



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVII
Product Code : 221304
Lot No. : FC21051B
Expiration date : 2026-03-20

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FC21051B	2026-03-23
R2 : Calcium Thromboplasstin	2 vials	FC21051B	2026-03-29
R3 : Substrate	2 vials	FC21051B	2026-03-21
R4 : Buffer	4 vials	FC21051B	2026-03-20

Analytical Data	Specification	Result
Calibration curve : reactivity, slope, linearity on Water-Bath	A405(200%) ≥ 0.80 A405(0%) ≤ 0.10 Delta A405(100-200%) ≥ 0.30 $R^2 \geq 0.98$	1.007 0.021 0.347 PASS
Detection Threshold	$\leq 5\%$	< 5%

Calibration Curve for information

Conc.	100%	50%	25%	0%
OD WB	0.660	0.390	0.216	0.021
Conc.	100%	50%	25%	0%
OD STAR	0.675	0.415	0.229	Mmin

	Acceptance Range	MV
NC	[82 - 102]	91
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 : 2023-12-07

Quality Control Manager : S. LECOURT

