



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

CERTIFICATE OF ANALYSIS

Product Description: BIOPHEN FXIa
Product Code: 220412
Lot No.: FB021717
Expiration date: 2024-07-22

Components	Quantity	Lot	Expiration Date
R1A: Human FX- FVIII:C	2 vials	FB021717	2024-11-09
R1B: Human FIX	2 vials	FB021717	2024-11-15
R2: Activation Reagent	2 vials	FB021717	2024-11-15
R3: Substrate	2 vials	FB021717	2024-07-30
R4: Buffer	2 vials	FB021717	2024-08-02
Cal: FXIa Calibrator	2 vials	FB021717	2024-07-22

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath A405 (C) ≥ 1.50 A405 (0) ≤ 0.100 Delta A405 (C/2; C) ≥ 0.30 R ² ≥ 0.98 Controls measured within acceptance ranges	1.73 0.046 0.80 PASS PASS
Detection Threshold	≤ 2.5 mIU/mL	< 2 mIU/mL

Calibration Curve for information

Conc.	43	21.5	10.8	5.4	2.7
OD WB	1.728	0.929	0.495	0.257	0.147
Conc.	43	22	11	5	3
OD STAR	1.354	0.713	0.317	0.136	0.059

	Acceptance Range	MV
C1	[8 - 14]	12
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: 2022-06-09

Quality Control Manager: S.LECOURT

