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

**INTENDED USE**
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.

**SUMMARY**
Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5kd. 1 cTnI is a part of a subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle. 2 After cardiac injury, cTnI is released into blood, with a release pattern similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for up to 10 days. 3 It is now a widely accepted and well-established biomarker of myocardial damage. 4,5 Currently, high specificity cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the peripartum period, after myocardial revascularization, and blunt chest trauma. 6 7 cTnI release has also been documented in cardiac disease with the use of radioactive lymphangiography, 8 unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery. 9,10 Because of the high discriminatory power of this myocardial, Troponin I has recently become the preferred biomarker for myocardial infarction. 11-14

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

**MATERIALS**
- **Test Cassette**
- **Drops**
- **Buffer**
- **Packaging**

**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 pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.

**For Serum/Plasma specimens:**
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Add the Fingerstick Whole Blood specimen to the test by using 2 drops of serum or plasma (approximately 50 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:
- Use a lancet to make a 2-mm deep puncture. Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the blood into a tube. Touch the end of the capillary tube to the blood until filled to approximately 75 μL. Start the timer. See illustration below.

3. Wait for the colored lines to appear. Read results at 10 minutes.

**INTERPRETATION OF RESULTS**

**Positive:** Two lines appear. One colored line should be in the control line region (C) and another appears colored line be in the test line region (T).  

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

**INVISIBLE:** 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 specimen. 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 immune 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 Rapid 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 as an aid in the diagnosis of myocardial infarction.
- Cholesterol: 800mg/dL  
  Triglycerides: 1,600mg/dL  
  Creatin: 200 mg/dL  
  Hemoglobin 1,000 mg/dL  
  Anti-HBs, Anti-HBc, Anti-HBe, Anti- HBV, Anti-HIV, Anti-Hep, MONO, anti-CMV, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no cross-reactivity.
- The following potentially interfering substances were added to cTnI negative and positive specimens. Acetaminophen: 1,000mg/dL, Acetylsalicylic Acid: 20 mg/dL, Ascorbic Acid: 100 mg/dL, Edetate Disodium: 100 mg/dL, Hemoglobin 1,000 mg/dL, Glucose: 600mg/dL, Cholesterol: 1,000mg/dL. None of the substances at the concentration tested interfered in the assay.

**PRECAUTIONS**
- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the vicinity where the specimens or kits are handled.
- Do not use test if it is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbial hazards throughout all procedures and follow standardized 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 this package in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable for 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 (Whole Blood/ Serum/ Plasma) can be performed using whole blood (from venipuncture or fingertip), serum, or plasma.
- To perform a **Fingertip 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 wrist for 20 seconds to facilitate the drainage of the middle section of the finger.
  - Puncture the skin with a sterile lancet. Wash 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 75 μL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to disperse the whole blood to the specimen area of the test cassette.
- 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 75 μL. Avoid air bubbles.
  - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to disperse the whole blood to the specimen area of the test cassette.
- Add 3 drops of whole blood specimen to the test area in 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 or 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 fingertip should be tested immediately.
- Bring specimen to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well before 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.