



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN™ FXIa

**Product Code :** 220412

**Lot No. :** FC097719

**Expiration date :** 2025-09-16

Components	Quantity	Lot	Expiration Date
R1A : Human FX- FVIII:C	2 vials	FC097719	2025-09-19
R1B : Human FIX	2 vials	FC097719	2025-09-29
R2 : Activation Reagent	2 vials	FC097719	2025-09-29
R3 : Substrate	2 vials	FC097719	2025-09-16
R4: Buffer	2 vials	FC097719	2025-09-19
Cal : FXIa Calibrator	2 vials	FC097719	2025-09-22

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath A405 (C) $\geq$ 1.50 A405 (0) $\leq$ 0.100 Delta A405 (C/2; C) $\geq$ 0.30 R <sup>2</sup> $\geq$ 0.98 Controls measured within acceptance ranges	2.153 0.095 0.822 PASS PASS
Detection Threshold	$\leq$ 2.5 mIU/ml	$<$ 1 mIU/ml

### Calibration Curve for information

Conc.	3.125	6.25	12.5	25	50
OD WB	0.285	0.462	0.784	1.331	2.153
Conc.	6.25	12.50	25	50	NA
OD STAR	0.337	0.670	1.166	2.007	NA

	Acceptance Range	MV
C1	[ 8 - 14 ]	11
C2	[ 22 - 32 ]	28

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 : 2023-05-16

Quality Control Manager : **S.LECOURT**