

BIOCARD™ Whole Blood Troponin I

07.08.2008

A rapid immunochromatographic test for the detection of cardiac Troponin I in human whole blood samples

SUMMARY AND EXPLANATION

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 after cardiac damage is broken up and the components are released into blood circulation. Troponin I is found in skeletal muscles as well, but it differs in its amino acid composition from cardiac Troponin I so that these two Troponins can be distinguished immunologically.

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 approx. 3-4 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.

Biocard Troponin I is a rapid immunochromatographic test for the detection of cardiac Troponin I in whole blood samples.

TEST PRINCIPLE

The Biocard Troponin I test is based on an one-step immunochromatography. The test device includes a chromatographic membrane with two immobilized antibody zones and a rehydratable mobile reagent with coloured particles applied on a filter material.

Testing is performed by adding with an exact volume pipette provided with the kit 150 µl of whole blood or plasma sample into the round sample well of the Biocard testing device. The sample flows through a filter containing the colored label zone. The sample-label conjugate and the free label migrate then into the membrane where they come into contact with primary and secondary antibody zones. In the test zone the conjugate with cTnI is captured by an anti-cTnI-antibody and a coloured 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. 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.

MATERIALS PROVIDED

BIOCARD Whole Blood Troponin I
Cat.no. 3-019-200, 20 tests

20 pcs Disposable Biocard Troponin I test devices packed in foil pouches
20 pcs Disposable exact volume pipettes
2 pcs Freeze-dried positive controls (3 and 30 ng/ml)
1 pc Negative control
1 pc Instruction for use

Materials needed but not provided with the kit: distilled water for rehydration of the controls and timer.

TEST PROCEDURE

Read the instruction for use with care before running a test. Test each sample with a new test device. Used test device and pipette can be disposed as laboratory waste.

A. Open the pouch protecting the test device immediately. Remove the test device from the pouch and place it on the bench. Do not touch the device during the testing time.

B. Perform a test with fresh, undiluted patient whole blood sample. Test can be performed either Heparinized or EDTA vena puncture whole blood. Samples should not be below room temperature before running a test. Troponin I is very unstable in controls and in the whole blood samples. Samples stored for more than 3 hours should not be used. Mix the whole blood sample carefully by turning the sample tube upside down couple of times before running a test. The Biocard Whole Blood Troponin I test is aimed only for fresh whole blood samples. Do not use patient whole blood samples which are coagulated, cooled or frozen. Do not use blood samples collected to citrate or gel tubes.

C. Fill the exact volume pipette with a 150 µl of undiluted fresh whole blood sample by slowly pressing the bulb and then slowly releasing the pressure on the bulb. Then pipette carefully the whole amount of whole blood sample into the sample well of the test device (marked with S). Read the result after 15 minutes. T indicates tests line, C is control line.

Positive result = two coloured (purple) lines: cTnI has been released into blood circulation.

Negative result = one coloured (purple) line: cTnI has not been released into blood circulation.

When the test result is negative or weak positive, it is recommended to perform a new test after 2-3 hours. When an infarction is suspected, it is recommended to run series of tests with fresh patient samples.

CONTROL PROCEDURE

Dilute freeze-dried positive control tablets (vials with red and blue labels) to 1.0 ml of distilled water. Mix carefully and allow it to dissolve in room temperature for 15 minutes. Mix again and perform the control testing in the same way as the patient sample testing above (test procedure). The negative control (vial with green label) is ready for use at once and it must be used as such without any dilution.

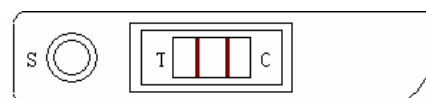
READING AND INTERPRETATION OF THE TEST RESULTS

Read the result 15 minutes after application of the sample. The test line may become more intensive after this time but the risk of a weak false positive result will increase simultaneously. Some samples may be very viscous and in those cases the result can be read when background of the reaction window has cleared up.

A positive result will remain practically unchanged for several hours or even days. If the result is kept for filing, remove the strip from the device following appropriate laboratory safety measures.

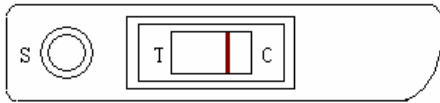
A positive result

A positive result (concentration of cTnI > 0.3 ng/ml) is indicated as two colored (purple) lines (T = test line and C = control line). If seen necessary, the intensity of the test line can be compared to the results with control sera.



A negative result

A negative result (concentration of cTnI is below the cut-off level of Biocard test) is indicated as only one colored (purple) line. cTnI has not been released into the blood circulation or it is under the detection limit.



When judging the test result from a series of samples, it is advisable to remember that the intensity of the test line increases if additional cTnI is released into blood stream. If the result given by Biocard Troponin I is in concordance with other diagnostic methods and clinical symptoms, the AMI diagnosis can be considered possible. When the test result is negative or in conflict with other results, it is imperative to perform a new test appr. 1 hour later.

Note: When assessing the final diagnosis, instead of relying solely on the test result given by Biocard Troponin I, it is necessary to take into consideration all patient information which may have an influence on the suspected AMI diagnosis.

INVALID TEST RESULT

If no coloured control line is formed in the control indicator window the test device is damaged and so the test result shall be rejected. In such a case repeat the test with a new test unit.

CONTROL

Proper performance of Biocard Troponin I can be checked by means of positive Biocard Troponin I serum controls and a negative Biocard Troponin I control. The kit contains: 2 vials of freeze-dried positive control samples made in human serum containing 3 and 30 ng/ml cTnI, respectively, and 1 vial of negative control buffer (0 ng/ml cTnI).

Controls are meant only for the intensity evaluation of test and control lines. It is very important that clinical testing is performed with fresh patient whole blood or plasma samples.

STABILITY AND STORAGE

Store the test devices at room temperature (+15...+30 °C). The controls shall be stored separately from the tests at +2...+8°C but for short period of 30 days the controls can be stored also at room temperature. After dissolving the controls they can be stored refrigerated not more than 5 days. Do not use controls which are frozen and melted

more than once. The shelf life of Biocard Troponin I is indicated on the pouches and on the kit.

PERFORMANCE CHARACTERISTICS

Test performance was evaluated using confirmed negative whole blood samples and by studying artificial samples containing Troponin I and miscellaneous interfering substances.

SENSITIVITY

The absolute detection limit of Biocard Whole Blood Troponin I was determined to be 0.3 ng cTnI/ml using standard samples with human serum.

The higher the cTnI concentration, the more intensive the test line is and the faster it appears. Even 500 µg/l cTnI gives a positive test result within reading time.

SPECIFICITY

When blood samples containing skeletal Troponin I (sTnI), Troponin C (TnC) and Troponin T (TnT) were tested with Biocard Troponin I, they did not bring any cross-reactions in the studied concentrations.

The main likely causes for false positive results include high titer RF-positive blood, blood containing plenty of complement components and highly lipemic and microbially contaminated (if stored samples are studied) plasma. Ask for our documentation file.

PRECAUTIONS AND LIMITATIONS

If instructions for use are not carefully followed, false results may appear

The Biocard Troponin I tests shall be used only for *in vitro* detection of whole blood or plasma cTnI according to the instructions for use. General laboratory procedures and precautions should be followed in the handling and disposal of specimen and testing materials.

Use each test device only once! Do not use expired test units or controls. Do not use test units if the aluminium foil pouch or the test device has been damaged during storage or transportation. Do not use such tests for diagnosis which do not produce a control line.

The controls contain material of human origin which have been tested and found negative for HIV antibodies, HCV and

HbsAg. Handle it with care as if capable of transmitting infectious agents.

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