



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX

Product Code : 221806

Lot No. : FC0040CL

Expiration date : 2025-06-22

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FC0040EBCL	2025-06-22
R2 : Xia	2 vials	FC0040ECCL	2025-07-05
R3 : Substrate	2 vials	FC0040EDCL	2025-07-01
R4: Buffer	4 vials	FC0040EECL	2025-06-27

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	1.855 0.507 PASS PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≈ 1.00 Delta A405 (10; 20%) ≥ 0.25 $R^2 \geq 0.98$	1.241 0.398 PASS
Detection Threshold High Range	$\leq 5\%$	< 1 %
Detection Threshold Low Range	$\leq 2\%$	< 1 %

Calibration Curve for information HIGH RANGE

Conc. WB	200%	100%	50%	25%	12,50%
OD WB	1.855	1.348	0.906	0.566	0.325
Conc. STAR	167%	100%	63%	50%	25%
OD STAR	1.087	0.800	0.560	0.478	0.240

	Acceptance Range	MV (STAR)
NC	[77 - 97]	89
AC	[28 - 38]	34

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	20%	10%	5%	2.5%
OD WB	1.241	0.843	0.551	0.335
Conc. STAR	29%	10%	7%	2%
OD STAR	0.772	0.384	2.264	0.107

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

Date of Approval : 2023-02-09

Quality Control Manager : S.LECOURT