PCT-W23 **The PCT Rapid Test Device (Whole Blood/Serum/Plasma)**

INTENDED USE

The PCT Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of Procalcitonin in human whole blood, serum or specimens. This kit is intended for use as an aid in the diagnosis of inflammation.

INTRODUCTION

Procalcitonin (PCT) is the precursor of calcitonin, and is normally produced in the C-cells of the thyroid gland. During systemic and severe infections, PCT is also produced rapidly in other tissues, and serum PCT concentrations increase to very high levels. Assicot *et al* first described PCT as an inflammation-induced protein in 1993. Since then, numerous clinical studies have demonstrated the utility of this marker. PCT is more specific for detecting bacterial infection than other inflammatory markers, such as C-reactive protein (CRP) and white blood cell counts (WBC), because viral infections, autoimmune and allergic disorders do not induce PCT.

PRINCIPLE

The PCT Rapid Test Device (Whole Blood/Serum/Plasma) detects procalcitonin through visual interpretation of color development on the internal strip. Anti-PCT antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-PCT antibodies conjugated to colored particles and precoated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are sufficient PCT in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Individually packed test devices
- Disposable pipettes
- Package insert
- Buffer

Materials Required but Not provided

- Specimen collection container
- Centrifuge
- Timer

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The PCT Rapid Test Device (Whole Blood/Serum/Plasma) is intended for use with human whole blood, serum, or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test., Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave 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. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolyzed, heat treated and contaminated specimens may cause erroneous results.
- There is a slight possibility that some specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test device. Repeat the test with a whole blood, serum or plasma specimen from the same patient using a new test device.

PROCEDURE

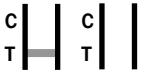
Bring tests, specimens, buffer, and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. Transfer 2 drops of serum/plasma (approximately 50 μL) or 3 drops of whole blood(approximately 75μL) to the specimen well of the device with the provided disposable pipette, and then start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   As the test begins to work, color will migrate across the membrane.
3. If the test fails to migrate across the membrane after 1 minute, add 1 drop of buffer to the specimen well (S).
4. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
External controls are not supplied with this kit. 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 OF THE TEST

1. The PCT Rapid Test Device (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of PCT. No meaning should be inferred from the color intensity or width of any apparent bands.
2. The PCT Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of procalcitonin in the specimen and should not be used as the sole criteria for the diagnosis of inflammation.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.5 ng/mL of PCT in specimens.
4. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

- **Specimen Correlation**
  The study was performed on 380 negative Whole blood/Serum/ Plasma specimens (EIA confirmed) and 275 positive Whole blood/Serum/ Plasma specimens (EIA confirmed) have been tested in the assays

Table 1 PCT Test Device vs. Commercial PCT kit

		Commercial PCT kit（EIA）		
		+	-	Total
PCT Test Device	+	272	0	272
	-	3	380	383
Total		275	380	655

Positive agreement with EIA: 272/(272+3) = 98.9 % (96.8% - 99.6%)*
Negative agreement with EIA: 380/(380+0) = 100% (99.0% - 100%)*
Total agreement with EIA: (272+380)/(272+3+380+0) = 99.5% (98.7% - 99.8%)*
* 95% Confidence Interval

- **Sensitivity**

  The test was calibrated by Roche Elecsys in such a way that a concentration of 0.5 ng/mL in the undiluted specimen materials yields a positive result.

  Hook effects could not be observed up to a concentration of 5000 ng/ml PCT.

- **Interference**

  No assay interference was demonstrated with spiked specimens containing potential interferents at the following concentrations.

bilirubin	6 mg/ml	Triglyceride	15 mg/ml
haemoglobin	10 mg/ml	cholesterol	5 mg/ml
albumin	110 mg/ml		

LITERATURE REFERENCES

1. American College of Chest Physicians/Society of Critical Care Medicine: Crit Care Med 1992, 20: 864-874.
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4. Fernandez Lopez A. et al.: Pediatr. Infect. Dis. J. 2003, 22:895-903.
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GLOSSARY OF SYMBOLS

ρ	Catalog number	0	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	In vitro diagnostic medical device	ε	Use by
μ	Manufacturer	T	Contains sufficient for <n> tests
σ	Do not reuse	A	Authorized representative in the European Community
Y	CE marking according to IVD Medical Devices Directive 98/79/EC		

μ
Assure Tech. (Hangzhou) Co., Ltd.
Building 4, No. 1418-50, Moganshan Road,
Gongshu District, Hangzhou,
310011 Zhejiang, P.R. China
contact@diareagent.com

Y A
Lotus NL B.V.
Koningin Julianaplein 10, le Verd,
2595AA, The Hague, Netherlands
peter@lotusnl.com