FIBRINOGEN
Liquid Reagent

KIT SPECIFICATIONS:

Catalogue No.	Quantity	Reagent	Storage
GL313FB	8 x 2ml	FIB Reagent 1	2 – 8 °C
	1 x 100ml	FIB Reagent 2	
	1 x 3.5ml	FIB Reagent 3	

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative determination of Fibrinogen. *For in vitro diagnostic use only.*

SUMMARY AND EXPLANATION:

Fibrinogen (Factor I), protein synthesized by the liver, is the substance used in the blood to form a clot. Its determination is used to evaluate abnormal blood clotting. Elevated Fibrinogen levels are observed in acute inflammations and in pregnancy; low values are observed in trombolitic therapy, in hepatic disease, in the congenital non fibrinogen, in DIC (Disseminated Intravascular Coagulation) and in pancreatitis (low values)[1]. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE OF THE TEST:

Fibrinogen in presence of an excess of thrombin concentration, changes into Fibrin. The time for clot formation in dilute plasma is inversely proportional to the fibrinogen concentration in the sample.

WARNINGS AND PRECAUTIONS:

In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety precautions:
Material Safety Data Sheet is available upon request.

Label Elements:

DANGER

H290 – May be corrosive to metals.
H302 – Harmful if swallowed.
H360 – May damage fertility or the unborn child.
H412 – Harmful to aquatic life with long lasting effects.

Follow the precautionary statements given in the MSDS and label of the product.

Handling precautions:

- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Refer to relevant user's manual or laboratory internal practice for routine maintenance procedures. Instrument settings are available upon request.

COMPONENTS:

Component	Ingredients
Reagent 1	Bovine Thrombin, ~100 NIH U/ml
Reagent 2	Imidazole Buffer, Sodium azide
Reagent 3	Caolin

REAGENT PREPARATION AND STABILITY:

Reagent 1: Dissolve the contents with 2ml of distilled water. Cap vial and mix gently to dissolve contents.
Stability: 7 days at 2-8ºC or 1 month at –20ºC, if immediately frozen and stored in the original container. Do not re-freeze.
Reagent 2: Mix before use.

If stored and handled properly, all unopened components are stable at 2-8°C until expiry date stated on the label. Avoid contamination.

TYPE OF SPECIMEN:

Plasma from venous puncture diluted 1/10 in trisodium citrate solution 3.8% (105 mmol/L). Mixing immediately the blood with anticoagulant. Avoid foaming the specimen. Centrifuge the sample at 3000 x g for 10 min and transfer the plasma to siliconized glass or plastic containers. Turbid, icteric, lipemic or hemolyzed samples may generate erroneous results. The sample is stable for 4 hours at room temperature (15-25ºC) or 28 days if immediately frozen at below 20ºC.

TEST PROCEDURE:

Materials required but not supplied:

- Analyser & Consumables
- General Laboratory Equipment
- Coagulation Calibrator

Assay procedure:
Refer to relevant user's manual for instructions on instrument start-up, loading components and samples, sample testing procedures, calculating and reporting results.

The reagent can be used by manual procedure, mechanical, photo-optical or other means of end clot detection.

1. Dilute the citrated plasma and Control 1/10 with Imidazole buffer: 50µL plasma + 450µL Imidazole buffer. The diluted sample must be processed in 1 hour.
2. Prepare the following dilutions of the Calibrator in Imidazole buffer.

Calibrator Dilution	1/40	1/30	1/20	1/10	1/5
IMIDAZOLE BUFFER (mL)	3.9	2.9	1.9	0.9	0.4
COAGULATION CAL (mL)	0.1	0.1	0.1	0.1	0.1
Factor	10/40*	10/30*	10/20*	10/10*	10/5*
Concentration (mg/dL)	0.25* x c	0.33* x c	0.5* x c	1* x c	2* x c

(c = Calibrator value)

3. Add 20µL of R3 to 0.2 mL of each dilution, and allow to reach 37ºC for 4-6 minutes.
4. Add 0.1 mL of R1 and time clot formation. Do not prewarm thrombin R1.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program:
Controls should be assayed:

- Prior reporting patient results.
- Following any maintenance procedure.
- At intervals established by the Q.C. laboratory programme.

REFERENCE RANGE:

200 - 400 mg/dL[1].
These values are for orientation purpose; each laboratory should establish its own reference range.

CALCULATIONS:

1. Calculate the mean of duplicate clotting times immediately after reaction. Use all five of the calibrator points to construct a log-log curve that plots fibrinogen concentration (mg/dL) vs. clotting time (s).
2. Draw the straight line of best fit. Examine the curve and, if necessary, omit non-linear points. The final curve must consist of at least three consecutive points. Constructing the curve with only the most linear points will produce the best recovery on control and patient samples.
3. The following curve is only orientative. It will change with lot and concentration of the calibrator, as well as, with the instrument used.

Time (Sec)	Concentration (mg/dL)	Concentration (g/L)
18.1	608	6.08
28.4	304	3.04
49.8	152	1.52
84.7	76	0.76
153.0	38	0.38

4. Find the clotting time of quality control and patient samples on the curve and read the corresponding fibrinogen value.
5. If clotting times for the 1/10 dilution fall outside the linear curve, prepare 1/5 or 1/15 dilutions as needed. If the sample is diluted 1/5, divide the result from the standard curve by 2; if the sample was diluted 1/15, multiply the curve result by 2 to get the final result.

PERFORMANCE CHARACTERISTICS

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values

Precision:

	Inter-assay (n=30)		
Mean (U/L)	144	294	488
CV (%)	5.9	3.4	2.9

Accuracy:
Results obtained using Glenbio reagents did not show systematic differences when compared with other commercial reagents.

Interferences:
Has been observed interferences in samples with fibrinogen degradation. Acute inflammatory reactions can elevate circulating fibrinogen. Hemolysis can cause clotting factor activation and end point detection interference. High paraprotein levels and drugs that activate the fibrinolytic system can interfere with fibrinogen assays. A list of drugs and other interfering substances with the determination has been reported[2,3].

BIBLIOGRAPHY:

1. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
2. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
3. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.

SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd. systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	STD	Aqueous Standard
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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