CE

Diagnostic Kit for Myoglobin (Myo)

A test for the diagnosis of myocardial infarction (MI) by measuring Myoglobin in human whole blood, Serum or plasma with the use of Immunofluorescence Analyzer.

English

- For *in-vitro* diagnostic use

PACKING SPECIFICATION
25 Tests/ Kit (07MY5025)

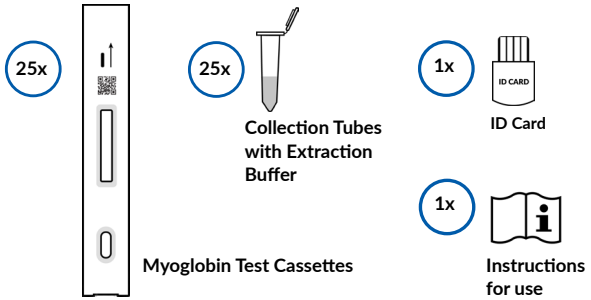
INTENDED USE
The Myoglobin Test Cassette (Whole Blood/Serum/Plasma) is intended for *in-vitro* quantitative determination of Myoglobin in human whole blood, serum or plasma as an aid in the diagnosis of Myocardial Infarction (MI). The test is intended for healthcare professionals use.

SUMMARY
Myoglobin (MYO) is a heme-protein normally found in skeletal and cardiac muscle with a molecular weight of 17.8 kDa. It constitutes about 2 percent of total muscle protein and is responsible for transporting oxygen within the muscle cells.[1] When the muscle cells are damaged, Myoglobin is released to the blood rapidly due to its relatively small size. Following the death of tissue associated with MI, Myoglobin is one of the first markers to rise above normal levels. The level of Myoglobin increases measurably above baseline within 2-4 hours post-infarct, peaking at 9-12 hours and returning to baseline within 24-36 hours.[2,3] A number of reports suggest the measurement of Myoglobin as a diagnostic aid in confirming the absence of myocardial infarction with negative predictive values of up to 100% reported at certain time periods after onset of symptoms.[4]

PRINCIPLE
The Myoglobin Test Cassette (Whole Blood/Serum/Plasma) detects Myoglobin based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains Myoglobin, it attaches to the fluorescent microspheres-conjugated anti-Myoglobin antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of Myoglobin in the sample correlates with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of Myoglobin in the sample can be calculated by Analyzer to show Myoglobin concentration in specimen.

REAGENTS
The test includes anti-Myoglobin antibody coated fluorophores and anti-Myoglobin antibody coated on the membrane.

MATERIALS PROVIDED



MATERIALS REQUIRED BUT NOT PROVIDED
- Immunofluorescence Analyzer MPQuanti® (07IMA001)
- Pipette
- Specimen Collection Containers
- Centrifuge
- Timer

PRECAUTIONS
1. For professional *in-vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The Myoglobin Test Cassette should only be used with the analyzer by medical professionals.

STORAGE AND STABILITY
1. The kit should be stored at 4 - 30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

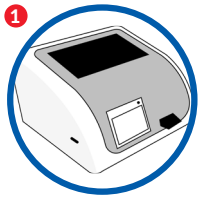
SAMPLE COLLECTION AND PREPARATION

Preperation
1. Before performing the test, please make sure that all components are brought to room temperature (15 - 30 °C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

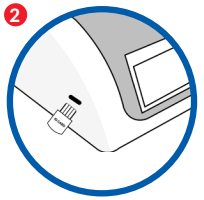
Sample Handling
1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum/ Plasma specimens may be stored at 2 - 8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2 - 8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

Sample Dilution / Sample Stability
1. The specimen (50 µL of serum / plasma / 75 µL of whole blood) can be added directly with the micro pipette into the buffer.
2. Close the tube and shake the sample by hand vigorously for approximately 10 seconds to mix the sample and dilution buffer.
3. Let the diluted sample homogenize for approximately 1 minute.
4. It is best to place the diluted sample on an ice pack and leave the sample at room temperature for no more than 8 hours.

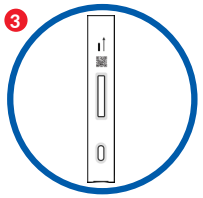
TEST PROCEDURE
Refer to Immunofluorescence Analyzer User Manual for the complete instructions for use of the Test. The test should be in room temperature.
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



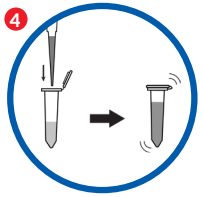
Turn on the Analyzer power.



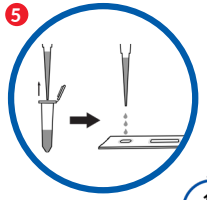
Take out the ID card and insert it into the Analyzer ID Card Slot. Choose test mode and/or sample type according to needs.



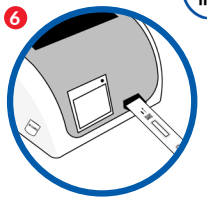
Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.



Place the test on a flat and clean surface.
Serum/Plasma: Pipette **50 µL of serum/plasma** into the buffer tube; mix the specimen and the buffer well.
Whole blood: Transfer **75 µL of whole blood** into the buffer tube with pipette; mix the specimen and the buffer well.



Add diluted specimen with a Pipette: Pipette **85 µL of diluted specimen** into the sample well of the test cassette. Start the timer at the same time.



Test results should be interpreted at **15 minutes** with the use of Immunofluorescence Analyzer.

Caution: There are different test modes of the Immunofluorescence Analyzer. The difference between them is incubation of the test cassette is outside or inside the analyzer. Choose test mode accordingly and confirm sample type. Consult the user manual of the analyzer for detailed operation information.
Operator must consult the Immunofluorescence Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

INTERPRETATION OF TEST RESULTS

Results read by Immunofluorescence Analyzer.
The result of tests for Myoglobin is calculated by Immunofluorescence Analyzer and display the result on the screen. For additional information, please refer to the user manual of Immunofluorescence Analyzer.
Linearity range of Myoglobin Test is 5 ~ 200 ng/mL.

QUALITY CONTROL

Each Myoglobin Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test device was inserted and read properly by Immunofluorescence Analyzer. An invalid result from the internal control causes an error message on Immunofluorescence Analyzer indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on Immunofluorescence Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Myoglobin Test Cassette (Whole Blood/Serum/Plasma) is for professional *in-vitro* diagnostic use, and should only be used for the quantitative detection of Myoglobin.
2. The Myoglobin Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of Myoglobin in the specimen and should not be used as the sole criterion for evaluating AMI.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of Myoglobin may produce a dose hook effect, resulting in incorrect interpretation of Myoglobin levels. High dose hook effect has not been observed with this test up to 200 ng/mL of Myoglobin.
5. The hematocrit level of the whole blood should be between 25% and 65%.
6. The results of Myoglobin Tests are based on measuring the levels of Myoglobin in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatment.

EXPECTED VALUES

Concentrations	Clinical Reference
<90 ng/mL	Not indicative of Acute Myocardial Infarction
>90 ng/mL	Indicative of Acute Myocardial Infarction

PERFORMANCE CHARACTERISTICS

1. Accuracy
The test deviation ≤±15%

2. Sensitivity
The Myoglobin Test Cassette (Whole Blood/Serum/Plasma) can detect levels of Myoglobin as
low as 5 ng/mL in whole blood, serum or plasma.

3. Detection range
5 ~ 200 ng/mL

4. Linearity range
5 ~ 200 ng/mL, R≥0.990

5. Precision
Intra-lot precision
Within-run precision has been determined by using 10 replicates of 5 specimens containing 0 ng/mL, 50 ng/mL, 100 ng/mL and 200 ng/mL of Myoglobin. C.V. is ≤15%.
Inter-lot precision
Between-run precision has been determined by using 10 replicates for each of three lots using 5 specimens containing 0 ng/mL, 50 ng/mL, 100 ng/mL and 200 ng/mL of Myoglobin. C.V. is ≤15%.

6. Cross-reactivity
Cross-reactivity studies were carried out with following analytes.
HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, anti-HIV, anti-*H.pylori*, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no crossreactivity.

7. Interfering Substances
The following potentially interfering substances were added to Myoglobin negative and positive specimens, respectively.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 20 mg/dL	Albumin: 10,500 mg/dL
Creatin: 200 mg/dL	Hemoglobin: 1,000 mg/dL
Bilirubin: 1,000 mg/dL	Oxalic Acid: 600 mg/dL
Cholesterol: 800 mg/dL	Triglycerides: 1,600 mg/dL

None of the substances at the concentration tested interfered in the assay.

8. Method comparison
The Myoglobin Test Cassette was compared with the results obtained with Cobas E602 for 98 samples. The correlation coefficient(r) is 0.981.

BIBLIOGRAPHY

1. Wong SS. Strategic utilization of cardiac markers for diagnosis of acute myocardial infarction. Ann Clin Lab Sci, 26:301-12, 1996.
2. Kagen LJ.Myoglobin methods and diagnostic uses.CRC Crit.Rev. Clin.Lab.Sci., 2:273,1978.
3. Chapelle JP.et al.Serum Myoglobin determinations in the assessment of acute myocardial infarction. Eur. Heart Journal, 3:122, 1982.
4. 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..

SYMBOLS

	Consult Instructions For Use	REF	Catalogue Number
IVD	For *In-vitro* Diagnostic use	EC REP	Authorized Representative
4℃ 30℃	Store at 4 °C ~ 30 °C		Do Not Reuse
	Keep away from Sunlight		Do Not Use if Package is Damaged
LOT	Lot Number	CE	European Conformity
	Manufacturer		Date of Manufacture
	Expiration Date	Σ	Tests per Kit
UDI	Unique Device Identifier		

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