C-reactive Protein (CRP) Assay Kits (Lateral Flow Immunoassay)

User Manual

【Product Name】

C-reactive Protein (CRP) Assay Kits (Lateral Flow Immunoassay)

【Intended Use】

The CRP Assay Kits is used to quantitatively measurement of the content of CRP in whole blood, serum, plasma.

CRP is a kind of acute phase protein, is an acute phase reactant produced by liver when it happens acute inflammation. Apply to predict CVD and test whether it has infection and inflammation.

【Principle】

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

【Packing Specification and Components】

Component	Packing Specification			
	10Tests / Kit	25Tests / Kit	50Tests / Kit	100Tests / Kit
Test Cartridge (contains a plastic straw, a desiccant, a test cartridge: CRP Polyclonal antibody, Rabbit anti- mouse IgG, CRP Monoclonal antibody labeled fluorescein)	10pcs	25pcs	50pcs	100pcs
Sample diluent	10 bottles	25 bottles	50 bottles	100 bottles
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.

【Sample Requirements】

1. The reagent kit apply to test serum, plasma (EDTA anticoagulant) or whole blood (EDTA anticoagulant).
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 under condition of -20°C, avoid freezing and thawing over and over again.
3. Samples should be with the room temp before test.
4. Samples should not be severe hemolysis, severe lipidemia or jaundice samples.

【Applicable Instrument】

FA series Lateral Flow Immunoassay Analyzer.

【Operation Step】

1. Sample assay

- Recover samples to the room temp 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 20uL sample into Sample diluent, After mixing for 1min，Use pipette to add 100uL mixing sample diluent 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 3 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: < 10.0 mg/L.

The reference value is measured a number of cases in the normal content of CRP in whole blood 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 or 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 ≤ 1.0 mg/L;
2. Measurement Range: 1.0 ~240.0mg/L.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 can not be mixed.
5. The test strip and pipette are for one-time disposable use only.
6. The instrument cannot be used to tumor diagnosis.

【Literature References】

[1] Jun Xu, et al. Progress of test method and clinical application for Hypersensitivity C-reactive Protein[J]. *Experimental and Laboratory Medicine*, 2011,29(6): 620-622.

[2] Na Song, et al. Comparison of two test method for C-reactive Protein[J]. *Laboratory Medicine*,2012,4: 257-260.

【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;

EC REP 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

CE