Atlas Medical

Troponin I (CTnI) Test Device (Whole blood /Serum/Plasma)

CE

IVD For *In-Vitro* diagnostic and professional use only

2 30°C Store at 2-30 °C

INTENDED USE

Atlas Troponin I Test Device 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).

INTRODUCTION

Troponin I is a part of a three subunit complex protein comprising of Troponin T and Troponin C. Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa.Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitivity of actomyosin ATPase activity in striated skeletal and cardiac muscle. 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. 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. Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.

Atlas Troponin I Test Device 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 Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is 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 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. 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.

MATERIALS

MATERIALS PROVIDED

- Test devices (anti-cTnI antibody coated colloid gold particles and capture reagent coated on the membrane, 0.03% proclin 300).
- Buffer.
- Droppers.
- Package insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container.
- Centrifuge.
- Timer.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- 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 all 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.
- The used test should be discarded according to local regulations.

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.

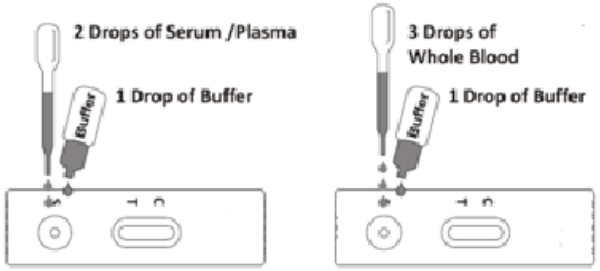
SPECIMEN COLLECTION AND PREPARATION

- The 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 75µL. 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.
- 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 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.

PROCEDURE

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.
3. For **Serum or Plasma,** specimens:
   Hold the dropper vertically and **transfer 2 drops of serum or plasma** (approximately 50 µL) to the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µL) and start the timer.
4. For **Whole Blood** specimens:
   Transfer **3 drops of whole blood specimen** (approximately 75 µL) to specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µL) and start the timer.
5. For **Fingerstick Whole Blood** specimens:
   Transfer **3 drops of Fingerstick whole blood specimen** (approximately 75 µL) to specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µL) and start the timer. See illustration below.
6. Wait for the colored line(s) to appear. **Read results at 10 minutes**. Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS

(See illustration below)

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.

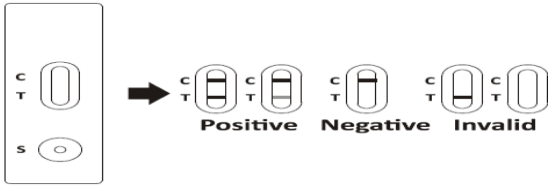
NEGATIVE:

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.
- Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device.

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. Neither the quantitative value nor the rate of increase in cTnI can be determined by this qualitative test.
2. The Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) 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 Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) cannot detect less than 0.5ng/mL of cTnI in pecimens. 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.

PERFORMANCE CHARACTERISTICS

1. 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 98.8% and the specificity is 98.9% relative to the leading EIA test.

Method		EIA		Total Result
Cardiac Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	Result	Positive	Negative	
	Positive	158	7	165
	Negative	2	603	605
Total Result		160	610	770

Relative sensitivity: 158/160=98.8% (95%CI*: 95.6%~99.8%).
Relative specificity: 603/610=98.9% (95%CI*: 97.7%~99.5%).
Accuracy: (158+603)/ (158+2+7+603) =98.8 %(95%CI*: 97.8%~99.5%).
*Confidence Intervals

2. 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.

Acetaminophen	20 mg/dL	Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	Gentisic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL	Albumin	10.500 mg/dL
Creatin	200 mg/dL	Hemoglobin	1000 mg/dL
Bilirubin	1000 mg/dL	Oxalic Acid	600 mg/dL
Cholesterol	800 mg/dL	Triglycerides	1600 mg/dL

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.

3. Interfering Substances

The following potentially interfering substances were added to cTnI negative and positive specimens.
None of the substances at the concentration tested interfered in the assay.

REFERENCES

1. Adams, et al. *Biochemical markers of myocardial injury*, Immunoassay Circulation 88: 750-763, 1993.
2. Mehegan JP, Tobacman LS. *Cooperative interaction between troponin molecules bound to the cardiac thin filament.* J.Biol.Chem. 266:966, 1991.
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.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry