Cardiac Troponin I (cTnI) Rapid Test Kit

(Fluorescence Immunochromatographic Assay)

Catalog Number: 5184C4X025，5184C4X050

INTENDED USE

This kit is suitable for in vitro quantitative detection of the concentration of Troponin I (cTnI)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.

The molecular weight of cTnI is about 24KD, and the N terminal of the molecule contains a translated back tail composed of 31 amino acids. cTnI levels increased a few hours after the onset of myocardial infarction symptoms, peaking at 12-16 hours, and remained elevated 4-9 days after the onset of myocardial infarction. A variety of other pathologies may induce troponin elevation in the condition of marked ischemic heart disease, but rarely show the typical pattern of elevation and decline in myocardial infarction. The generic definition of the third myocardial infarction in 2012 emphasizes that changes in cardiac biomarker values are one of the conditions. cTnI is the first biomarker for the diagnosis of 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 cTnI in human serum, plasma, whole blood and peripheral blood.

This product is pre-embedded with fluorescent microspheres labeled mouse anti-cTnI antibody and rabbit IgG antibody on the conjugate pad, and coated with mouse anti-cTnI antibody and goat anti-rabbit IgG antibody respectively on the test line and control line of nitrocellulose membrane. When the sample is tested, the cTnI antigen in the sample is combined with the fluorescent microspheres-labeled mouse anti-cTnI antibody embedded on the conjugate pad to form the fluorescent microspheres-labeled mouse anti-cTnI antibody-cTnI 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-cTnI antibody pre-coated, forming the double-antibody sandwich structure of fluorescent microspheres labeled mouse anti-cTnI antibody-cTnI-mouse anti-cTnI 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 cTnI in the sample is positively correlated with the fluorescence intensity of the test line. The concentration of cTnI in the sample is obtained through the test and analysis by the Immunofluorescence Analyzer.

COMPONENT

Materials provided with the test kits

1. The test card for a single copy of the aluminum foil bag packaging, containing the cTnI test card and desiccant, test card main components as follows: the backplane, sample pad, conjugate pad, nitrocellulose membrane, absorbent paper and plastic parts, the test line (T) was coated with anti-cTnI antibody, the quality control line (C) was coated with goat anti-rabbit IgG antibody, and the conjugate pad was embedded with fluorescent microspheres-labeled anti-cTnI antibody and rabbit IgG antibody. The identification code of the test card contains the item name, batch number, ID chip card contains the batch number, calibration curve, concentration unit, detection time and other information of the kit.
2. The sample diluent is a phosphate buffer.
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. Sample diluent is available on demand.

APPLICABLE INSTRUMENT

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. Samples may be serum, heparin anticoagulant plasma, sodium citrate anticoagulant plasma, EDTA anticoagulant plasma, and whole blood.
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 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.
5. Restore the sample to room temperature before test.
6. 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 instrument shall be carried out according to the operating instructions of the corresponding type of instrument.
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. It is recommended to restore the sample to room temperature before sampling.
3. Sampling: take 75 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 15min (please strictly control the time for 15min).
5. Detection: insert the detection card into the instrument before the end of the 15minutes countdown to the reaction of the detection card. After the end of the 15minutes countdown to the reaction, manually click "test" or the instrument 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 15minutes countdown, it will be deemed invalid and the sample shall be re-tested with a brand-new test card.

CALIBRATION

Traceability: Calibrator for calibration curve establishment are traceable to internal reference standards. This method has been standardized against the Abbott ARCHITECT STAT Troponin-I Reagent Kit.

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 cTnI in the sample.

REFERENCEINTERVAL

1. The study examined cTnI in 200 fresh serum from 0-80 years old. At the 95th position, the cTnI was 0.3ng/mL. Therefore, the cTnI reference interval for <0.3ng/mL.
2. Due to differences in geography, ethnicity, and age, it is recommended that each laboratory establish a reference interval with relevant clinical significance for the population of the region.

INTERPRETATION OF TEST RESULTS

1. The concentration of the sample cTnI measured is higher than the reference value range, and physiological changes or stress responses should be excluded. It is indeed abnormal and should be diagnosed in combination with clinical symptoms.

Item name	Test results	Clinical application recommendations
cTnI	0~0.3ng/mL	Normal level
	≥0.3ng/mL	This suggests a risk of myocardial infarction in this patient. Note: the blood concentration of cTnI increased 4-8 hours after the occurrence of myocardial infarction, peaked 12-16 hours after the occurrence of myocardial damage, and remained high for 5-9 days。

2. The measurement 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. Other factors can also cause errors in test results, 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. This reagent is suitable for the detection of human serum/plasma/whole blood samples, and the detection results of other samples may be wrong.
2. Please check the integrity and expiry date of the kit package before use, and then open the package. The package can only be opened at room temperature after cryopreservation.
3. Direct use of low temperature will affect test results.
4. Improper operation and other factors may affect the accuracy of the results.
5. Different batches of sample diluents cannot be mixed.
6. 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.
7. For samples whose cTnI concentration may be greater than the linear range, it is necessary to measure with normal saline after appropriate dilution, and the maximum dilution ratio of normal saline is 10 times.
8. 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 cTnI test results (C0) and hematocrit (P) can be substituted into the following formula for further correction, and the calculated results (C1) can be used as the final test results.

$$C1=0.625*C0/(1-P)$$

Or the corresponding correction coefficients of the test results C0 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)	C0						
Final result (ng/mL)	C1=C0*K						

9. As with all diagnostic reagents, the final diagnosis should be made by the doctor after the combination of various indicators and clinical symptoms.

PRODUCT PERFORMENCE INDEX

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

1. Reportable range: cTnI 0.1~400 ng/mL.
2. Linearity: cTnI 0.1~40 ng/mL, and the analysis performance meets the following requirements:
   a) the deviation of the measurement results shall be within 15%;
   b) linear correlation coefficient (r) should ≥0.9900.
3. Accuracy: the recovery rate should be in the range of 85% to 115%.
4. Detection limit: cTnI≤0.1ng/mL.
5. Repeatability: CV ≤10%.
6. Inter-batch variation: CV≤15%.
7. HOOK effect: when the cTnI concentration reached 80 ng/mL, no HOOK effect occurred.
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	Total Cholesterol	≤10mg/mL

PRECAUTIONS

1. This reagent is only used for in vitro diagnosis. It is disposable.
2. The kit should be sealed and kept away from moisture. The strip should be used as soon as possible after it is removed from the package to avoid being in the air for too long and being affected with damp.
3. Do not use samples that have been placed for too long or repeatedly frozen or thawed should not exceed three times.
4. The amount of specimen added should be accurate, or it may cause wrong results.
5. Used reagents and samples should be treated as medical waste with the risk of biological transmission, and pay attention to safe operation. The desiccant in the aluminum foil bag should not be taken internally.
6. Check whether the aluminum foil bag is damaged before test. If it is damaged, the test cannot be used, so as not to affect the judgment of test results.
7. Incorrect operation may affect the accuracy of the results, such as wet display window or insufficient amount.
8. If you have any questions or suggestions in the process of using this product, please contact us.

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		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		

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