OneStep
Procalcitonin RapiCard™ InstaTest
(Serum/Plasma)

REF 110512-1-44

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

INTENDED USE
The Cortez Diagnostics, Inc. Procalcitonin (PCT) RapiCard™ InstaTest (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Procalcitonin in serum or plasma.

SUMMARY AND EXPLANATION
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 Moullé 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.

TEST PRINCIPLE
The Cortez Diagnostics, Inc. PCT RapiCardTM InstaTest (Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of PCT in serum or plasma. The membrane is precoated 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 AND REAGENT
Reagent
The test cassette contains mouse anti-PCT antibody particles and mouse anti-PCT antibody coated on the membrane.

Materials provided
- Test cassettes
- Drippers
- Buffer
- Package insert

Materials required but not provided
- Specimen collection container
- Centrifuge
- Timer

PRECAUTION
Please read all the information in this package insert before performing the test.
- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimen or kits are handled.
- 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- 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 until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. The PCT RapiCardTM InstaTest (Serum/Plasma) can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. 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.
4. 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.
5. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

ASSAY PROCEDURE
Allow test cassette, serum or plasma specimen, 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. 40 µL) and start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
3. Wait for the colored line to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.
**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 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.

**PERFORMANCE CHARACTERISTICS**

**Sensitivity and Specificity**

The Cortez Diagnostics, Inc. PCT RapiCard™ (Serum/Plasma) has correctly identified a panel of specimens and has been compared to a leading commercial PCT ELISA test using clinical specimens. The results show that the relative sensitivity of the PCT RapiCard™ (Serum/Plasma) is 98.7%, and the relative specificity is 98.9%.

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<tr>
<th>Method</th>
<th>ELISA</th>
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<th>Negative</th>
<th>Total Results</th>
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<td>PCT RapiCard™</td>
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<td>2</td>
<td>233</td>
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<tr>
<td></td>
<td>Total Results</td>
<td>234</td>
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</table>

Relative Sensitivity: 98.7% (95%CI*: 96.3%–99.7%)  
Relative Specificity: 98.9% (95%CI*: 96.1%–99.9%)  
Accuracy: 98.8% (95%CI*: 97.2%–99.6%)  

* Confidence Interval

**EXPECTED VALUES**

The Cortez Diagnostics, Inc. PCT RapiCard™ (Serum/Plasma) has been compared with a leading commercial PCT ELISA test. The correlation between these two systems is over 98.8%.

**REFERENCE**

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<tr>
<td>CEpartner4U, Esdoornlaan 13, 3951DB Maarn. The Netherlands. <a href="http://www.cepartner4u.eu">www.cepartner4u.eu</a></td>
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Revision Date: 2017-02-28