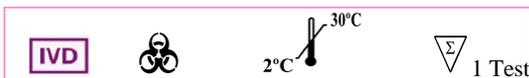


**OneStep
Troponin I
RapiCard™ InstaTest**

Cat#166771-1-21



INTENDED USE

The Cortez Diagnostics, Inc. OneStep Troponin I RapiCard™ InstaTest 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 specimens as an aid in the diagnosis of myocardial infarction.

SUMMARY AND EXPLANATION

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.

Troponin I 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 0.11 ng/mL (Bayer ACS: 180) or 1.5 ng/mL (Abbott AxSYM) 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.

The concentration of Troponin I is not standardized yet. The results from different assay system may vary significantly. Here is the summary of the sensitivity of Troponin I Test Card on the major assay systems.

SPECIMEN COLLECTION AND PREPARATION

1. The serum specimen should be collected under standard laboratory conditions
2. 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.
3. Sodium azide can be added as a preservative up to 0.1% without affecting the test results.

MATERIALS AND COMPONENTS

Materials provided with the test kits

1. TnI Test device

Materials required but not provided

1. Vacutainer tube, or other appropriate tube, without anticoagulant
2. Timer or clock
3. Micropipetter (0 –200 µL range) and pipet tips

ASSAY PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Place the transfer pipette 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 2-3 drops(100-150 µL) of sample into the sample well.
5. Read the result at 15 minutes.

RESULTS

- **Positive:** If two colored bands are visible within 15 minutes, the test result is positive and valid. The test result can be read as soon as a distinct colored band appears in the test area.Note: Specimens containing very low levels of cTnI may develop two color 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.

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.

PERFORMANCE CHARACTERISTICS

Sensitivity:

TnI test can detect cTnI with concentration of 1.5 ng/mL at Abbott AxSYM.

Accuracy:

| Result | Troponin I (Beckman Coulter Access AccuTnI) | | | | Correlation |
|----------|--|---------------|-----------------|-------------|-------------|
| | Negative (0 ng/mL) | | Positive | | |
| | 0ng/ml | 0.1-0.4 ng/ml | 0.41-0.49 ng/ml | ≥ 0.5 ng/ml | |
| Negative | 40 | 1 | 1 | 63 | 97.62% |
| Positive | 0 | 1 | 2 | 63 | 98.48% |
| Total | 40 | 2 | 3 | 63 | 108 |

Interference Testing:

The following substances were added to troponin I negative and 1.5 ng/mL troponin I (Abbott AxSYM) 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 |

REFERENCES

1. Adams JE, et al. Circulation, Vol. 88, 101-106 (1993)
2. Adams JE, et al. N. Eng. J. Med. Vol. 330, 670-674(1994)
3. Bodor GS, et al. Clin. Chem. Vol. 41, 1710-1715 (1995)
4. Brogan GX, et al. Academic Emerg. Med. Vol. 4, 6-12 (1997)
5. Tucker JF, et al. Academic Emerg. Med. Vol. 4, 13-21(1997)

LIMITATIONS OF PROCEDURE

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. 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.

STORAGE

Store the test device at 2 to 30oC. 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.
4. Store the test device at 2 to 30°C. Do Not Freeze.

| | | | |
|--|--|-----|---|
| <p>ISO 13485 ISO 9001</p>  <p>Diagnostic Automation/ Cortez Diagnostics, Inc. 23961 Craftsman Road, Suite E/F, Calabasas, California 91302 USA</p> | | | |
| Date Adopted | Cat # 166771-1-21 | | |
| 2012-08-01 | CORTEZ- OneStep Troponin I RapiCard™ InstaTest-2014 | | |
| <table border="1"> <tr> <td>EC</td> <td>REP</td> </tr> </table> | EC | REP | CEpartner4U , Esdoornlaan 13, 3951DB Maarn. The Netherlands. www.cepartner4u.eu |
| EC | REP | | |
| Revision Date: 09-03-2014 | | | |