ASTAM DIAGNOSTICS

PRODUCT INSERT

REF TRPD

PRATHAM® TROPONIN I TEST

A lateral flow chromatographic immunoassay for the qualitative detection of Cardiac Troponin I in human serum / plasma / whole blood.

INTENDED USE

PRATHAM® Troponin-I Test is an in vitro diagnostic test based on immunochromatographic assay. It is designed for qualitative determination of Cardiac Troponin-I (cTnI) in human serum / plasma / whole blood as an aid in the diagnosis of acute myocardial infarction (AMI).

INTRODUCTION

Cardiac Troponin-I (cTnI) is a cardiac muscle protein with a molecular weight of 22.5 kilodaltons. Together with Cardiac Troponin I (cTn-T) and Cardiac Troponin C (cTn-C), cTnI forms a Troponin complex in heart to play a pivotal role in the transmission of intracellular calcium signal actin-myosin interaction. There are some advantages that cTn-I has more specificity and sensitivity to AMI than cTn-T. The human cTn-I has an additional amino acid residue on its N-terminal that do not exist on the skeletal forms thus making cTn-I a specific marker for indicating Cardiac infarction. cTn-I is released into blood after the onset of AMI. However, CK-MB level returns to normal after 36-48 hours, while level of cTn-I remains elevated for up to 6-10 days. The level of cTn-I is very low in normal healthy people and not detected in patients with skeletal muscle injury. Therefore, cTn-I is a specific marker for diagnosis of AMI. cTn-I level may be falsely increased when the specimen is collected from renal failure patient.

TEST PRINCIPAL

PRATHAM® Troponin-I Tes is an immunochromatographic assay. When sample is added to sample well (S), it moves through the conjugate pad and mobilizes gold anti-cTn-I conjugate that is coated on the conjugate pad. The mixture moves along to the membrane by capillary action and reacts with anti-cTn-I antibody that is coated on the test region (T) of the nitrocellulose membrane. If cTn-I is present in the serum / plasma / at levels of 0.3 ng/mL or greater, a color pink / purple line appears in the test region (T). If cTn-I is present at a lower level, or not present in the specimen, No pink / purple line appear at the test region and one pink / purple line will appear at control line region (C). The sample continues to move to the control region and forms a colored line, indicating the test is working and the result is valid.

KIT COMPONENTS

1. Pouch contents: Test Cassette, Sample Dropper, Desiccant
2. Assay Buffer
3. Instruction for use

MATERIAL REQUIRED BUT NOT PROVIDED

Timer, Gloves, Micropipette, tips & centrifuge etc.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30ºC till the duration of self life as indicated on the pouch. Do not freeze. Once the pouch is opened, test card must be used immediately.

SPECIMEN COLLECTION AND STORAGE

1. No prior preparation of the patient is required.
2. Collect blood specimen by venipuncture according to the standard procedure.
3. Specimen (serum / plasma / whole blood) should be free of particulate matter and microbial contamination.
4. Preferably use fresh sample. However, specimen can be stored refrigerated for short duration. For long storage, freeze at -200C or below. Do not freeze whole blood sample. Specimen should not be frozen and thawed repeatedly.
5. Do not heat inactivate before use.
6. Turbid sample (microbial contamination) should not be used.
7. Specimens containing precipitate or particulate matter should be centrifuged prior to use.

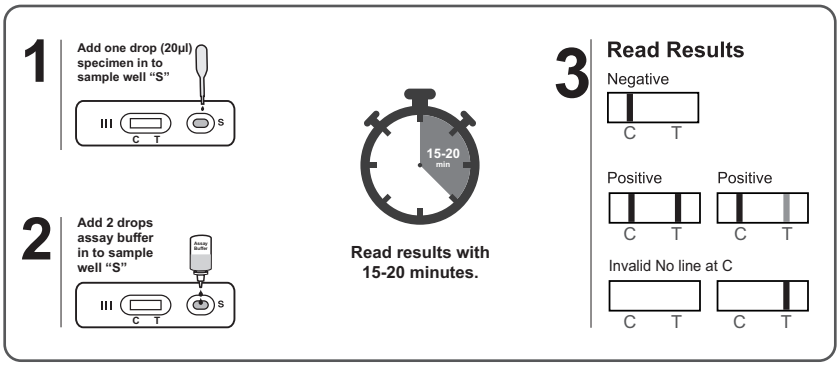
WARNING AND PRECAUTIONS

- Use product insert to perform the assay.
- Failure to follow the insert gives inaccurate test results.
- Do not use expired kit.
- Use separate sample collection tube or micro pipette tips for each sample to avoid cross contamination.
- Do not use hemolized blood specimens for testing.
- Do not throw away used device, sample tube and tips any were discard it in proper way as bio hazardous waste.
- Use of disposable gloves and bio-hazardous clothing while running the test.
- The test shall be performed by competent person only.
- Bring all reagents and specimen to room temperature before use.
- Spills should be decontaminated promptly with IPA or any other suitable disinfectant.
- Do not unwrap the packed until it attains room temperature.
- Do not re-use the test device.

TEST PROCEDURE

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Check the packaging is not damaged. If damaged, discard the test and use another test.
3. Open the pouch & check the desiccant. If color of desiccant does not show any change (Remains blue) you can use the test. If color changes then discard the test and use another test.
4. Add one drop (20µl) of serum /plasma/whole blood into the sample well.
5. Add 2 drops of assay/running buffer into the sample well using provided buffer vial.
6. Interpret test results within 15-20 minutes. Don't interpret results after 20 minutes.

INTERPRETATION OF RESULTS



Negative:

Appearance of only one pink / purple line at control line region 'C' and No pink / purple line at line region 'T' of the result window, indicates that specimen has no cTn-I and result is negative.

Positive:

Appearance of two pink / purple lines, one at test region 'T' and other at control line region 'C' of the result window, indicates that specimen has cTn-I and result is positive.

Invalid:

If there is no pink / purple line in the control line region 'C' of the result window, the result is invalid. This is due to deterioration of the test device or improper test procedure. Repeat the test with a new test device.

INTERNAL QUALITY CONTROL

An internal procedural control is included in the test. A coloured line appearing in the control region 'C' is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls are not supplied with this kit. It is recommended that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Handle the negative and positive controls in the same manner as patient specimens.

PERFORMANCE CHARACTERISTICS

IN-HOUSE EVALUATION

1. **Detection Limit: Troponin-I Test** can detect cTn-I with concentration of 0.5 ng/mL or greater.
2. **Clinical Accuracy:** Relative Sensitivity: 98% Relative Specificity: 98% Accuracy: 98%.

LIMITATION OF THE TEST

1. The test result should be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnosis AMI. A positive result from a patient suspected of AMI may be used as a rule-in diagnosis 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 the cTn-I into the blood stream.
2. Troponin-I test only provides qualitative result. A quantitative assay method must be used to determine the cTn-I concentration.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory finding have been evaluated.
4. Although Troponin-I test is accurate in detecting cTn-I, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained.
5. Some specimens with a high rheumatoid factor concentration may yield a nonspecific positive result.

EXPECTED VALUES

Troponin-I test is designed to yield a positive result for cTn-I concentration at 0.5 ng/mL or greater. The time required for blood cTn-I level to reach detectable levels has been found to be 4-6 hours after the onset of symptoms. cTn-I level reaches the maximum concentration after 12-24 hours after the onset, and then remains elevated for 6-10 days in some cases. Therefore, a negative result within the first hour of the onset of symptoms does not rule out AMI with certainty. If suspected repeat the test at appropriate intervals.

DISPOSAL

Consider all test devices run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Every precaution has been taken to ensure diagnostic ability and accuracy of this product. This product is used outside the control of manufacturer and distributors. Various factors including storage temperature, environment conditions, and procedural errors may affect the result. A person who is subject of the diagnosis should consult a doctor for further confirmation.

WARNING

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

REFERENCES

1. Adam JE et al., Cardiac troponin-I. A marker with high specificity for cardiac injury. Circulation. 1993, 88:101-106.
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3. Border GS et al., Cardiac Troponin-I is not expressed in fetal and healthy or diseased adult human skeletal muscle tissue. Clinical Chemistry. 1995, 41:1710-1715.
4. Britta UG et al., Implications of troponin testing in clinical medicine. Curr Control Trials in Cardiovasc Med. 2001, 2'75-84.
5. Brogen GX et al., Improved specificity of myoglobin plus carbonic anhydrous assay versus that of creatinine kinase-MB for early diagnosis of acute myocardial infarction. Ann Emerg Med. 1996, 27-22-28.
6. Brogen GX et al., Evaluation of a new assay for cardiac Troponin-I vs Creatine Kinase-MB for the diagnosis of acute myocardial infarction. Academic Emerg Med. 1997,4:6-12.
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8. Larue C et al., Cardiac specific immunoenzymometric assay of troponin I in the early phase of acute myocardial infarction. Clinical Chemistry. 1993, 39:972-979.

SYMBOLS

Read instructions for use	Name of Manufacturer	For single use only
No. of test	Expiry Date of Kit.	Date of manufacturing of IVD Kit
In-vitro diagnostic use	Keep away from Sunlight	Reference Catalogue Number
Storage Condition		

ASTAM DIAGNOSTICS

Manufactured By:
ASTAM DIAGNOSTICS PVT. LTD.
Plot No. H-125, RIICO Indl. Area, Kaharani, Bhiwadi Extn.
Alwar, Rajasthan-301019 (INDIA)
For feedback/queries contact customer care : 011-27358101