NT-proBNP Quantitative Test Cassette (Quantum Dot Fluorescence Immunochromatography) Instruction for Use

CE IVD REF

In Vitro Diagnosis
For Professional Use

【Product Name】

NT-proBNP Quantitative Test Cassette (Quantum Dot Fluorescence Immunochromatography)

【Package Specification】

25 tests/kit

【Intended Use】

For the quantitative detection of N-Terminal Pro-brain Natriuretic Peptide (NT-proBNP) in human whole blood, serum and plasma. For in vitro diagnostic use only.

【Test Principle】

This kit adopts the principle of quantum dot fluorescence immunoassay to quantitatively detect the concentration of NT-proBNP in human whole blood, serum and plasma using a sandwich double-antibody method. NT-proBNP antibody is coated on the nitrocellulose membrane (NC membrane) at the detection line (T) region, and chicken IgY antibodies are coated at the control line (C) region, along with a probe pad containing NT-proBNP 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 NT-proBNP captured. The higher the concentration of NT-proBNP 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 NT-proBNP based on a calibration curve preset in the instrument, in units of pg/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 cassette 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. Collect and separate whole blood, serum and plasma using conventional methods, and try to avoid hemolysis during the process. Hemolyzed samples cannot be used. All samples should be treated as infectious agents.
2. Plasma and whole blood samples may be anticoagulated with heparin sodium, EDTA•K2, and sodium citrate anticoagulants.
3. Specimens should be tested in a timely manner. After adding the anticoagulant, they should not be left at 18-28°C for more than 4 hours, as prolonged time may cause blood clotting or fibrinogen precipitation, resulting in inability to test.
4. Whole blood, serum and plasma specimens should not be left at 18~28 °C for more than 1 day. If the samples are free of bacterial contamination, they should not be stored at 2~8 °C for more than 3 days or at -20 °C for more than 1 month. Samples should not undergo more than 3 freeze-thaw cycles. Frozen samples should be thoroughly mixed after thawing.
5. If the specimens contains particulate matter, it will affect the test results. Samples with visible particles should be centrifuged, and the supernatant should be used for the experiment.
6. Do not test samples from patients with severe hemolysis, lipemia, or jaundice. Samples containing hemoglobin (concentration exceeding 5mg/mL), bilirubin (concentration exceeding 0.2mg/mL), or triglycerides (concentration exceeding 15mg/mL) should not be used for testing.
7. The specimen must be restored to 10 °C~30 °C before testing. Frozen samples should be completely thawed, reheated, 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 pipette to aspirate 100 μL of the sample; if the sample is whole blood, use pipette to aspirate 100μL of the sample ,vertically drip it into the sample well of the reagent card, immediately followed by one drop of sample diluent into the sample well.
6. 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 cassette 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) The company's internal quality control products or other approved and applicable quality control products can be used to conduct quality control on the product. The test results should be within the specified quality control range.

Note: Test should be completed under conditions of 10°C~30 °C and 35%-65% humidity.

【Reference Range】

The recommended reference interval for this Cassette is < 300 pg/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 test result is <300pg/mL, the sample is negative.
2. If the test result is ≥300pg/mL, the sample is positive.
3. 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.
4. The accuracy of the sample addition directly affects the accuracy of the test results.

5. 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~30°C before opening the packaging for use. Direct use at low temperatures may affect the test results.

【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.
2. If the test result does not match the clinical assessment, further tests are needed.
3. When bilirubin ≤0.5mg/mL, triglycerides ≤10mg/mL, and hemoglobin ≤5mg/mL, the deviation of the test result is within ±10%.
4. When the NT-proBNP concentration in the sample is ≤50000pg/mL, no HOOK effect will occur.
5. If the sample test result shows greater than 35000pg/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 firm adhesion of materials.
2. Migration Speed: The liquid migration rate should be no less than 10mm/minute.
3. Linear Range:
   In the range of 30pg/mL～25000pg/mL, the Liner Correlation Coefficient(R) value should be ≥0.990.
4. Precision:
   Using the enterprise internal control internal control accuracy reference material (C1, C2) for testing, the test result should be within the following ranges:

   Using the enterprise internal control internal control accuracy reference material C1 for testing, the instrument measurement range at 15 minutes should be 500pg/mL ± 15%;

   Using the enterprise internal contro internal control accuracy reference material C2 for testing, the instrument measurement range at 15 minutes should be 5000pg/mL ± 15%;

   Intra-lot Precision: Using the 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) ≤15%.

   Inter-lot Precision: For three lots of reagent kits, using the 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) ≤15%.
5. Detection Limit: Using the internal control detection limit reference material L1 for testing, the instrument measurement at 15 minutes should be ≤30pg/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 batch 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.

Reagent kits of different batch numbers should not be mixed, and ID cards and 8. test cassettes should not be mixed and used with different batch numbers.

8. 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】

IVD	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
2℃-30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Manufacturer:
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