



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ FXIa

Product Code : 220412

Lot No. : FB169018

Expiration date : 2025-04-06

Components	Quantity	Lot	Expiration Date
R1A : Human FX- FVIII:C	2 vials	FB169018	2025-05-02
R1B : Human FIX	2 vials	FB169018	2025-05-12
R2 : Activation Reagent	2 vials	FB169018	2025-05-30
R3 : Substrate	2 vials	FB169018	2025-04-25
R4: Buffer	2 vials	FB169018	2025-04-06
Cal : FXIa Calibrator	2 vials	FB169018	2025-04-21

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath	-
	A405 (C) ≥ 1.50	1.67
	A405 (0) ≤ 0.100	0.049
	Delta A405 (C/2; C) ≥ 0.30	0.73
	$R^2 \geq 0.98$	> 0.99
	Controls measured within acceptance ranges	PASS
Detection Threshold	≤ 2.5 mIU/ml	< 1 mIU/ml

Calibration Curve for information

Conc.	3	6	12	24	48
OD WB	0.149	0.271	0.496	0.939	1.669
Conc.	3	6	12	24	48
OD STAR	0.084	0.185	0.401	0.812	1.544

	Acceptance Range	MV
C1	[8 - 14]	10
C2	[22 - 32]	26

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 : 2023-01-05

Quality Control Manager : S. LECOURT