



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX

Product Code : 221802

Lot No. : F2000668

Expiration date : 2022-10-28

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	F204400668	2022-10-28
R2 : Xla	2 vials	F204400668	2022-11-19
R3 : Substrate	2 vials	F204400668	2022-11-12
R4: Buffer	2 vials	F204400668	2022-11-04

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	1.559 0.408 0.99 Measured values for controls in acceptance ranges
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≈ 1.00 Delta A405 (10; 20%) ≥ 0.25 $R^2 \geq 0.98$	1.007 0.322 0.99
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	1.559	1.151	0.791	0.491	0.293
Conc. STAR	167%	100%	63%	50%	25%
OD STAR	0.946	0.740	0.539	0.437	0.264

	Acceptance Range	MV (STAR)
NC	[84 - 104]	99%
AC	[27 - 37]	35%

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	20%	10%	5%	2.5%
OD WB	1.007	0.685	0.456	0.289
Conc. STAR	29%	10%	7%	2%
OD STAR	0.755	0.555	0.299	0.114

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

Date of Approval: 2020-06-25

Quality Control Manager: S. LECOURT