TROPONIN I (Trop I) RAPID TEST

INTENDED USE

Nuvision Troponin I Test is a rapid immunochromatographic assay for the qualitative detection of human Troponin I at or above the concentration of 0.5 ng/mL in human Whole blood, Serum or Plasma samples. It is intended for professional use as a tool in the diagnosis of acute myocardial infection.

SUMMARY

Cardiac Troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22.5 kilodaltons. In striated muscles (skeletal and cardiac), Troponin I forms a protein complex together with Troponin T and Troponin C. The Troponin complex dissociates during myocardial damage, and the individual protein components are released into the bloodstream. Although Troponin I is also found in skeletal muscles, and may be released after extensive physical stress, its form differs from the cardiac cTnI in its amino acid composition. This distinction allows the two forms of Troponin I to be distinguished immunologically and thereby ensures an accurate test assay that is specific only to cardiac Troponin I molecules.

Cardiac Troponin I (cTnI) is released into blood circulation 4 to 6 hours after the onset of cardiac damage. The normal whole blood or serum level of cTnI is less than 0.06 ng/ml. The cTnI levels can reach as high as 100-1300 ng/ml in some Acute Myocardial Infection patients, and may remain elevated for 5 to 7 days.

PRINCIPLE OF THE ASSAY

Nuvision Cardiac Troponin I (cTnI) Test Kit is a rapid immunochromatographic assay, which detects the presence of cTnI in human whole blood, serum/plasma samples. Monoclonal antibodies specifically against cTnI are conjugated with colloidal gold and deposited on the conjugate pad and also immobilized on the test line of the nitrocellulose membrane. When the serum, plasma sample is added the gold-antibody conjugate is rehydrated and the cTnI, if any in samples, interacts with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (T) where it is captured by immobilized antibodies, forming a visible pink line (Test band), indicating a positive result. If cTnI is absent in the sample, no pink line will appear in the Test Zone (T), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

- **Troponin I Test pouches**
- **Pouch contents: Test Cassette, Desiccant.**
- **Sample dropper**
- **1 Test instruction per box**

MATERIALS REQUIRED (BUT NOT PROVIDED)

- **Clean, specimen collection container.**
- **Clock or timer.**

WARNINGS AND PRECAUTIONS

- **For professional *in vitro* diagnostic use only. NOT FOR MEDICINAL USE.**
- **Do not reuse.**
- **Do not use if the product seal or the packaging is compromised.**
- **Do not use after the expiration date shown on the pouch.**
- **Do not use if the Desiccant pouch's color is changed to pink or colorless when the test pouch is opened.**
- **Do not mix and interchange different specimens.**
- **Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.**
- **Wash hands thoroughly after finishing the test.**
- **Do not eat, drink or smoke in the area where the specimens or kits are handled.**
- **Clean up spills thoroughly with appropriate disinfectants.**
- **Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.**
- **Dispose of all specimens and used devices in a proper bio- hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.**
- **Keep out of children's reach.**

SPECIMEN PREPARATION

- **For serum samples, collect blood in a tube without anticoagulant and allow it to clot.**
- **For plasma samples, collect blood in a tube containing anticoagulant.**
- **Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.**
- **Whole blood: whole blood should be collected in heparin, citrate, or EDTA containing tubes. Mix the blood by inversion and use it to the test.**
- **Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.**
- **It is recommended that Fresh samples should be used for testing. However, the samples may be stored at 2°C to 8°C for up to 24 hours and at -20°C for upto 1 month, if the tests cannot be performed immediately. Ensure that the samples are allowed to attain room temperature prior to use.**
  Note: Hemolytic samples should not be used!
- **Mix each specimen thoroughly prior to use. Do not heat or repeatedly freeze/thaw specimen.**

PROCEDURE

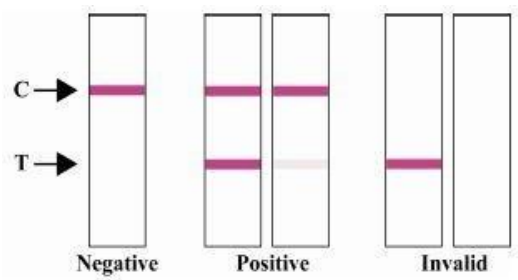
- **Bring the kit components to room temperature before testing.**
- **Open the pouch and remove the Test. Once opened, the test must be used immediately.**
- **Label the test cassette with patient's identity.**
- **For Serum/Plasma/Whole Blood samples: Hold the sample dropper vertically. Add three full drops (110-120 µL) of the specimen without air bubbles into the sample well on the testing device.**
- **Read the results at the end of 20 minutes.**

Note:

1. Some strong positive samples may show positive results before 5 minutes.

2. DO NOT READ RESULTS AFTER 30 MINUTES. To avoid confusion, discard the test device after interpreting the results.

INTERPRETATION OF RESULTS



Negative

A pink colored band appears only at the control region (C), indicating a cTnI concentration below 0.5 ng/ml.

Positive

A clear pink control band (C) and a detectable test band (T) appears on their respective regions, indicating a positive result for cTnI. Invalid

No visible band at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

Note:

The cut-off value can differ according the clinical situation of the patient. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

STORAGE AND STABILITY

- **Test device in the sealed pouch should be stored at 2°-30°C. Do not freeze the test device.**
- **If stored at 2°-8°C ensure that the device is brought to room temperature before opening.**
- **The test device should be kept away from direct sunlight, moisture and heat.**
- **Do not expose the kit over 30°C.**

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity studies were carried out in-house on fresh as well as frozen samples, from low risk as well as high risk groups.

Troponin I Samples	Positive	Negative	Total
Positive	21	01	22
Negative	01	103	104
Total	22	104	126

Relative Sensitivity: 94.45%, Relative Specificity: 99.00%, Overall agreement: 96.73%

LIMITATIONS

- **This product is an *in vitro* diagnostic test designed for professional use only.**
- **Humidity and temperature can adversely affect results.**
- **The instructions for the use of the test should be followed during testing procedures.**
- **There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.**
- **Although the test demonstrates superior accuracy in detecting cTnI, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.**

REFERENCES

1. **Adams, et al. Biochemical markers of myocardial injury, Immunoassay Circulation 88:750-763, 1993.**
2. **Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament. J.Biol.Chem. 266:966, 1991.**
3. **Adams, et al. Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I. N.Eng.J.Med 330:670, 1994.**
4. **Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation. Ann. Thorac. Surg. 61: 227, 1996.**
5. **Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000.**

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