D-dimer Assay Kit (Lateral Flow Immunoassay)

User Manual

【Product Name】

D-dimer Assay Kit (Lateral Flow Immunoassay)

【Intended Use】

The D-dimer Assay Kit is used to quantitatively determine the contentration of D-dimer in plasma sample. D-dimer is a fibrin degradation product (or FDP), a small protein fragment present in the blood after a blood clot is degraded by fibrinolysis. It is so named because it contains two crosslinked D fragments of the fibrin protein. D-dimer concentration may be determined by a blood test to help diagnose thrombosis. Since its introduction in the 1990s, it has become an important test performed in patients with suspected thrombotic disorders. While a negative result practically rules out thrombosis, a positive result can indicate thrombosis but does not rule out other potential causes. Its main use, therefore, is to exclude thromboembolic disease where the probability is low. In addition, it is used in the diagnosis of the blood disorder disseminated intravascular coagulation.

【Principle】

Lateral Flow Immunoassay: Adopt method of double mono-cloned antibody. D-dimer polyclonal antibody (T line) and rabbit anti-mouse IgG (C line) were coated on the NC membrane, and the fluorescein labeled D-dimer monoclonal antibody were coated on the conjugate pad. After the sample was added, the D-dimer react with the antibodies to form immune complexes. The concentration of immune complexes have positive correlation to the concentration of D-dimer in the sample. Through the standard curve achieved by scanning the RFID card with the FA series analyzer, the concentration of the D-dimer 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 dropper, a desiccant, a test cartridge: D-dimer Polyclonal antibody, Rabbit anti- mouse IgG, D-dimer Monoclonal antibody labeled fluorescein)	10pcs	25pcs	50pcs	100pcs
RFID Card	1pc	1pc	1pc	1pc
Sample diluent	10 vials	25 vials	50 vials	100 vials
User Manual	1pc	1pc	1pc	1pc

【Storage and Shelf Life】

Stored the assay kit 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 assay kit before expiration date marked on the box.

【Sample Requirements】

1. The assay kit applies to test plasma (citric acid 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 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. Do not test severely hemolysis, severe lipidemia or jaundice samples.

【Applicable Instrument】

FA series Lateral Flow Immunoassay Analyzer.

【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 kit;
- Add 100 μL sample into vial containing sample diluent, mix well and let stand on bench for 1min;
- Remove test cartridge, use plastic dropper to add 100 μL mixed sample to the sample well of test cartridge;
- Place the test cartridge with the sample to incubation channel, select the item to be tested. After the test cartridge were incubated at 37°C for 10 minutes, the corresponding incubation "Done" will appear on the channel display. Remove the test cartridge to the detection channel immediately, and press the "Test" button to perform sample test analysis.

【Reference Range】

Reference range: < 0.5 mg/L.

The reference value is measured a number of cases in the normal content of D-dimer in clinical 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 patients.

【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 emolysis (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≤ 0.1 mg/L;
2. Measurement Range: 0.1 mg/L-10.0 mg/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≤12%;
5. Inter-assay precision: low level CV≤15%, high level CV≤12%.

【Precautions】

1. Only for In-Vitro Diagnostic.
2. Please follow the instructions in use manual strictly. Test cartridge should be used within 1 hour once removed package, tested cartridge should be read timely after 10 minutes incubation finished, or the result will be invalid.
3. The resource material of test cartridge 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 are derived from human blood, the samples and test cartridge should be treated as potentially infectious source and disposed according to local regulation.
4. Different lot number of assays and RFID cards can not be mixed.
5. The test cartridge and plastic dropper are for one-time disposable use only.
6. The instrument cannot be used to tumor diagnosis.

【Literature References】

[1] Shijie Gu, LinY. Current knowledge and clinical application of D-dimer[J]. *Journal of Tianjin medical university*,2013,1.

[2] Mei Wang, Jinliang Wang. Clinical application progress of test of D-dimer[J]. *Journal of tianjin medical university*,2011,1.

【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

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