



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FIXa

Product Code : 221812

Lot No. : FC00444E

Expiration date : 2025-06-22

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FC00444E	2025-06-22
R2 : Activation Reagent	2 vials	FC00444E	2025-07-05
R3 : Substrate	2 vials	FC00444E	2025-07-01
R4: Buffer	2 vials	FC00444E	2025-06-27
Cal : FIXa Calibrator	2 vials	FC00444E	2025-06-23

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope	Water-Bath A405 (C/2) ≥ 1.5 Delta A405 (C/2; C/4) ≥ 0.30 $R^2 \geq 0.98$	2.716 0.86 0.99
Detection Threshold	≤ 0.2 mIU/ml	< 0.2 mIU/ml

Calibration Curve for information

Conc.	0.9	1.8	3.6	9.0	18.0
OD STAR	0.095	0.190	0.366	0.795	1.294
Conc.	0.9	1.8	3.6	9.0	18.0
OD WB	0.251	0.498	0.928	1.855	2.716

	Acceptance Range	MV
CI	[3.9 - 8.9]	6.1
CII	[9.6 - 16.6]	11.5

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 : 2023-02-03

Quality Control Manager : S.LECOURT