Fibrin/Fibrinogen Degradation Products Assay Kit (FDP)

Method: Latex Immunoturbidimetric Method

Cat . No.	Packing Size	Analyzer
EGS8611M	R1:1×60 ml R2:1×22 ml	For Hitachi917& OlympusAU640/400/600
EGB8601M	R1:1×60 ml R2:1×22 ml	For Hitachi 717 &ShimadzuCL7200/8000
EGD8611M	R1: 24×3.6ml R2: 12×2.6 ml	For Siemens Dupont/Siemens Behring Series
EGFDP460 BS	R1: 1×18ml、 R2: 1×6.5ml	For Mindray BS120/180/190/200/220/230/240/430/460/830
EGGFDP	R1: 1×18ml、 R2: 1×6.5 ml	For Semi Auto Analyser

INTENDED USE

For in vitro quantitative determination of Fibrin/ Fibrinogen Degradation Products in human serum or plasma.

CLINICAL SIGNIFICANCE

The Fibrinogen Degradation products (FDP) mainly reflect the fibrinolytic function. Increased in: a) primary fibrinolytic hyperactivity [1]; b) Secondary hyperfibrinolytic hypercoagulability, disseminated intravascular coagulation [2], renal disease [3], organ transplantation rejection, thrombolytic therapy, etc.; c) Vascular embolic diseases [4] (pulmonary embolism, myocardial infarction, occlusive cerebrovascular disease, deep venous thrombosis); d) leukemia after chemotherapy induction stage, hemorrhagic thrombocytosis, uremia, liver disease, etc. [5].

ASSAY PRINCIPLES

The FDP in the sample reacts with the FDP antibody coated with latex particles to form turbidity, resulting in the increase of absorbance. The change of absorbance is detected at 600nm, and the degree of change is proportional to the concentration of FDP.

REAGENT COMPOSITION

Contents	Concentration
Reagent 1 (R1)	
Tris buffer	50mmol/L
Reagent 2 (R2)	
Latex granules coated with mouse anti-human FDP monoclonal antibody	0.1%

STABILITY AND PREPARATION OF REAGENTS

1. Stable up to the expiry date when the reagent is sealed and stored in dark at 2-8 ℃.
2. Once opened, the reagents are stable for 28 days when refrigerated on the analyzer or refrigerator.
3.The production date and expiry date are shown on the label.

APPLICABLE INSTRUMENT

This kit is theoretically suitable for all biochemistry analyzers and spectrophotometers covering the wavelength range of 600nm.
It is recommended to use this kit on a biochemistry analyzer for testing according to laboratory conditions.

SAMPLE COLLECTION AND PREPARATION

Fresh serum or plasma (EDTA potassium or heparin lithium anticoagulant).
Samples can be kept stable at 2-8℃ for 7 days. -20℃ for 28 days

ASSAY PROCEDURE

Test Condition（Hitachi 917）

Main wavelength	600nm	Sample（S）	5 μl
Secondary wavelength	800 nm	Reagent 1（R1）	180μl
Reaction temperature	37℃	Reagent 2（R2）	65μl
Cuvette diameter	1cm	Reaction type	End-point method

Operate procedure

Add into Cuvette：	
Sample（S）	5μl
Reagent 1（R1）	180μl
Mix well and incubate for 300 seconds at 37℃	
Reagent 2（R2）	65μl
Mix well and incubate for 100 seconds at 37℃,200sec after read final absorbance △A; Calculate △A=A2-A1	

Note: Parameters above are only introduced with Hitachi 917 as an example. The parameters of different biochemistry analyzers are slightly different. Please read the manual carefully before setting parameters.

CALIBRATION

It is recommended to use BSBE calibrator.
1.According to the requirements of the calibration procedure in the operation manual of biochemistry analyzer, each laboratory establishes its own calibration procedure according to the specific conditions.

QUALITY CONTROL

It is recommended to use BSEB control. The absorbance of quality control should be within the labeled value range. If the results deviate from the scope, please find out the reason by following steps:
1. Check the parameter setting and light source.
2. Check the cleanliness of the cuvette and sampling needle.
3. Check whether water is contaminated or not. Bacterial growth can lead to incorrect results.
4. Check the reaction temperature.
5. Check the validity of the kit.

CALCULATION OF RESULTS

According to the specific calibration mode of the project, the instrument will automatically generate calibration curve and calculate the content of the measured object from the change value of absorbance in the sample.

REFERENCE RANGE

Serum : <5μg/mL.
Laboratories are suggested to establish its own reference interval according to age, sex, diet and region.

INTERFERENCE

The effect of rheumatoid factor ≤200IU/mL, bilirubin ≤20mg/dL, Intralipid ≤600mg/dL, hemoglobin ≤ 500 mg/dL is less than 10%

ACCURACY

Compared with competitors, the correlation coefficient r≥0.975,in the range of [2.5， 15.0] μg/mL, the absolute deviation should ≤±1.5 μ g/mL; in the range of (15.0， 80.0] μ g/mL, the relative deviation should ≤±10%.

SENSITIVITY

Beijing Strong Biotechnologies, Inc.
Add: 5/F,KuangYi Building,No.15,Hua Yuan Dong Lu,Haidian District,Beijing 100191,P.R.China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812
Web: http://en.bsbe.com.cn/ Email:overseas@bsbe.com.cn

When the sample concentration is 20.0 μg/mL, the absorbance change should between 0.0100～0.1000.

LINEARITY

In the range of [2.5,80.0] μg/mL,the linearity correlation coefficient r≥0.990， in the range of [2.5,15.0] μg/mL, the absolute deviation should ≤ ±1.5 μg/mL; in the range of (15,80.0] μg/mL, the relative deviation should ≤±10%.

PRECISION

Repeatability precision was obtained by testing control or sample for 20 times of repeated measurement. Intermediate precision was obtained by testing human samples or control for 2 batches 5 days, and each batch was measured for 5 times.The results are as follows:

a）Repeatability Precision （N=20）

	mean （μg/mL）	CV（%）
Level1	10.36	2.5
Level 2	30.15	1.3

b) Intermediate Precision (N=25)

	mean （μg/mL）	CV(%)
Level1	11.34	3.5
Level 2	31.05	1.9

SAFETY PRECAUTIONS AND WARNINGS

1. The reagent contains preservatives. If it enters the eyes, mouth or contact on the skin, please rinse it thoroughly with clean water immediately and go to the hospital if necessary.
2. The reagent contains preservatives, which can react strongly with copper, lead and other metals to form azide metal. Therefore, please dilute the waste liquid and flush the drain pipe to avoid residual when disposal.
3. Opened reagents should be sealed and stored according to the specified method. Expired product should not be used.
4. During testing, do not mix or exchange reagents with different batch numbers.
5. Please dispose of test tubes and other instruments that have been in contact with test specimens according to relevant medical waste treatment regulations. The following treatment options are available:

Sterilization with pressure sterilizer at 121℃ for 15 minutes (but waste containing hypochlorous acid solution should not be treated with pressure sterilizer), or immersion with hypochlorous acid solution (effective concentration is greater than 1000ppm) for more than one hour.

REFERENCES

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2. Yan Cunliang, Peng Liming. J Clin Clin Med, 2003,26(11) : 686-690. (in Chinese with English abstract
3. Hu Jinchuan, Yan Yan, Yang Qi, et al. Clinical significance of serum and urinary fibrinogen degradation products in the diagnosis and treatment of renal diseases [J].2008,12(4)
4. Huang Xianguo, Lu Yizhu, Li Tao. Preliminary analysis of the causes of fibrinogen elevation.2010, 2:111-112
5. Yang C, Tang R H, Liu C S, et al. Clinical analysis of blood coagulation routine and plasma fibrin degradation products in 890 patients. Thrombosis and Hemostasis.2011,1:26-28

INDEX OF SYMBOLS

	Manufacturer
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Beijing Strong Biotechnologies, Inc.
Add: 5/F,KuangYi Building,No.15,Hua Yuan Dong Lu,Haidian District,Beijing 100191,P.R.China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812
Web: http://en.bsbe.com.cn/ Email:overseas@bsbe.com.cn