Laboquick cTnI Cardiac Troponin I Test

cTnI Cardiac Troponin I Test User's Manual

One step quick test for detecting cTnI Cardiac Troponin I in human blood, serum or plasma
Only for Professional Use
Product Code: LBTI.01

Intended Use:
Laboquick cTnI Cardiac Troponin I cassette test is used as a diagnostic device aimed at qualitative detection of the Cardiac Troponin I (cTnI) on the immunochromatographic basis in the human serum, plasma and blood. It is used for helping diagnosis of Acute Myocardial infarction.

Summary:
Cardiac troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22.5 kilodaltons. In striated muscles (skeletal and cardiac) it forms a protein complex together with troponin T and troponin C. The troponin complex dissociates following 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, this form differs from 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 to only cardiac troponin I molecules. Cardiac troponin I (cTnI) is released into blood circulation 4 to 6 hours after the onset of cardiac damage. Normal whole blood/serum level of cTnI is below 0.06ng/ml, and the levels can reach as high as 100-1300ng/ml in some AMI patients, and may remain elevated for 5 to 7 days. Laboquick One Step Cardiac Troponin I (cTnI) Test is a rapid chromatographic immunoassay for the detection of cardiac troponin I in serum, plasma or blood samples. It can be used together with other diagnostic methods to assess cardiac damage caused by AMI.

Test Principle:
The Troponin I test is based on immunochromatographic principle. The test device includes a sample cavity which forms the material that makes the reagent move. Sample ped is held by a permeable membrane. Cardiac Troponin I in the specimen is bound by an antibody-gold conjugate forming an antibody-antigen complex. This complex migrates to the test zone (T) of the window, where it is captured by another anti-cTnI antibody immobilized on the membrane, forming a pink test line. This test is designed to yield a positive result for cTnI concentrations at 1.0 ng/ml or greater. The rest of the dye conjugate particles migrate to the control zone (C) of the window, where the dye conjugate is captured by another immobilized antibody (goat anti-mouse IgG), producing a pink control line even in the absence of cTnI. To serve as an internal process control, a control band was designed to indicate that the test is performed properly, and should always be seen after test is completed. Absence of a colored control line in the control region is an indication of an invalid result.

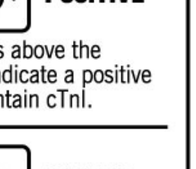
Package Contents:
Troponin I testing device, disposable plastic pipette, silica gel bag as humidifier.

Storage Conditions:
Troponin I testing device must be stored between +2 to +30°C and shouldn't frozen. Under these conditions, the device work stabile until the expiry date printed on the packaging, unless the package is opened.

Warnings and Cautions:
1.Read the instructions before use.
2.The device is just for outer body diagnosis and it is disposable.
3.Do not ever freeze the tests. If the test was stored in a refrigerator, wait the product reaches to the room temperature before use. The test must be carried out in room temperature (between +15..... +30 degrees).
4.Do not use a test after expiry date.
5.Only human blood serum or plasma can be used as a sample. Do not use navel cord blood because this blood prevents the movement of the colloidal gold and can cause messing up on the results.
6.Observe carefully the number of drops. Only 2 - 3 drops of sample must be dropped on test.
7.After removing the testing device from it's package, use it immediately.
8.If the package is torn, the device shouldn't be used.
9.To prevent mixing between samples, use a different disposable sample pipette for each test.
10. Read the positive test results at the latest in 10 minutes and the negative results in 20 minutes. The results that taken after 20 minutes shouldn't taken into consideration.
11. During the test, any cosmetic application shouldn't done, any liquids or food shouldn't be consumed and smoking is not suggested.
12. Getting the most successful results depends on fulfilling the test protocol. Dropping the sample with a pipette in appropriate proportions, application temperature and timing are very important for the results.
13. All the steps must be completed after the start of the test procedure.
14. Do not use the samples containing hemolytic, lipaemic or bacteria. These kinds of samples can cause false results.

Test Usage Procedure:

1. Test device must be at room temperature.
2. Remove the test from the package just before starting the test. Place the test on a flat surface.
3. Drop 2 - 3 drops of serum/plasma/blood sample in to the sample cavity. Any air bubble occurrence must be prevented.



4. Positive results can be read at least in 10 minutes and likewise the negative result in 20 minutes.
5. Results that occurred after 20 minutes must be ignored.
6. **Evaluating the results**

NEGATIVE

A single line that occurs on the section above the letter "C" in the result window indicates a negative result. This indicates that the sample does not contain cTnI.

POSITIVE

Two lines that occur on the both sections above the letters "C" and "T" in the result window indicate a positive result. This indicates that the sample contain cTnI.

INVALID

If there are no lines on the result window after the predetermined waiting period, the result is invalid. The test procedure could be carried out wrongly or the test can be malfunctioned. The test must be re-done with a new device.

Sample for Test:
Fresh human serum, plasma, blood sample will be used for this test.

Preparing The Sample For Test:
There is no need to make extra preparation for blood sample. In order to obtain the serum/plasma sample for the test, a blood sample is taken into a dry and clean vial and left for clotting. Then the serum is separated from the blood sample by centrifuging 15 minutes on 5000 RPM under room temperature.
The separated serum must be stored between +2 to +8°C unless it will be used. If it is necessary to store the sample more than three days, the sample must be frozen under -20°C or below.

Sensitivity:
The sensitivity of cassette test was determined as 1 ng/ml.

Test Limitations:
1. Troponin I test cannot be used only by itself to diagnose heart attack or cardiovascular illnesses. Further diagnosis has to be completed to get exact results.
2. The test device gives the best result in room temperature. Since the samples that frozen and thawed many times can include chunks, they may block the test device. As a result of this, the sample which can not move freely in the test device leaves a dark colored trail behind. Hence this makes the test results difficult to read.
3. The aim of this device is never to make a certain diagnosis. The results of this device must certainly supported by the experts with additional diagnostic methods.
4. Dropping more than 3 – 4 drops can cause test's giving false results
5. Test's being successful depends on completing all steps carefully.

References:

1. The New England journal of medicine (N Engl J Med), published in United States.
2. Anaesthesia (Anaesthesia), 2009-Sep; vol 64 (issue 9) : pp 953-60
3. Christenson RH, Apple FS, Morgan DL ve ark. (1998) Cardiac troponin I measurement with the Access immunoassay system:analytical and clinical performance characteristics. Clin Chem 44(1), 52-60
4. Hillis GS, Fox KAA. (1999) Cardiac troponins in chest pain. BMJ 319, 1451-1452
5. Elmalı Dr. Esra Turkish Journal of Biochemistry - Turk J Biochem 2005; 30 (3); 212-215.
6. Hamm CW, Giannitsis E, Katus HA. (2002) Cardiac troponin elevations in patients without acute coronary syndrome. Circulation 106, 2871.5.

HAM.LTKI.01
Rev.01
Date of Publication: 08.12.2009

Manufacturer:
Köroğlu Tıbbi Malz. San. ve Tic. Ltd. Şti.
1776/23 Sok. No:4/A Mevlana Mah.
Bornova-İzmir-Turkey
Tel: +90 (232) 388 73 74
Fax: +90 (232) 388 40 43
www.koroglugroup.com
e-mail: medical@koroglugroup.com

CE