



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

CERTIFICATE OF ANALYSIS

Product Description: BIOPHEN FIXa
Product Code: 221812
Lot No.: F2000548
Expiration date: 2022-10-10

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	F204B00548	2022-10-28
R2 : Activation Reagent	2 vials	F204B00548	2022-11-05
R3 : Substrate	2 vials	F204B00548	2022-10-17
R4: Buffer	2 vials	F204B00548	2022-10-21
Cal : FIXa Calibrator	2 vials	F204B00548	2022-10-10

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 ≥ 0.98	2.11 0.72 0.99
Detection Threshold	≤ 0.2 mIU/ml	< 0.1 mIU/ml

Calibration Curve for information

Conc.	0.86	1.73	3.46	8.65	17.30
OD STAR	0.065	0.134	0.265	0.565	0.917
Conc.	0.86	1.73	3.46	8.65	17.30
OD WB	0.191	0.372	0.665	1.393	2.110

	Acceptance Range	MV
CI	[3.0 - 8.0]	6.3
CII	[7.4 - 14.4]	10.9

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: 2020-06-18

Quality Control Manager: **S. LECOURT**