

A rapid test for the diagnosis of myocardial infarction (MI) to detect cardiac Troponin I (cTnI) qualitatively in whole blood, serum or plasma.
For professional *in vitro* diagnostic use only.

INTENDED USE

The Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of human cardiac Troponin I in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa. Troponin I is part of a three subunit complex, comprising of Troponin T and Troponin C. Along with troponomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle. After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the peroperative period, after major trauma, and blunt chest trauma. cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery. Because of its high specificity and sensitivity for myocardial infarction, Troponin I has recently become the most preferred biomarker for myocardial infarction.

The Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of anti-cTnI antibody coated particles and capture reagent to detect cTnI in whole blood, serum or plasma. The minimum detection level is 0.5 ng/mL.

PRINCIPLE

The Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of cardiac Troponin I (cTnI) in whole blood, serum or plasma. In this test procedure, capture reagent is immobilized in the test line region of the test. After specimen is added to the specimen well of the cassette, it reacts with anti-cTnI antibody coated colloid gold particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized capture reagent. The test format can detect cardiac Troponin I (cTnI) in specimens. If the specimen contains cardiac Troponin I (cTnI), a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain cardiac Troponin I (cTnI), a colored line will not appear in this region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains anti-cTnI antibody coated colloid gold particles and capture reagent coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test cassette if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

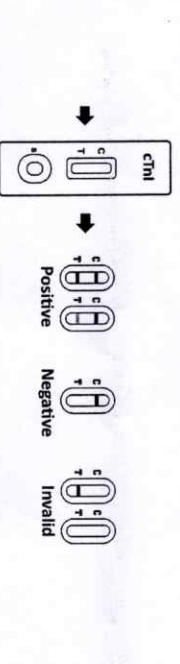
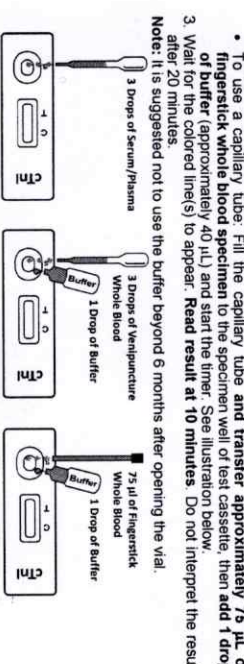
- The Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **Fingerstick Whole Blood specimens**:
 - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
 - Gently rub the hand from wrist to palm to form a rounded drop of blood over the puncture site.
- Add the **Fingerstick Whole Blood specimen** to the test by using a **capillary tube**:
 - Touch the end of the capillary tube to the blood until filled to approximately 75µL. Avoid air bubbles.
 - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.

- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C. If the test is to be run within 1 day of collection, Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
 - EDTA, K₂, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.
- [MATERIALS]**
- Test cassettes
 - Specimen collection Containers
 - Fingerstick whole blood
 - Lancets
 - Materials provided but not provided
 - Capillary tube
 - Timer
 - Heparinized capillary tubes and dispensing bulb

- Dropers
 - Butter
 - Package insert
- [DIRECTIONS FOR USE]**
- Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
 - Place the cassette on a clean and level surface.
 - For **Serum or Plasma specimen**:
 - Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 75 µL) to the specimen well and start the timer. See illustration below.
 - For **Whole Blood specimen**:
 - Hold the dropper vertically and transfer 3 drops of whole blood (approximately 75 µL) to the specimen well, then add 1 drop of buffer (approximately 40 µL), and start the timer. See illustration below.

- To use a capillary tube: Fill the capillary tube and transfer approximately 75 µL of fingerstick whole blood specimen to the specimen well of test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
 - Wait for the colored line(s) to appear. Read result at 10 minutes. Do not interpret the result after 20 minutes.
- Note:** It is suggested not to use the buffer beyond 6 months after opening the vial.



INTERPRETATION OF RESULTS

POSITIVE: Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T).
NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of cardiac Troponin I (cTnI) present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

INVALID: One colored line appears in the control line region (C). No line appears in the test line region (T).
Control line fails to appear, insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit, however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The Cardiac Troponin I Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of Troponin I in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in cTnI can be determined by this qualitative test.
- The Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the qualitative level of cTnI in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
- The Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) cannot detect less than 0.5 ng/mL of cTnI in specimens. A negative result at any time does not preclude the possibility of myocardial infarction.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

- High titers of heterophile antibodies (marked for rat, swine, and guinea pig) may interfere with the test result. Please consider Bgim interference as a possible error when a test result does not match the clinical presentation.
- There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 1 day may not run properly on the test cassette. Repeat the test with a serum or plasma specimen from the same patient using a new test cassette.

EXPECTED VALUES

The Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial cTnI Chemiluminescence immuno assay, demonstrating an overall accuracy of 99.1%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial cTnI Chemiluminescence immuno assay using clinical specimens. The results show that the sensitivity of the Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is 97.6%, and the specificity is 99.4% relative to the Chemiluminescence immuno assay.

| Method | Chemiluminescence immuno assay | | Total Results |
|---|--------------------------------|------------|---------------|
| | Positive | Negative | |
| Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) | 83 | 2 | 85 |
| | 2 | 358 | 360 |
| Total Results | 85 | 360 | 445 |

Relative Sensitivity: 97.6% (95%CI: 91.8%-99.7%)
Relative Specificity: 99.4% (95%CI: 98.0%-99.9%)
Accuracy: 99.1% (95%CI: 97.7%-99.8%)

Precision

Within-run precision has been determined by using 3 replicates of five specimens: a negative cTnI 1.0 ng/mL positive, cTnI 5.0 ng/mL positive, cTnI 10.0 ng/mL positive and cTnI 40.0 ng/mL positive. The negative, cTnI 1.0 ng/mL positive, cTnI 5.0 ng/mL positive, cTnI 10.0 ng/mL positive and cTnI 40.0 ng/mL positive values were correctly identified 99% of the time.

Between-run precision has been determined by 3 independent assays on the same five specimens: a negative, cTnI 1.0 ng/mL positive, cTnI 5.0 ng/mL positive, cTnI 10.0 ng/mL positive and cTnI 40.0 ng/mL positive specimens. Three different lots of the Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested over a 3-days period using negative, cTnI 1.0 ng/mL positive, cTnI 5.0 ng/mL positive, cTnI 10.0 ng/mL positive and cTnI 40.0 ng/mL positive specimens. The specimens were correctly identified 99% of the time.

The Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by 10,000 ng/mL Skeletal Troponin I, 2,000 ng/mL Troponin T, 20,000 ng/mL Cardiac Myosin, HbSA, HbSA, HbSA, HbSA, Anti-Syphilis, Anti-Rheumatoid Factor, Anti-HIV, Anti-Hepatitis, Anti-MOVD IgM, Anti-CMV IgG, Anti-Rubella IgG and Anti-Toxoplasmosis IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to cTnI negative and positive specimens.

| | |
|-------------------------|----------------------------|
| Acetaminophen: 20 mg/dL | Caffeine: 20 mg/dL |
| Ascorbic Acid: 20 mg/dL | Gentamicin: 20 mg/dL |
| Ascorbic Acid: 20 mg/dL | Albumin: 10,500 mg/dL |
| Cream: 200 mg/dL | Hemoglobin: 1,000 mg/dL |
| Bilirubin: 1,000 mg/dL | Oxalic Acid: 600 mg/dL |
| Cholesterol: 800 mg/dL | Triglycerides: 1,600 mg/dL |

None of the substances at the concentration tested interfered in the assay.

BIBLIOGRAPHY

- Adams et al. Biochemical markers of myocardial injury. Immunoassay Circulation 88:750-763, 1993.
- Meinhart JP. Tobacian US. Cooperative interaction between troponin molecules bound to the cardiac thin filament. J Biol Chem. 265:968, 1991.
- Adams, et al. Diagnosis of Pericardial myocardial infarction with measurements of cardiac troponin I. N Engl J Med 330:670, 1994.
- Hossain-Nia M, et al. Cardiac troponin I release in heart transplantation. Ann Thorac Surg 61: 227, 1996.
- Albert JS, et al. Myocardial infarction. Redefined. Joint European Society of Cardiology American College of Cardiology. J Am Coll Cardiol. 36(3):559, 2000.
- FDA. The FDA warns that biotin may interfere with lab tests. FDA safety communication.

Index of Symbols

| | | |
|---|---------------|---------------------------------|
| Caution | Tests per Kit | Authorized Representative in EU |
| For <i>in vitro</i> diagnostic use only | Use by | Do not reuse |
| Store between 2-30°C | Lot number | Catalog # |
| Do not use if package is damaged | Manufacturer | Consult instructions for use |

Hengzhou Alltest Biotech Co., Ltd.

1530, Trial Street 3, Technological Development Area
Hengzhou, 310015 P.R. China
Web: www.alltest.com.cn Email: info@alltest.com.cn



Medical CE-REP GmbH
Bismarckstr. 10,
46103 Münster,
Germany

Number: 145891402
Revision date: 2023-04-23