



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX

Product Code : 221806

Lot No. : FB1746BM

Expiration date : 2025-04-13

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FB1746BM	2025-05-02
R2 : Xla	2 vials	FB1746BM	2025-05-12
R3 : Substrate	2 vials	FB1746BM	2025-04-20
R4: Buffer	4 vials	FB1746BM	2025-04-13

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range) A405 (200%) ≥ 1.2 Delta A405 (100 ; 200%) ≥ 0.30 $R^2 \geq 0.98$ Measured values for controls in acceptance ranges	1.636 0.524 0.991 PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≈ 1.00 Delta A405 (10; 20%) ≥ 0.25 $R^2 \geq 0.98$	1.004 0.354 0.992
Detection Threshold High Range	$\leq 5\%$	< 1 %
Detection Threshold Low Range	$\leq 2\%$	< 1 %

Calibration Curve for information HIGH RANGE

Conc. WB	0%	12.5%	25%	50%	100%	200%	Acceptance Range	MV (STAR)
OD WB	0.016	0.301	0.506	0.787	1.112	1.636	NC [77 - 97]	92
Conc. STAR	0%	25%	50%	63%	100%	167%	AC [28 - 38]	37
OD STAR	Lin	0.242	0.407	0.478	0.647	0.916	MV = Measured value	

Calibration Curve for information LOW RANGE

Conc. WB	1%	2.5%	5%	10%	20%
OD WB	0.120	0.243	0.405	0.650	1.004
Conc. STAR	1%	2%	7%	10%	29%
OD STAR	0.054	0.105	0.309	0.423	0.884

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

Date of Approval : 2022-12-19

Quality Control Manager : S.LECOURT