SCREEN®

SCREEN TEST PROCALCITONINA (Whole Blood/Serum/Plasma) Package Insert

REF: SC-0999-25	English

A rapid test for the qualitative detection of Procalcitonin in human's whole blood, serum or plasma. For professional in vitro diagnostic use only.

INTENDED USE

The PCT Rapid Test Cassette (Whole Blood/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 Cassette (Whole Blood/Serum/Plasma) is a qualitative, lateral flowimmunoassay 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.

REAGENTS

The test device contains mouse anti-PCT antibody particles and mouse anti-PCT antibody coated on the membrane

PRECAUTIONS

Please read all the information in this package insert before performing the test.

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. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The PCT Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **Venipuncture Whole Blood specimens**: Collect anti-coagulated blood specimen (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory 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.
  - 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

MATERIALS

Materials provided

• Test cassettes • Droppers • Package insert • Buffer

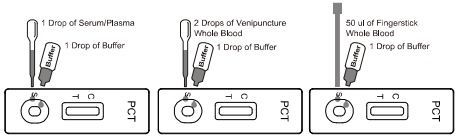
Materials required but not provided

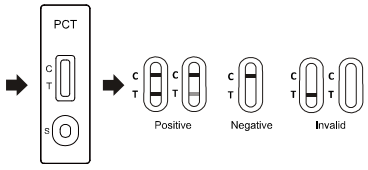
• Specimen collection containers • Centrifuge • Timer

DIRECTION FOR USE

Allow test cassette, serum or plasma specimen, and/or controls to equilibrate to room temperature (15-30℃) prior to testing.

1. Remove the Test Cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the Test Cassette on a clean and level surface.
   For **Serum or Plasma** specimens:
   Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 μL) to the specimen well (S) of the Test Cassette, and **add 1 drop of buffer** (approximately 40 μL), then start the timer. See illustration below.
   For **Venipuncture Whole Blood** specimens:
   Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 μL) to the specimen well (S) of the Test Cassette, and **add 1 drop of buffer** (approximately 40 μL), then start the timer. See illustration below.
   For **Fingerstick Whole Blood** specimens:
   To use a capillary tube: Fill the capillary tube and **transfer approximately 50 μL of fingerstick whole blood specimen** to the specimen well (S) of the Test Cassette, then **add 1 drop of buffer** (approximately 40 μL) and start the timer. See illustration below.
3. **The result should be read at 15 minutes**. Do not interpret the result after 20 minutes.





INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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.

CONTROLLO QUALITÀ

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 Cassette (Whole Blood/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 Cassette (Whole Blood/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.

EXPECTED VALUES

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

PERFORMANCES CHARACTERISTCS

Sensitivity

The PCT Rapid Test Cassette (Whole Blood/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 Cassette (Whole Blood /Serum /Plasma) is 98.7%, and the relative specificity is 98.9%.

Method		EIA		Total Results
PCT Rapid Test Cassette(Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	231	3	234
	Negative	3	280	283
Total Results		234	283	517

Relative Sensitivity: 98.7% (97.5%CI*: 96.3%-99.7%)
Relative Specificity: 98.9% (95%CI*: 96.9%-99.8%)
Accuracy: 98.8% (95%CI*: 97.8%-99.7%) *Confidence Intervals

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 Cassette (Whole Blood/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 Cassette (Whole Blood/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 Cassette (Whole Blood/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.

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.
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.

IINDEX OF SYMBOLS

	Consult Instructions For Use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

SCREEN ITALIA S.r.l.
Via dell'Artigianato, 16
06089 - Torgiano - Perugia - Italia
www.screenitalia.it info@screenitalia.it

CE

Number: 146173801
Efective Date: 2021-06-10