TROPONIN I CARD

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

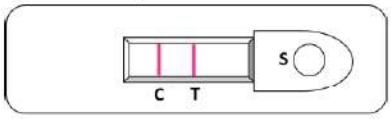
INTENDED USE: Test for qualitative detection troponin I in human whole blood, serum or plasma sample.

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 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 Control areas if the concentrations of troponin I is above established cut-off 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 cut-off 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 Instructions for Use

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Does not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

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.

Whole blood should be used immediately and should not be frozen. Do not use haemolysed, clotted or contaminated whole blood specimens.

TEST PROCEDURE

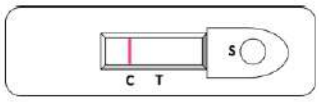
Allow test cassette, specimen, and/or buffer to equilibrate to room temperature (15-30 °C) prior to testing.

1. Remove the Test Cassette from the pouch and place it on a clean, flat, dry, level 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.

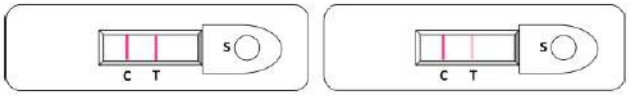
Note: Do not interpret the result after 20 minutes.

INTERPRETATION OF THE RESULTS

NEGATIVE RESULT:
Only one pink-purple coloured line appears at the control zone 'C' (Control line) the test result is negative



POSITIVE RESULT:
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.



INVALID TEST:
If no line appears in the control as well as the test region, the test should be repeated with fresh card.

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 OF THE TEST

1. The result of the Cardiac TnI 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.

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.

INTERNAL QUALITY CONTROL

The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required

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SYMBOLS:


Read Instruction for use

In Vitro Diagnostic Use Only


Manufactured by


Expiry Date


Storage Temperature

ANAMOL LABORATORIES PVT. LTD.
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ISO 9001 : 2015
ISO 13485 : 2003
GMP
CE