Procalcitonin (PCT) Assay Kits (Lateral Flow Immunoassay)

User Manual

【Product Name】
Procalcitonin (PCT) Assay Kits (Lateral Flow Immunoassay)

【Intended Use】

The PCT Assay Kits is used to quantitatively test the concentration of PCT in whole blood, serum or plasma. PCT is a peptide precursor of the hormone calcitonin, the latter being involved with calcium homeostasis. It is composed of 116 amino acids and is produced by para follicular cells(C cells) of the thyroid and by the neuroendocrine cells of the lung and the intestine.

The level of procalcitonin in the blood stream of healthy individuals is below the limit of detection (0.01 g/L) of clinical assays. The level of procalcitonin rises in a response to a pro inflammatory stimulus, especially of bacterial origin. In this case, it is produced mainly by the cells of the lung and the intestine. It does not rise significantly with viral or non-infectious inflammations. With the derangements that a severe infection with an associated systemic response brings, the blood levels of procalcitonin may rise to 100g/L. In serum, procalcitonin has a half-life of 25 to 30 hours. Remarkably the high procalcitonin levels produced during infections are not followed by a parallel increase in calcitonin or a decrease in serum calcium levels.

【Principle】
Lateral Flow Immunoassay: Adopt method of double mono-cloned antibody. PCT polyclonal antibody (T line) and rabbit anti-mouse IgG (C line) were coated on the NC membrane, and the fluorescein labeled PCT monoclonal antibody were coated on the conjugate pad. After the sample was added, the PCT react with the antibodies to form immune complexes. The concentration of immune complexes have positive correlation to the concentration of PCT in the sample. Through the standard curve achieved by scanning the RFID card with the FA series analyzer, the concentration of the PCT in the sample can be calculated.

【Packing Specification and Components】

Component	Packing Specification			
	10 Tests / Kit	25 Tests /Kit	50 Tests /Kit	100 Tests /Kit
Test Cartridge (contains a plastic straw, a desiccant, a test cartridge: PCT Polyclonal antibody, Rabbit anti- mouse, PCT Monoclonal antibody labelled fluorescein)	10pcs	25pcs	50pcs	100pcs
RFID Card	1pc	1pc	1pc	1pc
User Manual	1pc	1pc	1pc	1pc

【Storage and Shelf Life】

Stored the reagent kits at 4~30°C, in sealed aluminium foil bag;
Shelf life: 18 months;
Open-bag shelf life: 1 hour. Especially under condition of high temp or high humidity, it should be used immediately after open the package.
Use the reagent kit before expiration date marked on the box.

【Applicable Instrument】
FA series Lateral Flow Immunoassay Analyzer.

CE

【Sample Requirements】

1. The reagent kit apply to test serum.
2. Adopt common method of clinical laboratory to collect blood samples, it should be tested within 72 hours (Stored under condition of 2~8°C), or it needs to stored for one month maximum under condition of -20°C, avoid freezing and thawing over and over again.
3. Samples should be recovered to room temperature before test;
4. Samples should not be severe hemolysis, severe lipidemia or jaundice samples.

【Operation Step】

1. Sample assay

- Recover samples to the room temperature at first;
- After power on, take out the RFID card and put it on the Lateral Flow Immunoassay Analyzer, which will read the information from RFID card. Both the test item and lot number information should match the assay kits;
- Take out the test strip, add 100 μL sample to the load hole;
- Place the reagent test card with the sample added to any idle incubation channel, select the item to be tested. After the reagent test card were incubated at 37°C for 15 minutes, the corresponding incubation "Done" will appear on the channel display. Remove the reagent test card to the detection channel immediately, and press the "Test" button to perform sample test analysis.

2. Quality Control

There is no QC material in reagent kit of the product. It's suggested to use third party QC material. It's allowed that the testing results are in the range of reference range of the third party QC.

【Reference Range】

Reference range: < 0.5 ng/mL.

The reference value is measured a number of cases in the normal content of PCT in serum samples, based on the mean value X +2SD to be the upper limit. Recommends that each laboratory establish its own reference range according to the tested groups of patient.

【Limitation of Test Method】

1. Test result is used to auxiliary diagnosis; Appropriate clinical treatment should be taken in combination with clinical manifestations, medical history and other diagnostic results.
2. Severe hemolysis, severe hyperlipidemia or jaundice of the sample will cause inaccurate results. Samples with severe hemolysis (hemoglobin≥600 mg/dL), severe lipidemia (triglyceride≥4000 mg/dL), severe jaundice (bilirubin≥20 mg/dL), please do not test them.
3. Samples with high concentration of heterophilic antibodies or rheumatoid factor may lead to false positive results. Therefore, other clinical symptoms should be take into consideration to make a conclusion.

【Performance Indicators】

1. Limit: the lowest limit ≤ 0.1 ng/mL;
2. Measurement Range: 0.1~100.0 ng/mL.Correlation coefficient (r)≥0.9900;
3. Accuracy: For standard calibrator, bias between real concentration and standard concentration is ±15％;
4. Intra-assay precision: low level CV≤15%, high level CV≤10%;
5. Inter-assay precision: low level CV≤15%, high level CV≤10%.

【Precautions】

1. Only for In-Vitro Diagnostic.
2. Please follow the instructions in use manual strictly. Test strip should be used within 1 hour once removed package, tested strip should be read timely after 15 minutes incubation finished, or the result will be invalid.
3. The resource material of test strip has been inactivated at 60°C, and HBsAg, anti-HCV, anti-HIV(1&2), anti-TP has been tested negative which was approved by CFDA; But there is no test method to be absolute safe. Since all the samples that are taken from human blood, the samples and test strips should be treated as potentially infectious source and disposed according to local regulation.
4. Different lot number of reagents and RFID cards cannot be mixed.
5. The test strip and pipette are for one-time disposable use only.
6. The components of different lot of reagent cannot change.

CE

【Literature References】

[1] Santry C.Commissioning. PCT talenttobe assigned toconsortia[J]. *HealthServJ*,2010,120 (6233):4-5.
[2]Charlotte S. Reform. PCT chiefsfight lossofaccount ability statusand right toredundancy[J]. *Health Serv J*, 2011, 121 (6243):4-5.

【Symbol explanation】

Symbol	Interpretation of symbols
	manufacturer
	Authorized representative in the European Community
	Date of manufacture
	Expiration date
	Lot number
	Temperature limit
	Consult instructions for use
	For In Vitro Diagnostic Use
	Contains sufficient for <n> tests
	Catalog number
	CE marking of conformity

【Manufacturer's information】

Shenzhen Lifotronic Technology Co., Ltd.
Unit A, 4th Floor, Building 15, Yijing Estate, No.1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R.China
Mail：service@lifotronic.com;

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel.+49-40-2513175 Fax.+49-40-255726

【Version and Modification Date】

Version: 3.0
Modification Date: 2020.09.16