Troponin I Rapid Test
(Serum/Plasma/Whole Blood)

INTENDED USE
The Cardiac Troponin I Test 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 AND EXPLANATION OF THE TEST
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 Test 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 Troponin I Testis 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.

SPECIMEN COLLECTION AND PREPARATION
- This test can be used for whole blood, plasma, and serum samples. If serum samples are to be used, collect the blood in a tube without anticoagulant and allow clotting for at least 25 minutes before centrifugation. Whole blood or plasma samples using heparin or EDTA as the anticoagulant can be used for testing with this product. Other blood anticoagulants have not been evaluated. Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variation in these products may exist between manufacturers and, at times, from lot-to-lot. Use only clear, non-hemolysed specimens.
- The samples should be collected under standard laboratory conditions.
- Optimal results were obtained when patient samples were tested immediately after collection. Whole blood samples should be used within 4 hours after collection. Plasma or serum samples may be refrigerated for 24 hours at 2-8°C. If testing can not be performed within 24 hours, or for shipment of samples, freeze at -20°C or colder.12-13
- Sodium azide can be added as a preservative upto 0.1% without affecting the test results.
- Refrigerated or frozen serum or plasma specimen should reach

  room temperature and be homogeneous prior to testing.

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

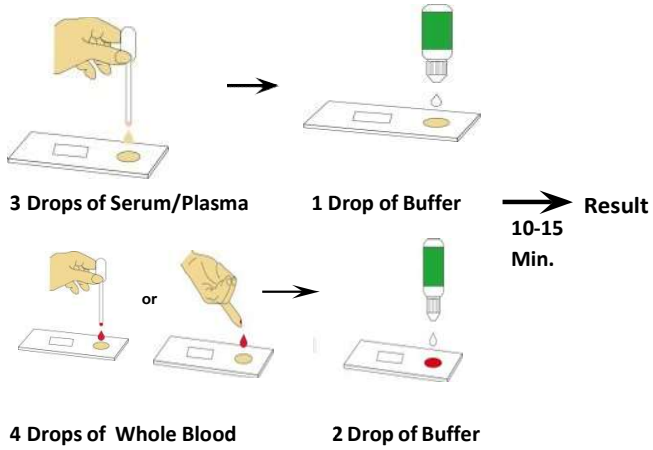
PRECAUTIONS
- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.

STORAGE AND STABILITY
1. 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.
2. Do not freeze. Do not use beyond the expiration date.

MATERIALS PROVIDED
- Test Device with activated silica gel
- Plastic dropper
- Assay Buffer Bottle.
- Insert (instruction for use)

MATERIALS REQUIRED BUT NOT PROVIDED
1. Specimen Collection Containers (For fingerstick whole blood)
2. Centrifuge
3. Timer
4. Lancets

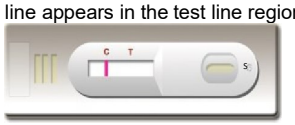
TEST PROCEDURE
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.
   For Serum or Plasma specimen:
   - Hold the dropper vertically and transfer **3 drops** of serum or plasma (approximately **75 µl**) to the specimen area, then add **1 drop** of buffer (approximately **40 µl**) and start the timer. See illustration below.
   - **For Venipuncture Whole Blood specimen:**
   - Hold the dropper vertically and transfer **4 drops** of whole blood (approximately **100 µl**) to the specimen well then add **2 drops** (**80 µl**) of buffer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 10-15 minutes.
   Note: *Do not interpret the result after 20 minutes.*



INTERPRETATION OF THE TEST
POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent 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 cardiacTroponinI (cTnI) present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.*

NEGATIVE: One colored line appears in the control line region(C). No line appears in the test line region (T).



INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure Review the pronedi ire 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 OF THE TEST

1. 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.
2. The Troponin I Test 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.
3. The Troponin I Test can not detect less than 0.5ng/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.
4. 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.
5. High levels of Biotin (Such as supplements marketed for hair, skin, and nail growth) may interfere with the test result. Please consider Biotin interference as a possible error when a test result doesn't match the clinical presentation6
6. There is as light 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 Troponin I Test has been compared with a leading commercial cTnI ELISA test, demonstrating an overall accuracy of 99.1%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Troponin I Test has been evaluated with a leading commercial cTnI ELISA test using clinical specimens. The results show that the sensitivity of the Troponin I Test is 99.4% and the specificity is 99.0% relative to the leading ELISA test.

Method		ELISA		Total Result
	Results	Positive	Negative	
	Positive	172	5	177
Cardiac Troponin I Rapid Test (Whole Blood/Serum/ Plasma)	Negative	1	472	473
Total Results		**173**	**477**	**650**

Relative sensitivity: 99.4%
Relative specificity: 99.0%
Accuracy : 99.1 %

Precision Intra-Assay

Within-run precision has been determined by using 15 replicates of five specimens: a negative, cTnI 1.0ng/mL positive, cTnI 5.0ng/mL positive, cTnI 10ng/mL positive and cTnI 40ng/mL positive. The negative, cTnI 1.0ng/mL positive, cTnI 5.0ng/mL positive, cTnI 10ng/mL positive and cTnI 40ng/mL positive values were correctly identified>99%ofthe time.

Precision Inter-Assay

Between-run precision has been determined by 15 independent assays on the same five specimens: a negative, cTnI 1.0ng/mL positive, cTnI 5.0ng/mL positive, cTnI 10ng/mL positive and cTnI40ng/mL positive specimens.

Three different lots of the Troponin I Test have been tested over a 3-day period using negative, cTnI 1.0ng/mL positive, cTnI 5.0ng/mL positive, cTnI 10ng/ mL positive and cTnI 40ng/mL positive specimens. The specimens were correctly identified>99% of the time.

Cross-reactivity

The Troponin I Test has been tested by 10,000ng/mL Skeletal Troponin I, 2,000ng/mL Troponin T, 20,000ng/mL Cardiac Myosin, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-H.pylori, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no cross-reactivity.

Interfering Substances

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

Acetaminophen : 20mg/dL
Acetylsalicylic Acid : 20mg/dL
Ascorbic Acid : 20mg/dL
Creatin : 200mg/dL
Bilirubin : 1,000mg/dL
Cholesterol : 800mg/dL
Caffeine : 20 mg/dL
Gentisic Acid : 20mg/dL
Albumin : 10,500mg/dL
Hemoglobin : 1,000mg/dL
OxalicAcid : 600mg/dL
Triglycerides : 1,600mg/dL

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

REFERENCES

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