



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX
Product Code : 221806
Lot No. : FE3268RM / FE3269
Expiration date : 2027-12-25

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FE3268EBRM / FE3269	2028-02-21
R2 : Xla	2 vials	FE3268ECRM / FE3269	2028-03-06
R3 : Substrate	2 vials	FE3268EDRM / FE2960	2027-12-25
R4: Buffer	4 vials	FE3268EERM / FE2960	2028-01-01

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	1.866 0.483 0.99 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	1.206 0.367 0.996
Detection Threshold High Range	≤ 5%	< 1%
Detection Threshold Low Range	≤ 2 %	< 1%

Calibration Curve for information HIGH RANGE

Conc. WB	0	12.5	25	50	100
OD WB	0.028	0.375	0.619	0.954	1.383
Conc. STAR	0	25	50	63	100
OD STAR	0.014	0.333	0.557	0.663	0.903

	Acceptance Range	MV
NC	[75-95]	85
AC	[29-39]	34

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	1	2.5	5	10	20
OD WB	0.175	0.341	0.546	0.840	1.206
Conc. STAR	0.8	1	2	7	10
OD STAR	0.062	0.084	0.144	0.301	0.412

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

Date of Approval : _____ Quality Control Manager : _____

Quality Control Approval

06 OCT. 2025
 S. LECOURT