



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. : FC17061D

Expiration date : 2026-01-17

Components	Quantity	Lot	Expiration Date
Normal Control	12 vials	FC1706DZ1D	2026-01-17

Analytical Data	Specification	Result
INR	<1.3	<1.3
aPTT sec LR Ratio	≤ 1.20	<1.20
Fibrinogen (Activity and Antigen)	> 2 g/L	Activity : 2.68g/L Antigen:2,74g/L
Thrombin time Ratio	≤ 1.20	<1.20
LA ratio	≤ 1.2	<1.20
Alpha 2 Anti plasmin	≥ 80 %	88%
Antithrombin (Activity and Antigen)	> 80 %	Activity:86% Antigen:86%
Factor II , V, VII, X and VII+ X	> 70 %	II:86% V: 88% VII: 85% X: 79% VII+X:84%
Factor VIII and IX	> 60 %	VIII:99% IX:87%
Factor XI and XII	> 70 %	XI: 82% XII: 85%
Factor XIII	> 60 %	92%
Free Protein S (Antigen)	> 70 %	118%
Plasminogen	> 75 %	92%
Protein C Chromogenic	> 80 %	90%
Protein C Clotting	> 60 %	91%
Protein C Antigen	> 70 %	78%
Protein S (Activity)	> 50 %	90%
von Willebrand Factor (Antigen)	> 60 %	107%
Act. PC-r (quantitative)	< 10 % FVL	1%

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

Date of Approval : 2023-10-24

Quality Control Manager : S.LECOURT