INSTRUCTIONS FOR USE

PROCALCITONIN RAPID TEST

Detection in Serum / Plasma

TOYO DIAGNOSTICS

Only for professional *in vitro* diagnostic use

Product Code: TPCT01
Procalcitonin Cassette Test.

INTENDED USE

Procalcitonin Test is a rapid qualitative immunoassay for the detection of Procalcitonin in human serum / plasma samples. It is used for diagnosing and controlling the treatment of severe, bacterial infection and sepsis.

BACKGROUND INFORMATION

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.

REAGENTS

Anti-HBs monoclonal antibody, goat anti-mouse IgG polyclonal antibody and anti-HBs monoclonal antibody conjugated with colloidal gold particles.

METHOD

Procalcitonin Test uses solid-phase immunochromatographic technology for the qualitative detection of Procalcitonin in Human serum/plasma. There are monoclonal Procalcitonin antibodies as the capture reagent immobilized to "T" test area of the test. While performing the test; serum / plasma sample dropped to the sample well reacts with the particles coated with anti-Procalcitonin antibodies. This complex migrates to the other end of the membrane by capillary action. If there is Procalcitonin in the sample, it binds to capture reagent in the "T" test area and create a visible, colored signal. If the sample does not contain Procalcitonin, colored line does not appear in the "T" test area. As a procedural control, a colored line always appears in the "C" control area indicating that proper volume of sample has been introduced and membrane wicking has occurred. These all changes are detected by Toyo ICA-Rapid Test Reader and the result can be read by display of the reader or obtained from printer.

PRECAUTIONS AND LIMITATIONS

1.For Professional and in vitro diagnostic use only.
2.Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
3.The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
4.Wear disposable gloves while performing the test.
5.Use a new dropper for each sample.
6.All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
7.Unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
8.This test will indicate only the presence or absence of Procalcitonin in the sample, and should not be used as the only basis for the diagnosis of sepsis.
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.
9. In same instances elevated Procalcitonin levels in due to non-infectious 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,<48 hours
- Severe cardiogenic shock

STORAGE

The test 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 should be used in maximum one hour after the foil is opened.

Kit components: Test, dropper, and instructions for use.

Additional materials required but not provided: Sample collection tube, centrifuge and timer.

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 test can be performed using serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible.

For 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.

For Plasma Samples: Collect blood into a collection tube with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma.

Do not use turbid, hemolyzed samples. If the sample cannot be tested on the day of collection, store the serum, plasma samples in a refrigerator or freezer. Do not freeze and thaw the serum, plasma samples repeatedly. Bring the samples to room temperature before testing. Frozen samples must be completely thawed and mixed well prior to testing. Turbid test samples should be centrifuged. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.

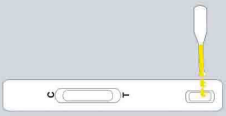
TEST PROCEDURE

1. Take the test device out of its pouch. Bring the tests and serum / plasma samples to room temperature.
2. Draw whole blood / serum / plasma into dropper and put 4 drops (120 µl) into the sample well of the cassette.
   Avoid the formation of any air bubbles.
3. Results should be read at 15 minutes as shown below. Do not interpret results beyond 20 minutes, results forming after 20 minutes should be regarded as invalid.

INTERPRETATION OF RESULTS

Negative: One colored line appears in the Control Zone (C) within 15 minutes. No colored line appears in the Test Zone (T). It is indicated that the amount of Procalcitonin in the sample is below 0,5 ng/ml.
Positive: Additional to read a colored line in the control region a red line in the test region appears. This result indicates that Procalcitonin could be detected. The color intensity of the lines may be different. The amount of Procalcitonin can be assessed of the test line intensity to the reference line intensities on the interpretation card.
Invalid: No colored line appears in the Control Zone (C) within 15 minutes. The test results is invalid, repeat the test with a new test device.

TOYO



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

Sensitivity and Specificity
Procalcitonin Test has been evaluated with an another brand PCT Rapid Test using clinical specimens. The results are as below;

Table: Procalcitonin Test vs. another brand PCT Rapid Test

Sensitivity: 98.11% **Specificity:** 98.89%			**Procalcitonin Test**		
			+	**-**	**Total**
	Another brand	**+**	52	1	53
		-	2	178	180
			54	179	233

Cut-off: 0,5 ng/ml

CROSS REACTIVITY

No cross reactivity was observed with specimens from patients infected with HAV, HIV, HCV, HBV, HTLV, TP and CMV.

INTERFERENCES

No interference was found with bilirubin (10 mg/dL), hemoglobin (20 mg/dL) or triglycerides (600 mg/dL) on the sensitivity and specificity of the test.

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.
http://www.rapid-diagnostics.org/rti-hepb-diag.htm

TÜRKLAB TIBBİ MALZEMELER SAN. TİC. A .Ş.
A.O.S.B 10040 Sok. No:20 Çiğli-İzmir / TURKEY
TEL: +90 232 376 80 81 FAX: +90 232 376 80 40 info@turklab.com.tr www.turklab.com.tr

SYMBOLS USED

CE 1434 — Manufacturer — Consult instruction for use — Attention, see instruction for use — IVD *In vitro* diagnostic medical device — For single use only — Number of test — REF Catalog number — Storage temperature — LOT Lot number — Expiry date