



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

## CERTIFICATE OF ANALYSIS

**Product Description** BIOPHEN™ FIX

**Product Code :** 221802

**Lot No. :** FC1957FV

**Expiration date :** 2026-02-27

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FC1957EBFV	2026-03-01
R2 : XIa	2 vials	FC1957ECFV	2026-03-08
R3 : Substrate	2 vials	FC1957EDFV	2026-03-03
R4: Buffer	2 vials	FC1957EEFV	2026-02-27

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range)	
	A405 (200%) ≥ 1.2	1.463
	Delta A405 (100 ; 200%) ≥ 0.30	0.443
	R <sup>2</sup> ≥ 0.98	PASS
Calibration curve : reactivity, linearity, and slope	Measured values for controls in acceptance ranges	PASS
	Water-Bath (Low Range)	
	A405 (20%) ≈ 1.00	0.894
	Delta A405 (10; 20%) ≥ 0.25	0.289
	R <sup>2</sup> ≥ 0.98	PASS
Detection Threshold High Range	≤ 5%	< 1 %
Detection Threshold Low Range	≤ 2%	< 1 %

### Calibration Curve for information HIGH RANGE

Conc. WB	200%	100%	50%	25%	12.5%
OD WB	1.463	1.020	0.681	0.419	0.238
Conc. STAR	167%	100%	63%	50%	25%
OD STAR	0.884	0.637	0.486	0.383	0.204

	Acceptance Range	MV (STAR)
NC	[ 77 - 97 ]	81
AC	[ 25 - 34 ]	29

MV = Measured value

### Calibration Curve for information LOW RANGE

Conc. WB	20%	10%	5%	2.5%
OD WB	0.894	0.605	0.386	0.231
Conc. STAR	29%	10%	7%	2%
OD STAR	0.680	0.328	0.238	0.089

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

Date of Approval : 2023-11-25

Quality Control Manager : S. LECOURT