RAPID TROPONIN I TEST CARD

FOR THE QUALITATIVE ASSESSMENT OF CARDIAC TROPONIN I
IN HUMAN SERUM OR PLASMA

Catalog Number: 1J02C1

For In Vitro Diagnostic Use Only

INTENDED USE
Rapid TnI Test 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.

SUMMARY
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. 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.

TEST PRINCIPLE
Rapid TnI Test is a sandwich immunoassay. When sample 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 at levels of 1.0 ng/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.

MATERIAL PROVIDED
1. Rapid TnI Test Card
2. Instructions for Use

MATERIALS REQUIRED BUT NOT SUPPLIED
1. Plasma: Vacutainer tube, or other appropriate tube, containing heparin or EDTA as an anticoagulant
2. Serum: Vacutainer tube, or other appropriate tube, without anticoagulant
3. Micropipetter (0-200 μL range) and pipet tips
4. Timer or clock

STORAGE
Store the test device at 4 to 30°C. Do Not Freeze.

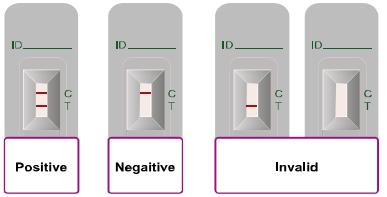
PRECAUTIONS
1. For in vitro diagnostic use only.
2. Do not use product beyond the expiration date.
3. Handle all specimens as potentially infectious.

SPECIMEN COLLECTION AND PREPARATION
1. EDTA is not recommended as the anti-coagulant for whole blood or plasma collection because it may interfere with the test results.
2. The serum or plasma specimen should be collected under standard laboratory conditions.
3. Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.
4. Patient samples performed best when tested immediately after collection. If specimens are to be stored, the red blood cells should be removed to avoid hemolysis. If the sample cannot be tested within 24 hours, serum or plasma should be frozen until the test can be performed. Allow sample to reach room temperature before proceeding.
5. Sodium azide can be added as a preservative up to 0.1% without affecting the test results.

QUALITY CONTROL
1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which are not provided with this test kit are commercially available.

PROCEDURE
1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Use micropipetter to transfer 80 μL of sample, or place the transfer pipette supplied with the device in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical position over the sample well of the test card and deliver 2 drops(80-100 μL) of sample into the sample well.
5. Read the result at 15 minutes.

INTERPRETATION OF RESULTS



Positive: If two colored bands are visible within 15 minutes, the test result is positive and valid.
Note: Specimens containing very low levels of cTnI may develop two colored bands over 15 minutes.

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

Invalid result: 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.

PERFORMANCE CHARACTERISTICS:
Sensitivity:
Rapid TnI test can detect cTnI with concentration of 1.0 ng/Ml.
Accuracy:
One hundred and thirty one specimens were tested. The Troponin I concentration was determined by Beckman Access. The test showed 98% of the specificity at Tn I negative samples and 98.4% of sensitivity at samples that had Tn I concentration higher than 1.0 ng/mL.

	Troponin I (Beckman Access)		
	Negative (0 ng/mL)	Tn I (0.08 – 0.92 ng/mL)	Tn I (≥ 1.0 ng/mL)
Number of specimen	51	16	64
Negative	50	8	1
Positive	1	8	63
Specificity/Sensitivity	98%	50%	98.4%

Interference testing:
The following substances were added to troponin I negative and 1.0 ng/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	500 mg/dL

LIMITATIONS
1. The test result 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.
2. Rapid TnI test only provides qualitative result. A quantitative assay 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.

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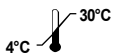
IVD  

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