



TROPONIN I (cTnI) ADVANCED 004A097

ulti med cTnI Test For Serum, Plasma or Whole Blood Specimens



INTENDED USE

The ulti med cTnI Test is a rapid chromatographic immunoassay for the qualitative detection of human cardiac Troponin I in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI). The analytical sensitivity of the test is 1 ng/ml by using the Cardiac Markers Control (Bio-Rad). This test is intended for professional use.

SUMMARY

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa. Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle. After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cardiac TnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma. cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery. Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.

MATERIALS PROVIDED

- cTnI test cassette with pipette in foil pouch (25 per kit box)
- Heparine tubes (25 per kit box)
- Instructions (1 per kit box)

MATERIALS REQUIRED, BUT NOT PROVIDED

- Stop watch
- Utensils for sample collection

PRECAUTIONS

The ulti med cTnI test kit should be stored at 4-30°C. If test kit is refrigerated, it should be brought to room temperature before use. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

SPECIMEN COLLECTION AND STORAGE

Whole Blood specimen collection: Collect an anticoagulated blood sample by using heparin as the anti-coagulant.

Note: Troponin I is very unstable in serum or whole blood specimens. Whole blood or serum specimen must be tested as soon as possible.

Plasma/Serum specimen collection:

1. Centrifuge whole blood to get plasma/serum specimen.
2. If specimens are not immediately tested, they should be refrigerated at 2-8°C. Specimens should be at room temperature before running a test.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS

- For in vitro diagnostic use only.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- Do not use the test kit if the pouch is damaged or the seal is broken.

PROCEDURE OF THE TEST

1. Remove the test cassette from the foil pouch, and place it on a flat, dry and clean surface.
2. Hold the sample dropper above the test cassette and add 1 hanging drop into the Sample Well. After the drop is absorbed into the Sample Well, add another hanging drop, repeat the procedure until a total of 3 hanging drops have been added to the Sample Well. If specimen drops are added too quickly, specially for blood specimen, it may cause clogging of the test.
3. As the test begins to work, you will see a purple coloured front move across the Result Window in the centre of the test cassette.
Note: If the purple coloured front does not begin to flow through the "Result Window" within 2 minutes, add one more drop of sample.
4. Interpret test results at 10 to 15 minutes. Do not interpret test results after more than 20 minutes.

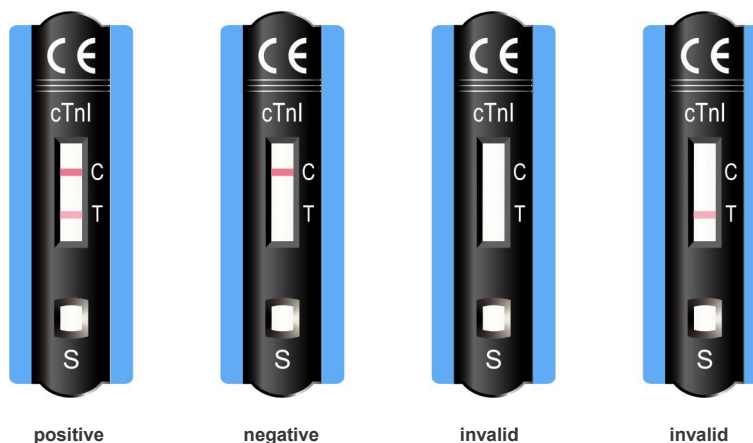
CAUTION: The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the interpretation time should be properly increased.



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INTERPRETATION OF THE TEST

- A purple line will appear at the section of the Result Window marked with "C". This line is the Control Line, which shows that the test is working properly.
- The section of the Result Window marked with "T" indicates the test results. If another coloured line appears in this section of the Result Window, this line is the Test Line.



Positive Result: The presence of two coloured lines ("T" line and "C" line) in the result window regardless of which line appears first indicates a positive result (Figure 1). **Note:** Generally, the higher the analyte level in the specimen, the stronger the "T" line colour will be. When the analyte concentration is close to but still within the sensitivity limit of the test, the colour of the "T" line will be very faint.

Negative Result: The presence of only one purple coloured line in the section marked "C" indicates a negative result (Figure 2).

Invalid Result: If after performing the test no line is visible in the Result Window, or only one line at "T", this result is considered invalid (Figures 3 and 4). Not following the procedures correctly or using a test kit that has deteriorated can cause invalid results. It is recommended that the specimen be re-tested. If the problem still persists, please contact your manufacturer and stop using the tests.

Note: A positive result will not change once it is established your answer at 20 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 20 minutes. Some specimens with a high rheumatoid factor concentration may yield a non-specific positive result.

LIMITATIONS OF THE TEST

Although the Ulti med cTnI Test is accurate in detecting cTnI, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. 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

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- *Troponin T and Myocardial Damage*, Lancet, 1991,338(8758):23-4, (editorial).

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| Manufacturer | Contents sufficient for <n> tests |
| For in vitro diagnostic use only | Lot. no. |
| For single use only | Use by |
| Read instructions for use | Store at |

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