antibody immobilized on the membrane, forming a burgundy-colored line. The rest of the colored particles migrate to the control zone (C) of the viewing area, where the conjugate is captured by an immobilized antibody, which contributes to producing a burgundy-colored 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 colored. Both the intensity of the test line and the speed of its appearance will increase with an increased concentration of cTnI in the sample.

**SAMPLE COLLECTION AND PREPARATION**
1. Follow standard clinical procedures to collect fresh whole blood or serum specimens.
2. Finger-stick is recommended to collect fresh whole blood specimens with 5mm heparin or citrate as the anticoagulant for this assay. Wipe fingertip with alcohol, then prick fingertip with a lancet in a quick motion.
3. If serum samples are to be used, collect blood in a tube without anticoagulant and allow to clot. Any sediment in serum specimens should be removed by centrifugation. Avoid using any turbid specimens, which may be contaminated by microorganisms.
4. 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.

**REAGENTS AND MATERIALS SUPPLIED**
1. 25 test devices, each sealed in foil pouch.
2. 25 plastic dropper pipettes, one with each test
3. One package insert.

**MATERIAL REQUIRED BUT NOT PROVIDED**
1. Specimen collection containers.
2. Timer

**ASSAY PROCEDURE**
1. Refrigerated specimens or other materials must be equilibrated to room temperature before testing.
2. Remove the test device from its pouch and place it on a flat surface. Label the cassette with the patient’s name or control number.
3. Use a plastic dropper pipette provided to add four drops (about 160 µl) of the whole blood specimen; for serum testing add 3 drops (about 120-130 µl) of the serum specimen to the sample well marked as “S” on the device.
4. Read the result at 15 minutes. Do not interpret results after 15 minutes.

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

1. **NEGATIVE:** If only the C line appears, the test indicates a negative result (free cTnI<1.7ng/ml or complex cTnI < 5.0 ng/ml)
2. **POSITIVE:** If both C line and T line appear in the viewing area, the test indicates a positive result (free cTnI >1.7ng/ml or complex cTnI > 5.0 ng/ml)
3. **INVALID:** There is no band visible in the control region within 5 minutes. Repeat the assay with a new test device.
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 this Troponin I test agrees with other diagnostics 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.

QUALITY CONTROL

Internal Controls: The Troponin I test contains built-in control feature, the C line. The appearance of the burgundy C line indicates that the test has been performed correctly; in particular, that the proper volume of specimen has been absorbed and capillary flow has occurred. The C line should always appear regardless of the presence of cTnI.

External Controls: Good laboratory practice recommends the use of quality controls to ensure proper test performance.

LIMITATIONS OF THE PROCEDURE

1. Other Clinical findings need to be considered to confirm diagnosis.
2. For in vitro diagnostic use only.
3. The test should be used for the detection of Troponin I in whole blood and serum only.
4. In some rare case due to high levels of certain antibodies such as human anti-mouse antibodies (HAMA), false positive might occur.

Bibliography

11. USA Center for Disease Control/National Institute of Health Manuel, “Biosafety in Microbiological and Biomedical Laboratories”, 1984

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