



HYPHEN BioMed
155 rue d'Eragny
95000 Neuville-sur-Oise
France

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN NORMAL CONTROL PLASMA

Product Code : 223201

Lot No. : FD1190KS

Expiration date : 2026-12-07

Components	Quantity	Lot	Expiration Date
Normal Control	12 vials	FD1190DZKS	2026-12-07

Analytical Data	Specification	Result
INR	<1.3	PASS
aPTT LR Ratio	≤ 1.20	PASS
Fibrinogen (Activity)	> 2 g/L	PASS
Fibrinogen (Antigen)	> 2 g/L	PASS
Thrombin time Ratio	≤ 1.20	PASS
LA ratio	≤ 1.2	PASS
Alpha 2 Anti plasmin	≥ 80 %	PASS
Antithrombin (Activity)	> 80 %	PASS
Antithrombin (Antigen)	> 80 %	PASS
Factor II	> 70 %	PASS
Factor V	> 70 %	PASS
Factor VII	> 70 %	PASS
Factor X	> 70 %	PASS
Factor VII+ X	> 70 %	PASS
Factor VIII	> 60 %	PASS
Factor IX	> 60 %	PASS
Factor XI	> 70 %	PASS
Factor XII	> 70 %	PASS
Factor XIII	> 60 %	PASS
Free Protein S (Antigen)	> 70 %	PASS
Plasminogen	> 75 %	PASS
Protein C Chromogenic	> 80 %	PASS
Protein C (Antigen)	> 70 %	PASS
Protein C Clotting	> 60 %	PASS
Protein S (Activity)	> 50 %	PASS
von Willebrand Factor (Antigen)	> 60 %	PASS
Act. PC-r (quantitative)	< 10 % FVL	PASS

This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.

Quality Control Approval

Date of Approval :

17 OCT. 2024

S. LECOURT

Quality Control Manager :