



A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVII

Product Code : 221304

Lot No. : FE230413

Expiration date : 2027-09-27

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FE230413	2027-10-04
R2 : Calcium Thromboplasstin	2 vials	FE230413	2027-10-10
R3 : Substrate	2 vials	FE230413	2027-09-27
R4 : Buffer	4 vials	FE230413	2027-09-28

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 $R^2 \geq 0.98$	1.186 0.032 0.399 PASS
Detection Threshold	$\leq 5\%$	$< 3\%$

Calibration Curve for information

Conc.	100%	50%	25%	0%
OD WB	0.787	0.431	0.234	0.032
Conc.	100%	50%	25%	0%
OD STAR	0.730	0.456	0.248	M<MMIN

	Acceptance Range	MV
NC	[81 - 101]	88
AC	[28 - 38]	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 : **Quality Control Approval**

Quality Control Manager :

27 MAI 2025

S. LECOURT

F820-11/BI/1304 v11