TROTONIN I RAPID TEST CARD
Immunochromatographic rapid test for Troponin I serum/plasma

CATALOG #: AN1006C

INTRODUCTION
Troponin I Rapid Test Card is an immunochromatography based one step in vitro test. It is designed for qualitative determination of cardiac Troponin I (cTnI) in human serum or plasma specimens as an aid in the diagnosis of myocardial infarction.

PRINCIPLE
Cardiac troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22.5 kilodaltons. Together with troponin T (TnT) and troponin C (TnC), TnI forms a troponin complex in heart to play a fundamental role in the transmission of intracellular calcium signal acting-myosin interaction. The human cTnI has an additional amino acid residues on its N-terminal that are not exist on the skeletal forms thus making cTnI a specific marker for indicating cardiac infarction. cTnI is released rapidly into blood after the onset of acute myocardial infarction (AMI). Its release pattern is similar to CK-MB (4-6 hours after the onset of AMI). However, CK-MB level returns to normal after 36-48 hours, while levels of cTnI remains elevated for up to 6-10 days. The level of cTnI is very low in normal healthy people, and not detected in patients with skeletal muscle injury. Therefore, cTnI is a specific marker for diagnosis of AMI.

Troponin I Rapid Test Card is a sandwich immunoassay. When serum sample is added to sample pad, it moves through the conjugate pad and mobilizes gold anti-cTnI conjugate that are coated on the conjugate pads. The mixture moves along the membrane by capillary action and reacts with anti-cTnI antibody that is coated on the test region of troponin I test strip.

If Troponin I is present at 0.3ng/ml or greater, the result is the formation of a colored band in the test region. If there is no cTnI in the sample, the area will remain colorless. The sample continues to move to the control area and forms a pink to purple color, indicating the test is working and the result is valid.

SPECIMEN COLLECTION
1. The specimen should be collected under standard laboratory conditions
2. Sodium azide can be added as a preservative up to 0.1% without affecting the test results.
3. Patient samples performed best when tested immediately after collection. If the sample cannot be tested within 24 hours, freeze until the test can be performed. Allow sample to reach room temperature before proceeding.

MATERIALS PROVIDED
Troponin I Test Card 25Test

STORAGE AND STABILITY
The test kit can be stored at room temperature (18 to 30°C).

TEST PROCEDURE
1. Bring all materials and specimens to room temperature.
2. Remove the test device from the sealed foil pouch.
3. Add 3-4 drops serum or plasma to the sample hole.
4. Read the results at 5-15 minutes for Troponin I after adding the sample.

INTERPRETATION OF RESULTS
Positive:
If control line and T line is appear, the test result is troponin I positive and valid.

Negative:
If test area has no color band and the control area displays a colored band, the result is negative and valid.

Invalid:
The test result is invalid if a colored band does not form in the control region. The sample must be re-tested, using a new test device.

PRECAUTION
1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Humidity and temperature can adversely affect results.

LIMITATION
1. A number of conditions, other than myocardial infarction, including polymyositis, dermatomyositis, systemic lupus erythematosus, shock, severe renal failure, or muscle damage caused by trauma, ischemia and inflammation, can cause elevated levels of myoglobin. These conditions should be considered with appropriate clinical evidence.
2. Recent cardio version or an anginal episode may increase myoglobin level.
3. Testing 12 hours or later after onset of myocardial infarction can produce misleading results, because serum levels may already have returned to normal range.
4. The test results should be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose AMI. A negative result obtained from a patient whose sample was taken at 2-16 hours after the onset of chest pain may help in ruling out 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 cTnI in to the bloodstream.
5. Troponin I test only provides qualitative result. A quantitative assay method must be used to determine myoglobin and/or cTnI concentration.
6. 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 findings have been evaluated.

PERFORMANCE CHARACTERISTICS
Sensitivity:
Troponin I Rapid Test Card can detect cTnI with concentration of 0.3 ng/ml or greater in the serum.

Interference testing:
The following substances were added to myoglobin and troponin I negative and 50ng/ml myoglobin spiked and 1.5ng/ml troponin I spiked serum samples. No interference was found with any of the substances at the following concentrations:

- Bilirubin 10 mg/dl
- Cholesterol 800 mg/dl
- Hemoglobin 250 mg/dl
- Triglyceride 1250 mg/dl

REFERENCES

FOR CLINICAL USE

Manufacturer:
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