Instruction for Fibrinogen Degradation Product (FDP) Detection Kit (Nephelometry)

【Product Name】

Generic name: Fibrinogen Degradation Product (FDP) Detection Kit

Trade name: FDP

English name: Fibrinogen Degradation Product (FDP) Detection Kit

【Package】

Specification 1: 25T/kit	REF: 32026051
Specification 2: 2X25T/kit	REF: 32080051
Specification 3: 50T/kit	REF: 32027051
Specification 4: 100T/kit	REF: 32028051
Specification 5: 150T/kit	REF: 32029051
Specification 6: 200T/kit	REF: 32030051
Specification 7: 250T/kit	REF: 32031051
Specification 8: 300T/kit	REF: 32032051

【 Intended Use】

The kit is used for the in vitro quantitative determination of FDP in human serum.

Clinically used to assist in the diagnosis of primary and secondary fibrinolytic hyper function related diseases

【Test Principle】

Once the FDP in the sample meet with its corresponding antibody in the liquid phase, there will be formation of antigen - antibody complex, which have a certain degree of turbidity. The level of turbidity is proportional to the amount of antigen present in the sample. By detecting the reaction change at specific wavelengths and referring to the multi-point calibration curve, the FDP content can be calculated.

【 Main Compositions】

1. Buffer solution: phosphate buffer 20mmol/L, sodium chloride 15.8g/L, PEG6000 4%
2. Antiserum: Anti-human FDP antibody latex particles.
3. Quality control product (optional): FDP-contained solution. Refer to the bottle stickers for specific target value.
4. Magcard: Load the calibration curve information of this batch
5. Stirrer: stainless steel

【Accessories Required But Not Provided】

1. Pipettor
2. Pipettor tips
3. Reaction cup

【Storage and Validity Period】

The sealed detection kit can be stored at 2-8℃ for 12 months. Do not freeze. Once opened, the reagents stored at 2-8℃ are stable for 30 days. Refer to the label for production date.

【Applicable Instruments】

Applicable for PA50&PA54 Specific Protein Analyzer and PA120& PA200 Fully-auto Specific Protein Analyzer manufactured by Genrui Biotech Inc.

【Sample Requirements】

Fresh human plasma (added with Citrate plasma and heparin plasma). Blood should be timely separated to avoid hemolysis

【Test Methods】

Bring all reagents to room temperature (18-25℃) before the use.

1. Test methods for PA50&PA54 Specific Protein Analyzer

1) After start up, the instrument displays the main measurement interface, select the test item and sample type at the item column (After the confirmation, it will default to this item and sample type in the future.).
2) Click “LOT” at the batch No. column to enter the card-swiping interface. Put the corresponding magcard onto the magnetic induction area, when a “di” sound heard, the magcard was successfully swiped, and the interface returns to the main measurement interface. For the same batch of reagents, no need to swipe the card again.
3) The instrument interface prompts “Input Cup!”
4) Take out one cuvette, put one stirrer into it, and then use the pipettor to accurately add in 300μl buffer solution, then add in 6μl sample.
5) Put the cuvette into the test channel, the instrument automatically stir for one time.
6) The instrument prompts “Please Add Antiserum”, then use the pipettor to accurately add in 100μl antiserum.
7) Immediately press the corresponding channel’s start button, the instrument will stir automatically. When the test finished, the instrument will automatically display and print the test result.
8) After the test, take out the cuvette, the instrument prompts “Input Cup!” do the next test.

2. Fully-auto specific protein analyzer (PA120, PA200) detection methods are as follows

1) Login fully-auto specific protein analyzer PA120, PA200 PC software, put the magcard onto the magnetic induction area, the instrument will prompt the card is successfully swiped for the same batch of reagents, only need swipe the card once.
2) Login the main measurement interface, apply for testing according to the items and sample types to be tested.
3) Put the test sample in place, then put the corresponding reagents at the specified locations and start the test, the instrument will automatically aspirate all the test samples and complete the measurement process. After the test is completed, you can view the measurement results and print the test results.
4) Please refer to PA120, PA200 manual for detailed description of instrument operation method.

【Reference Value】

Reference range: 0-5.0mg/L

It is recommended that the labs establish their own reference range.

【Explanation for the Test Results】

When used for diagnosis and treatment, Comprehensive judgment should be combined with the patient's history, symptoms and other results.

【 Calibration and QC】

1. Calibration

It is recommended to use an internationally recognized calibrator. The calibration period is 30 days. Recalibration is needed when replacing the

batch number of reagents.

2. QC

It is recommended to use normal and pathological values of biochemical quality control serum for indoor quality control, the measured control value should be within the limit, if the control value out of control, the laboratory should take appropriate corrective measures.

3. QC Solution (optional)

3.1 Product Name: FDP QC

3.2 Package Specification

0.2ml/bottle .3.3 Intended Use

Intended for in vitro diagnostic use in the quality control of diagnostic assays.

3.4 Main Composition: FDP antigen

3.5 Storage and Validity Period

The QC can be stored for 12 months at 2-8℃. It is stable for 30 days at 2~8℃ once opened.

3.6 Target and Limitation

Please refer to the label.

3.7 Test Method

The test procedure is same as sample test, please refer to the sample test method above.

【Limitations for the Test Results】

The diagnosis and treatment cannot only depend on this test result, please consider the clinical history and other laboratory test results at the same time. It is suggested that each laboratory builds up its own reference range based on its own patient group.

If the sample's test result is beyond the linearity range, please use distilled water to dilute the sample with integral multiples and re-test. The result should multiply the dilution times.

Bilirubin≤30 mg/dL; ascorbic acid≤20 mg/dL; These values have no effect on the determination

【Product Performance Indicators】

1. Blank limit: ≤2.5mg/L

2. Linearity range: 2.5-80mg/L, determination indicator: r ≥0.990

3. Measurement precision:

Repeatability: CV ≤10%, relative deviation of detection kit's inter batches (R) ≤ 10%

4. Accuracy: Bias% ≤ ±15%

【Precautions】

- Only used for in vitro diagnostic, please refer to the Operation Manual.
- Do not use the expired reagents. Shake the antiserum reagent well before use.
- Do not use reagents of different batches together.
- If accidentally splash the reagent on the human body surface such as skin, eyes, etc., rinse with water immediately, if eating go to hospital.

【Labels】

Label	Meaning
	Date of manufacture
	In vitro diagnostic medical device
	Manufacturer
	Biological risks
	Batch code
	Temperature limit
	Use-by date
	Authorized representative in the European Community
	Volume
	Consult instructions for use
	Do not re-use
	Keep away from sunlight
	Contains sufficient for <n>tests
	Catalogue number
	CE Marking

【Reference】

1. Protein Reference Unit Handbook of Clinical Immunology(1999), Milford Ward A,Riches PG,Fifield R ,SmithAM,Pub1,PRUPublications, Sheffield,UK

2. National clinical testing procedures the fourth edition.

【Manufacturer】

Genrui Biotech Inc.

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【Medical Devices' Manufacturing Permit No.】

Guangdong SFDA (State Food and Drug Administration) authorized Medical Device Manufacturing Permit No. 20041046

【Instruction Approved and Revised Date】

Approved date: May, 08th, 2017

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【Guarantee and Technical Support】

If invalid message repeats or need technical support, please contact Genrui Customer Service and Support Center