Instruction for cTnI/CK-MB/Myo (Cardiac panel) Test Kit (Immunofluorescence)

1. Product Name

Generic name: cTnI/CK-MB/Myo (Cardiac panel) Test Kit (Immunofluorescence)

Trade name: Cardiac panel

2. Package

Specification 1: 25T/kit REF: 52026005

Specification 2: 50T/kit REF: 52027005

3. Intended Use & Indication

For in vitro quantitative determination of cTnI/CK-MB/Myo content in human serum, plasma or whole blood.

It is mainly used in clinical auxiliary diagnosis of myocardial infarction, myopathy and other diseases.

Products for professional use only.

4. Test Principle

(1) When the test sample is added to the sample port on the test card, CK-MB in the sample combines with mouse anti-CK-MB monoclonal antibody which is coupled to fluorescent particles to form fluorescent particles - antibody - antigen complexes. This immune complex reaches to the test area (T1) along the nitrocellulose membrane and combines with the pre-coated mouse anti-CK-MB monoclonal antibody, its fluorescence intensity is proportional to the CK-MB content in the sample, the remaining fluorescent antibody reaches to the quality control area (C) and combines with pre-coated goat anti-mouse IgG. If the sample does not contain CK-MB, the test area will not appear fluorescence.

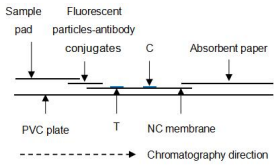
(2) When the test sample is added to the sample port on the test card, cTnI in the sample combines with mouse anti-cTnI monoclonal antibody which is coupled to fluorescent particles to form fluorescent particles - antibody - antigen complexes. This immune complex reaches to the test area (T2) along the nitrocellulose membrane and combines with the pre-coated mouse anti-cTnI monoclonal antibody, its fluorescence intensity is proportional to the cTnI content in the sample, the remaining fluorescent antibody reaches to the quality control area (C) and combines with pre-coated goat anti-mouse IgG. If the sample does not contain cTnI, the test area will not appear fluorescence.

(3) When the test sample is added to the sample port on the test card, Myo in the sample combines with mouse anti-Myo monoclonal antibody which is coupled to fluorescent particles to form fluorescent particles - antibody - antigen complexes. This immune complex reaches to the test area (T3) along the nitrocellulose membrane and combines with the pre-coated mouse anti-Myo monoclonal antibody, its fluorescence intensity is proportional to the Myo content in the sample, the remaining fluorescent antibody reaches to the quality control area (C) and combines with pre-coated goat anti-mouse IgG. If the sample does not contain Myo, the test area will not appear fluorescence.

5. Main Components& Additional required equipment

The test kit consists of test card, magcard, whole blood buffer and the instruction.

(1) The test card consists of the card housing and test strip. Test strip contains a sample pad, glass fiber (coated with mixture of fluorescent particles-cTnI/CK-MB/Myo antibody conjugates), nitrocellulose (NC) membrane (T1 is coated with CK-MB monoclonal antibody, T2 is coated with cTnI monoclonal antibody, T3 is coated with Myo monoclonal antibody, quality control area (C) is coated with goat anti-mouse IgG), absorbent paper and PVC plate. The diagram is as follows:



Schematic diagram of test strip

(2) Magcard: load calibration curve information for reagents with this batch.

(3) Whole blood buffer: the main component is phosphate buffer (PBS).

(4) Equipment: Applicable to FA50/FA120 Quantitative Immunoassay Analyzer manufactured by Genrui Biotech Inc.

6. Accessories Required But Not Provided

(1) Pipettes and pipette tips: 100 μL. (2) Timer

7. Special storage &Transport conditions

(1) The test kit can be stored at 2-30℃, aluminum foil bag in a sealed state is valid for 18 months , once opened, it is valid for 1 hour.

(2) Transport at 2-30℃.

8. Sample Requirements

(1) The optimal sample is fresh non-hemolyzed serum, plasma or whole blood. Recommended to use venous blood, results of other body fluids and samples may not be accurate.

(2) Complete the sample test within 24h at room temperature after the sample is collected. Keep serum and plasma refrigerated at 2-8℃ for not more than 7 days and frozen below -18℃ for not more than 1 month. Whole blood sample should not be frozen, store it at 2-8℃ for not more than 7 days.

(3) Bring the samples to room temperature before the test. Frozen samples need to be melted completely, re-warmed and mixed before use, avoid repeated freezing and thawing.

(4) Human serum or plasma is recommended to be used for testing. EDTA is recommended to be used as the coagulant.

9. Test procedure

Carefully read the reagent instruction before using the test kit and strictly operate according to the instruction to ensure reliable results. Bring all reagents to room temperature (18-25℃) before the use.

(1) Startup: Click “STD Mode” in the main menu to enter the measurement interface, click “Item” to select the desired test item and click “Type” to select the sample type.

(2) Click “Lot No.” to enter the card swiping interface, place magcard of the corresponding item to the magnetic induction zone, when hearing a “di” sound, the magcard is swiped successfully, check whether the magcard and the test card are of the same batch (Note: reagents are precalibrated and specific calibration curve parameters for each batch of reagents have been stored in the magcard).

(3)Sampling:

a) Serum/Plasma: Take 100μL serum or plasma, drop vertically to the sample port on the test card directly and start timing.

b) Whole blood: Take 100μL whole blood, drop vertically to the sample port on the test card directly, then add one drop of whole blood buffer to the sample port and start timing.

(4) Insert it into the analyzer’s test slot (the sample port end toward the inside). Click “Measure”, the instrument will automatically detect and print out the results after 15 minutes(If using “Fast Mode”, Keep it for 15 minutes and quickly Insert it into the analyzer’s test slot).

10. Reference interval

Reference range of CK-MB: < 5ng/mL Reference range of cTnI: < 0.3ng/mL

Reference range of Myo: < 58ng/mL

11. Explanation for Test Results

(1) When the control area (C) appears fluorescent strips, the analyzer will automatically detect the fluorescence and analyze the test card, and then provide quantitative results.

(2) When the control area (C) does not appear fluorescent strips, the analyzer cannot detect the

fluorescence and alarm automatically, indicating that the operation is incorrect or the test card is damaged, in this case, carefully read the instructions again and re-test with a new test card, if the problem still exists, immediately stop using products of this batch and contact your supplier.

(3) When the sample test results of cTnI are greater than 50ng/ml, the instrument displays > 50 ng/mL, when the test results are less than 0.1 ng/mL, the instrument displays < 0.1 ng/mL. When the sample test results of CK-MB are greater than 100ng/mL, the instrument displays > 100 ng/mL, when the test results are less than 0.3 ng/mL, the instrument displays < 0.3ng/mL. When the sample test results of Myo are greater than 400 ng/mL, the instrument displays > 400 ng/mL, when the test results are less than 2 ng/mL, the instrument displays < 2 ng/mL. If the result exceeds the linear range, dilute the sample with saline water by an integer multiple before testing, multiply the result by the dilution ratio.

(4) This test kit does not produce Hook effect within 500 ng/mL of CK-MB, 250 ng/mL of cTnI and 1500 ng/mL of Myo.

12. Detection limit

(1) This test kit is for in vitro diagnostic use only.

(2) Diagnosis and treatment can not only rely on this test result, taking into account the clinical history and other laboratory test results. Each laboratory is recommended to establish its own reference range based on the detected patient population.

13. Interfering substance

(1) Hemoglobin, bilirubin, cholesterol, triglycerides, HAMA antibody and rheumatoid factor in samples can interfere with the test results, the maximum allowable concentrations of hemoglobin is 5g/L, bilirubin is 2mg/mL, cholesterol is 15mg/mL, triglycerides is 30mg/mL, HAMA antibody is 40ng/mL, rheumatoid factor is 525IU/mL.

14. Product Performance Indicators

(1) Analysis sensitivity: CK-MB: ≤ 0.3 ng/mL , cTnI: ≤ 0.1ng/mL, Myo: ≤ 2 ng/mL.

(2) Linearity range: CK-MB: 0.3-100ng/mL, cTnI: 0.1-50ng/mL, Myo: 2-400ng/mL.

(Linear correlation coefficient: r ≥ 0.990)

(3) Measurement precision: Repeatability: CV ≤ 15%,

relative deviation of test kit's inter batches (R) ≤ 15%

(4) Accuracy: -15% ≤ Bias% ≤ +15%.

(5) The Interference test result:: -15% ≤ Bias% ≤ +15%.

15. Precautions

(1) Once opened, use the test cards as soon as possible, which may cause moisture. Do not re-use the test cards.

(2) Components in test kit of different batches cannot be used interchangeably.

(3) For substances containing sources of infection or suspected of containing sources of infection, there should be proper bio-safety assurance procedures. Pay attention to the following matters:

a) Wear gloves when handling sample or reagent for disinfection.

b) Disinfect spilled sample or reagent with disinfectant.

c) Disinfect or handle potential contamination sources of all samples or reagents in accordance with local regulations.

16. Explanation of graphic symbol

	Consult Instructions for use		Temperature Limitation
LOT	Lot No.		Expiry Date
IVD	In Vitro Diagnostic Reagent	CE	CONFORMITE EUROPEENNE
	Production Date		Biohazard
	Manufacturer		Volume
Σ	Contains sufficient for < n>tests		Keep away from sunlight
	Do not re-use		Dark dry preservation
EC REP	Authorized representative in the European community	REF	Catalogue number

17. Reference

(1) Ye yingwu, Wang yusan, Shen ziyu. Determination of serum myoglobin. National Guide to Clinical Laboratory Procedures (Third Edition), Department of Medical Administration in People's Republic of China, p.352-353.

(2) Ye yingwu, Wang yusan, Shen ziyu. Determination of serum troponin I. National Guide to Clinical Laboratory Procedures (Third Edition), Department of Medical Administration in People's Republic of China, p.353-354.

(3) Stein W. Creatine kinase (total activity), creatine kinase isoenzymes and variants. En: Thomas L, ed. Clinical laboratory diagnostics. Frankfurt: TH-Books Verlagsgesellschaft; 1998.p.71-80.

18. Metrological traceability

The kit was traced to the cTnI/CK-MB/Myo (Cardiac panel) Test Kit, Producted by Siemens Medical Diagnostic Co., Ltd.

19. Help Information

If you need help please contact after sales.

20. Manufacturer

Genrui Biotech Inc.

Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China.

Web: www.genrui-bio.com

21. Instruments & Applications

Genrui's Immunofluorescence products, designed to work in automated lab environment, which are compatible with the FA50 /FA120 Quantitative Immunoassay Analyzer. There may or may not be an application developed for you particular instrument, please visit the instrument section of our website.

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