Neutrophil Gelatinase Associated Lipocalin (NGAL) Quantitative Test Cassette (Quantum Dot Fluorescence Immunochromatography) Instruction For Use

CE IVD REF

In Vitro Diagnosis
For Professional Use

【Product Name】

Neutrophil Gelatinase Associated Lipocalin (NGAL) Quantitative Test Cassette (Quantum Dot Fluorescence Immunochromatography)

【Package Specification】

25 tests/kit

【Intended Use】

This kit is used for the detection of Neutrophil Gelatinase Associated Lipocalin (NGAL) levels in human whole blood, serum ,plasma or urine samples in vitro quantitatively.
For Professional Use Only.

【Test Principle】

The NGAL Test Cassette is a fluorescent lateral flow immunoassay, which adopts a double antibody sandwich method to quantitatively detect the concentration of NGAL in human whole blood, serum ,plasma or urine. The test consists of: 1) a probe conjugate pad containing anti-NGAL monoclonal antibody conjugated with fluorescent microspheres (antibody probe conjugate) and a control antibody (goat chicken IgY) conjugated with fluorescence microspheres, 2) a nitrocellulose membrane with immobilized antibodies in the test area (T line) and a control area (C line). The T line is pre-coated with another anti- NGAL antibody, and the C line is pre-coated with a control line antibody (chicken IgY). The specimen to be tested is added to the sampling hole of the test card, as the liquid flows, specimen to be tested first passes through the sample pad and forms a fluorescent complex with the probe pad fixed with quantum dot-labeled antibodies. The complex passes through the detection line and quality control lines, specifically immunobind with the antibodies in the detection line and quality control line respectively, and are captured by the coating antibodies on the nitrocellulose membrane to present fluorescent bands.
Intensity of the fluorescence signal reflects the amount of captured NGAL. The higher the concentration of NGAL in the sample, the more accumulated complexes on the detection line, the higher signal intensity will be tested out. Use a fluorescence immunoassay analyzer to analyze the photoelectric values of the quality control line and detection line, then the analyzer calculates the concentration of NGAL based on the calibration curve that has been preset inside the analyzer and displays the result in ng/ml.

【Main Material】

Main Material as below:
25 Test cassettes
25 Empty centrifuge tubes
1 Bottle of dilution
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 at 2~30°C, protected from light, and has a shelf life of 18 months.
2. The test cassette should be used within 1 hour after opening at a temperature of 2°C to 30°C and a humidity of 35% to 65%.

【Applicable Analyzer】

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

【Specimen Requirement】

1. This test card is suitable for the detection of whole blood, serum ,plasma or urine.Hemolyzed specimens cannot be used. All specimens should be treated as infectious agents.
2. Plasma specimens are allowed to use EDTA, heparin and sodium citrate anticoagulants.
3. One should neither drink too much nor too little water in the four hours prior to urine collection, and a clean container must be used to collect fresh urine.
4. whole blood, serum ,plasma or urine specimens should be stored at 18 to 28°C for no more than 1 day. If the specimen is free of bacterial contamination, it should be stored at 2 to 8°C for no more than 3 days, and at -2°C for no more than 3 month, repeated freezing and thawing should not occur more than 3 times. Frozen specimens should be thoroughly mixed after thawing.
5. If the sample contains particulate matter, it will affect the test results. Samples containing visible particles should be centrifuged and the supernatant should be taken for experiments.
6. Do not test samples from patients with hemolysis, lipemia and jaundice.
7. After sample collection, please complete the testing as soon as possible and avoid leaving the sample at room temperature for extended periods. Repeated freezing and thawing should be avoided (no more than two freeze-thaw cycles are allowed).The specimen must be restored to 10~30℃ before testing,gently turned and mixed;the use of a water bath to warm and thaw frozen samples is prohibited.

【Test Procedure】

1. When stored at low temperature, the test kit and diluent should be restored to 18~26℃ before use.
2. Turn on the analyzer according to the analyzer instruction manual.
3. Take out the ID card from the 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 removed test cassette should be used within 1 hour.(If the test card is taken out from the refrigerator, it needs to be equilibrated to room temperature before being removed from the sealed aluminum foil bag for use; otherwise, it will affect the experimental results).
5. Take 0.5 ml of the dilution into an empty centrifuge tube and set aside.
6. Accurately pipette 50μl of the sample into one sample diluent tube, oscillate to mix thoroughly, and keep it ready for use.Add 100μl of diluted sample to the sample well of the test card and start the clock.
7. Immediately insert the test cassette into the fluorescence immunoassay quantitative analyzer at 15 minutes of reaction, click the "Detect" button, the test results will automatically be displayed on the instrument screen, and the results can be saved and printed.
8. Used test cassettes should be treated as potentially biohazardous items.
9. 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 at a temperature of 18°C to 26°C and a humidity of 35% to 65%.

【Positive Judgment Value or Reference Interval】

Reference value: The concentration of NGAL in the urine of normal human should be ≤10 ng/ml; for normal human aged 17 to 50, the serum NGAL level is <73.94 ng/ml, and for those aged 50 to 90, the serum NGAL level is <87.85 ng/ml.
By analyzing the test results of NGAL in urine and whole blood, serum ,plasma samples from normal human through experiments, the 95%

reference range is calculated to determine the positive cut-off value or reference interval for this test kit.The reference value is verified with reference to similar products on the market. Due to racial and regional differences, each laboratory can establish its own reference interval based on actual conditions.

【Interpretation of Test Results】

1. Use the accompanying analyzer to analyze the test card and provide quantitative test results.
2. Some operational errors may lead to deviations in test results, such as using the test kit beyond its expiration date, inaccurate pipettes, excessively low indoor temperatures, and failure to follow the testing procedures outlined in the instructions. It is recommended that each laboratory establish its own quality control standards.
3. Due to factors such as methodological differences or variations in antibody specificity, there may be deviations in test results obtained from reagents produced by different manufacturers， therefore, direct comparison between them should be avoided to prevent erroneous medical interpretations.

【Limitations of Detection Method】

This kit is a fluorescence immunochromatography diagnostic kit and has inherent methodological limitations:

1. The test results can only be used as an auxiliary for doctors or other diagnoses and need to be combined with other clinical and laboratory data. If the test results are inconsistent with the clinical assessment, further examination is required.
2. This kit is for human human whole blood, serum ,plasma or urine testing.
3. Bilirubin ≤0.5mg/ml, triglycerides≤10mg/ml, hemoglobin≤5mg/ml would affect the test result, and the deviations are within ±10%.
4. HOOK effect does not appear when NGAL concentration is ≤10000ng/ml.
5. If the sample test result shows more than 5000ng/ml, it is recommended to dilute the sample with saline (the maximum dilution should not exceed 1:5), and the concentration value of the test obtained after the dilution should be calculated in accordance to the dilution ratio.

【Product Performance Indicator】

1. Appearance inspection: The product and outer packaging should be clean and smooth, with clear markings, complete components, and strong material attachment.
2. Migration speed: The liquid migration speed should not be less than 10mm/minute.
3. Linear range:

In the range of 10ng/ml - 1200ng/ml, the Correlation Coefficient(R) value should be ≥0.990.

4. Accuracy

Use company's internal control accuracy reference products (C1, C2) to test, and the test results should be within the following range:

1) Using company's internal control accuracy reference product C1: 50ng/ml for testing, the analyzer's measurement range is 50ng/ml±15% at 15 minutes;
2) Using company's internal control accuracy reference product C2: 300ng/ml for detection, the analyzer's measurement range is 300ng/ml±15% at 15 minutes;

5. Intra-Lot precision

Use the company's internal control precision reference materials (C9: 50ng/ml, C10: 300ng/ml) for 10 parallel tests each, and measure with the analyzer at 15 minutes. The concentration value variation coefficient CV ≤ 15%.

6. Inter-Lot precision

For the three batches of kits, the company's internal control precision reference materials (C9: 500ng/ml, C10: 2500ng/ml) were tested 10 times in parallel. The analyzer measured the concentration value at 15 minutes, and the concentration value variation coefficient CV ≤ 15%.

7. Detection limit

Use the company's internal control detection limit reference product L1 to test, and measure with the analyzer at 15 minutes. The result should be ≤5.0ng/ml.

8. Specificity

Using the company's internal control specific reference materials (C3, C4, C5, C6, C7, C8) to detect, the measured values of the analyzer should be less than 10.0 ng/ml at 15 minutes.

【Precautions】

1. This kit is only for in vitro diagnosis, one-time use, please do not re-use.
2. The test kit should be treated as contain infectious material.
3. Please check the integrity and expiration date of the kit packaging before use.
4. Please read the instructions for use of this reagent and instrument carefully before any operation.
5. Please strictly follow the instructions. After the test starts, it cannot be stopped in halfway. If it is stopped halfway, the test cannot be resumed. If a retest is needed, use new reagents and retested.
6. Each batch of reagents has corresponding parameters in the supporting analyzer, and the manufacturer regularly updates the parameters in the analyzer. If the new batch of product reagents is not recognized by the analyzer, please contact the manufacturer in time to update the parameters.
7. The test cassette shall not be used after more than 1 hour after opening.
8. Reagents with different batch numbers cannot be mixed, and ID cards and test cassettes must not be used with mixed batch numbers.
9. The experimental environment should be avoided from being too high. Test cassettes stored at low temperature need to be returned to room temperature before opening to avoid moisture absorption.
10. With regard to the warning on components of animal origin, the components of the kit contain serum proteins of bovine origin, which are collected from quarantined animals in non-infected areas and are negative for sterility, mycoplasma and viruses, but as of now, no test can ensure absolute safety, and the components should be treated as a potential source of infection.

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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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