SPECTRUM

The Creative Approach to Bioscience

FIBRINOGEN

REF: 590 001	50 test	REF: ZL-590 001	50 test
R1 Buffer Reagent	1 x 20 ml	R1 Buffer Reagent	1 x 20 ml
R2 Antiserum	1 x 2.5 ml	R2 Antiserum	1 x 2.5 ml

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended Use

In vitro diagnostic reagents for the quantitative determination of Fibrinogen in human plasma by turbidimetric immunoassay.

Background

Minimizing blood loss is accomplished by three events.One is a clumping of platelets in the blood at the site of injury.Another is a vasoconstriction of the injured vessel to reduce the flow through the break.The third event is aggregation of a protein, fibrin, into a clot – a stable three-dimensional lattice- that is strong enough to seal the damaged vessel while repairs are being made. Clotting occurs because a soluble blood plasma protein, fibrinogen, is partially hydrolysed to form fibrin. Elevated levels of fibrinogen in plasma are to be expected in inflammatory processes, after major trauma or surgery and also occur with metastasing tumours.Decreased levels of fibrinogen can occur in consumption coagulopathies, e.g. disseminated intravascular coagulation (DIC), primaryhyperfibrinolysis, hepatic insufficiency and genetic deficiency.Epidemiological studies have shown that elevated plasma levels of fibrinogen are associated with an increased risk of arteriosclerosis.

Test Principle

This Fibrinogen test is based upon the Fibrinogen antigen-antibody reaction.

Reagents

R1 Buffer Reagent
Phosphate buffered saline(pH 7.43).
Enhancer.
Sodium azide (0.95 g/L).

R2 Antiserum
Phosphate beffered saline(pH 7.43).
Polyclonal goat anti-human Fibrinogen (variable).
Sodium azide (0.95 g/L).

Materials required but not provided with the kit

1- Standard
Fibrinogen concentration is stated on the vial label.

2-***Controls***

Precautions and Warnings

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices. Disposal of all waste material should be in accordance with local guidelines. As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

Reagent Preparation, Storage and Stability

All reagents are supplied ready to use.
Reagents in the original vial are stable to the expiration date on the vial label when capped and stored at (2 - 8 ºC).

Fibrinogen Standard:
Reconstitute with 0.5 ml distelled water. mix gently and incubate at room temperature for 30 minutes before use.

Stability: 48 hours at 2 - 8 ºC or 2 weeks at at -20 ºC

Note: Standard should be diluted 1 : 10 in saline before use.

Specimen Collection and Preparation

Fresh or deep frozen citrate plasma. fibrinogen remain stable for 2 days at (2 - 8 ºC). If the test should be performed later, it is recommended to freeze the serum. Avoid successive freezing and thawing.Discard haemolysed or contaminated samples.
Note: Sample should be diluted 1 : 10 in saline before use.

Procedure

1 - Bring the reagents and the photometer to 37ºC

2 - Assay conditions:
Wavelength 340 nm
Temperature 37ºC
Cuvette 1cm light path
3 - Adjust the instrument to zero with distilled water .
4- Samples, Controls and Standard should be diluted 1 : 10 in saline.
5 - Pipette into a cuvette :

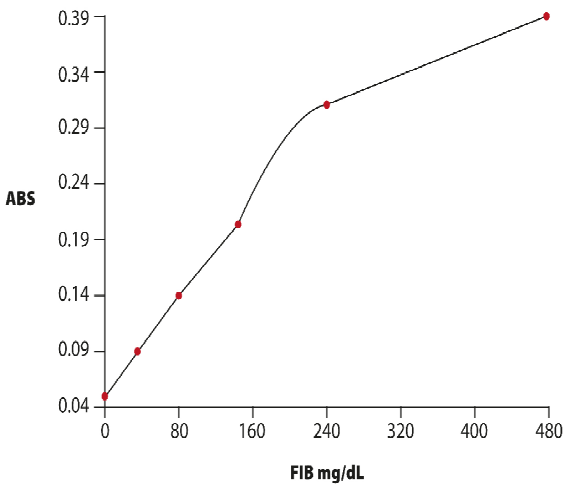
	Standard	Sample
Reagent (R1)	400 µl	400 µl
Standard (diluted)	5 µl	-----
Sample (diluted)	-----	5 µl
Mix, incubate for 2 minutes and record 1st reading (A1).		
Reagent (R2)	50 µl	50 µl

After addition of **R2,** incubate and after 5 minutes record 2nd reading (A2)

Calculation

Generate a reference curve by successive 1 : 2 dilutions of Standard in saline **(6 Points)**. Use Saline as zero point. Determine Δ absorbance of the sample and each calibrator as following:
Δ absorbance of sample = (A2 - A1) sample
Δ absorbance of each standard = (A2 - A1) for each Standard
Plot the calibration curve and obtain the result.

Example :



Sensitivity

4.5 mg/dL

Linearity

Up to 523 mg/L.
specimens showing higher concentration should be diluted 1+4 using physiological saline and repeat the assay (result×5).

Quality Controls

Control sera are recommended to monitor the perfomance of manual and automated assay procedures.
Each laboratory should establish its own Quality Control Scheme and corrective actions if controls do not meet the acceptable tolerances.

Expected Values

200 - 400 mg/dL .

Each laboratory should establish an expected range for the geographical area in which it is located.

References

1. Dati. F. et al., Klin. Lab 39, 669 (199 3)
2. Ernst, E. und Resch, K. L., Ann. Intern. Med. 118, 956 (1993)
3. Cremer, P. et al., Diagnose & Labor 42, 28 (1992

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
590 001	50 test
ZL-590 001	50 test

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