



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ FXIa

Product Code : 220412

Lot No. : FE2914

Expiration date : 2027-12-20

Components	Quantity	Lot	Expiration Date
R1A : Human FX- FVIII:C	2 vials	FE2914	2028-01-17
R1B : Human FIX	2 vials	FE2914	2028-01-21
R2 : Activation Reagent	2 vials	FE2914	2028-01-21
R3 : Substrate	2 vials	FE2914	2027-12-20
R4: Buffer	2 vials	FE2914	2028-01-14
Cal : FXIa Calibrator	2 vials	FE2914	2028-01-02

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath A405 (C) ≥ 1.50 A405 (0) ≤ 0.100 Delta A405 (C/2; C) ≥ 0.30 $R^2 \geq 0.98$ Controls measured within acceptance ranges	2.166 0.098 0.786 PASS PASS
Detection Threshold	≤ 2.5 mIU/ml	< 1 mIU/ml

Calibration Curve for information

Conc.	2.9	5.9	11.7	23.5	46.9
OD WB	0.304	0.486	0.817	1.38	2.166
Conc.	2.9	5.9	11.7	23.5	46.9
OD STAR	0.125	0.273	0.516	0.923	1.76

	Acceptance Range	MV
C1	[10 - 16]	14
C2	[29 - 39]	32

MV = Measured value

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

Date of Approval : 07 OCT. 2025

Quality Control Manager :

Isabelle CORNUEJOLS

Resp. Labo CQ