ISE S.r.l. CUSTOMISED SOLUTIONS FOR YOUR LABORATORY	EN	Fibrinogen			Instruction For Use	CE IVD	Rev.E - 15-11-22
	REF	R3330000040	R1: 1x 16.8 mL	R2: 1x 4.0 mL			
		A-R1100003301	R1: 1x 25.0 mL	R2: 1x 5.0 mL			

Intended Use
Quantitative determination of Fibrinogen (FIB) in human plasma by turbidimetric immunoassay.
For professional in vitro diagnostic use only.

Diagnostics Implications
Minimising 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), primary hyperfibrinolysis, hepatic insufficiency and genetic deficiency.
Epidemiological studies have shown that elevated plasma levels of fibrinogen are associated with an increased risk of arteriosclerosis.

Method
Measurement of antigen-antibody reaction by the end-point method.

Reagents Provided
The same reagents are supplied in different volume formats depending on the I.S.E. S.r.l. analysers utilised and installed reagent support.

Supplied Volumes

	Product Code	
	R3330000040	*A-R1100003301*
Vial size	*18 / 18 mL*	*50 / 20 mL*
Reagent 1	1 x 16.8 mL	1x 25.0 mL
Reagent 2	1x 4.0 mL	1x 5.0 mL

Reagent format

Reagent	*Format*	*Code*
Reagent 1 – Buffer (liquid)	Ready to Use	126C03
Reagent 2 – Antiserum (liquid)	Ready to Use	126C02

Reagent Contents

Reagent 1:	*Conc.*	*U.M.*
Phosphate buffered saline	-	-
Enhancer	-	-
Sodium azide	0,95	g/L
Reagent 2:		
Phosphate buffered saline	-	-
Polyclonal goat anti-human Fibrinogen	Variable	-
Sodium azide	0,95	g/L

Stability and Storage
The reagents are stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Reagents required but not supplied
1. Saline (9 g/L NaCl)
2. Calibrators and Controls

Key Reference	*Description*
R1300002201	Fibrinogen Standard, 0.5 mL
R1400001701	Fibrinogen Control, 1 mL

Lyophylized human plasma. Contains 0.95 g/L sodium azide. Value is stated in the insert.

Sample collection and storage
Use fresh citrate plasma. If the test cannot be carried out on the same day, the citrate plasma may be stored at 2-8°C for 48 hours. If stored for a longer period, the sample should be frozen.

General Assay Procedure
Application sheets are available upon request for use with I.S.E. S.r.l. automated systems. All applications not explicitly approved by I.S.E. S.r.l. cannot be guaranteed in terms of performance and must therefore be established by the operator.
Wavelength λ=340nm.

Sample/Control/Standard: Dilute 1:2 in saline 9 g/L. Control/Standard to be reconstituted.
Reference curve: generate a reference curve by diluting the Fibrinogen standard *Ref. R1300002201* 1:1, 1:2, 1:4, 1:8, 1:16 in saline 9 g/L. Use saline 9 g/L as zero point.

Quality control
It is necessary, each time the kit is used, to perform the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.
If erratic results occur, please contact an authorised ISE representative.

Normal Ranges
200 - 400 mg/dL.
Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

Performances
The performance characteristics for the Fibrinogen reagents were measured on a clinical chemistry analyzer.

Measuring range: 0 - 523 mg/dL
Detection Limit: 4.5 mg/dL
Hookeffect: No risk
Sensitivity: 0.0004802 ABS units/concentration unit

Precision of the method

Condition	*U.M.*	*Low*	*Medium*	*High*
Intra-Run	CV%	2.20	3.76	3.69
Inter-Run	CV%	3.15	2.56	3.69

Accuracy of the method

Control	*U.M.*	*Assigned*	*Measured*
Siemens	mg/dL	244 (207 – 281)	265.6
Aptec	mg/dL	282 (240 – 324)	276.9

Specificity: Monospecific.
Interferences: No interference for: Haemoglobin (1000 mg/dL), Bilirubin (30 mg/dL), Triglyceride (2500 mg/dL), Natrium Citrate (1000 mg/dL) and EDTA (10 mg/mL).
Limitations: None
Comparison with nephelometry: y = 0.9904x – 11.196 r = 0.9842
Stability at 2 - 8°C: At least 3 years after production.

Precautions and Warnings
1. In vitro diagnostic use only.
2. Refer to the safety data sheets (SDS) and take the necessary precautions for the use of laboratory reagents.
3. Do not use after expiry date and do not interchange reagents from different lots.
4. Replace caps on reagents immediately after use. Do not switch caps.
5. Do not pipet by mouth. Do not smoke, eat, drink or use cosmetics during the use of the reagent. Do not swallow.
6. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains whit water thoroughly after disposing of fluids containing sodium azide.
7. Polyethyleneglycol is not biohazardous.
8. Each donor unit used in the preparation of the reagents, standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA. However, the material must be considered potentially hazardous and handled with the same care as samples taken from patients.
9. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
10. Take care to avoid self-inoculation, splashing of mucous membranes or generation of aerosols. Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
11. In addition to the eventual risk indications regarding the active components, the reagents contain inactive components such as preservatives (e.g. sodium azide or others) and detergents. The total concentrations of these components are lower than the limits reported by the current directive sand following modification and amendments. However, it is recommended to handle reagents carefully, to avoid ingestion and contact with eyes, skin and mucus membranes and to use laboratory reagents according to good laboratory practice.
12. All human samples must be handled and disposed of as potentially infectious materials.

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Disposal of reagent
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

Reporting of serious incidents
The user must report (through the distributor) any serious accident occurring in relation to the device to both the manufacturer and the competent authority of the European Union Member State in which the user and / or patient is established. For other jurisdictions, reports of serious incidents must be produced in accordance with regulatory requirements.

Symbols on labels and packaging

IVD	In vitro diagnostic medical device
REF	Catalog Number
LOT	Lot number
	Manufacturer
	Expiry date
	Temperature limitation
	Consult Instructions for use
Rn	Reagent “n”

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

Revision history		
Rev.E	15-11-2022	Revision of the document