

FIBRINOGEN KIT

Diagnostic Reagent for quantitative in vitro determination of Fibrinogen (Clauss) in human plasma by clotting assay.

REF	Cont.	
T955500	5x 2 mL 3x 1 mL 1x 1 mL 1x 125 mL	Human Thrombin (Iyo.) Coag. Ref. Plasma Normal (Iyo.) Abnormal Coag. Ctrl. Plasma (Iyo.) IBS (Imidazole Buffered Saline)

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Method: Clotting Assay
 Temperature: 37°C
 Sample: Sodium Citrate Plasma

Number of Tests
 100 Tests manual method
 200 Tests micro method
 400 Tests quarter method

REAGENT COMPOSITION

Dialab Fibrinogen reagent is a freeze-dried, highly purified human alpha thrombin in buffered medium with calcium and stabilizer.

Coagulation Reference Plasma Normal
 Freeze-dried pooled human plasma from healthy donors, with stabilizer.

Abnormal Coagulation Control Plasma
 Freeze-dried pooled human plasma, with stabilizer, factors adjusted to be in the abnormal range.

IBS (Imidazole Buffered Saline)
 Sample Diluter

REAGENT PREPARATION

Dialab Fibrinogen reagent is dissolved with distilled water. Amount is indicated on the label. Keep the reagent at 18–25°C for 30 minutes. Swirl the vial gently before use and do not shake. Avoid the contact of fluid with the stopper.

For determination of Fibrinogen on Coagulometers from other companies than DIALAB, please follow the instructions of the manual.

Normal Coagulation Reference Plasma:
 See vial label for assigned Fibrinogen value. Reconstitute individual vial with 1 ml high purity water. Allow to stand at room temperature, with occasional swirling, for 15–20 min before use. Be certain all particulate matter is well dissolved.

Abnormal Coagulation Control Plasma
 Reconstitute individual vial with 1 ml high purity water. Allow to stand at room temperature, with occasional swirling, for 15–20 min before use. Be certain all particulate matter is well dissolved.

IBS (Imidazole Buffered Saline)
 Ready to use.

REAGENT STABILITY AND STORAGE

Dialab fibrinogen reagent in intact vial is stable until the expiration date given on the vial, when stored at 2–8°C.

Stability after reconstitution in the original vial:
 Three days at 22°C, five days at 15°C and seven days at 2–8°C. Do not freeze!

SAMPLE COLLECTION AND STORAGE

DIALAB-FIB requires freshly decalcified plasma. To obtain it, mix nine parts of freshly drawn venous blood with one part trisodium citrate. Mix the blood carefully and centrifuge plasma before testing. Refer to National Committee for Clinical Laboratory Standards (NCCLS) guidelines H3-A3 and H21-A3.

SAMPLE STABILITY AND STORAGE

Storage:	at 2–8°C	at –20°C	at –70°C
Stability:	2 hours	2 weeks	6 months

Freeze only once!

INTERFERING SUBSTANCES

Elevated Fibrin Degradation Products (>30 µg/ml) may result in prolonged clotting times. Further dilution of the test plasma (e.g. 1/20) will reduce FDP interference. Because of Heparin inhibition of Thrombin, prolonged clotting times will result at approximately 5 U/ml Heparin in the undiluted patient sample.

MANUAL TEST PROCEDURE

Calibration curve: Prepare 1:7, 1:10, 1:20, 1:30 dilutions of 0.1 ml Normal Coagulation Reference Plasma using 0.6, 0.9, 1.9, and 2.9 ml IBS respectively.

Samples/Control Plasma Abnormal: Dilute 1:10 in IBS.

Pipette into test tubes	Reference Plasma	Samples/Contr. Pl. Abnormal
Reference Plasma dilutions	200 µl	-
Samples/Contr. Pl. Abnormal	-	200 µl
Prewarm to 37°C for 2 minutes. Add forcibly:		
Human Thrombin (prewarmed to 37°C)	100 µl	100 µl
Note time for clot formation for all dilutions of Reference Plasma, patient samples* and Abnormal Control Plasma.		

*Patient samples should be run in duplicate.
 This Fibrinogen test is also suited for automated assays according to the instructions outlined in the instrument manual.

CALCULATION

Plot the mean clotting time of the double determinations of each dilution of the Reference Plasma in seconds versus assigned concentration values on log-log graph paper. For example, if the calibrated Normal Reference plasma is 240 mg/dl Fibrinogen, the 1:7, 1:10, 1:20, 1:30 dilutions have 34.3, 24, 12 and 8 mg/dl respectively.

Use the average of the patient clotting times and interpolate the Fibrinogen value from the standard curve. Multiply the Fibrinogen value from the curve by Dilution factor (x10) to obtain patient's Fibrinogen value.

REFERENCE RANGE

Typical CT results using a mechanical and photo-optical instrument are shown below. These values should be considered only guidelines as differences will result from different techniques and instrumentation being used by the laboratory.

Dilution	FBG (mg/dl)	CT (sec)
1:7	43	6.1
1:10	30	8.8
1:20	15	17.8
1:30	10	25.3

* It is recommended that each laboratory establishes its own normal range using the reagents, instrumentation and techniques commonly in use in the laboratory.

TEST PRINCIPLE

The Fibrinogen determination utilizes the Clauss clotting time method for the determination of plasma Fibrinogen levels, wherein excess Human Thrombin is used to clot diluted plasma. First, a standard curve is prepared using plasma of known Fibrinogen content, e.g. Normal Coagulation Reference Plasma at dilutions of 1:7, 1:10, 1:20 and 1:30. When Thrombin is added, the clotting time obtained is inversely proportional to the Fibrinogen content. Next, patient plasma, at a dilution of 1:10, is clotted with Thrombin and the resultant clotting time used to interpolate Fibrinogen level from the standard curve.

DIAGNOSTIC IMPLICATIONS

Fibrinogen is a glycoprotein of molecular weight approximately 340 kD. Its presence and intact function has a vital importance for normal blood coagulation. The enzyme Thrombin is the penultimate protein in the clotting sequence, acting upon soluble Fibrinogen and converting it to insoluble Fibrin. The fibrin is stabilized by Factor XIII. Normal plasma Fibrinogen levels range from 200–400 mg/dl, although levels as low as 10–20 mg/dl may occur in acquired or congenital hypofibrinogenemia. The determination of plasma Fibrinogen levels has proven to be a useful test in the diagnosis of hemorrhagic disorders relating to plasma Fibrinogen content. These include hyperfibrinogenemia, hypofibrinogenemia, dysfibrinogenemia and afibrinogenemia.

QUALITY CONTROL

Use Abnormal Coagulation Control Plasma as a check each time a standard curve is prepared. The Control value should be +/- 15% of the assigned value.

REF	Cont.	
T955101	10x 1 mL	Abnormal Coag. Control Plasma

CALIBRATION

Use Normal Coagulation Reference Plasma to set up a Calibration Curve:

REF	Cont.	
T955105	10x 1 mL	Normal Coag. Reference Plasma

WARNINGS AND PRECAUTIONS

- DIALAB Human Thrombin due to its ingredients should be handled with care, observing the precautions recommended for bio hazardous material.
- The reagent contains sodium azide. It can form metallic azides, which may be potentially explosive in metal plumbing. Execute proper precaution.
- Specimens, samples and all materials coming into contact with them should be handled as if capable of transmitting infection and disposed of with proper precautions.
- Avoid microbial contamination of the reagent or erroneous results may occur.
- Each unit of source plasma used in the preparation of this product has been tested and found negative for HIV, HCV, and HBsAg. However, no test can offer complete assurance that products derived from human blood will not transmit infectious disease. As with all materials of human origin, this product should be handled as a potentially infectious material.
- All reagents, waste and utilized disposable laboratory equipment should be considered as hazardous waste. Their handling and disposal should be done according to the valid hazardous material processing regulation.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

- Clauss, A., Acta Haemat. 17:237 (1957).
- National Committee for Clinical Laboratory Standards: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays.
- Koepke JA, Gilmer PR, Filip DJ, Eckstein JD, Sibley CA: Studies of fibrinogen measurement in the CAP survey program. Am J Clin Pathol; 63:984; 1975.

LOTSPECIFIC VALUES

Lot: 6618/980320/4	Expiry: 2020-03-31	
	Lot:	Fibrinogen target value
Abnormal Coag. Ctrl. Plasma	981019	70 - 170 mg/dL
Normal Coag. Ref. Plasma	980412	281 mg/dL

