



Myoglobin Rapid Test (Whole Blood/ Serum/ Plasma) Package Insert

REF CMYO-C41 English

Rapid test for the qualitative detection of myoglobin in whole blood, serum or plasma to support the diagnosis of myocardial infarctions (MI).
For professional in vitro diagnostic use only.

INTENDED USE

The RightSign myoglobin test cassette is a chromatographic, immunoassay-based rapid test for the qualitative detection of myoglobin in serum, plasma and whole blood specimens. It is used as an aid in the diagnosis of MI.

SUMMARY

Myoglobin (MYO) is a hemeprotein with a molecular weight of 17.8kDa, which is usually found in the heart and skeletal muscle. It represents 2% of the total muscle protein and is responsible for transporting oxygen in cells. Due to its small size, myoglobin is quickly released into the blood when cells are damaged. After tissue loss due to MI, myoglobin is one of the first parameters to rise above normal levels. Elevated myoglobin levels can be measured as early as 2-4 hours after the infarction; the peak is reached after 9-12 hours and the concentration returns to normal levels after 24-36 hours. Several studies recommend the measurement of myoglobin levels as a means to exclude MI since the reliability of negative test results (after a sufficient waiting time after the onset of symptoms) is almost 100%. This rapid test is based on a simple test principle that utilises a combination of fixed reagents and particles coated with anti-myoglobin antibodies to detect myoglobin in serum, plasma or whole blood. The detection limit (cut-off) is 50ng/ml.

PRINCIPLE

This test contains anti-myoglobin antibody-coated gold particles and reagents that are fixed on the membrane.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contained infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for the proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when the specimens are assayed.
- The used materials should be discarded according to local regulations regarding infectious agents.
- Humidity and temperature can adversely affect the results.
- Do not use the test if the foil pouch is damaged.

STORAGE AND STABILITY

The test in the sealed pouch can either be refrigerated or stored at room temperature (2-30°C). The test is stable through the expiration date printed on the sealed pouch and must remain in the sealed pouch until use. Do not use the test/ test materials after the expiration date and do not freeze them!

SPECIMEN COLLECTION AND PREPARATION

The RightSign myoglobin rapid test can be performed using whole blood, serum or plasma.

- To collect capillary whole blood from the finger tip**
 - Massage the patient's finger to improve blood circulation.
 - Disinfect the puncture site and use a sterile single-use lancet to puncture the finger.
 - Use a capillary tube or a pipette with small volume (min. 75µl) to transfer the specimen to the test cassette.
- When using serum or plasma**
 - Separate serum or plasma from the blood as soon as possible to prevent haemolysis. Only use clear, non-haemolysed sample material.
- The test should be performed immediately after the specimen has been collected. Do not leave the sample material at room temperature for longer periods of time. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, the specimen must be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Whole blood collected by fingerstick must be tested immediately.
- Bring the specimens and test materials to room temperature prior to testing. Frozen specimens must be completely thawed and mixed prior to testing. The specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of potentially infectious specimens and pathogens.

MATERIALS

Provided Materials

Test cassettes, disposable pipettes, buffer, package insert

Materials required but not provided

Specimen collection containers, timer, centrifuge

For capillary whole blood: sterile, disposable lancets and heparinised capillary tubes

TEST PERFORMANCE

Allow the test cassette, the specimen and/or the control solution to reach room temperature (15-30°C) before testing.

- Remove the test cassette from the sealed pouch after the test has reached room temperature.
- Place the cassette on a clean and level surface.

For Serum and Plasma Specimens

Hold the dropper vertically and transfer 2 drops of serum or plasma (approx. 50µl) to the specimen well. Add 1 drop of buffer (approx. 40µl) and start the timer.

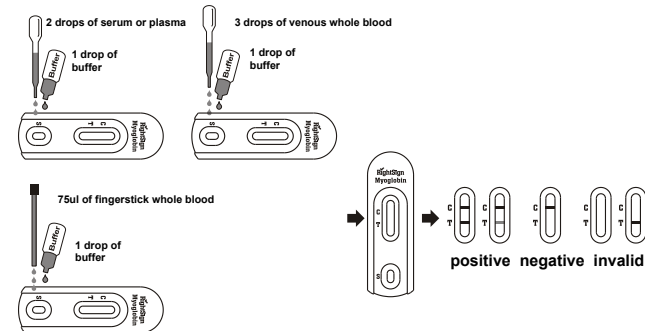
For Venous Whole Blood Specimens

Hold the dropper vertically and transfer 3 drops of whole blood (approx. 75µl) to the specimen well. Add 1 drop of buffer (approx. 40µl) and start the timer.

For Fingerstick Whole Blood Specimens

Use the capillary tube to collect approx. 75µl whole blood and transfer the specimen to the specimen well of the test cassette. Add 1 drop of buffer (approx. 40µl) and start the timer.

- Wait for the coloured line(s) to appear and read the results after 10 minutes. Do not interpret the results after 20 minutes.



INTERPRETATION OF RESULTS (please refer to the illustration above)

POSITIVE: 2 visible lines. One line appears in the test line region (T) and one appears in the control line region (C). This means that myoglobin has been detected in the specimen.

Note: The intensity of the colour in the test line region will vary depending on the myoglobin concentration present in the specimen. Therefore, any shade of colour in the test line region should be considered positive.

NEGATIVE: 1 visible line in the control line region (C). No coloured line appears in the test line region (T). A negative result means that the myoglobin concentration is below the minimum detection levels.

INVALID: no control line appears. No line appears in the control line region (C) and the results remain invalid even a line appears in the test line region (T). It is likely due to insufficient specimen application or incorrect procedural techniques. Review the procedure and repeat the test with a new cassette.

If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

This test is equipped with an integrated procedural control. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen application and adequate membrane wicking. Positive and negative control solutions are not supplied with this kit but their regular use is recommended.

LIMITATIONS

- The RightSign myoglobin rapid test is only intended for in vitro diagnostic use. It should only be used for detecting myoglobin in human whole blood, serum or plasma. It delivers no quantitative results and should not be used to estimate the increase of myoglobin levels.
- The test will only deliver qualitative results and should not be used as the sole criterion for diagnosing MI.
- This test cannot detect myoglobin levels below 50ng/ml. A negative result thus does not completely preclude the possibility of MI.
- As with all diagnostic tests, the results must be interpreted together with other clinical information available to the medical professional.
- Specimens with unusually high concentrations of heterophile antibodies or rheuma factors (RF) may affect the test results. Positive results should be confirmed with help of additional examinations.
- In some cases, it is possible that whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test cassette. In this case, please repeat the test with a new test cassette and a serum or plasma specimen of the same patient.

EXPECTED VALUES

This myoglobin test cassette has been compared with one of the leading EIA tests, demonstrating an overall accuracy of 98.1%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The RightSign myoglobin test has been evaluated with a leading commercial EIA test using clinical specimens. The results show a sensitivity of 99.9% and a specificity of 97.8%.

Myoglobin Rapid Test vs. EIA				
Method	EIA		Total Results	
	Results	Positive		
	Positive	104		
RightSign Myoglobin Rapid Test	Negative	0	651	651
		104	666	770

Relative sensitivity: 104/104=>99.9% (95%CI*: 97.2%~100.0%);
Relative specificity: 651/666=97.7% (95%CI*: 96.3%~98.7%);
Accuracy: (104+651)/(104+15+651)=98.1%(95%CI*: 96.8%~98.9%).
*Confidence interval

PRECISION

Intra-Array

To determine the precision between tests of the same batch, the following concentrations were examined 3 times with 5 specimens each: 0, 50, 100, 200 and 400ng/ml. The specimens were identified correctly in >99% of the cases.

Inter-Assay

To determine the precision between batches, the following 5 concentrations were examined with tests of 3 different batches: 0, 50, 100, 200 and 400ng/ml. The specimens were identified correctly in >99% of the cases.

Cross-Reactivity

The myoglobin test has been tested with HBsAg, HBsAb, HBeAg, HBeAb, HBCAb, syphilis, anti-HIV, anti-H.pylori, mononucleosis, anti-CMV, anti-rubella and anti-toxoplasmosis positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following, potentially interfering substances were added to myoglobin-negative and -positive specimens:

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic acid: 20 mg/dL	Gentisic acid: 20 mg/dL
Ascorbic acid: 20mg/dL	Albumin: 10,500mg/dL
Creatine: 200 mg/dL	Haemoglobin: 1,000 mg/dL
Bilirubin: 1,000mg/dL	Oxalic acid: 600mg/dL
Cholesterol: 800mg/dL	Triglyceride: 1,600mg/dL

BIBLIOGRAPHY

- Wong SS. Strategic utilization of cardiac markers for diagnosis of acute myocardial infarction. Ann Clin Lab Sci, 26:301-12, 1996.
- Kagen LJ. Myoglobin methods and diagnostic uses. CRC Crit. Rev. Clin. Lab. Sci., 2:273, 1978.
- Chapelle JP. et al. Serum myoglobin determinations in the assessment of acute myocardial infarction. Eur. Heart Journal, 3:122, 1982.
- Hamfelt A. et al. Use of biochemical tests for myocardial infarction in the county of Vasternorrland, a clinical chemistry routine for the diagnosis of myocardial infarction. Scand. J. Clin. Lab. Invest. Suppl., 200:20, 1990.

Index of Symbols

	Consult instructions for use		Tests per kit		Autorised representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot number		Catalog#
	Do not use if package is damaged				



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