Cardiac Troponin I Kit (cTnI)

10 Test

Only for in vitro use in clinical laboratory (IVD)

A rapid test for qualitative detection of Cardiac Troponin I in Serum or plasma.

Intended Use

The CTnI one step Troponin I test device is a chromatographic immuno assay for detection of human cardiac Troponin I in serum and plasma for detection of MI (Myocardial Infarction).

Clinical Significance

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22,500 Daltons. Together with Troponin T and C, it forms a structural complex which the components are released into the blood circulation after cardiac damage is broken up.Troponin I is founded in skeletal muscles as well, but it differs in its amino acid composition from cardiac Troponin I so that these two Troponins can be immunologically distinguished. Troponin I is released into blood stream soon after onset of acute cardiac damage. When sensitive immunological methods are utilized, a detectable level is reached approximately 4-6 hours after an acute myocardial infarction (AMI). cTnI concentration in normal serum is below 0.06 ng/ml. Levels as high as 100-300 ng/ml have been measured with some AMI patients. Troponin I is a rapid immunochromatographic test for the detection of cardiac Troponin I in serum and Plasma samples. It can be used together with other diagnostic methods to assess cardiac damage caused by a myocardiac infarction.

Principle

The EURO Troponin I test is based on immunochromatography. The test device includes a chromatographic membrane with two immobilized antibody zones and a rehydratable mobile reagent with colored particles applied on a filter material.

Testing is performed by adding the sample into the round sample well of the testing device. The sample flows through a filter containing the colored label zone. The sample and the label migrate then into the membrane where they come into contact with different reagent zones, In the test zone the particles with cTnI are captured by an anti-cTnI-antibody and a colored test line is formed. The rest of the particles will be captured by the second stationary antibody zone, thus forming the control line.

If the sample contains cTnI, intensity of the test line depends on the concentration of cTnI in the sample. The sensitivity of the test has been adjusted so that the level of cTnI in normal serum or plasma will not give a positive reaction. A slightly elevated level of cTnI (0.3 ng/ml) gives a marginally detectable test line. The higher the cTnI concentration, the more intensive the test line is and the faster it appears.

Kit Components

Trop I test device – 10 Nos
Disposable Pipettes – 10 Nos

Stability

The packed card should be stored at room temperature (2°C to 25 ° C) storage. It is stable up to expiry as mentioned in kit label.

Materials Required but not provided

Specimen Collection tubes , Centrifuge, Timer

Specimen Collection and Preperation

CTnI one step Troponin I test device can be perfomed using Serum or Plasma.

Sample Collection

1. Collect blood from patient in to a test tube.
2. Centrifuge and Separate Serum or plasma,and make sure testing should be done immediately with the specimen collection.
3 Bring Specimens to normal temperature before the test.

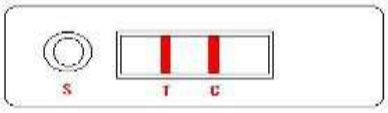
Assay Procedure

Before the operation carefully read manuals.
1.Bring the cards to room temperature from the package.
2.Bring the samples into room temperature.
3.Absorb fresh samples (Serum 80 µl or plasma 2-3 drops) with the plastic straw, then add the sample to the sample well.

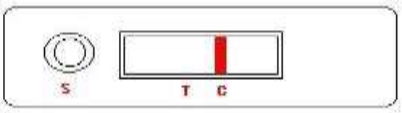
Results

Read the result from 15 to 20 minutes after adding the samples. It may cause the false positive result for over the limited time.

Positive: two red lines show that concentration of cTnI > 0.3 ng/ml). See as follows,



Negative: only one color band appearing in the control line (= cTnI concentrations below the critical value), see as follows,



Sensitivity

When the concentration of the cTnI standard soluble in sample is higher than **0.3** ng/ml, it can detect positive results.

Specificity

The sample containing skeletal Troponin I (sTnI), Troponin C (cTnC) and Troponin T (cTnT) has no effect on the test result.

Note:

1. The kit is only used in vitro measurement of cTnI in human serum or Plasma. Handle the waste according to the laboratory rules and regulations. Don't touch the test device within 10 to 15 minutes during the test.
2. Each test device can only be used once. Adjust batches and validity before use. Do not use expired and damaged products. And don't use the reactor without the positive control line
3. Use the kit according to the manual in order to avoid a false positive result. Fresh samples should be used within 3 hours. And the samples shouldn't be frozen repeatedly.
4. Don't rely on the single test result for the final result.
5. Do quality control test first before using the new batch.

References:

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2. Adams, ML. et al.: *Circulation*, 1 993, 88: 750~763.
3. Bordor, GS. et al.: *Clin. Chem.*, 1992, 38(11): 2203~ 2214.
4. Mair, J. et al.: *Coron. Artery Dis.*, 1994, 5: 865~872. 5. Mair, J. et al.: *Clin. Chem.*, 1995,41(9): 1266~1272.
6. Hamm, CW.: *Thromb. Res.*, 2001,sep.30; 103 suppl. 1: S63. Review.

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