

Troponin-I

Troponin I Test Device (Serum/Plasma/Whole Blood)

REF: 1173 001 30 test

A rapid test for the qualitative detection of Cardiac Troponin I in Human serum, plasma or whole blood.
For professional in vitro test use only.

INTENDED USE

For the rapid qualitative determination of Cardiac troponin I (cTnI) in human whole blood, serum and plasma as an aid in the diagnosis of myocardial infarction

SUMMARY

Troponin I (TnI) is part of the troponin complex which, together with tropomyosin, forms the main component that regulates the Ca²⁺-sensitive ATP-ase activity of actomyosin in striated muscle (skeletal and cardiac). The troponin complex consists of three subunits, troponin T (TnT), troponin I (TnI), and troponin C (TnC). Each subunit has a distinct function with TnC as the site of Ca²⁺ binding, TnT the tropomyosin binding, and TnI as the inhibitory subunit. Different isoforms of TnI exist in the skeletal and cardiac muscles (sTnI and cTnI, respectively) with distinct immunologic epitopes that allow the production of cardiac-specific TnI antibodies. The cardiac marker, troponin I has been established as useful tools in the diagnosis of acute myocardial infarction (AMI). Troponin I is found in blood at elevated concentrations approximately 4- 6 hours after the onset of chest pain and peak at 12-24 hours. Troponin I levels remain elevated for up to 14 days. The use of this marker is an aid in the diagnosis of AMI after myocardial infarction.

PRINCIPLE

The Troponin I Rapid Test Device employs a solid-phase chromatographic immunoassay technology to qualitatively detect the elevation of troponin I in human blood samples. When a sample of blood is dispensed into the sample well, red blood cells are removed by the built in separation system. Troponin I in the specimen makes a complex with the specific dye conjugate and biotinylated anti-troponin I antibody. This complex migrates through the test area containing immobilized streptavidin. The antibody dye-troponin I-biotinylated antibody complex bind to the immobilized streptavidin in the Test area. Unbound dye complexes migrate out of the Test area and are later captured in the Control area. Visible pinkish-purple bands will appear in the Test and Control areas if the concentrations of troponin I is above established cutoff values. If the troponin I concentration in the specimen is 0.6 ng/ml or greater, a band is present in the troponin I area. If a band is present only in the Control area, the test result is read as negative, indicating that the Troponin I concentrations are all below the cutoff values. If no band is present in the Control area, the test is invalid and another test must be run, regardless of the presence or absence of band(s) in the Test Area.

PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use beyond the expiration date.
- Use separate syringe or clean pipette tips for different specimens. Do not pipette by mouth.
- Do not smoke, eat or drink in areas in which specimens or kits are handled.
- Wear disposable gloves while handling specimens and running the tests, and thoroughly wash hands afterwards.
- All patient samples should be handled as if they are capable of transmitting diseases. Observe established good laboratory procedures for proper disposal of specimens, used pipette tips or syringes, and used test devices.
- The test device should remain in its sealed pouch until ready for use.
- Humidity and temperature can adversely affect results.

SYMBOLS IN PRODUCT LABELLING

	Authorised Representative		Temperature Limitation
	For in-vitro diagnostic use		Use by/Expiration Date
	Batch Code/Lot number		CAUTION. Consult instructions for use
	Catalogue Number		Manufactured by
	Consult instructions for use		

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30 °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.

SPECIMEN COLLECTION AND PREPARATION

Whole blood, plasma or serum may be used as samples for this procedure. Collect blood in a tube containing heparin as the anticoagulant. Guidelines recommended by the National Committee for Clinical Laboratory Standards (NCCLS) should be followed when collecting, transporting and processing patient samples. Since cTnI is relatively unstable, it is recommended that fresh samples be used as soon as possible to collect critical patient information. Heat inactivation of samples may lead to hemolysis or protein denaturation and therefore should be avoided.

Whole blood samples should be tested within 2 hours of collection. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test device(s)
- Sample diluent (1 x 5 mL)
- One plastic dropper.
- Instructions for use

Materials Required But Not Provided

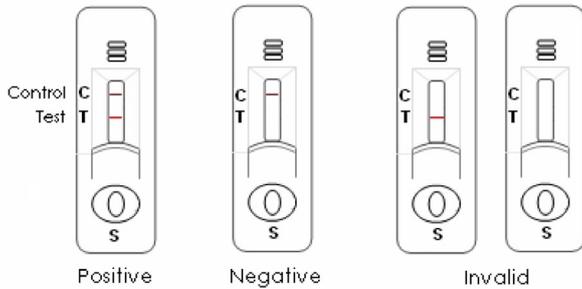
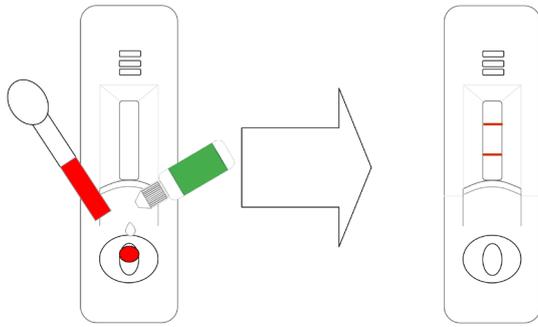
- Vacutainer tube containing heparin as an anticoagulant
- Timer
- Positive and Negative Controls
- Calibrated Pipette

ASSAY PROCEDURE

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3. Be sure to label the device with specimen's ID number.
4. **For whole blood test**
Apply 1 drop of whole blood (about 40-50 µL) into the sample well.
Then add 1 drop (about 35-50 µL) of Sample Diluent immediately.
5. **For serum or plasma test**
Fill the pipette dropper with the specimen.
Holding the dropper vertically, dispense 1 drop (about 30-45 µL) of specimen into the sample well making sure that there are no air bubbles.
Then add 1 drop (about 35-50 µL) of Sample Diluent immediately.
5. Set up timer.
6. Results can be read in 15 minutes. Positive results can be visible in as short as 1 minute.

NOTES:

- If the test has been stored in the refrigerator, allow it to return to room temperature before testing. Do not open the foil pouch until you are ready to perform the test.
- When the specimen is dispensed, do not position the pipette tip too high from the device's Sample area, in order to prevent the samples from splashing.



QUALITY CONTROL

Using individual Spectrum Troponin I Test Device cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request) under the following circumstances to monitor test performance:

1. A new operator uses the kit, prior to performing testing of specimens.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature used during storage of the kit falls outside of 2°C-30°C.
5. The temperature of the test area falls outside of 15°C-30°C.

INTERPRETATION OF RESULTS

Invalid:

A distinctive colored band in the control window should always appear. If no pink band is present in the Control window within 15 minutes, the test is invalid, and the sample should be run again with a new test device.

Negative result:

A color band will appear only in the control window, which indicates a negative result.

Positive result:

Two bands will appear in the control and test window, which indicates a positive result.

NOTES FOR RESULT INTERPRETATION:

- The color intensity of the Test and Control bands may increase beyond 15 minutes. As the membrane in the reading window dries up, the color intensity of the bands and background change and thus may interfere with reading the test results.
- For best results, the test result should be read at 15 minutes. The result, particularly a result which is negative before 15 minutes, should not be read beyond 15 minutes.
- The test bands will appear before the control band in most strong positive cases. The test bands may be darker than the control band.
- The test bands may appear after the control band in weak positive cases, and the test band may be weaker than the control band.

LIMITATION

The results of the Cardiac TnI Assay are to be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose myocardial infarction. A negative result obtained from a patient's sample 16 hours after the onset of chest pain may help in ruling out AMI. A positive assay result from a patient suspected of AMI may be used as an indicative of myocardial damage and requires further confirmation. Serial sampling of patients suspected of AMI is also recommended due to the delay between the onset of symptoms and the release of protein markers into the bloodstream. Samples containing an unusually high titer of certain antibodies, such as human anti mouse or human anti goat antibodies, may affect the performance of the test.

EXPECTED VALUES

The Cardiac Troponin I Assay is designed to yield a positive result for cTnI concentrations at or more than 0.6 ng/mL

PERFORMANCE CHARACTERISTICS

Sensitivity:

The Spectrum Troponin I Test Device can detect cTnI in serum or plasma with concentration of 1.0 ng /mL or greater.

Interference Substances:

Levels of the following substances do not appear to interfere with the Cardiac Troponin I Assay.

Human Albumin	16 g/dL
Bilirubin (unconjugated)	60 mg/dL
Free Hemoglobin	4 g/dL
Triglycerides	1,300 mg/dL

METHOD COMPARISON

Serum samples (n=121) collected from individuals after being admitted to a hospital emergency department with chest pain. The samples were tested with the Troponin I test and with FDA approved cardiac troponin I test kit. The correlation between the tests is shown below:

FDA approved Troponin I test

	Positive	Negative	Total
Spectrum	31	1	32
	1	88	89
Total	32	89	121

Comparative Sensitivity: 96.9 % (31/32)

Comparative Specificity: 98.9% (88/89)

Overall Agreement: 98.35 % (119/121)

BIBLIOGRAPHY

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ORDERING INFORMATION

CATALOG NO.	QUANTITY
1173 001	30 test