

High-sensitivity Cardiac Troponin I (hs-cTnI) Quantitative Test (Quantum Dot Fluorescence Immunochromatography) Instruction for Use



In Vitro Diagnosis
For Professional Use

【Product Name】

High-sensitivity Cardiac Troponin I (hs-cTnI) Quantitative Test (Quantum Dot Fluorescence Immunochromatography)

【Package Specification】

25 tests/kit

【Intended Use】

For the quantitative detection of cardiac troponin I (cTnI) in human whole blood, serum, plasma. For in vitro diagnostic use only.

【Test Principle】

This kit adopts the principle of fluorescent immunochromatography, and quantitatively detects the concentration of cTnI in human whole blood, serum and plasma using the sandwich method with double antibody. cTnI antibody is coated on the nitrocellulose membrane (NC membrane) at the detection line (T) region, and chicken IgY antibody is coated at the control line (C) region, along with a probe pad containing cTnI antibody labeled with quantum dots and goat anti-chicken IgY. When the sample to be tested is added to the sample well of the test cassette, along with the flow of liquid, the sample to be tested first passes through the sample pad, forming a fluorescent complex with the probe pad fixed with quantum dot-labeled antibody. The complex passes through the detection line and control line, and specifically binds to the antibody in the detection line and control line, captured by the coated antibody on the nitrocellulose membrane, presenting a fluorescent band.

The fluorescence signal intensity reflects the amount of cTnI captured. The higher the concentration of cTnI in the sample, the more complexes accumulate on the detection line, and the higher the signal intensity. A fluorescence immunoassay analyzer is used to analyze the photometric values of the control line and the detection line, and then the instrument calculates and displays the concentration of cTnI based on a calibration curve preset in the instrument, in units of ng/mL.

【Main Material】

Main Material as below:

- 25 Test cassettes
- 25 Deliver pipettes
- 1 Bottle of diluent
- 1 ID Card
- 1 User Manual

Material Required but not Provided:

1. Timer, thermometer, hygrometer;

Note: Components of different batches of reagent kits cannot be used interchangeably to avoid incorrect results.

【Storage Conditions and Validity Period】

1. The test kit should be stored out of direct sunlight at 2-30°C, with a shelf life of 18 months.
2. The test should be used within 1 hour after opening at a temperature of 10°C-30°C and humidity of 35%-65%.

【Applicable Analyzer】

Dry fluorescence immunoassay analyzer GKYG-500 produced by Dezhou Guoke Medical Technology Co.,Ltd.

【Specimen Requirement】

1. Suitable for human serum, plasma or whole blood samples, serum and plasma samples are recommended to be prioritized. Hemolyzed specimens cannot be used. All specimens should be treated as infectious agents.
2. Whole blood and plasma specimens are allowed to be treated with EDTA, heparin, or sodium citrate anticoagulants.
3. Whole blood, serum and plasma specimens should be stored at a temperature of 18~28°C for no more than 1 day. If the specimen is free of contamination such as bacteria, it should not be stored at 28°C for more than 3 days, or at -20°C for more than 1 month. The specimen should not undergo more than 3 freeze-thaw cycles. Thawed frozen specimens should be thoroughly mixed.
4. Particulate matter in the sample will affect the test results. Specimens containing visible particles should be centrifuged to obtain the supernatant for experimentation.
5. Do not test samples from patients with severe hemolysis, lipemia, or jaundice.
6. The sample must be equilibrated to a temperature of 10°C~30°C before testing. Frozen stored samples should be completely thawed, rewarmed, and thoroughly mixed before use.

【Test Procedure】

1. When stored at low temperatures, the test cassette and sample buffer should be restored to 10°C~30°C before use.
 2. Follow the instructions for use of the instrument to turn on the instrument.
 3. Take out the ID card from the reagent kit and read the ID card information at the card reading position of the fluorescence immunoassay analyzer.
 4. Tear open the outer packaging, take out the test cassette, and place it flat on the operating table. The test cassette should be used within 1 hour after being taken out.
 5. If the sample is serum or plasma, use a pipette to aspirate 100μL of the sample. If the sample is whole blood, use a pipette to aspirate 100μL of the sample, then vertically drop it into the sample well of the reagent card. Immediately add a drop of sample diluent into the sample well.
 6. Immediately Insert the test cassette into the fluorescence immunoassay analyzer immediately at 15 minutes of reaction, click the "Test" button, and the test result will be automatically displayed on the instrument screen, and can be saved and printed.
 7. Used test cassettes should be treated as potentially biohazardous materials.
 8. Quality control:
 - 1) C line is used as an indicator of the effectiveness of the test cassette, C line should appear in any cases.
 - 2) Internal reference materials of the company or other approved applicable control materials can be used for quality control of the product, and the test results should be within the specified control range.
- Note:** Test should be completed under conditions of 10°C to 30°C and 35% to 65% humidity.

【Reference Range】

The 95th percentile of the normal reference values for 213 cases of human whole blood, serum and plasma specimens: <50ng/mL.
The reference range is verified according to similar products already on the market. Due to differences in races and regions, each laboratory can establish its own reference range based on actual conditions.

【Interpretation of Test Results】

1. If the whole blood, serum and plasma sample is turbid, it may affect the flow rate of the sample, resulting in prolonged testing time or inability to test, which may lead to potentially incorrect test results. Please centrifuge and discard the precipitate before use.
2. The accuracy of the sample addition directly affects the accuracy of the test results.
3. Before use, check the integrity and expiration date of the reagent kit packaging, and then open the packaging. The reagent should be restored to 10°C to 30°C before opening the packaging for use. Direct use at low temperatures may affect the test results.
4. Whether a patient has an inflammatory bacterial infection should be determined by a physician based on the patient's clinical features, symptoms,

and other diagnostic methods.

【Limitations of Detection Method】

This test Kit belongs to the category of fluorescence immunoassay diagnostic reagents and has inherent limitations in methodology:

1. The test result can only be used as an auxiliary diagnosis for doctors or other diagnoses and needs to be combined with other clinical and laboratory data. If the test result does not match the clinical assessment, further tests are needed.
2. When bilirubin $\leq 0.5\text{mg/mL}$, triglycerides $\leq 10\text{mg/mL}$, and hemoglobin $\leq 5\text{mg/mL}$, the bias of the test result is within $\pm 10\%$.
3. When the cTnI concentration in the sample is $\leq 200\text{ng/mL}$, no HOOK effect will occur.
4. If the sample test result shows greater than 40ng/mL , it is recommended to dilute the sample with physiological saline (the maximum buffer factor should not exceed 1:5), and the concentration value of the sample after buffer is multiplied by the buffer factor to calculate the sample concentration value.

【Product Performance Indicator】

1. Appearance Inspection: The product and outer packaging should be clean, flat, with clear labeling, complete components, and materials adhered firmly.
2. Migration Speed: The liquid migration rate should be no less than 10mm/minute.
3. Linear Range: In the range of $2.5\text{ ng/mL} \sim 400\text{ng/mL}$, the Linear Correlation Coefficient(R) value should be ≥ 0.990 .
4. Precision: Using the enterprise internal control accuracy reference material (C1, C2) for testing, the test result should be within the following ranges:
 - 1) Using the enterprise internal control accuracy reference material C1 for testing, the instrument measurement range at 15 minutes should be $0.5\text{ng/mL} \pm 15\%$;
 - 2) Using the enterprise internal control accuracy reference material C2 for testing, the instrument measurement range at 15 minutes should be $5\text{ng/mL} \pm 15\%$;
5. Intra-lot Precision: Using the enterprise internal control precision reference material (C9, C10) for parallel testing 10 times, the instrument measurement at 15 minutes should have a coefficient of variation (CV) $\leq 15\%$.
6. Inter-lot Precision: For three batches of reagent kits, using the enterprise internal control precision reference material (C9, C10) for parallel testing 10 times, the instrument measurement at 15 minutes should have a coefficient of variation (CV) $\leq 15\%$.
7. Detection Limit: Using the enterprise internal control detection limit reference material L1 for testing, the instrument measurement at 15 minutes should be $\leq 2.5\text{ ng/mL}$.
8. Specificity: Using the enterprise internal control specificity reference material (C3, C4, C5) for testing, the instrument measurement at 15 minutes should be less than 2.5 ng/mL .

【Precautions】

1. This reagent kit is for in vitro diagnosis and single use only. Do not reuse.
2. The reagent kit should be treated as containing infectious materials.
3. Before use, check the integrity and expiration date of the reagent kit packaging.
4. Please read the instructions for use of this reagent and instrument carefully before all operations.
5. Please strictly follow the instructions for use. Once testing starts, it cannot be stopped midway. If testing is stopped midway, the test cannot be resumed, and if retesting is needed, the reagent must be updated and retested.
6. Each lot of reagents has corresponding parameters in the matching instrument. The manufacturer regularly updates the parameters in the instrument. If the new lot of reagent products is not recognized by the instrument, please contact the manufacturer to update the parameters.
7. The test cassette should not be used after being opened for more than 1 hour.
8. Reagent kits of different lot numbers should not be mixed, and ID cards and test cassettes should not be mixed and used with different batch numbers.
9. The experiment environment should not be too high. test cassettes stored

at low temperatures need to be restored to room temperature before opening to avoid moisture absorption.

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【 Index of Symbols 】

	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
	Temperature scope within which the product is reserved		Batch number
	Catalog #		Tests / box
	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		



Manufacturer:

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