TROPOTest - One Step cardiac Troponin I Test

Catalog # R-6505

For miniature size samples

For the qualitative determination of cardiac troponin I in human whole blood/serum/plasma (20 tests).

INTENDED USE

The *Novamed* One Step cardiac Troponin I Test Device is intended for the qualitative determination of cardiac troponin I in human whole blood, plasma or serum. Measurement of troponin I values is useful in the evaluation of acute myocardial infarction (AMI).

ASSAY SUMMARY

The 3-unit troponin complex (troponin I, T and C) is located on the actin filament and is essential for the calcium-mediated regulation of skeletal and cardiac muscle contraction(*1*). Cardiac troponin I (cTnI) is 24,000 Da(2) cardiac muscle protein known to be released into the bloodstream after the onset of Acute Myocardial Infarction (AMI) mainly as a binary complex Troponin I-C, and a tertiary complex Troponin I-T-C, and, to a lesser extent, in its free form [(3) ;and references therein]. Due to the discrepancies in the amino acid composition the cTnI and the skeletal muscle troponin I isoform (skTnI) are immunologically discernable (*4-6*). Hence, even though skTnI may be found in the bloodstream following extensive physical stress, or skeletal muscle damage, cTnI levels may still be accurately determined utilizing antibodies specific to the cardiac troponin I molecules(*7, 8*). Blood cTnI values augmentation is detected 4-6 hours subsequent to the myocardial damage, and the elevated levels then persist in the blood due to the slow release and degradation of the structural pool(*9, 10*), despite the relatively short half-life of cTnI and its complex(*11*). The *Novamed* TROPOTest device is a rapid qualitative lateral flow immuno-chromatographic immunoassay for the detection of cardiac troponin I in whole blood, plasma, or serum samples. It can be used in conjunction with other diagnostic methods to assess cardiac damage caused by AMI.

TEST PRINCIPLE

The *Novamed* One Step cardiac Troponin I Test Device is a lateral flow-based immunoassay designed for the detection of cTnI in human whole blood, plasma and serum samples. To perform the test, sample is loaded onto the assay sample input surface through the specimen well opening. The majority of blood cells, if present in the sample, are filtered out owing to the unique test structure, allowing only the plasma to flow down the assay membrane. cTnI in the specimen is bound by, and forms a complex with colloidal gold-conjugated mouse monoclonal antibodies. This complex migrates through the membrane towards the assay test line, also containing murine monoclonal antibodies, where a color band of variable intensity should form when the cTnI concentration is greater than, or equal to the assay sensitivity limit*. No line will appear in the test line area if specimen cTnI concentration is below this limit. The specimen-gold conjugate mixture then migrates further down the membrane through the assay control line to produce a color band. The assay is deemed invalid if the control line is not visible, and retesting should be performed.

KIT COMPONENTS

Each kit contains everything needed to perform 20 tests.

- 20 individually wrapped test devices.
- 1 buffer in a 3 ml dropper bottle
- 1 package insert.
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STORAGE AND STABILITY

The device should be stored in its sealed pouch at 15-25°C and under dry conditions. Expiration date is indicated on the pouch. Do not use if foil pouch seal is not intact!

WARNINGS AND PRECAUTIONS

1. For *in-vitro* diagnostic use only.
2. Always wear gloves when performing this procedure and treat all specimens and used devices as potentially infectious.
3. The *Novamed* One Step cardiac Troponin I Test Device should remain in foil pouch until ready for use. The pouch containing the test card must be completely sealed.
4. Do not use the *Novamed* One Step cardiac Troponin I Test Device beyond the expiration date printed on foil pouch.

TEST LIMITATIONS

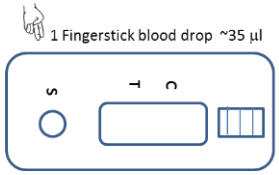
*The *Novamed* One Step cardiac Troponin I Test is a qualitative assay device capable of detecting elevations of cTnI levels above **1ng/ml.** Caution should be exercised when interpreting results obtained from samples expressing elevated level of substances known to interfere with lateral flow format tests, such as rheumatoid factor or antinuclear antibody, produced in certain diseases. These substances are generally known to impose both false positive and false negative results.

DIRECTIONS FOR USE

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.

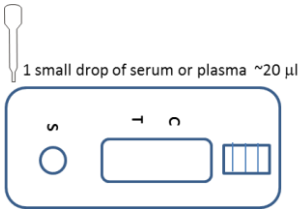
2. Place the test device on a clean and level surface.

a. **Whole blood** Allow 1 hanging drop (approximately 35-40 µL) to fall into the center of the specimen well (S) on the test device. After the sample is fully absorbed, wait 5-10 seconds and then add **2** drops of buffer (approximately 55 µL). See illustration below.



Add 2 drops of buffer

b. Serum/Plasma Apply 20 µL of the sample to the sample port (**S**) of the device. Once the sample is absorbed, wait 5-10 seconds and add **2** drops of buffer



Add 2 drops of buffer

3. Wait for the colored line(s) to appear. **Read results at 15-20 minutes. Do not interpret results after 20 minutes.**

QUALITY CONTROL

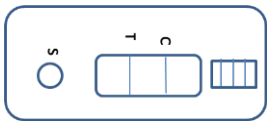
A colored line in the control line region (**C**) is the internal procedural control, which confirms sufficiency of the sample volume with or without buffer, adequate membrane wicking and correct procedural technique.

INTERPRETATION OF RESULTS

(Please refer to the illustration below)

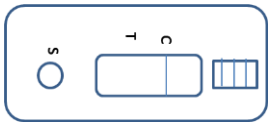
POSITIVE: Two distinct colored lines appear. One vivid colored line is visible in the control line region (**C**), and another apparent colored line should be detected in the test line region (Test).

IMPORTANT NOTE: The intensity of color in the test line region (**T**) is subject to variability reflecting the concentration of cTnI present in the specimen. Therefore, any shade of color in the test line region (**T**) should be considered positive.



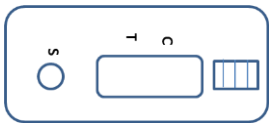
Positive test

NEGATIVE: One colored line appears in the control line region (C). No line is visible in the test line region (**T**).



Negative test

INVALID: Control line (C) fails to appear (test line may be present or absent). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Invalid test

CROSS-REACTIVITY

Sera containing known amounts of Skeletal Troponin I (up to 5,000ng/ml) have been tested with the device. No cross-reactivity was observed, indicating that the cTnI One Step cardiac Troponin I Test Device (Whole Blood) has a high degree of specificity for **cardiac** Troponin I.

PERFORMANCE EVALUATION

In a study conducted at a primary care medical center in Israel TROPOTest demonstrated a 92.4% rate of AMI detection (49 of the total 53 AMI cases enrolled) when sampled twice within first 4 hours of hospitalization (test results were read and interpreted by non-trained medical personnel). Specificity of AMI detection is 97%.

REFERENCES

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