Procalcitonin (PCT) Quantitative Test Cassette (Quantum Dot Fluorescence Immunochromatography) Instruction For Use

CE IVD REF

In Vitro Diagnosis
For Professional Use

【Product Name】

Procalcitonin (PCT) Quantitative Test Cassette (Quantum Dot Fluorescence Immunochromatography)

【Package Specification】

25 tests/kit

【Intended Use】

For the in vitro quantitative detection of procalcitonin (PCT) concentration in human whole blood ,serum and plasma.

It is mainly used clinically for the auxiliary diagnosis of bacterial infectious diseases. Monitor patients at risk for infection (e.g. immunosuppressive periods after surgery and organ transplantation, after multiple trauma) and patients requiring intensive care, to detect the systemic effects of bacterial infection or to detect septic complications. Evaluate the clinical course and prognosis of severe inflammatory diseases.

【Test Principle】

This kit adopts the principle of fluorescence immunochromatography and uses a double-antibody sandwich method to quantitatively detect the concentration of procalcitonin (PCT) in human whole blood, serum and plasma. PCT antibody is coated in the detection line (T) area of nitrocellulose membrane (NC membrane), and sheep anti-chicken IgY antibody is coated in the quality control line (C) area, coupled with PCT antibody immobilized with quantum dot labeling and chicken IgY probe pads. 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 PCT. The higher the concentration of procalcitonin (PCT) 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 PCT 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 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 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 10°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. 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 require anticoagulation with heparin sodium,EDTA.K2 and sodium citrate.
3. If the tested serum and plasma are used within 72 hours, they can be stored at 2℃ ~ 8℃, and can be stable for 1 year below -20℃.Repeated freezing and thawing must be avoided (freezing and thawing should not occur more than 2 times).
4. 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.
5. Do not test samples from patients with severe hemolysis, lipemia and jaundice.
6. The specimen must be restored to room temperature （10℃~30℃） before testing,and gently turned over to mix ,Prohibit the use of a water bath to warm and thaw frozen samples.

【Test Procedure】

1. When stored at low temperature, the test kit and diluent should be restored to 10℃~30℃ 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.
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 drip 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 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.
7. Used test cassettes should be treated as potentially biohazardous items.
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 at a temperature of 10°C to 30°C and a humidity of 35% to 65%.

【Positive Judgment Value or Reference Interval】

The recommended reference interval for this cassette is: ＜ 0.050ng/mL;

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. If the whole blood, serum and plasma sample is turbid, it will affect the flow rate of the sample, resulting in prolonged detection time or failure to detect, resulting in possible erroneous detection results. Please centrifuge and discard the sediment before use.
2. The accuracy of the sample amount will directly affect the accuracy of the test results.
3. Please check the integrity and expiration date of the kit package before use, then open the package. Low-temperature storage should be restored to 10℃~30℃ before opening the package for use. Direct use at low temperatures

will affect the test results.

4. Whether the patient has an inflammatory bacterial infection should be comprehensively judged by the physician based on the clinical characteristics and symptoms, as well as the patient's other diagnostic methods.

【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. Hemoglobin in hemolyzed samples is ≤5 mg/ml, bilirubin in jaundice samples is ≤0.5 mg/ml, and triglycerides are ≤10 mg/ml. The deviation of the test results is within ±15%.

3. When the PCT concentration in the sample is ≤400ng/ml, the HOOK effect will not occur.

4. If the sample test result shows that it is greater than 50ng/ml, it is recommended to dilute the sample with physiological saline (the maximum dilution factor should not exceed 1:10). The test concentration value obtained after dilution is multiplied by the dilution factor to calculate the sample concentration value.

【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 0.02ng/mL ~ 50ng/mL, the Liner Correlation Coefficient(R) value should be ≥0.990.

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

1) Use the company's internal control accuracy reference product C1: 0.5ng/ml to detect, and the analyzer's measurement range is 0.5ng/ml±15% at 15 minutes;

2) Use the company's internal control accuracy reference product C2: 10ng/ml to detect, and the analyzer's measurement range is 10ng/ml±15% at 15 minutes;

5. Intra-Lot precision
Use the company's internal control precision reference materials (C9: 0.5ng/ml, C10: 10ng/ml) to perform 10 parallel tests each, and measure with the analyzer at 15 minutes. The coefficient of variation of the concentration value CV ≤ 15%.

6. Inter-Lot precision
For three batches of kits, use the company's internal control precision reference materials (C9: 0.5ng/ml, C10: 10ng/ml) to perform 10 parallel tests each, and measure with the analyzer at 15 minutes. The coefficient of variation of the concentration value 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 ≤ 0.02ng/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 instrument should be less than 0.02ng/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.

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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:
Dezhou Guoke Medical Technology Co., Ltd
Add.: 28-31 axis, 1 and 2 span, No.2 workshop, (Zhongyuan Science and Technology Innovation Park) No. 6596 Dongfanghong East Road, Yuanqiao Town, Economic and Technological Development Zone, Dezhou City, Shandong Province,China
E-mail: office@guoke-medical.com

European Authorized Representative:
Riomavix S.L.
Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain
E-mail: riomavix@gmail.com