ACCUCARE
One Step Troponin I Test Device
(Serum / Plasma / Whole Blood)

ORDER INFORMATION

REF	Cont.
TPI 10	1X10 TEST

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 troponin complex, which together with tropomyosin, forms the main component that regulates the Ca^{+2} – sensitive ATP-ase activity of actomyosin is striated muscle (skeletal and cardiac). The troponin complex consists of three 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 exists 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 infraction (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 if this marker is an aid in the diagnosis of AMI after myocardial function.

PRINCIPLE
The Accucare 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 Test area and are later captured in the Control area. Visible pinkish-purple bands will appear in the test and Contol 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 diagnostics 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 disposables 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.

STORAGE & 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.

MATERIAL
Material Provided:
Test Device(s)
Instruction for use

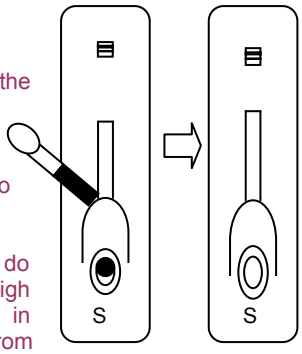
Material not Provided:
Vacutainer™ (Becton Dickinson, Rutherford, NJ, USA) tube, or equivalent, containing heparin as an anticoagulant.
Timer
Positive and Negative Controls
Calibrated Pipette

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 withing 2 hours of collection. If specimens are to be shipped, they should be packed in compliance with federal regulation covering the transportation of etiologic agents.

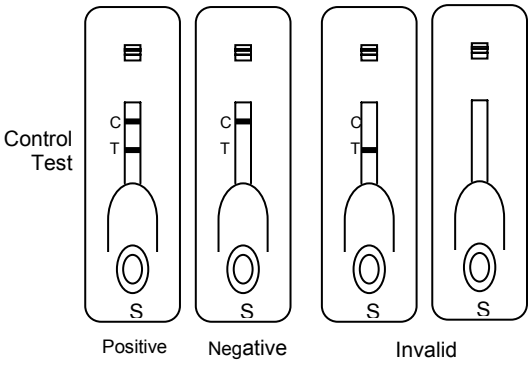
- **Optimal assay performance require strict adherence to the assay procedure described in this instruction sheet and any deviations from the procedure may lead to aberrant results.**

DIRECTION FOR USE
Open the foil pouch, remove the Cardiac test device, and lay the device on a level surface. Label the device with the patient's name or control number. Using a micropipette, add 80μL of whole blood (3 drops) or 60μL of serum (2 drops) or plasma specimen into the Sample well. Read the result in 15 minutes.

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 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 sample from splashing.



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 is most strong positive cases. The test bands may be darker than the control band.
- The test bands may appear after the control band is weak positive cases, and the test band may be weaker than the control band.

EXPECTED VALUE

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

LIMITATIONS

The result 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.

INTERFERING SUBSTANCES

Levels of he 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 COMPARISION

Serum samples (n=121) collected from individuals after being admitted to a hospital emergency department with chest pain. The samples were a tested with the ACCUCARE 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
	Positive	**31**	**1**	**32**
ACCUCARE	**Negative**	**1**	**88**	**89**
	Total	**32**	**89**	**121**

Compare Sensitivity	: 96.9% (31/32)
Comparitive Specificity	: 98.9% (88/89)
Overall Agreement	: 98.35% (119/121)

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