Troponin I One-Step Blood/Serum/Plasma Test Cat. H-001/H-002

Imunoassay for the Qualitative Determination of Troponin I and Troponin I/T/C Complex

INTENDED USE
Cardiac Troponin I (cTnI) is a specific protein marker found in cardiac muscles with a molecular weight of 23,000. Together with troponin T and C, it forms a structural complex. The cTnI and its complex are released into blood circulation soon after the onset of acute myocardial infarction (AMI). The elevated level could be detected approximately 10-20 hours after onset of AMI and until 10-15 days later. This quick one-step Troponin I test is a rapid, immunoassay for the qualitative determination of TnI and its complex in serum.

SUMMARY AND EXPLANATION
Two forms of cTnI, free cTnI and cTn I-T/C complex, are released into the bloodstream after cardiac damage. TnI is found in skeletal muscles (sTnI) as well, but it differs in its amino acid composition from cardiac TnI so that these two forms of TnI can be distinguished immunologically. The elevated level could be detected approximately 10-12 hours after onset of AMI. Not only is TnI a specific protein marker for AMI, its level also remains elevated between 6 to 50 ng/ml for 60-80 hrs after AMI. The quick one-step cTnI test is an easy, fast and visually read method that does not require instrumentation, such like ECG. The test system employs unique antibodies – one pair selectively identifies free cTnI, and one pair selectively identifies cTnI-T/C complex with a high degree of sensitivity.

PRINCIPLE
The quick one-step test utilizes a sandwich immunoassay system and the immunochromatographic detection assay, to be performed in one assay. If cTnI/cTnI-T-C is present in the sample in concentration above the detection level-0.5 ng/ml, a labeled specific monoclonal antibody-dye complex forms. This complex is then captured by another specific monoclonal antibody immobilized in the Test Zone ("T") of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will vary with the concentration of cTnI/cTnI-T-C in the sample. On the other hand, a color band will always appear at the control zone ("C").

MATERIALS REQUIRED BUT NOT SUPPLIED
1. Timing device.
2. Specimen collection container.

SAMPLE COLLECTION AND STORAGE
1. Fresh samples are preferred. While drawing blood, an anticoagulant reagent, such as EDTA must be added. Blood samples kept at refrigeration overnight may not be suitable for testing.
2. Plasma and serum stored in refrigeration for a few days usually are suitable for testing.

ASSAY PROCEDURE
Prior to use, bring all test components and patient samples to room temperature.

For Blood Test:
1. Remove the cassette from the foil pouch and place it on a clean, dry, level surface.
2. Hold the disposable dropper in a vertical position and Add 1 drop of blood into the Sample well of the test device.
3. And then after 30 seconds add 1 drop of coating buffer. Add 1 more drop, if there is no liquid flow through shown up on the membrane.
4. As soon as the sample reaches the view window, start timing.
5. Read result at 10 minutes.

For Serum/Plasma Test:
1. Remove the cassette from the foil pouch and place it on a clean, dry, level surface.
2. Hold the disposable dropper in a vertical position and Add 2 drops of sample (one by one) into the sample well of the test device. Allow each drop to soak in before adding the next one.
3. As soon as the sample reaches the view window, start timing.
4. Read result at 10 minutes.

RESULTS
- Positive Result:
  If both the Control band (C line) and the Test band (T line) appear, the result indicates that the cTnI is detected and the result is positive. The color intensities of C line and T line may not be the same.
- Negative Result:
  If the Control band (C line) appears, with no Test band (T line). The result is negative.
- Invalid Result:
  If a color band does not appear in the Control zone "C". The sample may have been added to the wrong window, or the test device may have deteriorated. The specimen should be re-tested using a new test device.

WARNINGS AND PRECAUTIONS
1. Wear disposable gloves while handling specimens. Wash hands thoroughly afterwards.
2. Wipe up spills thoroughly using an appropriate intermediate to high level disinfectant.
3. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious, in a biohazard container.
4. Avoid splashing or aerosol formation.
5. Do not use the Kit after the expiration date.
LIMITATIONS

1. This test is for in vitro diagnostic use only.
2. The test is limited to the detection of cTni/C and Tni-T-C levels in plasma/serum.
3. Although the test is very accurate in detecting elevated cTni/cTni-T-C, a low incidence of false positive results can occur, especially lysis samples, specimen form RF+ patient or patients who have anti-mouse antibodies.
4. The test is a qualitative screening assay and is not suggested for use in determining quantitative levels.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the results of a single test, but should only be made by a physician, after all clinical and laboratory findings have been evaluated.

SENSITIVITY AND PRECISION

The sensitivity of the Quick one-step cTni Test is 0.5 ng/ml. The unit is defined by Stratus II assay.

The precision of the Quick one-step cTni test was determined using replicate assays of samples from three different patient pools, with kits from three different production lots. Each specimen sample was run through ten parallel assays. The data demonstrated 100% precision for the duplicates of each sample and 100% precision using the test kits from different lots.

SPECIFICITY AND INTERFERENCE

The following substances were tested for cross-reactivity in cTni free serum and in normal serum containing cTni. None of the substances showed interference or cross-reactivity with the test.

<table>
<thead>
<tr>
<th>Substance Added</th>
<th>Concentration</th>
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<tbody>
<tr>
<td>Skeletal troponin I</td>
<td>1,000ng/ml</td>
</tr>
<tr>
<td>Cardiac troponin T</td>
<td>1,000ng/ml</td>
</tr>
<tr>
<td>Cardiac troponin C</td>
<td>1,000ng/ml</td>
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QUALITY CONTROL

Although the kit contains an internal quality control function (pink/rose color band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper kit performance. Quality control samples should be tested according to the quality control requirements established by your laboratory.

BIBLIOGRAPHY

5. Mair, et. al., Clin. Chem. 41(9):1266-1272