



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

## CERTIFICATE OF ANALYSIS

**Product Description** BIOPHEN™ FIX

**Product Code :** 221806

**Lot No. :** FD0956K8

**Expiration date :** 2026-10-30

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FD0956K8	2026-11-13
R2 : Xla	2 vials	FD0956K8	2026-12-07
R3 : Substrate	2 vials	FD0956K8	2026-10-31
R4: Buffer	4 vials	FD0956K8	2026-10-30

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range)	
	A405 (200%) $\geq 1.2$	1.717
	Delta A405 (100 ; 200%) $\geq 0.30$	0.545
	$R^2 \geq 0.98$	0.994
	Measured values for controls in acceptance ranges	PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range)	
	A405 (20%) $\approx 1.00$	1.125
	Delta A405 (10; 20%) $\geq 0.25$	0.388
	$R^2 \geq 0.98$	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	0.024	0.280	0.478	0.784	1.172
Conc. STAR	0	25	50	63	100
OD STAR	lin	0.231	0.381	0.488	0.660

	Acceptance Range	MV (STAR)
NC	[77-97]	88
AC	[27-37]	33

MV = Measured value

### Calibration Curve for information LOW RANGE

Conc. WB	1	2.5	5	10	20
OD WB	0.135	0.282	0.471	0.738	1.125
Conc. STAR	0.8	1	2	7	10
OD STAR	0.043	0.055	0.095	0.239	0.319

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

Date of Approval :

*De 07.10.24*

Quality Control Manager :

*[Signature]*

Claire DUNOIS  
 Dir. Etudes Clin. & Val.