



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX

Product Code : 221802

Lot No. : FC1957FV/FC1958FW

Expiration date : 2026-02-27

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FC1957EBFV/FC1958FW	2026-03-01
R2 : Xla	2 vials	FC1957ECFV/FC1958FW	2026-03-08
R3 : Substrate	2 vials	FC1957EDFV/FC1958FW	2026-03-03
R4: Buffer	2 vials	FC1957EEFV/FC1958FW	2026-02-27

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	1.463 0.443 PASS PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≈ 1.00 Delta A405 (10; 20%) ≥ 0.25 $R^2 \geq 0.98$	0.894 0.289 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%	12.5%
OD WB	1.463	1.020	0.681	0.419	0.238
Conc. STAR	167%	100%	63%	50%	25%
OD STAR	0.884	0.637	0.486	0.383	0.204

	Acceptance Range	MV (STAR)
NC	[77 - 97]	81
AC	[25 - 34]	29

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	20%	10%	5%	2.5%
OD WB	0.894	0.605	0.386	0.231
Conc. STAR	29%	10%	7%	2%
OD STAR	0.680	0.328	0.238	0.089

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

Date of Approval : 2023-10-19

Quality Control Manager : S.LECOURT