ACCUCARE™

ONE STEP TROPONIN I TEST DEVICE

(Serum / Plasma / Whole Blood)

One Step Rapid Card Test for detection of TROP I in Serum or Plasma
Only for *In Vitro Diagnostic* Use

ORDER INFORMATION

REF	CONT
TPI 10	10 Tests
TPI 25	25 Tests

CLINICAL SIGNIFICANCE

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.

KIT COMPONENTS

Test Device, Assay Buffer, Sample Dropper and Product Insert

STORAGE AND STABILITY

The sealed pouches in the kit can be stored 2-30°C till the expiration date printed on the sealed pouch. DO NOT FREEZE.

PRECAUTIONS

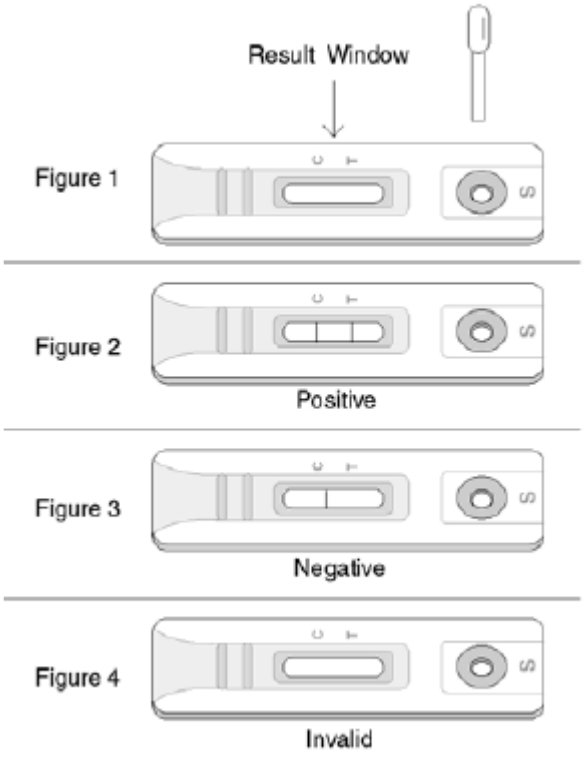
1. Handle all specimens as if they contain infectious agents.
2. Wear protective disposable gloves when specimens are being tested.
3. The Device is sensitive to Humidity as well as heat. Therefore take out the device from seal pouch before test.
4. Dispose all the samples and kit properly as per the instruction after test in accordance in GLP
5. Read the instructions carefully before performing the test.

SPECIMEN COLLECTION AND PREPARATION

1. Uses human whole blood, serum or Plasma as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. **Fresh anticoagulated whole blood should be used as test specimen.** EDTA or Heparin or oxalate can be used as a suitable anticoagulant.
4. Whole blood should be used immediately and should not be frozen. Do not use haemolysed, clotted or contaminated whole blood specimens.

DIRECTION FOR USE

1. Bring the sealed Pouch to room temperature, open the pouch and remove the device and place it on a clean flat surface.
2. Add 2 drops (40µL) Whole Blood or 2 drops (40µL) of serum or plasma in sample well “S” using the dropper provided.
3. Add 2 drop of the Assay buffer.
4. Allow reaction to occur in next 20 minutes.
5. The test should be read between 20 minutes after addition of serum samples.



INTERPRETATION OF RESULTS

1. **Negative**: Only one pink-purple colored line appears at the control zone ‘C’ (Control line) the test result is negative
2. **Positive**: In addition to the colored line in the control region a clearly distinguishable pink purple colored line also appears in the test region ‘T’ (Test line) indicating a positive result.
3. **Invalid**: If no line appears in the control as well as the test region, the test should be repeated with fresh card.

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
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EXPECTED VALUE

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

LIMITATIONS

1. The result of the Cardiac Tnl Assay is to be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose myocardial infarction.
2. A negative result obtained from a patient's sample 16 hours after the onset of chest pain may help in ruling out AMI.
3. A positive assay result from a patient suspected of AMI may be used as an indicative of myocardial damage and requires further confirmation.
4. 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.
5. 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.

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