



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVII
Product Code : 221304
Lot No. : F1903305
Expiration date : 2022-06-25

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	F191503305	2022-06-27
R2 : Calcium Thromboplasstin	2 vials	F191503305	2022-07-23
R3 : Substrate	2 vials	F191503305	2022-06-25
R4 : Buffer	4 vials	F191503305	2022-07-22

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 ≥ 0.98	A405(200%) = 1.37 A405(0%) < 0.01 Delta A405(100-200%) = 0,39 R ² = 0.99
Detection Threshold	≤ 5%	< 4%

Calibration Curve for information (*)

(*) CC078: New interpolation (polynomial degree 2)

Conc.	100%	50%	25%	0%
OD WB	0.98	0.61	0.34	0
Conc.	100%	50%	25%	0%
OD STAR	0.90	0.55	0.30	M < M Min

	Acceptance Range	MV
NC	[84 - 104]	90
AC	[29 - 39]	36

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: 2020-03-26

Quality Control Manager: S. LECOURT

