GB CLOT-FDP
Fibrin and Fibrinogen Degradation Products

GENUINE BIOSYSTEM

Kit contents	Pack size	Cat no.
GB CLOT- FDP Reagent	120T	GBCFDP120T

[Intended Use]

In vitro test for the quantitative determination of fibrin (fibrinogen) degradation product concentration in plasma.

In primary hyper fibrinolysis, the fibrin (fibrinogen) degradation product (FDP) concentration significantly increases. In secondary hyper fibrinolysis caused by hyper coagulable state, disseminated intravascular coagulation, pulmonary embolism, rejection after organ transplantation, pregnancy-induced hypertension, malignant tumor, heart, hepatic and renal diseases, phlebothrombosis, thrombolytic therapy, etc., the FDP concentration increases.

[Principle]

This Reagent uses the Latex-enhanced Immunoturbidimetric Assay to test the fibrin (fibrinogen) degradation product concentration in human plasma. Latex particles of uniform size are coated with monoclonal antibodies to the fibrin (fibrinogen) degradation product. The antigen/antibody complexes produced by the addition of samples containing FDP lead to an increase in the turbidity of the test reactants. The change of absorbance is dependent on the concentration of fibrin (fibrinogen) degradation product in the sample. The precipitate is determined turbidimetrically. The unit of measurement results is mg/L.

[Reagents Composition]

The reagent is composed of R1, R2, calibrator and QC. The main components are as follows:

Reagent 1 (R1) is composed of PBS buffer and surfactant.

Reagent 2 (R2) is composed of PBS buffer, surfactant and latex particles coated with monoclonal anti-human FDP antibodies (mouse). Calibrator (optional): FDP and preservative.

QC (optional): FDP and preservative

The calibrator is from human-derived samples. The FDP concentration is on the calibrator label. The definite value of FDP calibrator can be traced to the SUNBIO calibrator.

[Storage and Stability]

Store at 2-8℃ in the dark. Do not freeze the reagent! The storage life of reagents is 12 months and the storage life of the calibrator and QC is 18 months. Opened reagents are stable for 12 days and the opened calibrator and QC are stable for 24 hours when stored at 2˚C~8˚C.

[Instruments]

This reagent is mainly applicable to the following types of semi-automated or automated biochemical analyzers and coagulation analyzer It is suggested that you verify test results according to the actual situation of the laboratory when using this reagent

[Specimen]

Venous blood is collected in the blood collection tube containing 0.109mol/L sodium citrate of 1/10 volume. Centrifuge the blood, and get the upper plasma. Hemolyzed samples should be avoided. Conduct the test on the date of collection. If the sample collected cannot be tested on the same day, store it at -20˚C (it is suggested to use itwithin one month). Before use, soak it in water at 37˚C for rapid re-dissolution. Never freeze and melt it again.

[Test Procedure]

(1) Test Condition:

Temperature	37˚C	Sample Size	10μL
Main Wavelength	570nm	Volume of R1	150μL
Assay Method	Endpoint Method	Volume of R2	50μL
Delay Time	10s~30s	Test Time	60s~120s
Calibration Mode	Multi-point Nonlinear		

(2) Calibration Procedure:

Use a calibrator supporting the reagent, conduct multi-point nonlinear calibration, dilute the calibrator with physiological saline, and establish a working curve with physiological saline as the zero point.

Tube No.	1	2	3	4	5	6
Stoste : Physiological Saline	Physiological Saline	1: 4	2: 3	3: 2	4: 1	Stoste
Concentration	0.0	X/5	2X/5	3X/5	4X/5	X

Calibration frequency depends on the frequency of use If the lot number of the reagent changes, the instrument is repaired or maintained or the critical component is replaced, the QC results shift or exceed the specified range, etc., recalibration is necessary. Until the QC tests pass again, procedure returns to normal.

(3) QC Procedure

Test the QC supporting the reagent. Only when the test results are in the QC range can the samples be tested. In normal cases, each time a patient's sample is to be tested, the QC selected should be tested at least once. If the lot number of the reagent changes, the instrument is repaired or maintained or the critical component is replaced, the determination results of the QC shift or exceed the specified range, etc., the QC selected should be tested at least once.

The handling procedure to be followed when the determination results of the QC shift or exceed the specified range:1) retest the QC selected; 2) if the determination results are unchanged, consider replacing with a new bottle of QC for redetermination; 3) if the determination results are still unchanged, consider recalibration before determination of the QC; 4) if the determination results are still unchanged, consider replacing with a new bottle (or lot) of reagent for redetermination; 5) if the determination results are still unchanged, consider contacting our Technical Service Department.

4. Calculation:

$$= \frac{\text{Absorbance of Sample tube } A_u}{\text{Absorbance of Calibration tube } A_s} \times \text{Calibrator Concentration (mg/L)}$$

[Reference Values]

0 mg/L~5mg/L (n=210, 95% confidence limit).

Due to the normal and reasonable difference between regions and

individuals as well as the different test methods adopted, the values of FDP concentration may vary. It is suggested that each laboratory establish its own reference values for the population that it serves.

[Interpretation of Test Results]

A professional should audit the test results. Affected by the age, sex, diet and region, the results in the reference interval are usually regarded as normal; if the results exceed the range, re-determination should be conducted for confirmation. The test results reflect the status at the time only, the results should be assessed in conjunction with the clinical and other test indicators. If the test results do not agree or even contradict with the clinical situation, analysis should be conducted to find the causes.

[Limitations of the Procedure]

1 The linear range of the reagent is 2.5mg/L～80mgg/L(37˚C). For a sample exceeding the linear range, dilute it with physiological saline before the test.

2 This assay is affected by many pre-test factors, including sample collection and storage, proficiency of technicians, interfering substances, etc. These factors must be strictly controlled.

[Performance Characteristics]

Linear Range: 2.5mg/L~80mg/L (37˚C). The correlation coefficient (r) should be ≥ 0.990.

Repeatability: CV ≤ 10%.

Lot Tolerance: ≤ 15%.

Accuracy: Relative Deviation ≤ ±15%.

[Notes]

1. The reagent is only for in vitro diagnosis andd operated by medical professionals or trained workers.
2. The volume of the reagent and the sample can be changed proportionally according to the different instrument requirements. Specific setting parameters are available from the manufacturer.
3. Use calibrators supporting this reagent or those recommended to calibrate the instrument.
4. For a reagent of a different lot number, please use the calibrator to conduct recalibration before testing.
5. Do not exchange or mix the components of reagents of different lot numbers. Do not mix reagents newly opened with those used, otherwise the stability of reagents may decrease.
6. The reagents contain chemicals. Do not eat the mistakenly or expose your skin or mucous membrane to them. In case of eye, mouth or skin contact, flush with plenty of clear water, go to the doctor if necessary.
7. The liquid waste from the plasma test presents potential biohazard risk. Personal protections are necessary and dispose the liquid waste in accordance with the local regulations.
8. Kit test results are only as a reference for clinical diagnosis.

[References]

1. Moresco RN, Halla-Junior R, Vargas LCR, et al. Association between plasma levels of D-dimer and fibrinogen/fibrin degradation products(FDP) for exclusion of thromboembolic disorders. J Thromb Thrombolysis, 2006,21:199-202.
2. Rafael Noal Moresco, Luis Claudio Rosa Vargas, Lucia Silla. Estimation of the levels of D-dimer by use fo an alternative method based in the reaction time of fibrinogen/fibrin degradation products assay. Journal of Thrombolysis, 2007, 24(1):73-76.
3. Ye Yingwu and Wang Yusan, National Guide to Clinical Laboratory Procedures (Third Edition), Southeast University Publishing House, Nov. 2006.

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