



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

## CERTIFICATE OF ANALYSIS

**Product Description:** BIOPHEN FACTOR X

**Product Code:** 221705

**Lot No.:** FB12811A

**Expiration date:** 2025-01-24

Components	Quantity	Lot	Expiration Date
R1: Substrate	4 vials	FB12811A	2025-01-27
R2: RVV	4 vials	FB12811A	2025-02-02
R3: Buffer	4 vials	FB12811A	2025-01-24

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	A405 (1:5) $\geq 0.75$ Delta A405 (1:5 ; 1:10) $\geq 0.35$ $R^2 \geq 0.98$ Measured values for controls in acceptance ranges	1.033 0.51 PASS PASS
Detection Threshold	$\leq 5\%$	< 2 %

### Calibration Curve for information

STAR

Conc.	0	25	50	100%	200%
OD	0.000	0.116	0.256	0.520	1.033

MV = Measured value

	Acceptance Range	MV
NC	[ 70 - 90 ]	86%
AC	[ 28 - 38 ]	36%

*This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.*

Date of Approval: 2022-09-02

Quality Control Manager: S.LECOURT