**Troponin I Rapid Test-Cassette (Whole blood/Serum / Plasma)**

**INTENDED USE**

The Troponin I Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of cardiac Troponin I (cTnI) and its complex in human whole blood, serum or plasma at the level equal or higher than 1 ng/mL. It is intended to be used as a screening test and as an aid in the diagnosis of acute myocardial infarction (AMI). Any reactive specimen with the Troponin I Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

**SUMMARY AND EXPLANATION OF THE TEST**

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 the heart to play a fundamental role in the transmission of intracellular calcium signal actin-myosin interaction. The human cTnI has additional amino acid residues in its N-terminal that do not exist in the skeletal forms thus making cTnI a specific cardiac marker. Normally, the level of cTnI in the blood is very low. cTnI is released into the bloodstream in forms of free cTnI and cTnI-C-T complex at 4-6 hours after myocardial cell damage. The elevated level of cTnI could be as high as 50 ng/ml during 60-80 hours after AMI and remains detectable for up to 10-14 days post AMI. Therefore, circulating cTnI is a specific and sensitive marker for AMI. The Troponin I Rapid Test is intended to detect elevated troponin I and its complex in human whole blood, serum or plasma in less than 10 minutes by untrained or minimally skilled personnel, without laboratory equipment requirement.

**TEST PRINCIPLE**

The Troponin I Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-cTnI antibody conjugated with colloid gold (antibody conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with polyclonal anti-cTnI antibody, and the C band is pre-coated with goat anti-mouse IgG antibody. When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. Elevated cTnI if present in the specimen will bind to the antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-cTnI antibodies, forming a burgundy colored T band, indicating a cTnI positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of goat anti-mouse IgG/mouse IgG-gold conjugate immunocomplex regardless of the presence of cTnI in the specimen. Otherwise, the test result is invalid and the specimen must be retested with another device.

**REAGENTS AND MATERIALS PROVIDED**

1. Each sealed in a foil pouch with three items inside:
   a. One cassette device.
   b. One plastic dropper.
   c. One desiccant.
2. One package insert (instruction).

**MATERIALS REQUIRED AND AVAILABLE FOR PURCHASE**

1. Positive Control (1 vial, red cap, 1 mL, Cat # R3001-P)
2. Negative Control (1 vial, green cap, 1 mL, Cat # 3001-N)

**MATERIALS REQUIRED BUT NOT PROVIDED**

1. Clock or Timer

**WARNINGS AND PRECAUTIONS**

**For in Vitro Diagnostic Use**

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test result.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15°C -30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolized blood specimen for testing.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10. Dispose of all specimens and materials used to perform the test as biohazardous waste.
11. Handle the Negative and Positive Control in the same manner as patient specimens.
12. The testing results should be read within 10 minutes after a specimen is applied to the sample well or sample pad of the device. Reading result after 10 minutes may give erroneous results.
13. Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

1) Collect Whole Blood, serum or plasma specimens following regular clinical laboratory procedures.
2) Test specimens as soon as possible after collecting.

   Storage: Whole Blood can not be frozen. A specimen should be refrigerated if not used the same day of collection. Serum and plasma Specimens should be frozen if not used within 3 days of collecting. Avoid freezing and thawing the specimens more than 2-3 times before using. Store specimens at 2°C-8°C if not tested immediately. The specimens should be frozen at -20°C for longer storage.

   Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with specimen's ID number.
Step 4: Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 2-3 drops (about 60-90 μL) of specimen into the sample well making sure that there are no air bubbles.

   Note: Add 1 drop of Saline or Phosphate-Saline buffer (common buffers used in clinic not provided in the kit) into the sample well if flow migration is not observed within 30 seconds in the result window, which could occur with a highly viscous specimen.

Step 5: Set up the timer.

Step 6: Results can be read in 10 minutes. Positive results can be visible in as short as 1 minute.

   Don't read result after 10 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

Using individual Troponin I Rapid Test cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request) under the following circumstances to monitor test performance:
1. A new operator uses the kit, prior to performing testing of specimens.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature used during storage of the kit falls outside of 2°C-30°C.
5. The temperature of the test area falls outside of 15°C-30°C.

Expected results are as follows:

**Negative Control**
Only the C band shows color development. The T band shows no color development.

**Positive Control**
Both C and T bands show color development.

The appearance of any burgundy color in the T band, regardless of intensity, must be considered as presence of the band.

**INTERPRETATION OF ASSAY RESULT**

1. **NEGATIVE RESULT**: If only the C band is developed, the test indicates that no detectable cTnI is present in the specimen. The result is negative.
2. **POSITIVE RESULT**: If both C and T bands are developed, the test indicates that the level of cTnI is equal or higher than 1 ng/mL. The result is positive.
   
   *Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.*
3. **INVALID**: If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.

![Image of assay results](image)

**PERFORMANCE CHARACTERISTICS**

**Sensitivity:**
The Troponin I Rapid Test can detect cTnI in serum or plasma with concentration of 1.0 ng/mL or greater.

**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 1250 mg/DL

**LIMITATIONS OF TEST**

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of elevated Troponin I in whole blood, serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Troponin I Rapid Test is limited to the qualitative detection of Troponin I at the level equal or higher than 1 ng/mL in human whole blood, serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates the level of cTnI is not detectable. However, a negative test result does not preclude the possibility of AMI.
4. A negative result can occur if the level of cTnI present in the specimen is below the detection limits of the assay, or the cTnI that are detected are not present during the stage of AMI in which a sample is collected.
5. 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.
4. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES
