

# BIOCARD™ Myoglobin

01.08.2008

Cat.No. 3-021-000

## A rapid immunochromatographic test for the detection of Myoglobin from human serum samples

Read the instructions for use carefully before running a test. Perform the test in a well illuminated place.

### INTRODUCTION

Myoglobin is an oxygen binding protein found in cardiac muscle but also in skeletal muscle. When muscles are damaged due to lack of oxygen, trauma etc., Myoglobin is released into blood circulation where it can be detected by means of sensitive immunological methods.

Myoglobin concentration in normal serum is 6,0 – 85,0 ng/ml. Despite the fact that Myoglobin is released to serum after muscular damage and in case of many diseases, several studies have clearly indicated that Myoglobin is a successful tool for the assessment of myocardial damage, as well.

Myoglobin appears in serum 1-4 hours after the onset of an acute myocardial infarction (AMI), well before most of the other markers. The concentration of Myoglobin is determined by the size of damage in the cardiac muscle. Because the renal threshold of Myoglobin is relative low, its level in serum will decrease rapidly. As a result, Myoglobin and Troponin I form an ideal pair of markers in the diagnosis of cardiac infarctions.

### TEST PRINCIPLE

The BIOCARD™ Myoglobin test is based on immunochromatography. The reaction takes place in a nitrocellulose membrane. A Myoglobin-specific monoclonal antibody has been applied to the membrane to form the test reaction zone. The other antibody is bound on coloured latex particles to form the label, which is applied on the filter.

If the sample contains Myoglobin, it reacts with the label antibody. In the test zone the particles with Myoglobin are captured by an anti-Myoglobin-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. A control line is always formed when the test is working properly.

Testing is performed by adding 3 drops (app. 100 µl) of fresh serum sample into the round sample well of the BIOCARD™ testing device. The sample flows through the membrane and the result can be read in 10-15 minutes.

If a sample contains Myoglobin, the intensity of the test line depends on the concentration of Myoglobin in the sample. The cut-off value of the Biocard™ test has been adjusted at 70 ng/ml. At this level, a faint test line will appear 15 minutes after application of the sample. Samples containing up to 50 000 ng/ml Myoglobin give an intensifying reaction.

### MATERIALS PROVIDED

BIOCARD™ MYOGLOBIN  
Cat.no. 3-021-000, 20 tests

- 20 pcs Disposable Biocard™ Myoglobin test devices
- 20 pcs Disposable pipettes
- 1 pc Negative control
- 2 pcs Freeze-dried positive controls (100 and 1000 ng/ml)
- 1 pc Instructions for use

Not included:

- Distilled water and pipette for rehydration of the controls.
- Timer

### SAMPLES

Perform the test with serum or plasma. Do not use whole blood.

Use either conventional methods or fast separation tubes for the collection of serum samples. Use EDTA or Heparinized test tubes for the collection of the plasma sample. Do not use blood samples collected to citrate or gel tubes.

Samples shall be stored refrigerated (+2...+8 °C). Sera can be frozen (under -20 °C) for long-term storage.

### TEST PROCEDURE

**A.** Bring the controls and samples to room temperature (10-20 minutes).

**B.** Remove the test device from the pouch (one device for each specimen) and place the device on the bench. Do not touch the device during the 10-15 minutes testing time.

**C.** Pipette dropwise **3 free-falling drops** (totally app. 100 µl) of undiluted serum sample into the round sample well of the device. Perform a control test with a new test device. Control testing is imperative when a new kit is taken into use, when the testing person is changed, when you are unsure of test performance or the test result or when otherwise seen necessary in frames of the GLP guidelines.

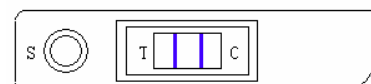
When an infarction is suspected, it is recommended to run a series of tests with samples at a certain interval, for example at an 1 hour interval.

### READING AND INTERPRETATION OF THE TEST RESULTS

Read the result 15 minutes after application of the specimen. The test line may become more intensive even after this time until all particles have migrated past the test reaction zone. Some serum samples may be very viscous and in those cases the result can be read when the background in the reaction window has cleared up.

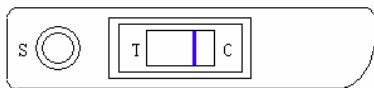
A positive result will remain practically unchanged for several hours or even days. If the result is kept for filing, remove the strip from the plastic device following appropriate laboratory safety measures. Dry strips keep well for years.

**A positive result** (concentration of Myoglobin > 70 ng/ml) is indicated as a weak coloured test line and a clear coloured control line. The test line will become more intensive when Myoglobin concentration increases. If seen necessary, intensity of the test line can be compared to the results with control sera.



A POSITIVE RESULT

A **negative result** (concentration of Myoglobin is below cut-off level) is indicated by the absence of a test line and the presence of a coloured control line only.



#### A NEGATIVE RESULT

When judging the result from a series of samples, it is advisable to pay attention to any change in intensity of the test line. If the result given by BIOCARD™ Myoglobin is in accordance with other test results and the 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 app. 1 hour later with a new sample and also to use BIOCARD™ Troponin I test.

**Note:** When establishing the final diagnosis, instead of using only the result given by BIOCARD™ Myoglobin, it is necessary to take into consideration other test results and all patient information which may affect the suspected AMI diagnosis.

#### CONTROLS

Proper performance of BIOCARD™ Myoglobin can be checked with positive BIOCARD™ Myoglobin serum controls (100 and 1000 ng/ml) and a negative BIOCARD™ Myoglobin control. The kit contains: 2 vials of freeze-dried positive control samples and 1 vial of negative control buffer.

The **negative control buffer** (vial with green label, 1,0 ml buffer solution) is **ready for use at once** and it must be used as such without any dilution. The two **positive controls** (vials with red and blue labels) **must be diluted to 1,0 ml with distilled water** before use.

#### STABILITY AND STORAGE

Store the test devices at ambient temperature (+2...+27 °C). The shelf life of BIOCARD™ Myoglobin is 24 months. The expiry date is indicated on the pouches and the kit.

After arrival to the laboratory, the controls shall be stored separately from the tests at +2...+ 8 °C, but for a short period of 30 days the controls can be stored also at room temperature. The

controls keep well for 24 months when re-refrigerated. After dissolving, the control shall be stored refrigerated for 7 days.

#### PERFORMANCE

##### CHARACTERISTICS

Test performance was evaluated by comparing BIOCARD™ test result with quantitative myoglobin assay results (HUCH).

##### Quantitative myoglobin assay (HUCH)

	+	-
BIOCARD™ +	90	16
Myoglobin -	10	79

##### Sensitivity

The sensitivity of the test with the cut-off value 70 ng/ml was 90,0%.

##### Specificity

The specificity of the test with the cut-off value 70 ng/ml was 83,2%.

When various amounts of cardiac or skeletal Troponin I were added to the serum samples, the samples gave negative result with BIOCARD™ Myoglobin. Even high concentrations (20-40 g/l) of haemoglobin did not cause cross-reactions.

RF-positive serum samples showed a negative result with the BIOCARD™ Test. Likewise, samples from healthy persons gave a negative result.

#### PRECAUTIONS AND LIMITATIONS

- The Biocard Myoglobin tests shall be used only for *in vitro* detection of Myoglobin according to the instruction for use.
- General laboratory procedures and precautions should be followed in the handling and disposal of specimens and testing materials.
- Use each test device only once!
- Do not use tests, controls or accessories from different kits.
- Check that the lot and exp. dates match on the test pouches and control vials.
- Do not use expired test units or controls.
- Do not use test units if the aluminum 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 positive controls contain material of human and animal origin. Handle it with care as if capable of transmitting infectious agents.

#### BIBLIOGRAPHY

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#### Manufacturer:

Ani Biotech Oy, Tiilitie 3,  
01720 VANTAA, FINLAND  
Tel. +358-20-155 7518  
Fax +358-20-155 7517  
<http://www.anibiotech.fi>  
e-mail: [info@anibiotech.fi](mailto:info@anibiotech.fi)

