todylaboratories®

Coagulation Reagents CE

FIB Liquid Kit. Fibrinogen Determination (FIB) Kit liquid

CAT NO	DESCRIPTION	PACK SIZE
C12CR1003	Fibrinogen Determination	5ml, buffer

Intended Use:

It is for the quantitative determination of fibrinogen. Fibrinogen is a circulating plasma protein manufactured by the liver. Thrombin converts fibrinogen to fibrin in the final stage of blood coagulation. Low fibrinogen levels can occur as a result of severe liver disease or due to a disorder such as disseminated intravascular coagulation (DIC). Fibrinogen is quantified by adding thrombin to a series of successively more dilute plasma samples and comparing clotting time to a control series. A coagulation analyzer is used to determine clotting time which will be inversely proportional to the concentration of fibrinogen.

Principle:

Quantitative measurement of fibrinogen is most commonly done using the Clauses technique that involves measuring the clotting time of dilute plasma after the addition of thrombin. At high thrombin concentrations (100IU/ml) and low fibrinogen concentrations, the fibrinogen level is directly proportional to the thrombin clotting time plotted on log-log graph paper.

Materials:

MATERIALS PROVIDED

• R1 (Liquid FIB): Bovine Thrombin (Approximately 100 NIH Units/ml), BSA 0.5%, pH 7.2 ± 0.2 Buffers 5%,0.2% Sodium Azide, Stabilizers.

MATERIALS REQUIRED BUT NOT PROVIDED:

• R2 (FIB Buffer): Imidazole Buffer Solution (IBS): Imidazole buffer in saline solution, pH 7.2 ± 0.2, with 0.2% Sodium Azide as preservative

Test procedures

A. Specimen Collection

1. FIB Reagent is for standby at room temperature.
2. Reconstitute FIB calibration plasma as per quantity marked in vial label with distilled water. Mix well, and keep for 10 min at room temperature before use.

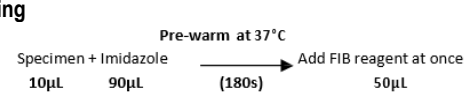
Proportion of calibrator to mixture	Mixture quantity	FIB concentration in mixture	Adding FIB reagent
1:5	100 µL	5.72 g/L	50 µL
1:10	100 µL	2.86 g/L	50 µL
1:20	100 µL	1.43 g/L	50 µL
1:30	100 µL	0.95 g/L	50 µL

B. Fibrinogen calibration

1. Please check FIB concentration marked in vial label. Dilute and prepare different concentration of FIB calibrator with imidazole buffer. Take the concentration of 2.86g/L as an example:

Note: There may be different FIB calibrator concentration at different instrument, the most important is original concentration must be inputted correctly. Regarding calibration parameter setting, please take operator manual as reference.

C. Testing



(a) Pipet 100 µL of mixture (diluted calibrator) into a test tube and pre-warm for 3 minutes at 37°C.

(b) Add 50 µL of Thrombin Reagent and immediately start the timing device.

(c) As for semi-automated coagulation analyzer, record the clotting time and to obtain the average value.

(d) As for semi-automated coagulation analyzer, obtain the clotting times on each concentration of the Fibrinogen Calibrator.

Note: as for semi-automated coagulation analyzer (LG-PABER or LG-PABER-I), count time simultaneously when you add FIB reagent. As for automated coagulation analyzer, it can time clotting automatically

D. Please perform this test according to the appropriate Instrument Operator's Manual

Results:

Standard Curve

1. Use the fibrinogen graph paper to construct the reference standard curve.
2. Plot the mean clotting time for each dilution of the Fibrinogen Calibrator on the Y-axis and the concentration of each dilution on the X-axis. Construct a best-fit straight line using all 4 points.

Test Plasma

1. Plot the mean clotting time of the 1:10 dilution on the reference curve.
2. Interpolate the result by drawing a straight line from the clotting time point down through the X- axis to give the fibrinogen concentration in mg/dl. For plasmas with dilutions of other than 1:10.

i.e.1:20, the concentration read from the curve must be multiplied by the dilution factor. If a dilution of 1:20 was used then 2 to compensate for the dilution must multiply the result.

ATTENTION

1. It is stable for 30 days after opening when stored at 2-8°C
2. Throughout testing all test tubes, syringes and pipettes should be plastic.
3. If blood cell <20% or >55%, then adjust the proportion of the plasma and anticoagulant: anticoagulant= 0.00185 x plasma x (100-patient blood cell.)
4. Each laboratory should establish a Quality Control program that includes both normal and abnormal control plasmas to evaluate instrument, reagent tested daily prior to performing tests on patient plasmas. Monthly quality control charts are recommended to determine the mean and standard deviation of each of the daily control plasma. All assays should include controls, and if any of the controls are outside the established reference ranges, then the assay should be considered invalid and no patient results should be reported.
5. In order to avoid error, suggest re-dilute plasma if test time is beyond the range of standard curve: if the test time is longer than point(dilution: 1:20), dilute as per 1:5, then test again, the result multiplied by 0.5 , if the test time is shorter than point(dilution: 1:5), dilute as per 1:20, then test again, the result multiplied by 2.
6. If reagent plot, instrument and ambient condition are changed, it is suggested that make standard curve again

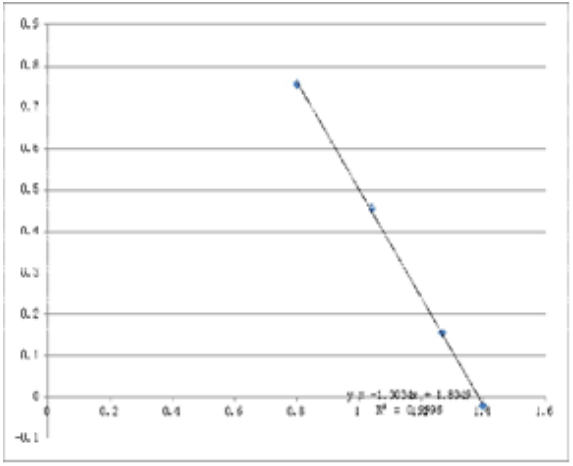
Reference values:

2.0-4.0 g/L

Suggest each laboratory to establish its own control reference range.

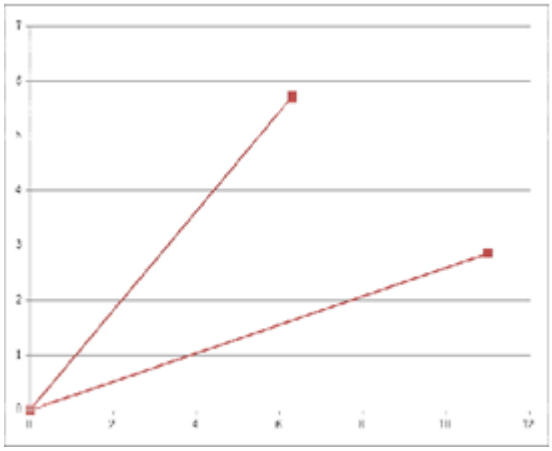
Logarithmic coordinate

Time (s)	Concentration (g/L)	Time (log)	Concentration (log)
6.3	5.72	0.799340549	0.757396029
11	2.86	1.041392685	0.456366033
18.5	1.43	1.267171728	0.155336037
25	0.95	1.397940009	-0.02227639



Curve

Time (s)	Concentration (g/L)
6.3	5.72
11	2.86
18.5	1.43
25	0.95



REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		

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