Myoglobin (Myo) Rapid Test Kit

(Fluorescence Immunochromatographic Assay)

Catalog Number: 5174C4X025,5174C4X050

INTENDED USE

This test is suitable for in vitro quantitative detection of the concentration of myoglobin in human serum, plasma and whole blood. This product is used for testing in medical and health institutions for the auxiliary diagnosis of myocardial infarction.

Myoglobin (Myo) is an oxygen-binding protein, which widely exists in skeletal muscle, myocardium and smooth muscle, accounting for about 2% of all muscle proteins. Myo has a molecular weight of 17.8KD, which is relatively small compared with the molecular weight of cardiac markers. It is a binding protein consisting of a peptide chain and a heme cofactor, located in the cytoplasm. From the point of view of pathophysiology, the occurrence of cardiac markers is related to the molecular size and the location in cells. The smaller the molecular weight of the marker, the easier it is to penetrate the intercellular space to the blood. High concentration substances in the cytoplasm appear earlier in the blood than substances and structural proteins in the nucleus or mitochondria. Myo occurs early in myocardial injury, Myo is the earliest marker of myocardial injury after acute myocardial infarction (AMI).

Detection of myoglobin in blood can be used as the most sensitive index in the early diagnosis of acute myocardial infarction (AMI). Myo negative can exclude the possibility of acute myocardial infarction. Myo combined with electrocardiogram can improve the accuracy of early diagnosis of acute myocardial infarction. In addition to acute myocardial infarction, the level of Myo in serum increases during thoracotomy, excessive physical exercise, skeletal muscle trauma, progressive muscle atrophy, shock, severe renal failure and intramuscular injection. Therefore, Myo detection should be combined with other detection indicators and clinical symptoms as a basis for judging myocardial infarction.

PRINCIPLE OF THE PROCEDURE

This test uses highly specific double antibody sandwich method principle and fluorescence immunochromatography analysis technology to quantitatively detect the amount of Myo antigen in human serum, plasma and whole blood samples.

This product is pre-embedded with fluorescent microspheres labeled mouse anti-Myo antibody and rabbit IgG antibody on the conjugate pad, and coated with mouse anti-Myo antibody and goat anti-rabbit IgG antibody respectively on the test line and control line of nitrocellulose membrane. When the sample is tested, the Myo antigen in the sample is combined with the fluorescent microspheres-labeled mouse anti-Myo antibody embedded on the conjugate pad to form the fluorescent microspheres-labeled mouse anti-Myo antibody-Myo immune complex. Under the action of chromatography, the immune complex flows along the nitrocellulose membrane to the end of the absorbent filter paper. On the test line, the immune complex is captured by the mouse anti-Myo antibody pre-coated, forming the double-antibody sandwich structure of fluorescent microspheres labeled mouse anti-Myo antibody-Myo-mouse anti-Myo antibody and enriching. When the samples pass the control line, the rabbit IgG antibody labeled with fluorescent particles is enriched by combining with the pre-coated goat anti-rabbit IgG antibody. The concentration of Myo in the sample is positively correlated with the fluorescence intensity of the test line. The concentration of Myo in the sample is obtained through the test and analysis by the Immunofluorescence Analyzer.

COMPONENT

Materials provided with the test kits

1. Testing card for a single copy of the aluminum foil bag packaging, containing Myo test card and desiccant, Myo test card main components as follows: the backplane, sample pad, conjugate pad, nitrocellulose membrane, blotting paper and plastic parts, the test line (T) was coated with anti-Myo antibody, the quality control line (C) was coated with goat anti-rabbit IgG antibody, and the conjugate pad was embedded with fluorescent microspheres-labeled fluorescent microspheres-labeled anti-Myo antibody and rabbit IgG antibody. The identification code of the test card contains the item name and barcode number, and the ID card contains the name, batch number, calibration curve, concentration unit, detection time and other information of the kit.
2. The main component of the whole blood buffer is 20mM, pH7.4 PBS solution.
3. Main components:

Specifications / Ingredients	25 tests/kit	50 tests/kit
Test card with desiccant in a sealed foil pouch	25	50
Sample diluent	25	50
Pipette tip	25	50
ID chip	1	1
Instruction for use	1	1

4. The components in different batches of kits are not interchangeable.

MATERIALS REQUIRED BUT NOT PROVIDED

- The immunofluorescence analyzer
- Transfer Pipette
- Specimen Collection Containers
- Centrifuge (for serum/plasma specimen only)
- Timer

STORAGE AND STABILITY

1. Kits should be stored in 2°C~30°C in a cool, dark, dry place preservation, valid for 24 months, frozen or in use after the period of validity of avoid by all means.
2. The test card should be in aluminum foil bag after opening, to the specified environment (temperature 2°C~35°C, humidity 40%~90%) used within 60 minutes.
3. The production date and expiration date are shown on the label.

APPLICABLE EQUIPMENT

This Test Kit is applicable to the Immunofluorescence Analyzer CHF100, CHF200, CHF300, CHF400, CHF500, CHF600, CHF800, produced by Dongguan Tronho Medical Technology Co., Ltd.

SAMPLE COLLECTION AND STORAGE

1. It is suitable for serum, plasma or whole blood samples. The commonly used anticoagulants (heparin, EDTA or sodium citrate) have no effect on the results of this kit.
2. Samples should be collected according to routine clinical methods and avoid hemolysis.
3. Serum and plasma samples collection: If serum or plasma specimens are not tested immediately, they should be refrigerated at 2°C~8°C and test within 7 days. For long time storage, they should be -20°C cryopreservation, to avoid repeated freezing and thawing.
4. Collection of whole blood samples: collect venous blood with disposable vacuum blood collection containing

5. anticoagulant without separation and directly as the test sample. Whole blood samples can be in 2°C~8°C kept in refrigerator for 3 days, not cryopreservation.
6. Restore the sample to room temperature before test.
7. Obvious hemolysis, lipohemia and jaundice samples should not be used.

TEST PROCEDURE

Before the test, the instruction manual of the product and the operation manual of the detector must be read completely, and the reagent should be restored to room temperature before the test. The test operation cannot be carried out under the condition that the room temperature is not restored, so as not to affect the accuracy of the test results.

Operation process：

1. Instrument preparation: turn on the power of the Immunofluorescence Analyzer, select the test mode (immediate test, standard test or batch test), read the reagent ID chip, select the sample type and test items. The specific operation of the equipment shall be carried out according to the operating instructions of the corresponding type of equipment.
2. Preparation of reagents: balance the reagent or sample to room temperature, tear open the aluminum foil bag, take out the test card, and lay it flat on a flat operating table.
3. Sampling: take 8 μL serum or plasma or whole blood samples from the pipette, add the samples to the sample diluents and fully mix them for 60 seconds.
4. Add sample: take out the test card from the package and add 100μL mixed samples from the pipette to the sample well of the test card. Let stand at room temperature for 15mins (please strictly control the time for 15mins).
5. Detection: insert the test card into the equipment before the 15 minutes countdown to the reaction of the test card. After the 15 minutes countdown to the reaction, manually click "test" or the equipment will automatically test the test card according to the detection mode selected by the user, and record, read and print the test results. If the test card fails to be tested in time after the 15 minutes countdown to the reaction is completed, it will be deemed invalid and the sample shall be re-tested with anew test card.

CALIBRATION

Traceability: Calibrator for calibration curve establishment are traceable to internal reference standards. This method has been standardized against the Roche Elecsys Myoglobin STAT assay.

The calibration curve of the reagent is embedded in ID chip. The fluorescence analyzer substitutes the test signal of the detection card into the calibration curve to calculate the concentration of Myo in the sample.

REFERENCEINTERVAL

1. Normal reference value: Myo<80ng/mL.
2. Due to the differences in geography, race and age, it is suggested that each laboratory should establish a Myo reference interval with relevant clinical significance suitable for the local population.

INTERPRETATION OF TEST RESULTS

1. When the concentration of Myo in the sample is higher than the reference value range, the factor of thoracotomy, excessive physical exercise, skeletal muscle trauma, progressive muscle atrophy, shock, severe renal failure and intramuscular injection, etc. should be excluded. Indeed abnormal, should be combined with clinical symptoms of diagnosis.

Item name	Test results	Clinical application recommendations
Myo	<80ng/mL	Normal level
	≥80ng/mL	It indicates that the patient is at risk of myocardial infarction, Note: Myo is released into the blood earlier than other myocardial enzymes, and the blood concentration increases beyond the normal level within the first two hours. Symptoms peak 6 to 8 hours after onset. The concentration returned to normal within 20~36 hours after tissue injury.

2. The determination results of this method are only suitable for the reference value range established by this method, and are not directly comparable with the results of other methods.
3. Errors in test results may also be caused by other factors, including technical reasons, operational errors and other sample factors.

QUALITY CONTROL

This product used in conjunction with immunofluorescence analyzer contains internal control for routine quality control requirements. This internal control is performed each time when a patient sample is tested. This control indicates whether the test cartridge was inserted and read properly by immunofluorescence analyzer. An invalid result from the internal control causes an error message on analyzer indicating that the test should be repeated.

LIMITATIONS

1. The positive results of this reagent can only be used as a basis for the diagnosis of diseases. It is suggested that the diagnosis be confirmed by combining other pathological features and test methods.
2. This reagent is suitable for the detection of human serum, plasma or whole blood samples, and the test results of other samples may be wrong.
3. The reagent is used to test the concentration of Myoglobin concentration by immunological principle. Temperature will affect the results. Before using cryopreserved reagents, balance them to room temperature. Direct use of cryopreserved reagents will affect the test results.
4. This reagent is used to quantitatively test the concentration of Myoglobin concentration. It needs reagent, ID card and suitable equipment. Please make sure that the batch number of the test reagent and ID card is the same before use. The equipment is of suitable type, and the correct test results can not be obtained if it is used beyond expectation.
5. Different batches of whole blood buffer cannot be mixed.
6. Improper operation may affect the accuracy of the results.
7. Human anti-mouse antibody (HAMA) may be present in patients who have received murine monoclonal immunotherapy. This kit has been developed to minimize the impact of these antibodies on test results through special methods. However, test results should be carefully evaluated when patients are known to have these antibodies.
8. For samples whose Myo concentration may be greater than the linear range, it is necessary to measure with normal saline after appropriate dilution, multiply the test result by dilution multiple as the final test result of the sample. Maximum dilution factor is 100 times.
9. The erythrocyte volume (hematocrit) of the whole blood samples will affect the test results. The test result has been

corrected and compensated for whole blood sample. But in order to obtain more accurate results, individual Myo test results(C_0) and hematocrit (P) can be substituted into the following formula for further correction, and the calculated results (C_1) can be used as the final test results.

$$C_1=0.625*C_0/(1-P)$$

Or the corresponding correction coefficients of the test results C_0 multiplied by the table below can be used as the final test results.

Hct(%)	0.2	0.25	0.3	0.35	0.4	0.45	0.5
CC(K)	0.78	0.83	0.89	0.96	1.04	1.14	1.25
Hct(%)	0.55	0.6	0.65	0.7	0.75	0.8	
CC(K)	1.39	1.56	1.79	2.08	2.50	3.13	
Result (ng/mL)	C_0						
Final result (ng/mL)	$C_1=C_0*K$						

PRODUCT PERFORMENCE INDEX

Internal calibration products were used for evaluation, and the performance indicators of the kit meet the standards. The specific performance indicators are as follows:

1. Linearity: Myo 5ng/mL~500ng/mL, Linear correlation coefficient(r)≥0.9900.
2. Accuracy: the relative Bias% should be within±15%.
3. Detection limit: Myo≤ 5ng/mL.
4. Repeatability: CV ≤10%.
5. Inter-batch variation: CV≤15%.
6. HOOK effect: when Myo concentration reached 600ng/mL, there was no HOOK effect.
7. Specificity: there was no cross reaction with troponin I (cTnI), N-terminal natriuretic peptide (NT-proBNP), creatine kinase isoenzyme (CK-MB), rheumatoid factor (RF).
8. Interference experiment: the following substances were tested at the concentration shown, and no interference was found.

Bilirubin	≤12mg/dL	Hemoglobin	≤6mg/mL
Triglyceride	≤15mg/mL	Tortal Cholesterol	≤10mg/mL

PRECAUTIONS

1. The reagent is a disposable diagnostic reagent in vitro, which is only used for the detection of human serum, plasma or whole blood. The operation should be carried out strictly according to the instructions. Do not use expired and damaged products.
2. The kit should be sealed and kept away from moisture. Reagents or samples stored at low temperature should be balanced to room temperature before they can be used.
3. If clinical samples need to be frozen at -20°C or below, it is recommended that the frozen storage time should not exceed three months and repeated freezing and thawing should not exceed three times.
4. Reagents should be used as soon as possible after removal from aluminum foil bags, so as to avoid exposure to air for too long and affecting test results due to dampness.
5. Do not use samples that have been placed for too long, bacteria and odor.
6. Please operate in accordance with the laboratory testing procedures for infectious diseases. Waste after use should be treated in accordance with infectious substances and should not be discarded at will.
7. Incorrect operation may affect the accuracy of the results, such as insufficient sample mixing, wet display window or insufficient amount, inaccurate detection time, etc.
8. Components in different batch should not be mixed.

BIBLIOGRAPHY

1. National Clinical Laboratory Procedures (third edition,2006). Department of Medical Administration, Ministry of Health.
2. Wang yiyi, Zhang jue, Wang xiaoyue.Application of Ischemia Modified Albumin, Troponin, Myoglobin and Creatine Kinase Isozyme in Early Detection of Acute Coronary Syndrome[J].Labeled Immunoassays and Clinical Medicine | Lab Immun Clin Med,2014,21(06):671-673.
3. Zhang lihong. Diagnostic Value of Serum Cardiac Calcium and Myoglobin in Patients with Acute Myocardial Infarction[J]. Cardiovascular Disease Journal Of integrated traditional Chinese and Western Medicine,2016,4(33):58-59.
4. Guo rui jing. The Application value of rapid detection in the diagnosis of acute myocardial infarction[J]. Chinese Journal of Laboratory Pathologist | Chin J Lab Pathol,2016,8(04):199-201.
5. Gibler W B, Gibler C D, Weinshenker E, et al. Myoglobin as an early indicator of acute myocardial infarction[J]. Annals of emergency medicine, 1987, 16(8): 851-856.

KEY TO SYMBOLS USED

COMPONENT	Materials Included	ID CHIP	ID Chip
TEST CARD	Test Card with Desiccant in a Sealed Foil Pouch	TIP	Pipette Tip
DILUENT	Sample Diluent	IFU	Instruction for Use
	Consult Instructions For Use		Date of Manufacturer
	Store at 2℃~30℃		Do Not Reuse
	Expiration Date	REF	Catalogue Number
	Manufacturer		Keep away from Sunlight
LOT	Lot Number	Σ	Tests per Kit
EC REP	Authorized Representative		Keep Dry
IVD	In Vitro Diagnostic Medical Device	MAN.ADD.	The address of manufacture factory
FICA	Fluorescence Immunochromatographic Assay		

Guangzhou Decheng Biotechnology Co., LTD
Room 218, Building 2, No.68, Nanxiang Road, Science City, Huangpu District, 510000, Guangzhou P.R.China
TEL:+86-020-82557192
service@dochekbio.com
www.dochekbio.com

EC REP
Caretechion GmbH
Niederrheinstr. 71,
40474 Duesseldorf, Germany.

CE