



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVII
Product Code : 221304
Lot No. : F1900909
Expiration date : 2022-01-07

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	F191400909	2022-01-07
R2 : Calcium Thromboplasstin	2 vials	F191400909	2022-01-24
R3 : Substrate	2 vials	F191400909	2022-01-10
R4 : Buffer	4 vials	F191400909	2022-01-07

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	1.18 0.002 0.35 0.99
Detection Threshold	≤ 5%	< 1 %

Calibration Curve for information

Conc.	100%	50%	25%	0%
OD WB	0.838	0.512	0.285	0.002
Conc.	100	50	25	0
OD STAR	0.751	0.450	0.249	0.001

	Acceptance Range	MV
NC	[84 - 104]	95
AC	[29 - 39]	38

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 : 2019-10-02

Quality Control Manager : **S. LECOURT**

