



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVII
Product Code : 221304
Lot No. : FD037212
Expiration date : 2026-08-11

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FD037212	2026-08-17
R2 : Calcium Thromboplasstin	2 vials	FD037212	2026-09-05
R3 : Substrate	2 vials	FD037212	2026-08-11
R4 : Buffer	4 vials	FD037212	2026-09-04

Analytical Data	Specification	Result
Calibration curve : reactivity, slope, linearity on Water-Bath	A405(200%) \geq 0.80	1.17
	A405(0%) \leq 0.10	0.025
	Delta A405(100-200%) \geq 0.30	0.32
	R ² \geq 0.98	1.00
Detection Threshold	\leq 5%	< 1 %

Calibration Curve for information

Conc.	200%	100%	50%	25%
OD WB	1.172	0.851	0.572	0.337
Conc.	200%	100%	50%	25%
OD STAR	0.994	0.674	0.407	0.231

	Acceptance Range	MV (STAR)
NC	[75 - 95]	80
AC	[23 - 31]	27

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 :

Quality Control Approval

Quality Control Manager :

08 AVR. 2024

S. LECOURT

