

1. INTENDED USE

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

2. INTRODUCTION

Cardiac Troponin I (cTnI) is a regulatory protein specific to cardiac muscle and is released into the bloodstream following myocardial injury. Elevated cTnI levels are a sensitive and specific marker for acute myocardial infarction (AMI) and other forms of cardiac damage. Rapid detection of Troponin I assists clinicians in the early diagnosis and management of patients with suspected acute coronary syndromes. The Biokits Troponin I Rapid Test provides a rapid qualitative result to support clinical decision-making.

3. PRINCIPLE OF THE TEST

The Biokits Troponin I 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). Troponin I present in the specimen binds to colloidal gold-conjugated anti-Troponin I antibodies and migrates along the nitrocellulose membrane by capillary action. The antigen-antibody complexes are captured by immobilized anti-Troponin I antibodies at the test line region, producing a visible colored line when Troponin I is present above the assay cut-off. The control line is coated with polyclonal antibodies and reacts with a colored control conjugate, producing a visible line independent of Troponin I concentration, thereby confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched Troponin I Test Devices with desiccant
2. Sample Dropper
3. Assay Buffer
4. 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 Troponin I concentration.
2. A negative result does not exclude myocardial injury, particularly if the specimen is collected early after symptom onset.
3. Troponin I levels may be elevated in conditions other than acute myocardial infarction, such as myocarditis or severe cardiac stress.
4. Clinical decisions should not be based solely on this test; results must be interpreted in conjunction with clinical findings and other diagnostic 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.

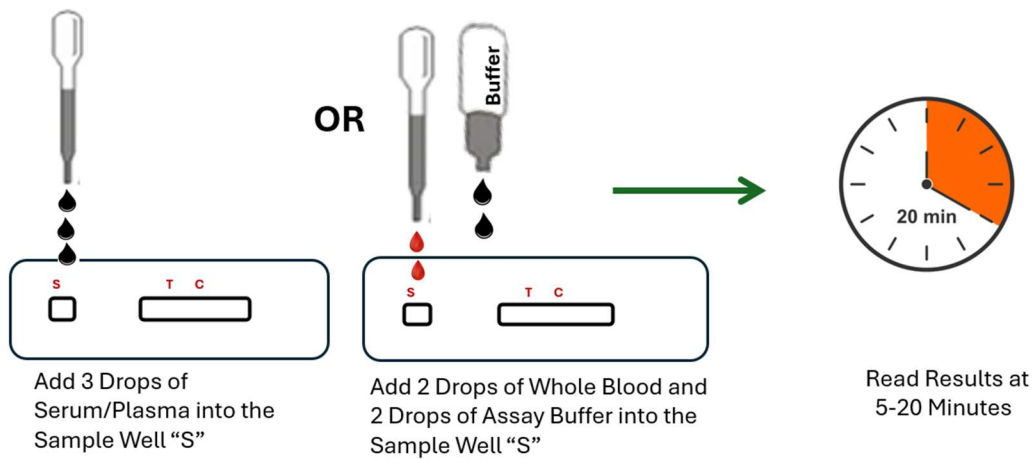
9. REFERENCES

1. Thygesen K, et al. *Fourth Universal Definition of Myocardial Infarction (2018)*. European Heart Journal. 2019;40(3):237–269.

SPECIMEN COLLECTION AND STORAGE

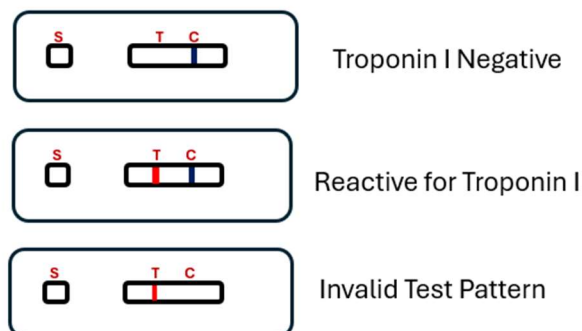
Category	Details
Accepted Specimens	<ul style="list-style-type: none"> ✓ Whole blood (finger prick or venous) ✓ Serum ✓ Plasma (EDTA, citrate, heparin)
Collection	<ul style="list-style-type: none"> ✓ Finger prick or venous blood using standard procedures ✓ For serum: allow to clot, then centrifuge For 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



Note: Do not read results after 20 min- it may give incorrect results !

RESULT INTERPRETATION



PERFORMANCE CHARACTERISTICS

- ✓ Clinical Sensitivity: 100%
- ✓ Clinical Specificity: 99.7%
- ✓ Analytical Sensitivity (Limit of Detection): 0.3 ng/mL for Serum/Plasma and 0.5 ng/ml for Whole Blood.