Diagnostic Kit for procalcitonin（Immunochromatographic assay）

User manual

【Product Name】

Diagnostic Kit for procalcitonin（Immunochromatographic assay）

【Packing Specification】

25 Tests/kit、40 Tests/kit

【Intended Use】

The product is used to determine the content of procalcitonin (PCT) in whole blood, plasma and serum of human body and is mainly used clinically for auxiliary diagnosis of bacterial infectious diseases.

【Test Principle】

The kit uses immunochromatographic assay. First, PCT antigen in the sample combines with the fluorescently-labeled PCT monoclonal antibody conjugate. Then, it continues to move and combines with another PCT monoclonal antibody fixed on the nitrocellulose membrane to form double-antibody sandwich immune complex in the position of the nitrocellulose membrane test line and analyze and obtain quantitative test result using NIR-1000 dry fluoroimmunoassay analyser.

【Main Ingredients】

Name	Loading capacity	Ingredient
Test card	25/40	The product consists of fluorescent mat (coated with fluorescently-labeled PCT monoclonal murine antibody), nitrocellulose membrane (coated with PCT monoclonal murine antibody and goat anti mouse IgG antibody), absorbent paper and bottom lining, and so on.
Sample diluent	25/40	Phosphate buffer
ID card	1	Record standard curve information of this batch of reagents

Ingredients of kits of different batch numbers cannot be exchanged.

【Storage Conditions and Validity】

The product should be stored at 4℃-30℃ in a dry and dark place, sealed using aluminum foil bag and must not be frozen. The storage life is 18 months. The test card should be unpacked at room temprature (15℃-30℃) and should be used in 15min after unpacked at a temperature of (15-30)℃ and relative humidity of 20%-90%.

See outer packing for production date, batch number and expiry date.

【Applicable Instrument】

Mod:NIR-1000 Dry Fluoroimmunoassay Analyser produced by WWHS Biotech.Inc.

【Sample Requirements】

1. Samples tested by the product include serum and EDTA·Na_2 anticoagulant plasma, EDTA·K_2 anticoagulant plasma, sodium citrate (anticoagulant tube with sodium citrate: blood=1:9) anticoagulant plasma, EDTA·Na_2 anticoagulant whole blood, EDTA·K_2 anticoagulant whole blood, and sodium citrate (anticoagulant tube with sodium citrate: blood=1:9) anticoagulant whole blood.
2. Collect venous blood using coventional laboratory method. Clinical samples should be tested at room temperature (15℃-30℃) in 4h after collected. Whole blood specimens can be stored at (2-8)℃ for 24h; serum or plasma specimens can be stored at (2-8)℃ for 7 days and at -20ºC for 30 days.
3. The sample must be rewarmed to room temperature (15-30)℃ before test. Frozen samples should be completely melted, rewarmed and mixed before use and should not be frozen repeatedly.
4. Please do not test samples of severe hemolysis, severe lipoidemia and icterus.

【Test Method】

1. Please thoroughly read the specification before test. Frozen test card and sample should be placed at room temperature (15-30)℃ for at least 30min before use.
2. Start NIR-1000 dry fluoroimmunoassay analyser and verify quality control according to the specification. (Note: Reagent has been calibrated in advance and calibration curve parameters of each batch of reagents have been stored in the information card. Insert the information card before use and carry out test without re-calibration after passing quality inspection; otherwise, identify the cause before test.)
3. Take out the test card from the aluminum foil bag and use it within 15min
4. Place the test card on a clean horizontal table top and label it.
5. Serum, plasma or whole blood specimen: Take 100μL of sample and add it into 300μL of buffer solution (1:3). Then, mix the solution evenly, take 100μL of the solution and add it into the test card well.
6. Insert the test card into NIR-1000 dry fluoroimmunoassay analyser and press 【Fixed time test】 to keep time for 10min automatically. The analyzer will judge and read the test result automatically and display it in the screen. Or insert the test card into the analyzer after 10min and press 【Instant test】, the instrument will judge and read the test result automatically.

【Reference Interval】

Determine 254 healthy people aged 18-68 and carry out statistical analysis. Result shows that the upper limit of the reference value is 0.5ng/mL at the 95^{th} percentile, so the reference interval is less than 0.5ng/mL.

The laboratory should establish a reference range according to characteristics of local people.

【Interpretation of Test Results】

1. The kit can be used for auxiliary test only. If test result is abnormal, retest timely and judge combined with clinical symptoms.
2. For samples whose PCT concentration is lower than 0.2ng/mL and higher than 100ng/mL, test result is "＜0.2ng/mL" and "＞100ng/mL" respectively.

【Limitation of Test Method】

1. The kit can be used to test whole blood, plasma and serum specimens of human body only.
2. Due to limitations of serological methods for antigen and antibody response, the test result cannot be used as the only basis for clinical diagnosis and should be evaluated together with all existing clinical and experimental data.
3. The content of triglyceride contained in the sample is no more than 10mg/mL, that of hemoglobin is no more than 6mg/mL and that of bilirubin is no more than 0.6mg/mL, and the relative deviation is limited to ±15%.
4. When PCT concentration of samples is less than 250ng/mL, Hook effect is not observed.
5. When human anti mouse concentration of samples is less than 50ng/mL, HAMA effect will not be observed.
6. When RF concentration of samples is less than 2000 IU/mL, the test result will not be affected.

【Product Performance Indicators】

1. Detection limit

Test 5 low-value samples whose concentration is approximate to LOD (0.2ng/mL) 5 times respectively and sort the test results. There should be no more than 3 test results lower than the blank value (0.12ng/mL).

2. Accuracy

The relative deviation to the target value is limited to ±15%.

3. Precision

Within-run precision CV≤15%; between-run relative limit R≤15%.

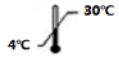
4. Linearity range

Within the specified linearity range (0.2-100) ng/mL, linearly dependent coefficient r≥0.990.

【Precautions】

1. The kit can be used for in vitro diagnosis only.
2. Test card is single-use and it cannot be reused.
3. Please inspect packaging integrity and validity of kit before use and then unpack the product. If the product is stored at low temperature, restore to room temperature (15℃-30℃) before unpacking and use. Reagent cannot be used if packaging is damaged and the validity period expires.
4. Take the test card out of the aluminum foil bag and carry out experiment in 15min. Do not place it in the air for a long time to avoid dampness.
5. It is required to strictly comply with the requirements for sample collection and storage. If the sample is turbid, please centrifuge and precipitate it before use.
6. The kit contains products from animals. Eligible information about animal source and sanitary condition cannot absolutely ensure inexistence of infectious pathogen. Therefore, these products should be disposed of as latent infective material, and all samples, reagents and latent contaminants should be disinfected and disposed of according to relevant local regulations.
7. Too high or too low hematocrit of red cells may affect whole blood test result, so verification should be conducted using other methods .

【Interpretation of Signs】

	Temperature limit		Do not re-use
	Keep away from sunlight	IVD	In vitro diagnostic medical device
	Keep dry		Consult instructions for use

【References】

[1] Ding Ning, Yu Xuezhong, et al. Expert Consensus on Clinical Application of Procalcitonin (PCT) in Emergency Treatment [J]. Chinese Journal of Emergency Medicine, 2012, 21(9): 944-951.

[2] Zheng Pingrong. Rational Use of Antibiotics. Clinical Rational Drug Use, 2010, 3 (10): 80.

[3] Li Bo, Du Zengqing. Ni Linxian. Research on Application of Procalcitonin (PCT) in Diagnosis of Paediatric Central Infectious Diseases [J]. Chinese Pediatric Emergency Medicine, 2003, 10(3): 154-155.

【Basic Information】

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