



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.: FB06661C

Expiration date: 2024-10-14

Components	Quantity	Lot	Expiration Date
Normal Control	12 vials	FB0666DZ1C	2024-10-14

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: 2.86 g/L Antigen: 2.84 g/L
Thrombin time Ratio	≤ 1.20	< 1.20
LA ratio	≤ 1.2	< 1.20
Alpha 2 Anti plasmin	≥ 80 %	95%
Antithrombin (Activity and Antigen)	> 80 %	Activity: 90% Antigen: 86%
Factor II , V, VII, X and VII+ X	> 70 %	Factor II: 86% , V: 91%, VII: 92%, X: 80% VII+X: 82%
Factor VIII and IX	> 60 %	Factor VIII: 90% IX: 87%
Factor XI and XII	> 70 %	Factor XI: 89%, XII: 93%
Factor XIII	> 60 %	100%
Free Protein S (Antigen)	> 70 %	115%
Plasminogen	> 75 %	99%
Protein C Chromogenic	> 80 %	94%
Protein C Clotting	> 60 %	99%
Protein C Antigen	> 70 %	83%
Protein S (Activity)	> 50 %	95%
von Willebrand Factor (Antigen)	> 60 %	98%
Act. PC-r (quantitative)	< 10 % FVL	1%

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

of

Date of Approval: 2022-07-19

Quality Control Manager: S. LECOURT