



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX

Product Code : 221806

Lot No. : FE2315PN

Expiration date : 2027-07-13

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FE2315EBPN	2027-09-17
R2 : Xla	2 vials	FE2315ECPN	2027-09-20
R3 : Substrate	2 vials	FE2315EDPN	2027-07-13
R4: Buffer	4 vials	FE2315EEPEN	2027-07-16

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	1.591 0.490 0.995 PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≈ 1.00 Delta A405 (10; 20%) ≥ 0.25 $R^2 \geq 0.98$	1.088 0.356 0.996
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	0.013	0.253	0.430	0.711	1.101
Conc. STAR	0	25	50	63	100
OD STAR	lin	0.231	0.405	0.502	0.707

	Acceptance Range	MV (STAR)
NC	[75-95]	81
AC	[29-39]	35

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	1	2.5	5	10	20
OD WB	0.129	0.263	0.452	0.733	1.088
Conc. STAR	0.8	1	2	7	10
OD STAR	0.033	0.050	0.101	0.273	0.567

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 Approval

Quality Control Manager :

12 MAI 2025

S. LECOURT