



## **VBL TROPONIN I Serum Cassette Test**

A rapid chromatographic immunoassay for the detection of cardiac Troponin I in serum samples

### **Summary and Explanation**

Cardiac Troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22.5 kilodaltons. In the heart it forms a protein complex together with Troponin T and Troponin C. The Troponin complex is broken up following myocardial damage, and the individual protein components are released into the bloodstream. Although Troponin I is also found in skeletal muscles, 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.

Cardiac Troponin I is released to blood circulation soon after the onset of cardiac damage. Approximately 4 to 6 hours following an acute myocardial infarction (AMI), a detectable level of cTnI can be detected with our immunochromatographic test. While the normal serum level of cTnI is below 0.06ng/ml, levels as high as 100-1300ng/ml in some AMI patients.

The VBL Troponin I Serum Test is a rapid chromatographic immunoassay for the detection of cardiac Troponin I in serum samples. It can be used together with other diagnostic methods to assess cardiac damage caused by AMI.

### **Test Principle**

The VBL Troponin I test strip is a colloidal gold/antibody complex based immunoassay designed for the qualitative determination of cTnI in serum samples.

To perform the VBL Troponin I Serum test, serum is dispensed into the sample well of the cassette. Cardiac Troponin I that is present in the serum is bound by 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 purple-coloured line. The rest of the particles migrate to the control zone (C) of the window, where dye conjugate is captured by an immobilized antibody, producing a purple-coloured control line even in the absence of cTnI.

If the specimen contains an elevated level of cardiac Troponin I, the test line (T) will appear coloured. Both the intensity of the test line and the speed of its appearance will increase with an increased concentration of cTnI in the sample.

## Specimen Collection and Preparation

Collect blood in a tube without anticoagulant and allow to clot. Since cardiac proteins are relatively unstable, it is recommended that fresh samples be used as soon as possible to collect critical patient information. Heat inactivation of samples may lead to hemolysis or protein denaturation and therefore should be avoided.

## Storage and Handling

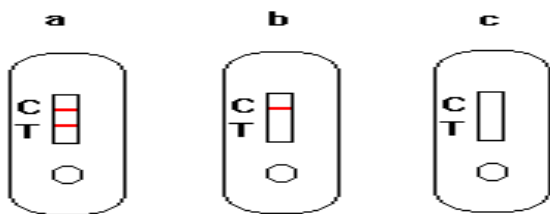
- \* store the VBL Troponin I Serum Test at room temperature
- \* the shelf life of the test is indicated on the test pouch
- \* wear disposable glove while handling specimens and thoroughly wash hands afterwards. All patient samples should be handled as if they are potentially infectious.
- \* if serum or plasma samples have been stored in the refrigerator, allow them to return to room temperature before testing

## Test Procedure

1. Open the foil pouch and lay the cassette on a level surface
2. Label the cassette with the patient's name or control number.
3. Add 3 drops (120uL) of serum into the sample well.
4. Read the test result at 15 minutes.

## Interpretation of Test Results

Read the result 15 minutes after application of the specimen. The test line may become more intensive after this time but the risk of a weak false positive result will increase simultaneously.



- a. A positive test result (cTnI >1.7ng/ml or 5ng/ml ternery complex) is indicated by a coloured test line (T) and a coloured control line (C)
- b. A negative test result is indicated by the presence of a coloured control line (C) and the absence of a test line(T)
- c. An invalid test result is indicated by the absence of both a test line (T) and a control line (C). If an invalid test result is obtained, it is recommended that the specimen be retested.

When judging the test result, it is important to remember the intensity of the test line increases with increased concentration on cTnI in the patient's bloodstream. If the result given by the VBL Troponin I test agrees with other diagnostic methods and clinical symptoms, the AMI diagnosis can be considered probable. When the test result is negative or is in conflict with other results, it is imperative to perform a new test approximately one hour later. If the second result is negative and if the last sample was taken more than 6 hours after a suspected AMI case, then the patient has likely not suffered from AMI.