Atlas Medical

FIB Liquid Kit

Fibrinogen Determination (FIB) liquid kit

IVD For *in -vitro* diagnostic and professional use only

2°C 8°C **Store at 2-8°C** CE

Introduction

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.

MATERIAL

MATERIALS PROVIDED

R1 (Liquid FIB)	1% thrombin, 0.1% sodium benzoate, 1% aminoacetic acid, 1.3% sodium chloride, 0.05% Tris
R2 (FIB buffer) (Optional)	Imidazole Buffer Solution (IBS): Imidazole buffer in saline solution, with Sodium azide 0.2%.
Package Insert	

Packaging Content

- REF **8.02.69.0.0001 (Fibrinogen Reagent Bulk)**
- REF **8.02.69.1.0001 (Fibrinogen Buffer Bulk)**
- REF **8.02.69.0.0005 (1x5mL Fibrinogen Reagent)**
- REF **8.02.69.0.0100 (1x5ml Fibrinogen Reagent, 1x9ml Fibrinogen Buffer)**

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use the test beyond the labeled expiry date.
- Protective clothing should be worn when handling the reagents.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.
- Follow the instructions for use carefully before testing.
- Do not use these reagents if the label is not available or damage.
- Do not use the kit if damaged or the glass vial are broken or leaking and discard the contents immediately.
- Wash hands and test tabletop with water and soap once the testing is done.
- Close the vial tightly after each test.
- Reagents contain 0.2% Sodium Azide which is toxic and can be absorbed through the skin. When drained, the drains should be thoroughly flushed with water.
- Do not freeze and thaw the reagent.
- Do not mix components from kits with different lot numbers.
- All test tubes, syringes and pipettes should be plastic.
- During testing; incubation time should be kept constant and incubation temperature should be maintained at 36.5-37.5°C.
- If spillage of reagent occurs clean with disinfectants (used could be irritable so handle with care).
- Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.
- Control sera are recommended to monitor the performance of assay procedures.
- If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

Specimen Collection

1. A sample of the patient's blood is obtained by venipuncture in a tube with 0.109M sodium citrate as an anticoagulant at a 9:1 ratio. Centrifuge the whole blood specimen at 2500xg for 15 minutes. Aspirate the plasma using a plastic pipette and place it in a plastic test tube. Perform the Prothrombin Time assay within 4 hours.
2. Reconstitute the normal control plasma and abnormal control plasma according to the package insert included within.
3. 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	5.80 g/L	50 µL
1:10	100 µL	2.90 g/L	50 µL
1:20	100 µL	1.45 g/L	50 µL
1:30	100 µL	0.725 g/L	50 µL

TEST PROCEDURES

A. 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 2.90 g/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.

B. Testing

Specimen +	Imidazole	Pre-warm at 37°C →	Add FIB reagent at once
10µL	**90µL**	**(180s)**	**50µL**

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 FIB Reagent and immediately start the timing device.
c) As for semi-auto 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.

RESULTS

A. 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.

B. 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.

Time (s)	Conc.(g/L)	Time (log)	Conc.(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
			-0.99980187

REFERENCE

Reference Range: 2.0-4.0 g/L.

Suggest each laboratory to establish its own control reference range.

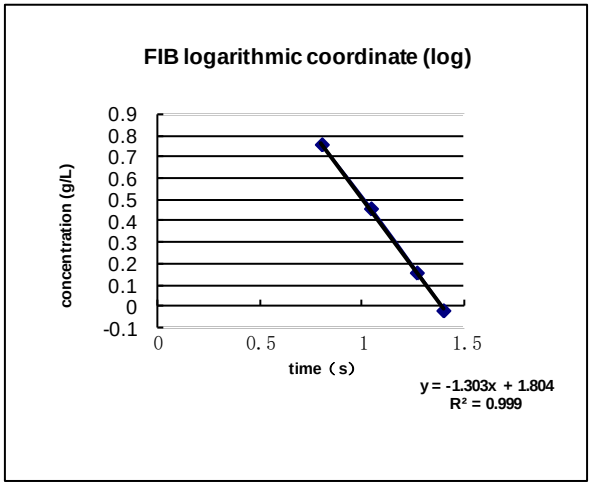
ATTENTION

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.

PERFORMANCE CHARACTARISTICS

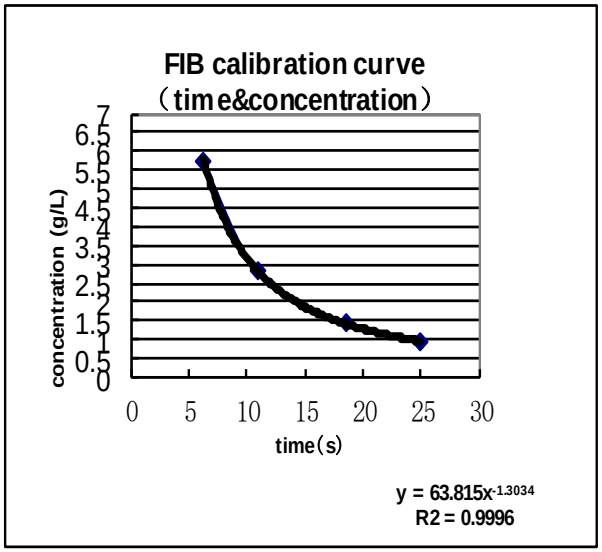
1. **Precision:** The precision (Within Run and Between Run) of FIB reagent has been tested using normal and abnormal controls. The results show that the precision is ≤ 5%.
2. **Accuracy:** Atlas FIB reagent tested using reference materials has a concentration 2-53 g/L three times. The tested result show that relative deviation between the calculated mean and labeled value of reference material does not exceed 15%.
3. **Clinical Study:** Atlas FIB reagent was compared with FIB commercial reagent. The study was performed using 60 samples obtained from two clinical instuations (30 samples from each instituation). The results obtained did not show systematic differences when compared other commercial kits.

LOGARITHMIC COORDINATE



CURVE

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



ATLAS Medical GmbH
Ludwig-Erhard Ring 3
15827 Blankenfelde-Mahlow
Germany
Tel: +49 - 33708 – 3550 30
Email: Info@atlas-medical.com
Website: www.atlas-medical.com

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry