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, immunnoassay-based rapid test for the qualitative detection of myoglobin in serum, plasma and whole blood specimens. It is intended to be used in the following situations:

- To support the diagnosis of myocardial infarctions (MI).
- Rapid test for the qualitative detection of myoglobin in whole blood, serum or plasma.

SUMMARY

Myoglobin (MYO) is a hemoprotein 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 used to support the diagnosis of MI before other parameters (e.g., troponins) are 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

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling the test kit.
4. The used materials should be discarded according to local regulations regarding infectious agents.
5. Humidity and temperature can adversely affect the results.
6. Do not use the test kit 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 in the sealed pouch on the printed expiration date and must remain in the sealed pouch until use. Do not use the test kit material 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
  - Gently massage the patient’s finger to improve blood circulation.
  - Disinfect the puncture site and use a sterile single-use lancet to puncture the skin.
  - 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 clotting. Do not use clear, non-lysed 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 and vacuumed should be stored at 2°C to 8°C and run within 2 days of collection. Whole blood collected by fingerstick cannot be re-tested.

- Bring the specimens and test materials to room temperature prior to testing. Frozen specimens may be used after thawing and a new re-test is performed. 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 transportation of potentially infectious specimens and pathogens.

MATERIALS

Provided Materials

- Test cassettes, disposable pipettes, buffer, package insert

Materials required but not provided

- Specimen collection container or 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.
1. Remove the test cassette from the sealed pouch after the test has reached room temperature.
2. 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 Capillary Whole Blood

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.

3. 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

Positive: 2 visible lines. One line appears in the control line region (C) and one appears in the test line region (T). This means that myoglobin has been detected 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 region (C). This means that the test has not run properly. The specimens were identified correctly in >99% of the cases.

For Fingerstick Whole Blood Specimens

1. Use a capillary tube or a pipette with small volume (min. 75μl) to transfer the specimen well of the test cassette. Add 1 drop of buffer (approx. 40μl) and start the timer.

2. Place the fetal lancet on the puncture site and gently press down to puncture the finger.

3. This test cannot detect myoglobin levels below 50ng/ml. A negative result thus does not completely exclude the possibility of MI.

4. With all diagnostic tests, the results must be interpreted together with other clinical information available to the medical professional.

5. 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.

6. 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%.

PREPARATION CHARACTERISTICS

Sensitivity and Specificity

The RightSign myoglobin 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%.

BIBLIOGRAPHY


Distribution:

- Praxisdienst GmbH & Co. KG
- Trieter Str. 43-47
- D-54340 Longich
- info@praxisdienst.co.uk
- Praxisdienst GmbH & Co. KG
- 179, Furtal Road, Zhaoqin Street,
- Yuhang District, Hangzhou, P. R. China
- Distribution:
- Shanghai International Handling Corp. (Europe)
- Effeffebox, 2027 Hangzhou, Germany
- EC
- RP509303
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