

BIOCARD™ Troponin I

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A rapid immunochromatographic test for the detection of cardiac Troponin I in human serum samples.

REF 3-019-000

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. 4-6 hours after an acute myocardial infarction (AMI). Troponin I level is highest 14-20 hours after AMI and remain elevated 5-8 days thereafter. 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 serum samples. It can be used together with other diagnostic methods to assess cardiac damage caused by a myocardial infarction.

TEST PRINCIPLE

Biocard 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 coloured particles applied on a filter material.

Testing is performed by adding 3 drops (totally approx. 100 µl) of serum sample into the round sample well of the Biocard testing device. The sample flows through a filter containing the coloured 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 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. The sensitivity of the Biocard test has been adjusted so that the level of cTnI in normal serum 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.

MATERIALS PROVIDED

BIOCARD TROPONIN I
REF 3-019-000, 20 tests

20 pcs Disposable **Biocard Troponin I** test devices packed in foil pouches
20 pcs Disposable pipettes
1 pc Instruction for use

TEST PROCEDURE

Read the instruction for use with care before running a test.

① Remove a testing device from the pouch (one device for each specimen and for each control) and place the device on the bench. Do not touch the device during the 10-15-minute testing time. Troponin I is very unstable in controls and in serum samples. Samples stored for more than 3 h at room temperature shall not be used. For later testing, freeze the samples immediately after collection and thaw them to ambient temperature before use. Samples frozen and melted once should not be refrozen.

② Bring the controls and samples to room temperature (20 minutes).

③ Pipette dropwise **3 free-falling drops (totally approx. 100 µl) of undiluted fresh serum sample** into the sample well (S) of the test device.



When an infarction is suspected, it is recommended to run a series of tests with samples taken at a certain interval.

READING AND INTERPRETATION OF THE TEST RESULTS

Read the result **10-15 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. Some serum 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 (=2 coloured red lines, concentration of cTnI > 0.3 ng/ml) is indicated as a weak coloured test line and a clear coloured control line. If seen necessary, intensity of the test line can be compared to the results with control sera.

Positive



A negative result (=1 coloured red line, control line, concentration of cTnI is below the cut-off level of the Biocard test) is indicated by the absence of a test line and the presence of a coloured control line only.

Negative



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 probable. When the test result is negative or in conflict with other results, it is imperative to perform a new test approx. 1 hour later. If even the second result is negative and if the last sample was taken more than 6 hours after a suspected AMI case, the patient has likely not suffered from AMI.

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.

CONTROLS

A control set (REF 3-019-800) is available separately. 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 control set contains: 2 vials of freeze-dried positive control samples made in human serum and 1 vial of negative control buffer. They contain 0, 3 and 30 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 serum samples.

STABILITY AND STORAGE

Store the test devices at ambient temperature (+2...+27°C). 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 and positive sera from suspected AMI patients and by studying artificial samples containing Troponin I and miscellaneous interfering substances.

Sensitivity

The absolute detection limit of **Biocard Troponin I** was determined to be 0.1 ng cTnI/ml using standard samples made in human serum.

In a study of clinical samples, all positive samples (22/22) were correctly indicated by **Biocard Troponin I**, thus giving a sensitivity of 100 %.

Biocard Troponin I		TUCH *
+	-	+
22	-	+
14	84	-

* A verified diagnosis of the Turku University Central Hospital

Specificity

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

In a study of clinical samples, **Biocard Troponin I** gave a false positive result in 14 cases and a correct reaction in 84 cases when 98 negative proven samples were evaluated, thus establishing a specificity of 86,0 %. Taking all correct positive and negative results into consideration, an overall accuracy of 88,3 % (106/120) was established.

METHOD	sensitivity *	specificity
	%	%
Biocard Troponin I	100	86
TR-IFMA	82	95
EIA	44	91

* Sensitivity compared to a verified diagnosis of Turku University Central Hospital
TR-IFMA = Time resolved immunofluorometric assay
EIA = Enzyme immunoassay

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

PRECAUTIONS AND LIMITATIONS

The **Biocard Troponin I** tests shall be used only for *in vitro* detection of serum cTnI according to the instruction 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.

Attention: Patient serum samples for testing must be fresh and at room temperature.

Test results with samples frozen and thawed more than once may result in a false positive reaction.

BIBLIOGRAPHY

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