ImmunoScience INDIA

ImmunoQuick
PCT

Rapid PCT Detection Test – Device

A rapid test for semiquantitative determination of Procalcitonin in serum/plasma/whole blood

For Self - Testing & In-Vitro Diagnostic Use Only **Store at 4°C to 30°C**

OVERVIEW

Procalcitonin (PCT) is a small protein that comprises 116 amino acid residues with a molecular weight of approximately 13 kDa. PCT is produced normally in C-cells of the thyroid glands. Initially, the elevated levels of PCT in patients with a system infection of bacterial origin was reported and PCT is now considered to be the main marker of systemic inflammation and sepsis. It was shown that "inflammatory" PCT is not produced in C-cells. Cells of neuroendocrine origin are presumably the source of PCT during inflammation. The detection of PCT takes a considerable role in diagnosis and monitoring the sepsis as well as patient response to the medication.

INTENDED USE

The Rapid PCT Detection Test - Device is a rapid immune-chromatographic assay for the semi-quantitative detection of Procalcitonin in human serum/plasma/ whole blood. It is used for diagnosing and monitoring of severe, bacterial infection and sepsis.
This test is for healthcare professional use.

PRINCIPLE

Rapid PCT Detection Test - Device is a semi quantitative, chromatographic immunoassay for the determination of PCT in whole blood, serum or plasma. The membrane is pre-coated with PCT mAb on the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with the nanoparticle coated with PCT antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with capture Ab on the membrane and generate a colored line. The presence of this colored line in the test line 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.

CONTENTS OF KIT

1. Test Device with desiccant
2. Dropper.
3. Assay Buffer.
4. Package Insert.

OPTIONAL MATERIAL REQUIRED

1. Stopwatch

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the test.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose hygienically in domestic waste.
5. Do not touch the membrane.
6. Treat the samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether director cons sequential rising out for related to an incorrect diagnosis.

SPECIMEN COLLECTION

Fresh anti coagulated whole blood should be used as a test sample. EDTA or Heparin or Oxalate can be used as suitable anticoagulants. Fresh serum or plasma can also be used as a test sample. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to three days before testing. Clotted, contaminated or hemolyzed blood samples should not be used for performing the test.

Fresh finger pricked blood samples can also be used as a sample for testing

TEST PROCEDURE

1. Bring the kit components to room temperature before testing.
2. Open the pouch and retrieve the test and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.
3. Label the test with patient's identity. Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
4. Keep the device on plain surface & add one drop (Approx.30 µl) serum/plasma or two drops (Approx.60 µl) whole blood sample in sample 'S' well by using dropper.
5. Add 1 drop of assay buffer in sample well "S".
6. Start the timer.
7. Read the result at 15 minutes. Do not read the result after 20 minutes.

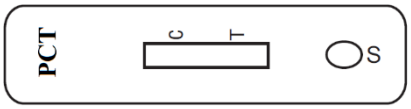
INTERPRETATION OF RESULTS

Negative for sepsis PCT: If colored line appears at control region 'C' & no colored band appears at test region T, then sample contains normal levels of PCT (less than 0.5 ng/ml).

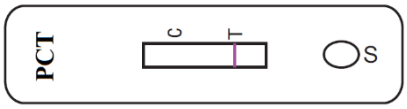
Positive (PCT higher than normal range): A distinct clearly visible colored line appears at control region 'C' and at the test region 'T', then specimen contains higher amount of PCT than normal range.

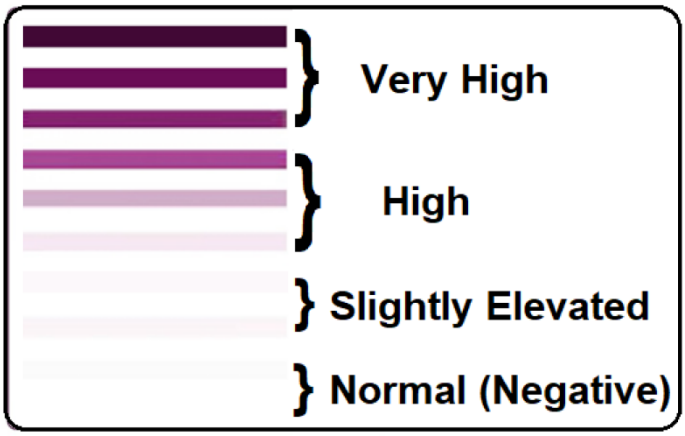
Invalid: Test should be considered invalid and repeat the test using fresh test if

a. No line appears at control side 'C' and line appears only at test side 'T'.



b. No line appears at control side 'C' and test side 'T'.





LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, reference correlation should be considered.
3. Any modification to the above procedure and / or uses of other reagents will invalidate the test procedure.
4. The test is limited to the determination of PCT, Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product.Thisproduct is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

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