Diagnostic Reagents Limited

UK CA

Fibrinogen Standard Plasma

Catalogue Number: FSPX450

For *in vitro* diagnostic use only.

Intended Use
Diagen Fibrinogen Standard Plasma may be used as a Reference in the quantitative determination of fibrinogen in citrated human plasma. The value has been defined against the SSC/ISTH Secondary coagulation standard Lot #3 using the Clauss method [(1)].

Summary and Principle
Fibrinogen is an essential plasma protein that is synthesised in the hepatocyte. It comprises of three different polypeptide chains (Aα, Bβ and γ) linked by disulphide bridges, of which there are two. Thrombin cleaves the Aα and Bβ chains releasing fibrinopeptides A and B, respectively, from the amino-terminal ends. Once the fibrinopeptides are released, the resulting fibrin monomers undergo polymerization and form an insoluble fibrin clot [(2)]. The clotting time of a dilution of plasma with a standard concentration of thrombin is inversely related to the fibrinogen concentration.

Reagent
Standard Fibrinogen Plasma **10 vials**

Lyophilised, buffered plasma, collected from a pool of donors to give a reference plasma with fibrinogen levels in the normal range. For reconstitution remove cap and stopper, add 0.5 mL of distilled water, replace stopper and swirl gently. Please allow 5 to 10 minutes for complete solution.

Warnings and Precautions
POTENTIAL BIOHAZARD MATERIAL.

Diagen Fibrinogen Standard Plasma is of human origin. All donor units used in production of this product have been found negative for anti HIV, anti HCV, HBsAg and Syphilis by approved methods. However, all plasma of human origin should be considered as potentially infectious and handled appropriately. Please refer to the relevant SDS Sheet for handling and safety procedures. Dispose of all waste materials according to the stated international, national, and local regulations.

Collection of Blood Samples
Blood (9 parts) is collected into 1 part of 3.2% trisodium citrate and the plasma obtained by centrifugation at 2500 g for 15 minutes. The plasma should be stored in stoppered tubes. The use of 3.2% citrate containing 5% HEPES buffer improves the stability of both fresh and deep-frozen plasma.

Procedure
For the relevant procedure and method, please refer to the pack insert provided with the test reagent or kit. Diagnostic Reagents Ltd manufactures a Fibrinogen Determination Kit that uses the Clauss method of determination (FIBC440), for more information please contact sales@diagen.co.uk.

Expected Values
The normal range for Fibrinogen using the Clauss technique is: 1.7 – 4.0 g/L

Using the Clauss method of determination, the value obtained is detailed below.

LOT: FS EXPIRY: **/**** VALUE: *.**g/L**
S.D: *.**

Storage and stability
The unopened freeze-dried vials are **best stored deep frozen** but may be stored for up to 3 years at 2 - 8°C without deterioration. Once reconstituted, the contents of the vial are stable for up to 8 hours when held at 2 - 8°C.

Packaging
10 x 0.5 mL vials

References
1. Clauss A. Gerinnungsphysiologische Schnellmethode zur Bestimmung des Fibrinogens, Acta Haemat. 1957;17: 237.1.
2. Hantgan, R.R., Francis, C.W. & Marder, V.J. (1994) Fibrinogen structure and physiology. In: Hemostasis and Thrombosis: Basic Principles & Clinical Practice (ed. by R.W. Colman, J. Hirsh, V.J. Marder & E.W. Salzman), pp. 277–300. JB Lippincott, Philadelphia.

Key guide to symbols

REF	Manufacturers catalogue number.	Consult instructions for use.	
LOT	Manufacturers batch number.	Recon.	Requires reconstitution.
IVD	For *in vitro* diagnostic use only.		Product expiry date.
	Biological risks.	+4°C -20°C	Store at 4°C or below. Best stored deep frozen.

Manufacturer.

Diagnostic Reagents Ltd.
Thame
Oxon, OX9 3NY
UK
Tel:+44(0)1844 212426
Email: sales@diagen.co.uk
Website: www.diagen.co.uk

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