Myo Rapid Quantitative Test

Catalog No.: BT2102

INTENDED USE

The Biotime Myo (myoglobin) Rapid Quantitative Test is intended to quantify the concentration of Myo in human serum or plasma on Biotime FIA Analyzers by fluorescent immunoassay. It is used as an aid detection of acute myocardial infarction.
-Fluorescent immunoassay
-Myocardial infarction
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

This product is used to detect concentration of Myoglobin (Myo) in human serum and plasma. Myoglobin is an iron- and oxygen-binding protein found in the muscle tissue of vertebrates. In human body, myoglobin is only found in the bloodstream after muscle injury. While muscle injury occurs, myoglobin could be released into blood rapidly and exceeds the normal level in about 1 hour. Thus myoglobin is a sensitive marker for muscle injury, making it a potential marker for heart attack in patients with chest pain. However, elevated myoglobin has low specificity for acute myocardial infarction (AMI) and thus CK-MB, cardiac Troponin, ECG, and clinical signs should be taken into account to make the diagnosis[1-3].

PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the sample and the buffer is mixed and applied into the test cartridge, the Myo in the sample and the mouse anti-Myo monoclonal antibody labeled with fluorescent microsphere form a reaction intermediate complex. During lateral flow, the intermediate complex moves along the nitrocellulose membrane to a detection line (T-line: coated with Myo specific monoclonal antibodies). The intermediate complex will be captured by T-line to form final reaction compound sandwich. Thus the fluorescent signal on detection line is positively correlated with the concentration of Myo in human blood.
The fluorescent signal from microspheres of compound sandwich will be detected and calculated according to the calibration curve (in SD card provided with the reagents) to represent the concentration of Myo in human serum or plasma.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only. Please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for single use. Once the pouch is opened, it should be used within 30 minutes to avoid test failure caused by the moisture absorption.
4. While using the test cartridge and instruments, vibration and strong electromagnetic environment should be avoided.
5. Lot number of buffers and test cartridges must be matched.
6. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. Otherwise, it may cause damages to the instrument.

MATERIAL

Material Provided
1. Test cartridge 25 tests/kit
2. Detection buffer 25 tubes/kit
3. SD card 1 piece/kit
4. Instructions for Use 1 copy/kit

Material Required But Not Provided
1. Biotime FIA Analyzer
2. Pipette and pipette tips(range 5-50μL and range 10-100μL)
3. Specimen Collection Containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-8℃, the shelf life is 24 months.
2. Store Myo Rapid Quantitative Test Cartridge at 2-30℃, the shelf life is 24 months.
3. Test Cartridge should be used within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with serum or plasma.
2. The test specimen should be EDTA-K2 anticoagulant tube or heparin anti-coagulated tube for plasma，pro-coagulant tube for serum.
3. The collection of the sample: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected in time, it can be stored in refrigerator at 2-8℃ for no more than 7 days, or at -20℃ for no more than 6 months. Samples must be recovered to the room temperature before tests.
4. Separate the serum or plasma as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to operation manual of Biotime FIA analyzer for details.
The test should be operated at room temperature(~25℃).
Step 1: Preparation
Check/insert SD card into the equipment.
Take out one tube of buffer from refrigerator and balance it to room temperature.
Step 2: Sampling
Take 10μL of plasma or serum with a transfer pipette and add it into the buffer tube.
Step 3: Mixing
Mix well the specimen with buffer by tapping or inverting the tube several times.
Step 4: Loading
Take 80μL of sample mixture and load it into the well of the test cartridge.
Note: Step 2 to step 4 should be completed within 1 minute to ensure the accuracy of the test results.
Step 5: Testing
Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 15 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

REFERENCE INTERVAL

Normal reference interval: <55.0ng/mL
Note: Individual reference range is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. The test sample should be serum or plasma specimen.
2. Human anti-mouse antibody (HAMA) may be presented in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies[4].
3. Other factors also can induce the false results, including the technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy
Myo control materials with two different concentrations were tested by every lot of Test Cartridges, and the deviations were within ±15%.
Assay Range: 2.5-400.0ng/mL
The Lowest Detection Limit: 2.5ng/mL
Linearity
A serial concentrations of Myo reference materials from 20.0-400.0ng/mL were tested, and the correlation coefficient (R) is ≥ 0.9900.
Intra-lot Precision
Intra-lot precision was determined by testing of Myo reference materials using 10 test cartridges from the same lot. The C.V. is ≤ 15%.
Inter-lot Precision
Inter-lot precision was determined by testing of Myo reference materials using 30 test cartridges from 3 consecutive lots randomly (10 test cartridges from each lot).The C.V. is ≤ 15%.
Specificity

Number	antigen	Concentration of antigen	Test result of Myo
1	cTnI	30ng/mL	<2.5ng/mL
2	cTnT	30ng/mL	<2.5ng/mL
3	CK-MB	60ng/mL	<2.5ng/mL
4	ABP	1000 ng/mL	<2.5ng/mL
5	Aspirin	0.3ng/mL	<2.5ng/mL
6	Digoxin	200ng/mL	<2.5ng/mL

SYMBOLS

Symbol	Description	Symbol	Description
REF	Catalogue number	IVD	In vitro diagnostic medical device
LOT	Lot number		Consult instructions for use
	Date of manufacture		Keep dry
	Expiry date		Keep away from sunlight

	Manufacturer	2℃ 8℃	Store at 2-8℃
	Do not re-use	2℃ 30℃	Store at 2-30℃
EC REP	European authorized representative	CE	CE mark

BIBLIOGRAPHY OF SUGGESTED READING

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Xiamen Biotime Biotechnology Co., Ltd.
Address: 2F/3F/4F/5F, No.188, Pingcheng South Road, Haicang Street, Haicang District, Xiamen City, Fujian Province, 361026, P. R. China.

EC REP
Lotus NL B. V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Tel: +31644168999

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