

1. INTENDED USE

The Biokits Procalcitonin (PCT) Rapid Test is an in-vitro diagnostic, immunochromatographic assay for the qualitative detection of Procalcitonin (PCT) in human serum or plasma or Whole Blood. This test is intended for professional use only.

2. INTRODUCTION

Procalcitonin (PCT) is a precursor of the hormone calcitonin and is normally present at very low levels in healthy individuals. During systemic bacterial infections and sepsis, PCT levels rise significantly and correlate with the severity of infection. Measurement of PCT is widely used to aid in the early diagnosis of bacterial infections, sepsis, and to support antibiotic therapy decisions. The Biokits PCT Rapid Test provides a rapid qualitative result to assist clinicians in the evaluation of severe bacterial infections.

3. PRINCIPLE OF THE TEST

The Biokits Procalcitonin (PCT) Rapid Test is a lateral-flow immunochromatographic assay with a two-line detection system consisting of a test line (T) and a control line (C). Procalcitonin present in the specimen binds to colloidal gold-conjugated anti-PCT antibodies and migrates along the nitrocellulose membrane by capillary action. The antigen-antibody complexes are captured by immobilized anti-PCT antibodies at the test line region, producing a visible colored line when PCT concentrations are ≥ 2 ng/mL. The control line is coated with polyclonal antibodies and reacts with a colored control conjugate, producing a visible line independent of PCT concentration, thereby confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched PCT Test Devices with desiccant
2. Assay Diluent / Buffer vial(s)
3. Instructions for Use (IFU)

5. KIT STORAGE AND STABILITY

1. Store at 2–30°C. Do not freeze.
2. Protect from direct sunlight and humidity.
3. Use the device immediately after opening the foil pouch.

4. Do not use if the pouch is damaged or the seal is broken.
5. Do not mix components from different lots.
6. Use before the expiry date printed on the packaging.

6. PRECAUTIONS

1. For In-Vitro Diagnostic Use Only.
2. Do not reuse the test device.
3. Avoid testing hemolytic, lipemic, or icteric specimens.
4. Use separate droppers or pipette tips for each specimen to prevent cross-contamination.
5. Wear gloves and adhere to standard laboratory biosafety practices.
6. Do not eat, drink, or smoke in the testing area.
7. Dispose of all used materials as per biomedical waste regulations.
8. Ensure all reagents and specimens are at room temperature before testing.

7. LIMITATIONS

1. This test is qualitative and does not provide an exact PCT concentration.
2. PCT levels below 2 ng/mL may not be detected.
3. Elevated PCT levels may occur in conditions other than bacterial infection, such as major trauma, surgery, or severe systemic inflammation.
4. Clinical decisions should not be based solely on this test; results must be interpreted in conjunction with clinical findings and other laboratory investigations.
5. The test is validated only for human serum or plasma.

8. SAFETY INFORMATION

1. Handle all specimens as potentially infectious.
2. Use appropriate PPE such as gloves, lab coat, and eye protection.
3. Clean spills thoroughly with suitable disinfectants.
4. Dispose of used test components according to biomedical waste disposal guidelines.
5. Do not pipette by mouth.

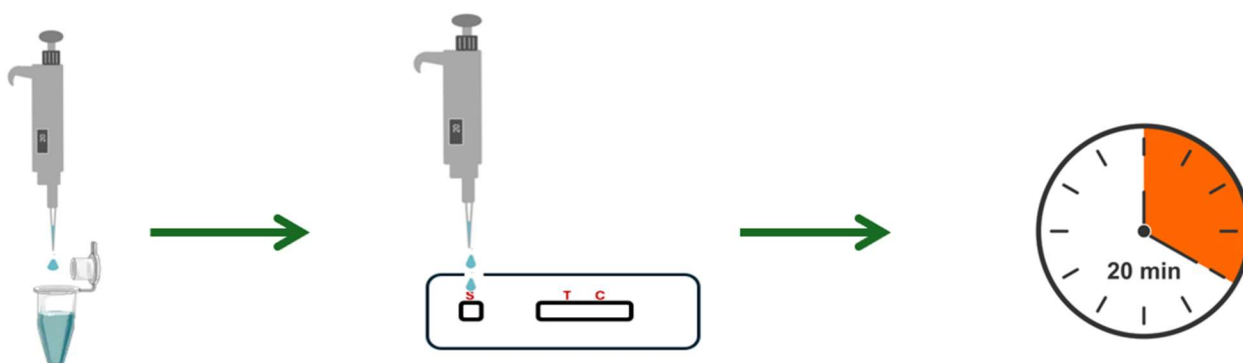
9. REFERENCES

1. Becker KL, et al. *Procalcitonin in sepsis and systemic inflammation: a harmful biomarker and a therapeutic target*. British Journal of Pharmacology. 2010;159(2):253–264.

SPECIMEN COLLECTION AND STORAGE

Category	Details
Accepted Specimens	<ul style="list-style-type: none"> ✓ Whole blood (finger prick or venous) ✓ Serum ✓ Plasma (EDTA, citrate, heparin)
Collection	<ul style="list-style-type: none"> ✓ Finger prick or venous blood using standard procedures ✓ For serum: allow to clot, then centrifuge ✓ For plasma: centrifuge anticoagulated blood
Storage	<ul style="list-style-type: none"> ✓ Test as early as possible ✓ Store at 2–8°C for up to 3 days ✓ For longer storage, freeze serum/plasma at –20°C Avoid freeze–thaw cycles

TEST PROCEDURE



Add 60 ul Plasma (OR)
100 ul Whole Blood Sample
into the Dilution Buffer

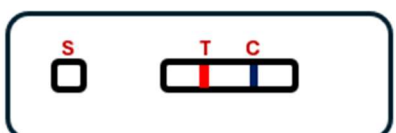
Mix Well and Transfer 100 ul of
Diluted Sample into the Sample Well (S)

Read Results at the
end of 20 Minutes

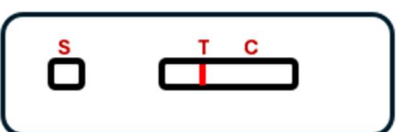
RESULT INTERPRETATION



PCT is Lesser than 2 ng/ml



PCT is higher then 2 ng/ml



Invalid Test Pattern