

Procalcitonin (PCT) Test Kit (Colloidal Gold) Catalog #: CGLF-PCT-20

• EXPECTED USAGE

This kit is used to detect the concentration of procalcitonin (PCT) in human serum via immunochromatographic technology.

• BACKGROUND

Procalcitonin (PCT) is a peptide precursor composed of 116 amino acids, with a molecular weight of 13KD. Healthy individuals have minute/negligible levels in their serum. In a response to a bacterial stimulus, PCT levels rise significantly, especially in severe sepsis and septic shock. PCT can therefore be an indicator of early sepsis and also lower respiratory tract infections.

• DETECTION PRINCIPLES

This kit uses immunochromatography techniques, where an anti-human PCT monoclonal antibody and quality control-coated antibody are coated onto a solid-phase nitrocellulose membrane. Another anti-human PCT monoclonal antibody and quality control are labeled with colloidal gold. If the PCT concentration in the sample is over 0.2 ng / mL, PCT can bind to the gold-labeled PCT antibody to form a complex. This complex moves forward along the test strip where it binds to the anti-PCT antibody in the detection area. This creates an immobilized “anti-PCT antibody – PCT – gold-labeled anti-PCT antibody” sandwich complex which turns red. If the PCT concentration in the sample is less than 0.2 ng / mL, no sandwich complexes can be formed in the detection area. Additionally, the color intensity in the detection area is proportional to the PCT concentration. Thus, the concentration range of PCT in test samples can be read according to the colorimetric reference card.

Whether there is PCT or not in the test sample, a control color band will appear in the quality control area. This color band is used to determine if there was sufficient sample volume, if the chromatographic process was normal, and serves as an internal control standard.

• KIT COMPONENTS

The kit contains the following components. The entire kit can be used for 20 PCT level measurements.

- 20 individually packaged detection cassettes. Each individual package contains:
 - A detection cassette for the detection of PCT in the sample
 - A disposable plastic pipette
 - A desiccant pack
- 20 colorimetric reference cards
 - For determination of PCT range
- 1 Product Manual

Kit and/or packages should be stored at 4 – 30° centigrade, dry, and away from light.

Note: The components in different batches cannot be used interchangeably.

• STORAGE AND STABILITY

Store kit and individual packages at 4 – 30° centigrade, dry, and away from light. Overall kit and individual cassettes are good for 18 months. Avoid freezing. The individual package should only be opened when detection begins.

• SAMPLE COLLECTION AND STORAGE

Sample collection

The kit is suitable for human serum. Whole blood samples can be collected according to medical standard operation procedures, and the serum separated after collection. No special treatment is required. Hemolysis, lipidemic blood, and jaundiced samples are not recommended. Samples should be sent to the testing facility following collection. Transportation should be in accordance with local regulations.

Sample preservation

Samples should be tested as soon as possible once collected. If no PCT is detectable, samples can be stored at 0 to 4 degrees centigrade for 24 hours or at -20 degrees centigrade for 3 months. Avoid freeze thaws.

Sample Amount

Add 3 drops of samples with the pipette supplied or 85 µL with a laboratory pipette.

• TESTING METHODS

1. Before testing, read the manual completely.
2. Bring the PCT cassettes and samples to room temperature (20 – 27°C).
3. Add 3 drops of samples with the pipette supplied, or 85 µL with a laboratory pipette, into the sample hole on the cassette. Record the time and compare with the reference colorimetric card.

4. The results should be read in 20 to 25 minutes. The test is not valid after 25 minutes.
5. Document the result on a provided reference card.
6. Mark with an "x" to correspond with the relative intensity of the color band on the reference colorimetric card, to record the testing result. Please also mark down the lot number and time of the measurement.

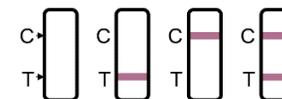
• EVALUATION OF TESTING RESULTS

SIRS, sepsis, severe sepsis, and septic shock are classified according to the consensus conference-based guidelines of American College of Chest Physicians / Society of Critical Care Medicine.

Reference Concentrations	Interpretation
PCT <0.5ng / mL	A low risk of sepsis and / or septic shock
PCT ≥0.5ng / mL and <2ng / mL	May be a systemic infection (sepsis), but there might be other reasons increasing PCT.
PCT ≥2ng / mL and <10ng / mL	Likely systemic infection, excluding other known reasons
PCT ≥10ng / mL	Likely severe sepsis or septic shock

Results Interpretation

Read the testing results in 20 to 25 minutes after adding samples. First, read the color band in control band “C” to see if the result is valid or not (see figure below).



- **No color bands or color band only at the test result location “T”:** Test result is invalid, as no control band appears.
- **Control band “C” only:** Test result is a valid negative. Results is concentration of PCT lower than 0.2 ng/mL.
- **Both test band “T” and control band “C” appear:** Test result is valid positive. Result is a concentration of PCT higher than 0.2 ng/mL.
 - For a valid positive test, the intensity of the color band is proportional to PCT concentration. Therefore, the concentration range of PCT in the test sample can be read according to the colorimetric card.

Notes:

(1) Bacterial infection can also lead to low concentration of PCT. For example, local bacterial infection and early infection stages of subacute endocarditis. Positive PCT samples should therefore be re-tested and re-assessed.
(2) In other cases, PCT levels may increase independent of a septic infection, including, but not limited to:

- Infants less than 48 hours of age (physiological increase).
 - The days before and after trauma, large-scale surgery, burns, treatment with OKT3 antibodies, and other drugs stimulating an inflammatory response.
 - Samples with invasive fungal infections, and acute attack of plasmodium falciparum malaria.
 - Samples with long or severe cardiogenic shock, or long-term severe organ perfusion abnormalities.
 - Samples with severe cirrhosis, and acute or regional viral hepatitis.
- **Performance characteristics**
 - Width of test strip within cassette: (4.0 ± 0.1) mm.
 - Liquid migration speed: liquid migration speed should not be less than 10mm / min.
 - Minimum detection limit: 0.2ng / mL.
 - Coincidence rate of positive reference materials: Cassettes are calibrated with positive reference material (0.5ng / mL, 2ng / mL, and 10ng / mL). The color of reference material was consistent with the reference colorimetric card.
 - Coincidence rate of negative reference materials: Cassettes are tested with 5 calibrated negative reference materials (<0.2ng / mL). These resulted in no color band in the “T” section.
 - Repeatability: Cassettes were tested with a precision reference. The resulting color band and reaction result were consistent with reference colorimetric card.
 - Batch-to-batch variation: Cassettes were tested with a precision reference. The color band and reaction results were consistent with reference colorimetric card.
 - Interference substances:
 - Repeatability and reaction results were affected if hemoglobin concentration was over 60µg / mL (hemolyzed).
 - Repeatability and reaction results were affected if triglyceride concentration was over 40µg / mL (lipidemic).
 - Hook effect: Hook effect was observed if levels exceeded 1500 ng / mL.

- Control test: A total of 220 clinical specimens (73 positive and 147 negative) were detected with the Procalcitonin Detection Kit (immunochromatographic assay) produced by BRAHMS GmbH. By comparison of the RayBiotech PCT Test Kit and the BRAHMS PCT detection kit, the positive correlation rate was 100%, the negative rate was 100%, and the total coincidence rate was 100%, with a Youden index of 1. Therefore, the consistency between control kits and the RayBiotech PCT Test kit was good.

• SAFETY MEASURES

- Warning statements
 - This kit is intended for use only in accordance with the instructions contained herein. It is intended for use as an in vitro test within the specifications and limits described in the product description. It is not intended for other uses.
 - The kit is limited to detection of PCT in human serum samples. The reliability of other body fluid samples has not been fully evaluated.
 - If the product is exposed to moisture, results may be compromised.
 - Check the product expiration and package integrity before use. Do not use if individual packaging is damaged.
 - All tests should be in accordance with the relevant state departments promulgated by the relevant laboratory norms and requirements. Prevent cross-contamination.
- Waste treatment
 - This product contains animal-derived substances that may be contaminated by the samples during operation. There are no known methods to fully ensure the presence of non-infectious substances. All reagent components, samples and wastes should be treated as infectious agents.

• REFERENCES

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