



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX
Product Code : 221802
Lot No. : FD0737JW
Expiration date : 2026-09-25

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FD0737EBJW	2026-10-02
R2 : Xla	2 vials	FD0737ECJW	2026-10-16
R3 : Substrate	2 vials	FD0737EDJW	2026-09-29
R4: Buffer	2 vials	FD0737EEJW	2026-09-25

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range)	
	A405 (200%) ≥ 1.2	1.610
	Delta A405 (100 ; 200%) ≥ 0.30	0.446
	R ² ≥ 0.98	0.988
	Measured values for controls in acceptance ranges	PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range)	
	A405 (20%) ≈ 1.00	1.173
	Delta A405 (10; 20%) ≥ 0.25	0.385
	R ² ≥ 0.98	0.987
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	0.012	0.273	0.491	0.776	1.164
Conc. STAR	0	25	50	63	100
OD STAR	Lin	0.277	0.508	0.563	0.798

	Acceptance Range	MV (STAR)
NC	[77-97]	88
AC	[27-37]	32

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	1	2.5	5	10	20
OD WB	0.125	0.298	0.512	0.788	1.173
Conc. STAR	0.8	1	2	7	10
OD STAR	0.040	0.061	0.115	0.290	0.356

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 :

22 MAI 2024

S. LECOURT