Troponin I Rapid Test Device
Package Insert

Cat: CTI-402 **Specimens:** Whole Blood/Serum/Plasma
Version: 02 **Effective Date:** 2015-02

For professional *in vitro* diagnostic use only.

INTENDED USE

The Troponin I Rapid Test Device (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.1 Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.2 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 perioperative period, after marathon runs, and blunt chest trauma.3 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.4 Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.5

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

PRINCIPLE

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of cTnI in whole blood, serum or plasma. The membrane is pre-coated with capture reagent on the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-cTnI antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with capture reagent on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates 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.

KIT COMPONENTS

Individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions
Disposable pipettes	For adding specimens use
Buffer	Phosphate buffered saline and preservative
Package insert	For operation instruction

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test device should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.
- 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 device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. Do not freeze. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARETION

- The Troponin I Rapid Test Device (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 then allow to dry. Massage the hand without touching the puncture. Puncture the skin with a sterile lancet. Wipe away the first sign of blood. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site. Add the Fingerstick Whole Blood specimen to the test device by using a **capillary tube or hanging drops.**
- 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 specimen collection. 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 2 days 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.

MATERIALS

Materials Provided

- Test devices
- Buffer
- Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

Allow test device, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.
   For **Whole Blood, Serum or Plasma** specimens:
   Hold the dropper vertically and transfer **2 drops of specimen** (or approximately 50 µL) to the specimen well (S) of the test device, then add **1 drop of buffer** and start the timer.
   For **Fingerstick Whole Blood** specimens:
   To use a capillary tube: Fill the capillary tube and **transfer approximately 50 µL (or 2 drops) of fingerstick whole blood** specimen to the specimen well (S) of the test device, then add **1 drop of buffer** and start the timer.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret results after 20 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT:

*A colored band appears in the control band region (C) and another colored band appears in the T band region.

NEGATIVE RESULT:

One colored band appears in the control band region (C). No band appears in the test band region (T).

INVALID RESULT:

Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of cTnI present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is 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

IMITATIONS

1. The Troponin I Rapid Test Device (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.
2. The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the qualitative level of cardiac Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
3. The Troponin I Rapid Test Device (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.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. 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.

EXPECTED VALUES

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) has been compared with a leading commercial cTnI EIA test, demonstrating an overall accuracy of 98.7%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial cTnI EIA test using clinical specimens. The results show that the sensitivity of the Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is 98.3% and the specificity is 98.4% relative to the leading EIA test.

Troponin I Rapid Test Device vs. EIA

Method		EIA Test		Total Results
Troponin I Rapid Test Device	Results	Positive	Negative	
	Positive	113	6	119
	Negative	2	493	495
Total Results		115	499	614

Relative Sensitivity: 98.3%(95.9%-100%)* Relative Specificity: 98.8%(97.8%-99.8%)*
Accuracy: 98.7%(97.8%-99.6%)* *95% Confidence Interval

RRECISION

Intra-Assay

Within-run precision has been determined by using replicates of 10 tests for each of three lots using cTnI specimen levels at 0 ng/mL, 5 ng/mL, 10 ng/mL, 20 ng/mL, and 40 ng/mL. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same five specimens: 0ng/mL, 5ng/mL, 10 ng/mL, 20 ng/mL, and 40 ng/mL of Troponin I. Three different lots of the One Step cTnI Test Device (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-Reactivity

Sera containing known amounts of antibodies to cTnI have been tested with 10,000ng/mL Skeletal Troponin I, 2,000 ng/mL Troponin T, and 20,000 ng/mL Cardiac Myosin. No cross-reactivity was observed, indicating that the cTnI Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) has a high degree of specificity for cardiac Troponin I.

Interfering Substances

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) has been tested and no interference was observed in specimens containing 110 mg/mL human albumin, 6 mg/mL bilirubin, 10 mg/mL hemoglobin, 5 mg/mL cholesterol and 15 mg/mL triglycerides.

The following compounds have also been tested using Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) and no interference was observed at a concentration of 50µg/mL.

Acetaminophen	Captopril	Furosemide	Oxazepam
Acetylsalicylic Acid	Chloramphanicol	Flunarizine Hydrochloride	Pentoxifylline
Anisodamine	Chlordiazepoxide	Hydrochlorothiazide	Phenobarbital
Ascorbic Acid	Cilazapril	Isosorbide Mononitrate	Quinine
Atenolol	Diclofenac	Labetalol	Ramipril
Atorvastatin Calcium	Digoxin	Metoprolol Tartrate	DL-Tyrosine
Bisoprolol Fumarate	Erythromycin	Moracizine Hydrochloride	Trimethoprim
Caffeine	Felodipine	Nifedipine	Verapamil

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4. Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation. Ann. Thorac. Surg. 61: 227, 1996.