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

Package Insert

REF 0280003	English

A rapid test for the diagnosis of myocardial infarction (MI) to detect cardiac Troponin I (cTnI) 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 semi quantification 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 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 0.3ng/mL.

【PRINCIPLE】

The Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is a semi-quantitative, 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 area 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.

The mouse IgG-colloidal gold conjugate and unbound complex, if any, moves further to the reference region (R) that contains pre-calibrated anti mouse IgG antibodies, corresponding to 1 ng/ml cTnI, immobilized on the membrane. The intensity of the pink purple colored band at the reference region (R) corresponds to a cTnI concentration of 1 ng/ml. The reference band would form even in a negative specimen. Semi-quantitative information about the concentration of cTnI can be deduced by comparing the intensity of the test band against the reference band. If the intensity of test band is less than the reference band, cardiac Troponin I (cTnI) concentration is equal to or above 0.3 ng/ml and less than 1 ng/ml. If the intensity of the test band is equal to or greater than reference band, cardiac Troponin I (cTnI) concentration is equal to or greater than 1 ng/ml.

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. A goat antibody is employed in the control line system.

【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.
- 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 Caridiac Troponin I (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 finger 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 50 µL. 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 area of the test cassette.
  - Add the Fingerstick Whole Blood specimen to the test by using **hanging drops**:
    - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- 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 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 Cassettes
- Droppers
- Buffer
- Package insert

Materials required but not provided

- Specimen collection Containers
- Centrifuge
- Timer

For fingerstick whole blood

- Lancets
- Heparinized capillary tubes and dispensing bulb

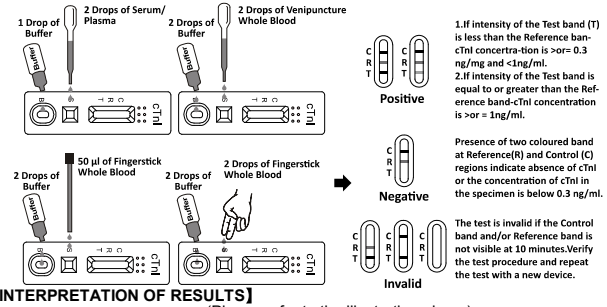
【DIRECTIONS FOR USE】

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 **2 drops of serum or plasma (approximately 50 µL)** to the specimen area (S), then **add 1 drops of buffer** (approximately **40 µL**) to the buffer area (B), and start the timer. See illustration below.

   For **Venipuncture Whole Blood** specimen:
   - Hold the dropper vertically and transfer **2 drops of whole blood** (approximately **50 µL**) to the specimen area (S), then **add 2 drops of buffer** (approximately **80 µL**) to the buffer area (B), and start the timer. See illustration below.

   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube **and transfer approximately 50 µL of fingerstick whole blood specimen** to the specimen area (S) of test cassette, then **add 2 drops of buffer** (approximately 80 µL) to the buffer area (B) and start the timer. See illustration below.
   - To use hanging drops: Allow **2 hanging drops of fingerstick whole blood specimen** (approximately 50 µL) to fall into the specimen area (S) of test cassette, then **add 2 drops of buffer** (approximately 80 µL) to the buffer area (B) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Three lines appear. Two colored lines should be in the control line region (C) and reference line region (R), 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 cardiac Troponin I (cTnI) present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: Colored line appears in the control line region (C) and reference line region (R). No line appears in the test line region (T).

INVALID: Control or/and reference lines fail 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】

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.
2. The Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the semi quantitative level of cTnI in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
3. The Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) cannot detect less than 0.3ng/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.
6. There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days 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 EIA test, demonstrating an overall accuracy of 98.8%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The Cardiac Troponin I Rapid Test Cassette (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 Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is 98.9% and the specificity is 98.8% relative to the leading EIA test.

Method		EIA		Total Result
Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	183	6	189
	Negative	2	503	505
Total Result		185	509	694

Relative sensitivity: 183/185=98.9% (95%CI*: 96.1%~99.9%);
Relative specificity: 503/509=98.8% (95%CI*: 97.5%~99.6%);
Accuracy: (183+503)/(183+2+6+503)=98.8%(95%CI*: 97.7%~99.5%)
*Confidence Intervals

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% of the time.

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 cTnI 40ng/mL positive specimens. Three different lots of the Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) 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 Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) 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: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 20mg/dL	Albumin: 10,500mg/dL
Creatin: 200 mg/dL	Hemoglobin 1,000 mg/dL
Bilirubin: 1,000mg/dL	Oxalic Acid: 600mg/dL
Cholesterol: 800mg/dL	Triglycerides: 1,600mg/dL

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

【BIBLIOGRAPHY】

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3. Adams, et al. Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I. N.Eng.J.Med 330:670, 1994.
4. Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation. Ann. Thorac. Surg. 61: 227, 1996.
5. Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

Manufacturer:

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