



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

CERTIFICATE OF ANALYSIS

Product Description: BIOPHEN FIXa
Product Code: 221812
Lot No.: F2001287
Expiration date: 2023-03-17

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	F204C01287	2023-04-03
R2 : Activation Reagent	2 vials	F204C01287	2023-04-10
R3 : Substrate	2 vials	F204C01287	2023-03-20
R4: Buffer	2 vials	F204C01287	2023-03-17
Cal : FIXa Calibrator	2 vials	F204C01287	2023-03-19

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope	Water-Bath A405 (C/2) ≥ 1.5 Delta A405 (C/2; C/4) ≥ 0.30 $R^2 \geq 0.98$	2.378 0.701 $R^2 = 0.99$
Detection Threshold	≤ 0.2 mIU/ml	< 0.1 mIU/ml

Calibration Curve for information

Conc.	22	11	4.4	2.2	1.10
OD STAR	1.100	0.725	0.336	0.176	0.083
Conc.	22	11	4.4	2.2	1.10
OD WB	2.378	1.678	1.005	0.469	0.240

	Acceptance Range	MV (STAR)
CI	[2.6 - 7.6]	5.8
CII	[7.7 - 14.7]	11.9

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: 2020-11-13

Quality Control Manager: