Procalcitonin (PCT) Test card (Colloidal Gold)

INTENDED USE

Procalcitonin (PCT) Test card(Colloidal Gold)is a rapid and convenient immunochromatographic assay for the semi-quantitative detection of human Procalcitonin in serum or plasma . It is intended for professional use as an aid in the diagnosis the treatment of severe bacterial infection and sepsis.

SUMMARY

PCT levels are elevated in bacterial sepsis, especially severe sepsis and septic shock. PCT can be used as a prognostic indicator of sepsis, and it is also a reliable indicator of acute severe pancreatitis and its main complications. For patients with community-acquired respiratory infections and air-conditioning-induced pneumonia, PCT can be used as an indicator of antibiotic selection and efficacy judgment.

This test is an immunological diagnostic test used for detection of PCT antigen based on the colloidal gold-immunochromatography assay. This method is rapid and convenient to use and requires few equipment.It can be performed within 15-20 minutes by minimally skilled personnel.

PRINCIPLE OF THE TEST

Procalcitonin (PCT) Test card(Colloidal Gold) is an antigen-capture immunochromatographic assay, detecting PCT in blood samples. Monoclonal antibodies specifically against PCT are conjugated with colloidal gold and deposited on the conjugate pad . When an adequate volume of the test sample is added 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 red line (Test line) indicating a positive result. If PCT is absent or below Minimum detection limit(0.2ng/ml) in the sample, no red line will appear in the Test Zone (T), indicating a negative result.Absence of a red control line in the Control Zone is an indication of an invalid result.

Reagents And Materials Supplied

Materials Provided:

Component Name	1T/box	20T/box	25T/box	50T/box
Disposable Dropper	1	20	25	50
Desiccant	1	20	25	50
Disposable Test Card	1	20	25	50
Instruction Manual	1	1	1	1

Materials Required But Not Supplied

1. sample collection and preparation device and disinfecting sterile wipes
2. Clock or timer

Reagents And Materials Supplied

1. For in vitro diagnostic use only.
2.For professional use only.
3.Read the package insert in its entirety prior to performing the test. Failure to follow the package insert instructions may result in an invalid test result.
4. Keep the test device sealed until use. Once the device pouch has been opened, the test device must be used immediately.
5. Do not use device if the sealed pouch is visibly damaged.
6.Do not use product after indicated expiration date
7.Follow your clinical and/or laboratory safety guidelines in the collection, handling, storage and disposal of patient samples and all items exposed to patient samples.
8. Wipe any spills of sera or plasma promptly with disinfectant.
9.The test is for single use only. Do not re-use under any circumstances.
10.Humidity and temperature can adversely affect results.
11.Dispose of all samples and used test components in appropriately approved and labeled biohazard waste containers.
12.Keep out of children's reach.

SPECIMEN PREPARATION

1.For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
2.For plasma samples, collect blood in a tube containing anticoagulant.
3.Separate serum or plasma from blood as soon as possible to avoid hemolysis.
4.Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
5.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

Before using this product, please check all the items in the box. Please do not tear the aluminum foil bag in advance before you are ready for the test.
1. Take out the aluminum foil bag in the kit and equilibrate at room temperature.
2. Tear the aluminum foil bag, take out the test card and the dropper. The test card should be used as soon as possible within 1 hour after it is taken out.
3. Use a dropper to draw the sample , and drop 3 drops(about 100 μl) of the sample into the sample well of the test card.
4. Read the result in 15-20 minutes.

RESULT INTERPRETATIONS

1.Negative
A red band appears at the control region(C), and the T band is not appeard or the color of the T band is weaker than that of the color block "0.5"indicating a PCT concentration below 0.5ng/ml.
2.Positive
A red band appears on the control region(C) and test region(T)，and the color of the T band is near or stronger than that of color block "0.5", and indicating a positive result for PCT.
Comparing the color of the test card with the reference card，and then determining the PCT concentration range.
3.Invalid
No visible band at the control region (C). Repeat with a new test device.

Result Records:

If the PCT concentration is less than 0.5ng/ml,The T band is not appeard or the color of the T band is weaker than that of the color block "0.5".
If the PCT concentration is between 0.5ng/ml – 2ng/ml，The color of the T band is between that of color block "0.5" and color block "2".
If the PCT concentration is between 2ng/ml – 10ng/ml，The color of the T band is between that of color block "2" and color block "10".
If the PCT concentration is more than 10ng/ml，The color of the T band is stronger than that of color block "10".

Interpretation of test results

PCT level ＜ 0.5ng/ml	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 ≤ PCT level ＜	It has a moderate risk for progression to a severe systemic infection. The patient should be closely

2ng/ml	monitored clinically and re-assessed for PCT levels within 6-24 hours.
2≤PCT level ＜10ng/ml	It has a high risk for progression to a severe systemic infection or sepsis.
PCT level ≥ 10ng/ml	It has a high likelihood of severe sepsis or septic shock.It may has de high risk of death.

Note:

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 less than 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

1.good laboratory practice recommends the use of an outside control to ensure proper

2.Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

Storage And Stability

1. The original packaging should be stored in a dry place at 2-30°C and protected from light.

2. The shelf life of the test kit is 1 year from date of manufacture. Refer to the product labels for stated expiration date.

3. The original packaging can be transported at 2-37℃ for 20 days.

4. After opening the inner package, the test card will become invalid due to moisture absorption, please use it within 1 hour.

Performance characteristics

1. product compliance rate:

The coincidence rate of 3 different gradients (0.5ng/ml, 2ng/ml, 10ng/ml) of positive quality control products is 100%.

The compliance rate of negative control products is 100%.

It has a Good repeatability

It has a good inter-assay precision and intra-assay precision.

2. Cross-reaction:

The product does not have cross reaction with positive specimens of Human calcitonin (1mg/ml), human calcitonin (100ng/ml), human α-calcitonin gene-related peptide (100ng/ml) and human β-calcitonin gene-related peptide (100ng/ml).

3. Interfering substances:

When the triglyceride content is≤5g/L,the hemoglobin content is ≤4g/L,bilirubin ≤0.8g/L，Rheumatoid factor≤500U/ml，ascorbic acid ≤4g/L ， the total bilirubin ≤0.4g/Lwill not interfere with the detection results of this product.

4. Clinical evaluation

A total of 180 specimens were collected from symptomatic patients and healthy individuals. Specimens were tested by Procalcitonin (PCT) Test card (Colloidal Gold). The Procalcitonin (PCT) Quantitative Detection Kit (Fluorescence Immunochromatography) is used as the reference test method. The result shows that the relative sensitivity is 96.51%, the relative specificity is 96.51, and the overall agreement is 95.00%.

5.Hook effect

Within the concentration of 1μg/ml, the test result of this product does not show a hook effect.

6. The minimum detection limit

The minimum detection limit of PCT is 0.2ng/ml

LIMITATIONS

1.This product is an in vitro diagnostic test designed for professional use only.

2.Humidity and temperature can adversely affect results.

3.The instructions for the use of the test should be followed during testing procedures.

4.This test detects the presence of antigen to PCT in the specimen ,But it should not be used as the sole criterion for the diagnosis of infection.

5.As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

Symbols

	Manufacturer		Date of manufacture
	Authorised Representative in the European community		Use by
	Caution		Batch code
	Do not reuse		Keep dry
	Do not use if package is damaged		Total number of tests
	instructions for use		in vitro diagnostic
	CE mark		Temperature limit

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