

1. INTENDED USE

The Biokits CRP Rapid Test is an In-vitro diagnostic, immunochromatographic assay for the qualitative detection of C-reactive protein (CRP) in human whole blood, serum, or plasma. This test is intended for **professional use only**.

2. INTRODUCTION

C-reactive protein (CRP) is an acute-phase reactant produced by the liver in response to inflammation, bacterial infections, autoimmune conditions, and tissue injury. CRP levels increase rapidly within hours of an inflammatory stimulus and often exceed 100 mg/L in significant bacterial infections. Rapid detection of CRP assists clinicians in differentiating bacterial from viral infections, evaluating inflammatory status, guiding antibiotic decision-making, and monitoring treatment response. The Biokits CRP Rapid Test provides a qualitative indication of CRP levels based on two predetermined cut-off points of **10 mg/L and 40 mg/L**.

3. PRINCIPLE OF THE TEST

The Biokits CRP Rapid Test is a lateral-flow immunochromatographic assay with a three-line detection system comprising a control line (C) and two test lines (T1 and T2). CRP in the sample binds to gold-conjugated anti-CRP antibodies and migrates along the membrane by capillary action. The CRP-antibody complexes are captured by immobilized anti-CRP antibodies at the test line regions, producing a visible T1 line at CRP concentrations ≥ 10 mg/L and a T2 line at concentrations ≥ 40 mg/L. The control line is coated with polyclonal antibodies and reacts with colored microsphere control conjugate to produce a visible line independent of CRP concentration, confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched CRP Test Devices with desiccant
2. Assay 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 CRP concentration.
2. CRP levels below 10 mg/L may not be detected even in early inflammation.
3. Extremely high CRP levels may rarely cause a hook effect.
4. Incorrect specimen handling, insufficient sample volume, or deviation from instructions may yield invalid results.
5. Clinical decisions should not be based solely on this test; additional clinical and laboratory evaluations are required.
6. The test is validated only for human whole blood, 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.

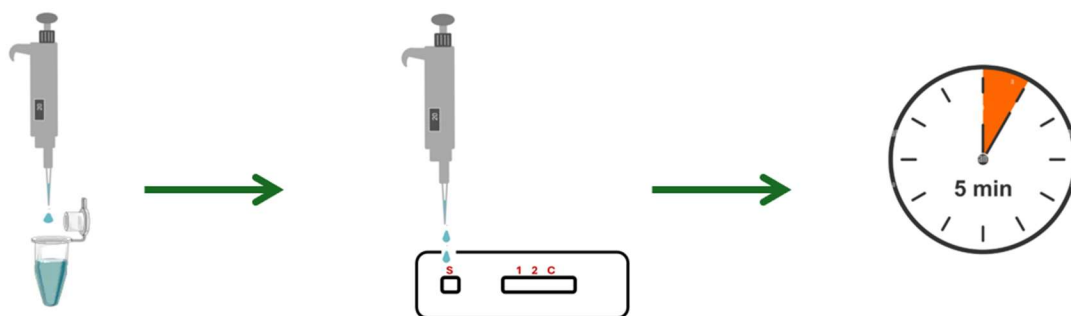
9. REFERENCES

1. Pepys MB, Hirschfield GM. "C-reactive protein: a critical update." *Journal of Clinical Investigation*. 2003;111(12):1805–1812.

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



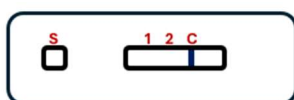
Add 5 ul Serum (OR)
10 ul Whole Blood Sample
into the Dilution Buffer

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

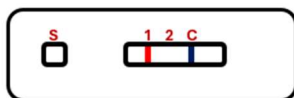
Read Results at the
end of 5 Minutes

Note: Do not read results after 5 min- it may give incorrect results !

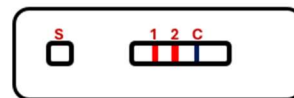
RESULT INTERPRETATION



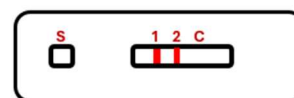
Negative Result – CRP level is less than 10 mg/Lit



Reactive- CRP is Higher than 10 mg/Lit
but Lesser than 40 mg/lit ng/ml



Reactive- CRP is Higher than 40 mg/Lit



Invalid Test Pattern