/ml	Systemic inflammatory response associated with bacterial infection
T1,T2and T3 appear	PCT level is above 10.0ng/ml	Progressing on sever sepsis or septic shock



Invalid: No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

Procalcitonin Test has been evaluated with samples obtained from a population of symptomatic and asymptomatic individuals. FEIA (fluorescence enzyme immunoassay) method is used as a reference and following results obtained.

Method	Result	FEIA				Total
		Negative 0-0.5 ng/ml	Positive 0.5-2.0 ng/ml	2.0-10 ng/ml	≥10 ng/ml	
PCT Semi-Quantitative Rapid Test Cassette	0-0.5ng/ml	99	1	0	0	100
	0.5-2.0ng/ml	1	26	1	0	28
	2.0-10ng/ml	0	0	23	0	23
	≥10ng/ml	0	0	0	8	8
Total		100	27	24	8	159
% Relative Accuracy		99.0%	96.3%	95.8%	100%	98.1%

Sensitivity: 96.6% (*95%CI: 88.3%~99.6%) Specificity: 99.0 % (*95%CI: 94.6%~99.9%) Accuracy: 98.1 (*95%CI*: 94.6%~99.6%)

*95% Confidence Range

Precision

Intra-Assay

Assays were carried out to determine assay reproducibility using replicates of 10 tests in three different runs for each of three lots using PCT specimen levels at 0ng/ml, 0.5ng/ml, 2.0ng/ml, 10.0ng/ml and 100ng/ml. The specimens were correctly identified >99.9% of the time.

Inter-Assay

Between-run precision has been determined by using the same five specimens of negative, low positive and high positive of Procalcitonin in 3 independent assays.

Between-run precision has been determined by using the five PCT specimen levels at 0ng/ml, 0.5ng/ml, 2.0ng/ml, 10.0ng/ml and 100ng/ml of PCT in 3 independent assays. Three different lots of the PCT Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99.9% of the time.

Cross-reactivity

The Procalcitonin Test (Whole Blood/Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive samples. The results showed no cross-reactivity.

Interfering Substances

No interference was observed in samples containing up to 20 mg/mL Human Albumin, 6 mg/mL Bilirubin, 10 mg/mL Hemachrome, 5 mg/mL Cholesterol and 15 mg/mL Triglyceride.

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