GB CLOT – FIB
(FIBRINOGEN REAGENT)

Kit contents	Contents	Cat no.
GB CLOT- FIB Reagent	200T	GBCFIB200T

[Intended Use]
It is intended for in vitro determination of Fibrinogen (FIB) concentration in human plasma.

[Principle]
Based on the principle of the Clause clotting Method, in the presence of excessive thrombin, the coagulation time of the diluted plasma for test shows inversely proportional to its fibrinogen concentration in log-log. The time of coagulation is measured on the instrument using the optical nephelometry method, and the fibrinogen concentration is obtained from the standard curve.

[Reagents Composition]
Kit consists of R1, R2, and R3.
R1: FIB Reagent: Bovine thrombin, stabilizer;
R2: Imidazole Buffer: imidazole;
R3: FIB Reference Plasma: Fibrinogen, stabilizer.

[Storage and Stability]
The reagents store at 2-8℃. Do not freeze! The shelf life is 24 months. After opened vials reconstituted and stored at 2～8℃, FIB Reagent is stable for 7 days, FIB Reference Plasma is stable for 8 hours.

[Instruments]
Semi-automated or automated coagulation analyzers

[Specimen]
1. Nine parts of freshly drawn venous blood are collected into one part of anticoagulant and 0.109mol/L trisodium citrate. Centrifuge at room temperature at 3000rpm for 12 minutes. The light yellow liquid on top is the poor platelet plasma for test.
2. Store the plasma at room temperature and test it within 2 hours.
3. If the plasma can't be tested timely, separate with a plastic straw and it is stable for 2 weeks at -20℃. Melt rapidly at 37℃ and gently mix immediately before test.
Refer to CLSI H21 for further instructions on specimen collection and preparation.

[Test Procedure]
1. Preparation of Reagent
Add distilled water to FIB Reagent according to the packing volume stated on the vial label of FIB Reagent, gently shake and mix well, and allow to stand at room temperature (15～25℃) for 15 min. Add 1.0mL distilled water to each vial of FIB Reference Plasma, gently shake and mix well, and allow to stand at room temperature for 15 min.
2. Preparation of Standard Curve
According to the table below, use Imidazole Buffer to dilute Reference Plasma into solutions at different dilution ratios and measure the coagulation time of the diluted plasmas.
Take the dilution ratio of 1:10 as the assigned value of FIB, the theoretical concentration as the y axis, and the corresponding coagulation time as the x axis to prepare the standard curve on the log-log coordinate.

Dilution Ratio	Plasma (μL)	Buffer (μL)	FIB Concentration (g/L)
1:5	50	200	Assigned value × 2
1:10	50	450	Assigned value × 1
1:15	50	700	Assigned value × 2/3
1:20	50	950	Assigned value × 1/2
1:30	50	1,450	Assigned value × 1/3

3. Assay with the semi-automated coagulation analyzer.
Dilute the plasma for test with Imidazole Buffer into 1:10 dilution, i.e. one part of plasma and nine parts of buffer.
Take 100uL diluted plasma and incubate at 37℃ for 3 min.→
Add 50uL FIB Reagent balanced at room temperature and record the coagulation time of the plasma.
* Note: If the plasma is diluted at the ratio of 1:10 and the coagulation time is out of the range of the standard curve, in order to reduce the error, dilute the plasma at the ratio of 1:5 or 1:20 before test, multiply the result by 0.5 or 2, and calculate the actual concentration of FIB.
4. Assay with the automated coagulation analyzer.
Conduct the test according to the operation steps of the automated coagulation analyzer. For the doses of plasma and reagent, refer to the above conditions.
5. Calculation
According to the coagulation time, the FIB concentration can be obtained from the standard curve.

[Expected Values]
2 ~ 4 g/L.
Each laboratory should establish its own reference ranges.
[Interpretation of Test Results]
FIB concentrations are reported in g/L. Test results are associated with the reference ranges of the individual laboratory.
[Limitations of the Procedure]
1. The course of coagulation includes a series of reactions from activation of factors to fibrin formation. Therefore, test results may be affected by therapeutic drugs (interferent), test operations, test systems, etc., which should be considered.
2. Reagent contamination or contamination of sample containers, straws, etc. by blood coagulation reagent may cause blood coagulation disorders, so strict control is required.
3. Too high a FIB degradation product (FDP) concentration may prolong the coagulation time and cause a false low level of FIB.
[Performance Characteristics]
1. Repeatability: The coefficient of variation (CV) of the results of repeated tests with QC plasma should not exceed 5.0% for normal values or 8.0% for abnormal values
2. Difference between Vials: The difference between vials should not exceed 6.0% when QC plasma is used for testing.
3. Linearity: Within the FIB test range, The linear correlation coefficient r should be > 0.98.
[Notes]
1. The product is for in vitro diagnosis and used by persons with major in medical laboratory or trained persons only.
2. During the test, use plastic or siliconized test tubes, straws and syringes only. Do not use those made of common glass.
3. The plasma for test must not be anticoagulated by EDTA, heparin or oxalate.
4. Hemolyzed or lipemic plasma may affect test results.
5. When the batch numbers of reagents or the environmental conditions are changed, prepare new standard curve.
[References]
1. National Guide to Clinical Laboratory Procedures (Third Edition), Southeast University Publishing House, 2006.
2. Grannis GF. Clin Chem. 1970, 16(6):486–494.

IVD CE

Genuine Biosystem Private Limited
Plot 97 & 98, Kattabomman street, Parvathy nagar Extn,
Old Perungalatur, Chennai-600063.TN.India
Ph:044-48681845 , Email:info@gb-group.co.in,
Web: www.genuinebiosystem.com