Procalcitonin(PCT) Rapid Test Kit(Colloidal Gold)

CE IVD

PRODUCT NAME
Procalcitonin(PCT) Rapid Test Kit(Colloidal Gold)

SPECIFICATION
25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE
The PCT Rapid Test (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Procalcitonin in serum or plasma.

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 a system 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 Rapid Test (Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of PCT in serum or plasma. The membrane is pre-coated with anti-PCT antibody on the test line region of the strip. During testing, the serum or plasma specimen reacts with the particle coated with anti-PCT antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-PCT antibody on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. 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.

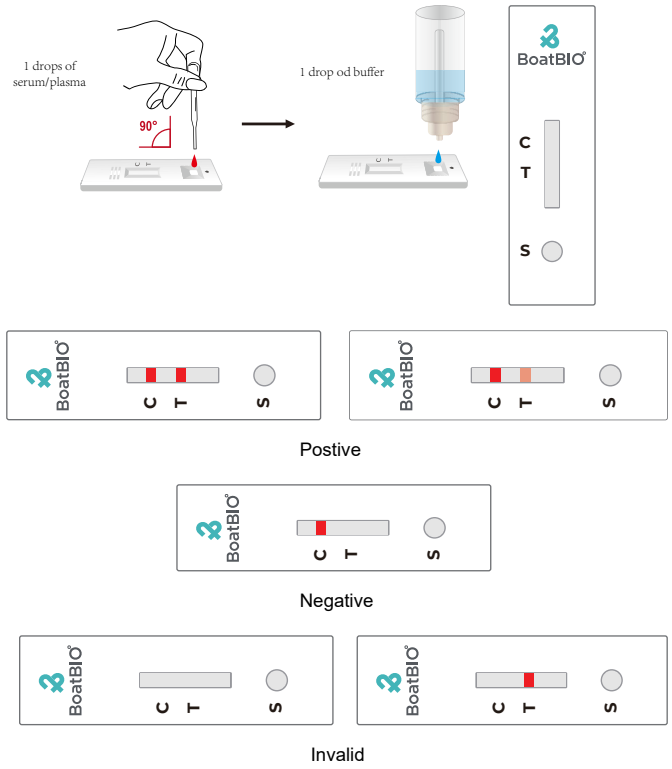
MATERIALS
Materials provided
• Test devices • Package insert • Buffer • Droppers
Materials Required but Not Provided
• Timer
• Specimen collection containers
• Centrifuge

WARNINGS AND PRECAUTIONS
1.For professional in vitro diagnostic use only. Do not use after the expiration date.
2.Do not eat, drink or smoke in the area where the specimen or kits are handled.
3.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.
4.Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested .
5.Humidity and temperature can adversely affect results.

STORAGE AND STABILITY
Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
•The PCT Rapid Test can be performed using serum or plasma.
•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.
•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 federal regulations covering the transportation of etiologic agents.

DIRECTIONS FOR USE
Allow test devices, specimen, buffer and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.
1.Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2.Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25 µL) to the specimen well of test cassette, then add 1 drop of buffer (approx. 40µL) and start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
5.Wait for the colored line to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes



INTERPRETATION OF RESULTS
POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of PCT antigen present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).
INVALID: Control line fails to appear. 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 cassette. If the **problem persists,** discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL
Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS
1.The PCT Rapid Test (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of PCT in serum or plasma specimen.
2.The PCT Rapid Test (Serum/Plasma) cannot detect less than 1ng/ml of PCT in specimens.
3.As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4.In same instances elevated Procalcitonin levels in due to noninfectious reasons can be observed:
•During the first days after trauma or surgical intervention burns, release of proinflammatoric cytokines, lung cancer (oat cell carcinoma), Medullary Thyroid Carcinoma (C-Cell Carcinoma).
• New born children, < 48hours.
• Severe cardiogenic shock.

EXPECT VALUE
The PCT Rapid Test (Serum/Plasma) has been compared with a leading commercial PCT EIA test. The correlation between these two systems is over 98.8%.

PERFORMANCE CHARACTERISTICS
The PCT Rapid Test (Serum/Plasma) has correctly identified a panel of specimens and has been compared to a leading commercial PCT EIA test using clinical specimens. The results show that the relative sensitivity of the PCT Rapid Test
(Whole Blood /Serum /Plasma) is xxx%, and the relative specificity is xxx%.

Method		EIA Test		Total Results
PCT Rapid Test(Serum/Plasma)	Results	Positive	Negative	
	Positive	104	2	106
	Negative	2	256	258
Total Results		106	258	364

Relative Sensitivity: 98.1%(93.3%-99.8%)*
Relative Specificity: 99.2%(97.3%-99.9%)*
Accuracy: 98.9%(97.2%-99.7%)* *95% Confidence Interval

Precision
Intra-Assay
Within-run precision has been determined by using 15 replicates of three specimens containing negative, low positive and high positive. The negative and positive values were correctly identified 99% of the time.
Inter-Assay
Between-run precision has been determined by using the same three specimens of negative, low positive and high positive of PCT in 15 independent assays. Three different lots of the PCT Rapid Test (Serum/Plasma) has been tested over a 10-days period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.
Cross-reactivity
The PCT Rapid Test (Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity
Interfering Substances
The PCT Rapid Test (Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed.
In addition, no interference was observed in specimens containing up to 2,000 mg/dL Hemoglobin, 1000 mg/dL Bilirubin, and 2000 mg/dL human serum Albumin.

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		

BASIC INFORMATION

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