Spectrum For Diagnostic Industries

Cardiac Troponin I Rapid Test Cassette

(Serum/Plasma/Whole Blood)

REF: 516 30 030 30 test

INTENDED USE

The Cardiac Troponin I Rapid Test Cassette (Serum,Plasma and whole blood) is a rapid chromatographic immunoassay for the qualitative determination of Cardiac troponin I (cTnI) in human whole blood, serum and plasma as an aid in the diagnosis of myocardial infarction

SUMMARY

The Cardiac **Troponin I** (TnI) is part of the troponin complex which, together with tropomyosin, forms the main component that regulates the Ca+2-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 Ca+2 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.

TEST PRINCIPLE

The Troponin I Rapid Test Cassette 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.

REAGENTS AND MATERIALS PROVIDED

1- The test contains anti-cTnI antibody coated colloid gold particles and capture reagent coated on the membrane.Test Cassettes
2- Buffer
3- Droppers
4- Package inserts.

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge
- Lancets

WARNINGS AND 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.

REAGENT PREPARATION AND STORAGE INSTRUCTION

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

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.

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 <u>Serum or Plasma</u> specimen:

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

For <u>Venipuncture Whole Blood</u> specimen:

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

For <u>Finger stick Whole Blood</u> specimen:

- To use a capillary tube: Fill the capillary tube and transfer approximately 75 μL of fingerstick whole blood specimen to the specimen area 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 area 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.

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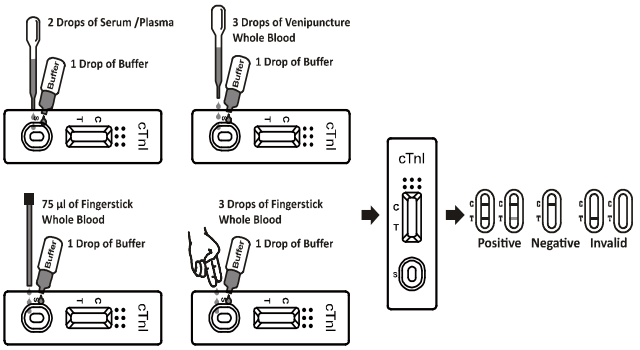

INTERPRETATION OF RESULTS

(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) may 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 apparent colored 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

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.

PERFORMANCE CHARACTERISTICS

Sensitivity:

The Spectrum Troponin I Test Device can detect cTnI in serum or plasma, whole blood 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 approved cardiac troponin I test kit. The correlation between the tests is shown below:

approved Troponin I test

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

Comparative Sensitivity: 96.9 %
Comparative Specificity: 98.9%
Overall Agreement: 98.35 %

REFERENCES

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