One Step Procalcitonin (PCT) Test

Instructions For Use

Format: Cassette
Specimen: Serum/Plasma
Catalog Number: A03-23-222

* Please read the instructions carefully before use

INTENDED USE

Artron One-Step Procalcitonin (PCT) Test is a rapid and convenient immunochromatographic assay for the semi-quantitative detection of human Procalcitonin in serum or plasma at or above the level of 0.5 ng/ml. It is intended for professional use as an aid in the diagnosis and controlling the treatment of severe bacterial infection and sepsis. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the results of the tests.

SUMMARY AND PRINCIPLE OF THE ASSAY

Procalcitonin (PCT) is a peptide precursor of the hormone calcitonin, which is involved in calcium homeostasis. It is composed of 116 amino acids and is produced by parafollicular cells (C cells) of the thyroid and by the neuroendocrine cells of the lung and the intestine. In serum, PCT has a half-life of 25 to 30 hours.

Determination of normal values with a high sensitive assay revealed the normal values to be below 0.05ng/ml in healthy individuals. PCT serum concentrations are elevated in clinically relevant infections and continue to rise with the increasing severity of the disease. The diagnostic value of PCT is important due to the close correlation between PCT concentration and the severity of inflammation. The level of PCT rises in a response to a proinflammatory stimulus, especially of bacterial origin. It does not rise significantly with viral or non-infectious inflammations. With the derangements that a severe infection with an associated systemic response brings, the blood levels of PCT may rise to over 10ng/ml.

PCT is now considered as an innovative and highly specific marker for the diagnosis of clinically relevant bacterial infections and sepsis. PCT supports early diagnosis and clinical decision making which could direct an effective therapy at the right time, avoiding unnecessary spending and antibiotic prescribing for critically ill patients.

Artron One Step PCT test device is an antigen-capture immunochromatographic assay, detecting PCT in blood samples. Monoclonal antibodies specifically against PCT are 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the Test Zone (T) on the nitrocellulose membrane. When an adequate volume of the test sample is added the gold-antibody conjugate is rehydrated and the PCT, if any in the sample, will interact with the colloidal gold conjugated antibodies. The antigen-antibody-colloidal gold complex then will migrate towards the test window until the Test Zone (T) where they will be captured by immobilized antibodies, forming a visible pink line (Test line) indicating a positive result. The color intensity of the band is directly proportionate to the PCT concentration of the sample and PCT concentration ranges (<0.5ng/ml, ≥0.5ng/ml, ≥2ng/ml, ≥10ng/ml) can be determined by comparing the band color with a reference card. If PCT is absent or below 0.5 ng/ml in the sample, no pink line will appear in the Test Zone (T), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

- 25 Test kits (pouches) per box
- Pouch contents: Test Cassette, Sample dropper, Desiccant.
- 1 Test instruction per box
- 1 Reference card per box

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clean, specimen collection container.
- Clock or timer.

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not reuse.

- Do not use if the product seal or the packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.
- Wash hands thoroughly after finishing the test.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

SPECIMEN PREPARATION

- For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
- For plasma samples, collect blood in a tube containing anticoagulant.
- 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 the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
- The blood may be stored at 2ºC to 8ºC for up to three days if the tests cannot be performed immediately. Ensure that the blood samples are allowed to attain room temperature prior to use.

Note: Hemolytic samples should not be used!

TEST PROCEDURES

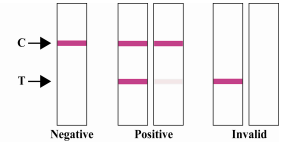
1. Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.

2. Hold the sample dropper vertically. Add three full drops (120 µl) of the specimen without air bubbles into the sample well that is marked with an arrow on the testing device

3. Read the result in 30 minutes. Read results as shown under interpretation of Results.

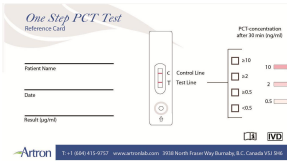
DO NOT INTERPRET RESULTS AFTER 45 MINUTES

RESULT INTERPRETATIONS



Negative
A pink colored band appears only at the control region (C), indicating a PCT concentration below 0.5ng/ml.

Positive
A clear pink control band (C) and a detectable test band (T) appears on their respective regions, indicating a positive result for PCT.



The PCT concentration range is then determined by comparing the color intensity of the test band with the color blocks of the reference card. Use the respective reference card supplied with the kit for comparison purposes.

Invalid
No visible band at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

Result Records:

- PCT concentration is less than 0.5ng/ml: no T band or the intensity of the T band is weaker than that of color block "0.5".
- PCT concentration is between 0.5ng/ml – 2ng/ml: The intensity of the T band is stronger than that of color block "0.5" but weaker than that of color block "2".
- PCT concentration is between 2ng/ml – 10ng/ml: The intensity of the T band is stronger than that of color block "2" but weaker than that of color block "10".
- PCT concentration is more than 10ng/ml: The intensity of the T band is stronger than that of color block "10".

To document the test result, the concentration range which corresponds to the color intensity of the test band is marked with a cross on the reference card. To archive the test result, the fully completed reference card can be stored in the patient's file.

Reference Ranges

The reference ranges below are given for orientation purpose only

<0.5 ng/ml	Localized infection is possible Lower risk for progression to severe systemic infection	Caution: PCT level below 0.5 ng/ml does not exclude an infection. Localized infections may be associated with these low levels. Also, if the PCT measurement is done at an early stage of a bacterial infection (< 6 hours), PCT value may still be low.
≥ 0.5 - < 2 ng/ml	Systemic infection (sepsis) possible	Moderate risk for progression to a severe systemic infection. The patient should be closely monitored clinically and re-assessed for PCT levels within 6-24 hours.
≥ 2 - <10 ng/ml	Systemic infection (sepsis) likely	High risk for progression to a severe systemic infection
≥ 10 ng/ml	High likelihood of severe sepsis or septic shock	Important systemic inflammatory response, almost exclusively due to severe bacterial sepsis or septic shock

Note:
Increased PCT levels may not always be related to an infection. There are a few cases where PCT can be elevated by non-infectious causes, such as: Neonates < 48 hours of life; the first day of a major trauma, major surgical intervention; patients with severe liver cirrhosis and chronic viral hepatitis, etc.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- This product is an *in vitro* diagnostic test designed for professional use only.
- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting PCT, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. 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.
- Artron One Step PCT test has a sensitivity of 0.5ng/ml and can therefore only be used for diagnosis of invasive bacterial infection, not for localized infections.

MANUFACTURER CONTACT INFORMATION

Artron Laboratories Inc.
3938 North Fraser Way
Burnaby, BC
V5J 5H6 Canada

Tel: +1 604.415.9757
Fax: +1 604.415.9795
www.artronlab.com
info@artronlab.com