



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

CERTIFICATE OF ANALYSIS

Product Description: BIOPHEN™ FIX

Product Code: 221806

Lot No.: FB02129A / FB021199

Expiration date: 2024-07-19

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FB0212EB9A/FB021199	2024-07-19
R2 : Xla	2 vials	FB0212EC9A/FB021199	2024-09-22
R3 : Substrate	2 vials	FB0212ED9A/FB021199	2024-07-30
R4: Buffer	4 vials	FB0212EE9A/FB021199	2024-07-26

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 ≥ 0.98 Measured values for controls in acceptance ranges	1.502 0.378 PASS PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≈ 1.00 Delta A405 (10; 20%) ≥ 0.25 R ² ≥ 0.98	0.880 0.288 PASS
Detection Threshold High Range	≤ 5%	< 1 %
Detection Threshold Low Range	≤ 2 %	< 1 %

Calibration Curve for information HIGH RANGE

Conc. WB	12.5%	25%	50%	100%	200%
OD WB	0.287	0.502	0.793	1.124	1.502
Conc. STAR	25%	50%	62.5%	100%	167%
OD STAR	0.209	0.375	0.411	0.545	0.777

	Acceptance Range	MV (STAR)
NC	[79 - 99]	89
AC	[28 - 38]	35

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	2.5%	5%	10%	20%
OD WB	0.232	0.388	0.592	0.880
Conc. STAR	2%	7%	10%	29%
OD STAR	0.081	0.212	0.274	0.543

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

Date of Approval: 2022-04-20

Quality Control Manager: **S.LECOURT**