



CORTEZ DIAGNOSTICS, INC.

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See external label



2°C-30°C



Σ=25 or 50 tests



Cat. #166774-1

MYOGLOBIN WHOLE BLOOD TEST

*FOR THE QUANTITATIVE ASSESSMENT OF HUMAN MYOGLOBIN IN
HUMAN SERUM, WHOLE BLOOD OR PLASMA*

Catalog No. 166774-1
For in vitro Diagnostic Use

INTENDED USE

The Cortez Diagnostics MYOGLOBIN test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of myoglobin in human serum specimens. The presence of myoglobin in serum, whole blood or plasma specimens at level 100 ng/ml or higher can be detected in 10 minutes.

SUMMARY AND EXPLANATION

Myoglobin is a low molecular weight, cytoplasmic serum protein. Due to its low molecular weight, myoglobin is released more rapidly when muscle cells are damaged than other markers. Serum concentration of myoglobin increases above the normal range as early as 1 hour after myocardial infarction, and peak in approximately 4 to 8 hours after onset. Therefore, myoglobin is better suited for the early diagnosis of acute myocardial infarction (AMI).

Cortez Diagnostics MYOGLOBIN test is a sandwich immunoassay. When serum sample is added to sample pad, it moves through the conjugate pad and mobilizes gold anti-myoglobin conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-myoglobin antibody that is coated on the test region. If myoglobin is present at levels of 100 ng/ml or greater, the result is the formation of a colored band in the test region. If there is no myoglobin in the sample, the area will remain colorless. The sample continues to move to the control area and forms a pink to purple color, indicating the test is working and the result is valid.

MATERIAL PROVIDED

1. Cortez Diagnostics MYOGLOBIN (WB) Test device

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Whole blood or plasma: Vacutainer tube, or other appropriate tube, containing heparin or EDTA as an anticoagulant
2. Serum: Vacutainer tube, or other appropriate tube, without anticoagulant
3. Micropipetter (0-200 µl range) and pipet tips
4. Timer or clock

STORAGE

Store the test device at 2 to 30°C. Do Not Freeze.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use product beyond the expiration date.
3. Handle all specimens as potentially infectious.

SPECIMEN COLLECTION AND PREPARATION

The serum, whole blood or plasma specimen should be collected under standard laboratory conditions. Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided. Patient samples performed best when tested immediately after collection. If specimens are to be stored, the red blood cells should be removed to avoid hemolysis. If the sample cannot be tested within 24 hours, serum or plasma should be frozen until the test can be performed. Whole blood samples should be refrigerated at 2–8°C instead of being frozen. Allow sample to reach room temperature before proceeding. Sodium azide can be added as a preservative up to 0.1% without affecting the test results.

QUALITY CONTROL

The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and reagents are reactive.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Use micropipetter to transfer 150 µl of sample, or place the transfer pipette supplied with the device in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical position over the sample well of the test card and deliver 3-4 drops (120-160 µl) of sample into the sample well.
5. Read the result between 5 and 10 minutes.

To confirm a negative result, you should wait for 10 minutes to read the result.

As soon as you see the test line within 10 minutes, the test can be finished.

Do not interpret the result after 15 minutes.

INTERPRETATION OF RESULTS

Positive:

If two colored bands are visible within 10 minutes, the test result is positive and valid.

Note: Specimens containing very low levels of myoglobin may develop two colored bands over 10 minutes.

Negative:

If test area has no color band and the control area displays a colored band, the result is negative and valid.

Invalid result:

The test result is invalid if a colored band does not form in the control region. The sample must be re-tested, using a new test device.

LIMITATIONS OF THE PROCEDURE

A number of conditions, other than myocardial infarction, including polymyositis, dermatomyositis, systemic lupus erythematosus, shock, severe renal failure, or muscle damage caused by trauma, Recent cardioversion ischemia and inflammation, can cause elevated levels of myoglobin. These conditions should be considered with appropriate clinical evidence.

1. Recent cardioversion or an anginal episode may increase myoglobin level.
2. Testing 12 hours or later after onset of myocardial infarction can produce misleading results, because serum levels may already have returned to normal range.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Normal serum myoglobin levels range from 30 to 90 ng/ml. After 1 hour of the onset of myocardial infarction, serum myoglobin level can elevate to 200 ng/ml or even higher. During the peak hour, myoglobin level can be as high as 900 ng/ml. The level of myoglobin usually returns to normal 12 hours after the onset of the myocardial infarction. Elevated myoglobin level has also been observed in patients with other diseases as mentioned in LIMITATIONS OF THE PROCEDURE.

PERFORMANCE CHARACTERISTICS

Sensitivity:

Cortez Diagnostics MYOGLOBIN test can detect myoglobin with concentration of 100 ng/ml or greater.

Interference testing:

The following substances were added to myoglobin negative and 100 ng/ml myoglobin spiked serum samples. No interference was found with any of the substances at the following concentrations:

Bilirubin	10 mg/dl
Cholesterol	800 mg/dl
Hemoglobin	250 mg/dl
Triglyceride	1250 mg/dl

REFERENCES

1. Clinical Laboratory Tests, values and implication, Springhouse Corporation (1991)
2. Fred S Apple, Clinical Chemistry, Vol. 97, No. 2, 217-225 (1992)
3. Gibler WB., et al. Ann Emerg Med, Vol. 16, 851-856 (1987)
4. Montague C, Kircher T. Am J. Clin. Pathol., Vol. 104, 472-476 (1995)



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