



Troponin I

RAPU04A097

History

Resume of change :

Previous Version : 111123-1	Current Version : 190717-1
Ancient protocol	New protocol
LOT : 111123-1	Version : 190717-1
P.I. Number : 111123-1	P.I. Number cleared
No history	History added



Troponin I

en

In-vitro diagnostic test for the qualitative detection of human cardiac Troponin I

in whole blood, serum or plasma

RAPU04A097

IN VITRO DIAGNOSTIC

DIAsource ImmunoAssays SA - Rue du Bosquet 2, B-1348 Louvain-la-Neuve, Belgium - Tel: +32 10 84 99 11 - Fax : +32 10 84 99 90

INTENDED USE

The DIAsource 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 DIAsource 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 0.5ng/mL.

PRINCIPLE

The DIAsource Troponin I Test 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 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 cannot 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 up to 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.
- 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 beyond the expiration date.

MATERIALS PROVIDED

CARD	20 Troponin Test Cassettes
PIPETTE	20 Droppers
BUF	Buffer 1, 3 ml

- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen Collection Containers (For fingerstick whole blood)
- Centrifuge
- Timer
- Lancets
- Heparinized capillary tubes and dispensing bulb

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:

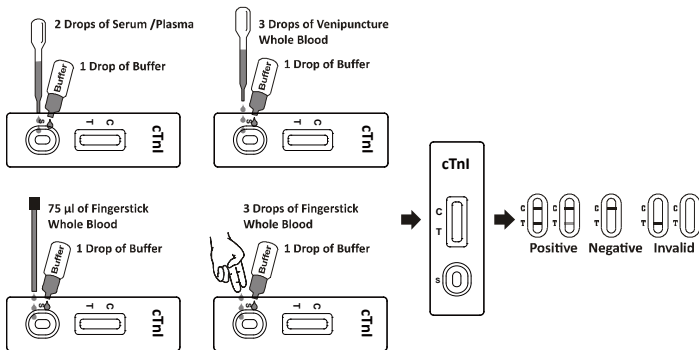
- Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50 µL) to the specimen well, then add 1 drop of buffer (approximately 40 µL), and start the timer. See illustration below.

For **Venipuncture Whole Blood** specimen:

- Hold the dropper vertically and transfer 3 drops of whole blood (approximately 75 µL) to the specimen well, then add 1 drop of buffer (approximately 40 µL), and start the timer. See illustration below.

For **Fingerstick Whole Blood** specimen:

- To use a capillary tube: Fill the capillary tube and transfer approximately 75 µL of fingerstick whole blood specimen to the specimen well of test cassette, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
 - To use hanging drops: Allow 3 hanging drops of fingerstick whole blood specimen (approximately 75 µL) to fall into the specimen well of test cassette, then add 1 drop of buffer (approximately 40 µL) 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 THE TEST

(Please refer to the illustration above)

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 cardiac Troponin I (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 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 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 DAsource 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 DAsource Troponin I Test cannot 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.
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. 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 presentation.
7. There is a slight 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 DAsource 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 DIIAsource Troponin I Test has been evaluated with a leading commercial cTnI ELISA test using clinical specimens. The results show that the sensitivity of the DIIAsource Troponin I Test is 99.4% and the specificity is 99.0% relative to the leading ELISA test.

Method	ELISA		Total Results
	Results		
DIIAsource Troponin I Test	Positive	172	177
	Negative	1	473
	Total Results	173	650

Relative sensitivity: 172/173=99.4% (95% CI*: 96.8%~99.9%);

Relative specificity: 472/477=99.0% (95% CI*: 97.6%~99.7%);

Accuracy: (172+472)/(172+1+5+472)=99.1%(95% CI*: 98.0%~99.7%). *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.

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 cTnI 40ng/mL positive specimens. Three different lots of the DIIAsource 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 DIIAsource 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: 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.

REFERENCES

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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
6. FDA. The FDA warns that biotin may interfere with lab tests: FDA safety communication.

SYMBOLS

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

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