

# CTnI

## One Step Troponin I Test Device (Whole Blood/Serum/Plasma) Package Insert

A rapid, one step test for the qualitative detection of cardiac Troponin I in whole blood, serum or plasma.

For professional *in vitro* diagnostic use only.

### INTENDED USE

The cTnI One Step Troponin I 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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.<sup>5</sup>

The cTnI One Step Troponin I 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 cTnI One Step Troponin I 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.

### REAGENTS

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

### 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 PREPARATION

- The cTnI One Step Troponin I 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 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 device by using a **capillary tube**:
  - Touch the end of the capillary tube to the blood until filled to approximately 80 µL. Avoid air bubbles.
- Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.
- Add the Fingerstick Whole Blood specimen to the test device by using **hanging drops**:
  - Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
  - Allow 3-4 hanging drops of fingerstick whole blood to fall into the specimen well (S) of the test device, or move the patient's finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).
- 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
- Package insert
- Droppers

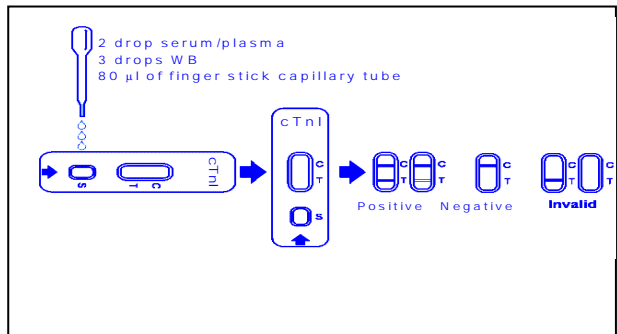
#### Materials Required But Not Provided

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

### DIRECTIONS FOR USE

Allow test device, specimen, 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 device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface.
  - For **Serum or Plasma** specimens: Hold the dropper vertically and **transfer 2 drops of serum or plasma** (approximately 80 µL) to the specimen well (S) of the test device, and start the timer. See illustration below.
  - For **Venipuncture Whole Blood** specimens: Hold the dropper vertically and **transfer 3 drops of venipuncture whole blood** (approximately 120 µL) to the specimen well (S) of the test device, and start the timer. See illustration.
  - For **Fingerstick Whole Blood** specimens:
    - To use a capillary tube: Fill the capillary tube and **transfer approximately 80 µL of Fingerstick whole blood** specimen to the specimen well (S) of the test device, and start the timer. See illustration below.
    - To use hanging drops: Allow **4 hanging drops of fingerstick whole blood specimen** (approximately 80 µL) to fall into the center of the specimen well (S) on the test device, and start the timer. See illustration below.
- Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not



interpret results after 20 minutes.

### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

**INVALID: Control line (C) 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

### 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.

### LIMITATIONS

- The cTnI One Step Troponin I 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.
- The cTnI One Step Troponin I 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.
- The cTnI One Step Troponin I 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.
- 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.

### EXPECTED VALUES

The cTnI One Step Troponin I Test Device (Whole Blood/Serum/Plasma) has been compared with a leading commercial cTnI EIA test, demonstrating an overall accuracy of 98.5%.

### PERFORMANCE CHARACTERISTICS

#### Sensitivity and Specificity

The cTnI One Step Troponin I 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 cTnI One Step Troponin I Test Device (Whole Blood/Serum/Plasma) is 98.5% and the specificity is 98.4% relative to the leading EIA test.

#### One Step cTnI Test Device vs. EIA

Method	EIA Test		Total Results
	Positive	Negative	
One Step cTnI Test Device	Positive	197	205
	Negative	3	508
<b>Total Results</b>		200	713

Relative Sensitivity: 98.5%(95.7%-99.7%)\* Relative Specificity: 98.4%(97.0%-99.3%)\*

Accuracy: 98.5%(97.3%-99.2%)\* \*95% Confidence Interval

#### Precision

##### 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: 0 ng/mL, 5 ng/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 10,000 ng/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 One Step Troponin I Test Device (Whole Blood/Serum/Plasma) has a high degree of specificity for cardiac Troponin I.

##### Interfering Substances

The cTnI One Step Troponin I 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 cTnI One Step Troponin I Test Device (Whole Blood/Serum/Plasma) and no interference was observed at a concentration of 50 µg/mL.

Acetaminophen	Captopril	Furosemide	Oxazepam
Acetylsalicylic Acid	Chloramphenicol	Flunarizine Hydrochloride	Pentoxifyline
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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Revision A (20.07.2006)

PPI361A01