



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX

Product Code : 221801

Lot No. : FC2406HE

Expiration date : 2026-05-15

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FC2406EBHE	2026-07-17
R2 : Xla	2 vials	FC2406ECHE	2026-07-27
R3 : Substrate	2 vials	FC2406EDHE	2026-05-23
R4: Buffer	2 vials	FC2406EEHE	2026-05-15

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range)	
	A405 (200%) ≥ 1.2	1.423
	Delta A405 (100 ; 200%) ≥ 0.30	0.409
	$R^2 \geq 0.98$	0.989
	Measured values for controls in acceptance ranges	PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range)	
	A405 (20%) ≈ 1.00	0.852
	Delta A405 (10; 20%) ≥ 0.25	0.278
	$R^2 \geq 0.98$	0.994
Detection Threshold High Range	$\leq 5\%$	< 1%
Detection Threshold Low Range	$\leq 2\%$	< 1%

Calibration Curve for information HIGH RANGE

Conc. WB	0	13	25	50	100
OD WB	0.008	0.216	0.393	0.655	1.014
Conc. STAR	0	25	50	63	100
OD STAR	LIN	0.181	0.349	0.405	0.583

	Acceptance Range	MV (STAR)
NC	[77-97]	89
AC	[27-37]	35

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	1	3	5	10	20
OD WB	0.089	0.203	0.331	0.574	0.852
Conc. STAR	0.8	1	2	7	10
OD STAR	0.036	0.043	0.087	0.234	0.311

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 :

07 MARS 2024

S. LECOURT