hscTnI Rapid Quantitative Test

CE IVD

Catalog No.: BT0201201

INTENDED USE

The Biotime hscTnI (highly sensitive cardiac troponin I) Rapid Quantitative Test is intended to quantify the concentration of cTnI in human serum, plasma or whole blood on Biotime FIA Analyzers by fluorescent immunoassay. It is used as an aid detection of 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 cardiac troponin I (cTnI) in human serum,plasma or whole blood. The troponin complex, consisting of cTnI, troponin T (TnT) and troponin C (TnC), can adjust the interaction between actin and myosin. Concentration of cTnI is pretty low in healthy human blood. However, when acute myocardium infarction occurs, cTnI is released into blood quickly, which leads to rapid increase of cTnI concentration in hours and last 6 to 10 days. Therefore, blood cTnI concentration is regarded as a marker for myocardial infarction[1-3].

PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the sample and the buffer are mixed and applied into the test cartridge, the cTnI in the sample and the mouse anti-cTnI 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 cTnI 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 cTnI 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 cTnI in human blood.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only. Please do not use expired products.
2. All 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 10~100μL size)
3. Specimen Collection Containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-8℃, and the shelf life is 24 months.
2. Store the test cartridge at 2-30℃, and the shelf life is 24 months.
3. Test Cartridge should be used within 30 min after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with human serum,plasma or whole blood specimen only.
2. The specimen collection container should be procoagulant tubes or heparin anticoagulant tube.
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 test.
4. Separate plasma as soon as possible to avoid hemolysis.

TEST PROCEDURES

Please refer to the operation manual of Biotime FIA analyzers for details. The test should be operated at room temperature (~25℃).

Step 1: Preparation

Check the lot number and insert SD card into the equipment.Take out one tube of buffer from refrigerator and balance it to room temperature.

Step 2: Sampling

Take 40μL of serum/plasma or 60μL of whole blood 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.

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: <40pg/mL

Note: Individual reference range is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. The test sample should be serum, plasma or whole blood.
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

cTnI control materials with two different concentrations were tested by every lot of Test Cartridges, and the deviations were within ±15%.

Assay Range: 20-40000pg/mL

Limit of blank： ≤10pg/mL

Limit of detection: 20pg/mL

Limit of quantitation： 20pg/mL

Linearity

A serial concentrations of cTnI reference materials at 20-40000pg/mL were tested, and the correlation coefficient (R) is ≥ 0.9900.

Precision

Intra-lot Precision

Intra-lot precision C.V. is ≤ 15.0%

Inter-lot Precision

Inter-lot precision was determined by testing of cTnI reference materials. The C.V. is ≤15.0%.

Specificity

The following substances were not found to cross-react with cTnI in this concentration range.

Number	Antigen	Concentration of antigen	Test result of hscTnI
1	sTnI	1000μg/L	<40pg/mL
2	cTnC	1000μg/L	<40pg/mL
3	cTnT	1000μg/L	<40pg/mL

SYMBOLS

Symbol	Description	Symbol	Description
REF	Catalogue number	IVD	In vitro diagnostic medical device
LOT	Batch code		Consult instructions for use
	Date of manufacture		Keep dry

	Use-by date		Keep away from sunlight
	Manufacturer	2℃ 30℃	Temperature limit
	Do not re-use	EC REP	Authorized representative in the European Community/European Union
CE	CE mark		

BIBLIOGRAPHY OF SUGGESTED READING

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4. Hansen JH. HAMA Interfernce with Murine Monoclonal Antibody-Based Imminoassays [J]. J of Clinical Immunoassay. 1993.16: 294-299.

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