



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX

Product Code : 221806

Lot No. : FE2961R1 / FE2960

Expiration date : 2027-12-25

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FE2961EBR1 / FE2960	2028-01-17
R2 : Xla	2 vials	FE2961ECR1 / FE2960	2028-01-24
R3 : Substrate	2 vials	FE2961EDR1 / FE2960	2027-12-25
R4: Buffer	4 vials	FE2961EER1 / 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 $R^2 \geq 0.98$ Measured values for controls in acceptance ranges	1.553 0.391 0.988 PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≈ 1.00 Delta A405 (10; 20%) ≥ 0.25 $R^2 \geq 0.98$	1.119 0.352 0.995
Detection Threshold High Range	$\leq 5\%$	< 1%
Detection Threshold Low Range	$\leq 2\%$	< 1%

Calibration Curve for information HIGH RANGE

Conc. WB	0	12.5	25	50	100
OD WB	0.024	0.324	0.537	0.818	1.162
Conc. STAR	0	25	50	63	100
OD STAR	0.010	0.294	0.492	0.547	0.695

	Acceptance Range	MV (STAR)
NC	[75-95]	87
AC	[29-39]	33

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	1	2.5	5	10	20
OD WB	0.172	0.335	0.523	0.767	1.119
Conc. STAR	0.8	1	2	7	10
OD STAR	0.063	0.079	0.136	0.330	0.402

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

11 SEP. 2025

S. LECOURT