Instruction for Procalcitonin (PCT) Test Kit (Immunofluorescence)

1. Product Name

Generic name: Procalcitonin (PCT) Test Kit (Immunofluorescence)

Trade name: PCT

2. Package

Specification 1: 25T/kit   REF: 52026007

Specification 2: 50T/kit   REF: 52027007

3. Intended Use & Indication

For in vitro quantitative determination of procalcitonin (PCT) content in human serum, plasma or whole blood. It is mainly used in clinical auxiliary diagnosis of bacterial infectious diseases. Products for professional use only.

4. Test Principle

When the test sample is added to the sample port on the test card, PCT in the sample combines with antibody coated on a glass fiber and coupled with fluorescent particles to form fluorescent particles - antibody - antigen complexes. This immune complex reaches to the test area (T) along the nitrocellulose membrane and combines with the pre-coated monoclonal antibody of mouse anti-PCT, its fluorescence intensity is proportional to the PCT content in the sample, the remaining fluorescent antibody particle reaches to the quality control area (C) and combines with pre-coated goat anti-mouse IgG.

5. Main Components& Additional required equipment

The test kit consists of test card, magcard, whole blood buffer and the instruction.

(1) The test card consists of the card housing and test strip. Test strip contains a sample pad, glass fiber (coated with fluorescent particles-PCT antibody conjugates), nitrocellulose (NC) membrane (test area (T) is coated with PCT monoclonal antibody, quality control area (C) is coated with goat anti-mouse IgG), absorbent paper and PVC plate.

Diagram is as follows:
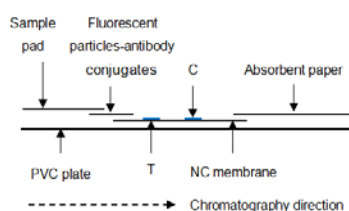
Schematic diagram of test strip

(2) Magcard: load calibration curve information for reagents .

(3)Whole blood buffer: the main component is phosphate buffer (PBS).

(4) Equipment: Applicable to FA50/FA120 Quantitative Immunoassay Analyzer manufactured by Genrui Biotech Inc.

6. Accessories Required But Not Provided

(1) Pipettes and pipette tips: 100 μL.

(2) Timer.

7. Special storage &Transport conditions

(1) The test kit can be stored at 2-30℃, aluminum foil bag in a sealed state is valid for 18 months , once opened, it is valid for 1 hour.

(2) Transport at 2-30℃.

8. Sample Requirements

(1) The optimal sample is fresh non-hemolyzed serum, plasma or whole blood. Recommended to use venous blood, results of other body fluids and samples may not be accurate.

(2) Complete the sample test within 24h at room temperature after the sample is collected. Keep serum and plasma refrigerated at 2-8℃ for not more than 7 days and frozen below -18℃ for not more than 1 month. Whole blood sample should not be frozen, store it at 2-8℃ for not more than 7 days.

(3) Bring the samples to room temperature before the test. Frozen samples need to be melted completely, re-warmed and mixed before use, avoid repeated freezing and thawing.

(4) Human serum or plasma is recommended to be used for testing. EDTA is recommended to be used as the coagulant.

9. Test Method

Carefully read the reagent instruction before using the test kit and strictly operate according to the instruction to ensure reliable results. Bring all reagents to room temperature (18-25℃) before use.

(1) Startup: Click "STD Mode" in the main menu to enter the measurement interface, click "Item" to select the desired test item and click "Type" to select the sample type.

(2) Click "Lot No." to enter the card swiping interface, place magcard of the corresponding item to the magnetic induction zone, when hearing a "di" sound, the magcard is swiped successfully, check whether the magcard and the test card are of the same batch. (Note: reagents are precalibrated and specific calibration curve parameters for each batch of reagents have been stored in the magcard.)

(3)Sampling:

a) Serum/Plasma: Take 100μL serum or plasma, drop vertically to the sample port on the test card directly and start timing.

b) Whole blood: Take 100μL whole blood, drop vertically to the sample port on the test card directly, then add one drop of whole blood buffer to the sample port and start timing.

(4) Insert it into the analyzer's test slot (the sample port end toward the inside). Click "Measure", the instrument will automatically detect and print out the results after 15 minutes(If using "Fast Mode", Keep it for 15 minutes and quickly Insert it into the analyzer's test slot).

10. Reference Value

Reference range: < 0.5 ng/mL.

11. Explanation for Test Results

(1) When the control area (C) appears fluorescent strips, the analyzer will automatically detect the fluorescence and analyze the test card, and then provide quantitative results.

(2) When the control area (C) does not appear fluorescent strips, the analyzer cannot detect the fluorescence and alarm automatically, indicating that the operation is incorrect or the test card is damaged, in this case, carefully read the instructions again and re-test with a new test card, if the problem still exists, immediately stop

using products of this batch and contact your supplier.

(3) When the sample test results are greater than 100 ng/mL, the instrument displays > 100 ng/mL, when the test results are less than 0.1 ng/mL, the instrument displays < 0.1 ng/mL. The former can be diluted with saline water by an integer multiple before testing, multiply the result by the dilution ratio.

(4) This test kit does not produce Hook effect within 1000 ng/mL.

12. Detection limit

(1) This test kit is for in vitro diagnostic use only.

(2) Diagnosis and treatment can not only rely on this test result, taking into account the clinical history and other laboratory test results. Each laboratory is recommended to establish its own reference range based on the detected patient population.

13. Interfering substance

(1) Hemoglobin, bilirubin, cholesterol, triglycerides, HAMA antibody and rheumatoid factor in samples can interfere with the test results, the maximum allowable concentrations of hemoglobin is 5 g/L, bilirubin is 2 mg/mL, cholesterol is 15 mg/mL, triglycerides is 30 mg/mL, HAMA antibody is 40 ng/mL, rheumatoid factor is 525 IU/mL.

14. Product Performance Indicators

(1) Analysis sensitivity: ≤ 0.1 ng/mL

(2) Linearity range: 0.1-100 ng/mL (Linear correlation coefficient: r ≥ 0.990)

(3) Measurement precision: Repeatability: CV ≤ 15%, relative deviation of test kit's inter batches (R) ≤ 15%

(4) Accuracy: -15% ≤ Bias% ≤ +15%.

(5) The Interference test result: -15% ≤ Bias% ≤ +15%.

15. Precautions

(1) Once opened, use the test cards as soon as possible, which may cause moisture. Do not re-use the test cards.

(2) Components in test kit of different batches cannot be used interchangeably.

(3) For substances containing sources of infection or suspected of containing sources of infection, there should be proper bio-safety assurance procedures. Pay attention to the following matters:

a) Wear gloves when handling sample or reagent for disinfection.

b) Disinfect spilled sample or reagent with disinfectant.

c) Disinfect or handle potential contamination sources of all samples or reagents in accordance with local regulations.

16. Explanation of graphic symbol

📖	Consult Instructions for use	🌡	Temperature Limitation
LOT	Lot No.	⧗	Expiry Date
IVD	In Vitro Diagnostic Reagent	CE	CONFORMITE EUROPEENNE

�	Production Date	☣	Biohazard
🏭	Manufacturer	🔋	Volume
Σ	Contains sufficient for < n>tests	☀	Keep away from sunlight
⊘	Do not re-use	☂	Dark dry preservation
EC REP	Authorized representative in the European community	REF	Catalogue number

17. Reference

(1) Simon P, Milbrandt EB, EmLet LL. Procalcitonin-guided antibiotics in severe sepsis. Crit Care. 2008; 12(6): 309.

(2) Simon L, Gauvin F, Amre DK et al. Serum procalcitonin and C-reactive protein levels as markers of bacterial infection: a systematic review and meta-analysis. Clin Infect Dis. 2004, 39(2): 206-217.

(3) Meisner M. Procalcitonin (PCT)-A new innovative infection parameter. Biochemical and clinical aspects, Thieme Stuttgart, New York 2000, ISBN: 3-13-105503-0.

18. Metrological traceability

The kit was traced to the Procalcitonin (PCT) Test Kit, Producted by Roche Diagnostic GmbH.

19. Help Information

If you need help please contact after sales.

20. Manufacturer

🏭 Genrui Biotech Inc.

Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China.

Web: www.genrui-bio.com

21. Instruments & Applications

Genrui's Immunofluorescence products, designed to work in automated lab environment, which are compatible with the FA50/FA120 Quantitative Immunoassay Analyzer. There may or may not be an application developed for you particular instrument, please visit the instrument section of our website.

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