TROPONIN-I CARD

(Whole Blood/Serum/Plasma)

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Ref. RDT-TRP.107, 10 Test

INTENDED USE

CARD test for detection of Cardiac Troponin–I in human Whole Blood/Serum /Plasma.

INTRODUCTION

One Step Troponin I test is chromatographic immunoassay. It is designed for qualitative determination of cardiac troponin I (cTnI) in human whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction.

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 actin-myosin interaction. Although troponin I is also found in skeletal muscle, cardiac troponin I (cTnI) has an additional amino acid residues on its N-terminal which distinguishes it from its skeletal muscle form making cTnI a specific marker for indicating cardiac infarction. cTnI is released rapidly into blood stream soon 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, when levels of cTnI remains elevated for up to 6-10 days. The level of cTnI is below 0.06ng/ml in average in healthy people, and also not detected in the patients with skeletal muscle injury. Therefore, cTnI is a specific marker for diagnosis of AMI patients. The level of cTnI may reach 100-1300ng/ml in some AMI patients.

PRINCIPLE

The One-Step Troponin I Test is a chromatographic immunoassay for the qualitative determination of cTnI in human whole blood, serum or plasma. When specimen is added to sample pad, it moves through the conjugate pad and mobilizes gold anti-cTnI conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-cTnI antibody that is coated on the test region. If cTnI is present, the result is the formation of a pink-purple line 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-purple line, indicating the test is working and the result is valid.

PRESENTATION

	10 Tests
Troponin-I Cards	10 Cards

PRECAUTION

- For professional and IN VITRO diagnostic use only.
- The test device should remain in the sealed pouch until use. Do not use after the expiration date.
- All serum or plasma specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded in a proper biohazard container after testing.
- Avoid cross-contamination of serum samples by changing a new specimen pipette for each sample.

STORAGE AND STABILITY

Troponin I test card should be stored at 2°C-40°C. The card may be stored at room temperature but not exceeding 40°C in the original sealed pouch. The shelf life or expiry of the card is printed on the pouch as well as on the carton label. The test kit should be kept away from direct sunlight, moisture and heat.

SAMPLE COLLECTION AND STORAGE

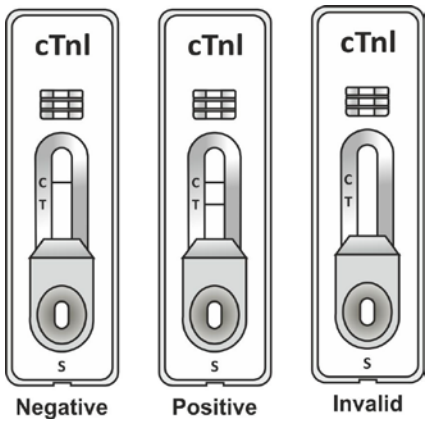
1. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2°C-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C
2. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

TEST PROCEDURE

1. Read package insert carefully before testing. Allow the test devices, whole blood, serum or plasma to equilibrate to room temperature prior to testing. Do not open pouches until ready to perform the assay.
2. Remove the test device from the foil pouch and use it as soon as possible.
3. Place the test device on a clean and level surface. Hold the dropper provided vertically and transfer 3 drops of specimen **(Whole Blood/Serum/Plasma)** (approx. 90 µl) to the specimen well (S) in the test device.
4. The result should be read between 10 to 15 minutes.

INTERPRETATION OF RESULTS

- Negative : One pink-purple line appears in the control region (C),
- Positive : Two pink-purple lines should be observed in the viewing window. The color intensity of the test line may be weaker or stronger than that of the control line.
- Invalid : A total absence of colored line in both regions or no colored line appears in the control (C) region is an indication of procedure error and / or the test reagent deterioration. Repeat the test with new cassette.



SENSITIVITY

The One-Step Troponin I Test designed to yield a positive result for cTnI concentrations at 0.5 ng/ml or greater.

LIMITATIONS

1. The test result should be used in conjunction with other clinical information such as clinical signs/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 into the blood stream.
2. The Troponin I test only provides qualitative result. A quantitative method must be used to determine the cTnI 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 findings have been evaluated.

REFERENCES

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