



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

## CERTIFICATE OF ANALYSIS

**Product Description** BIOPHEN™ FIX  
**Product Code :** 221806  
**Lot No. :** FE01652J / FE01662K  
**Expiration date :** 2027-07-13

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FE0165EB2J / FE01662K	2027-08-23
R2 : Xla	2 vials	FE0165EC2J / FE01662K	2027-08-06
R3 : Substrate	2 vials	FE0165ED2J / FE01662K	2027-07-13
R4: Buffer	4 vials	FE0165EE2J / FE01662K	2027-07-16

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range)	
	A405 (200%) $\geq 1.2$	1.609
	Delta A405 (100 ; 200%) $\geq 0.30$	0.542
	R <sup>2</sup> $\geq 0.98$	0.998
	Measured values for controls in acceptance ranges	PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range)	
	A405 (20%) $\approx 1.00$	1.039
	Delta A405 (10; 20%) $\geq 0.25$	0.389
	R <sup>2</sup> $\geq 0.98$	0.999
Detection Threshold High Range	$\leq 5\%$	< 2%
Detection Threshold Low Range	$\leq 2\%$	< 1%

### Calibration Curve for information HIGH RANGE

Conc. WB	0	12.5	25	50	100
OD WB	0.050	0.240	0.400	0.662	1.067
Conc. STAR	25	50	63	100	167
OD STAR	0.171	0.339	0.395	0.565	0.933

	Acceptance Range	MV (STAR)
NC	[75-95]	85
AC	[29-39]	33

MV = Measured value

### Calibration Curve for information LOW RANGE

Conc. WB	1	2.5	5	10	20
OD WB	0.122	0.225	0.379	0.650	1.039
Conc. STAR	1	2	7	10	29
OD STAR	0.052	0.085	0.242	0.355	0.726

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 :

20 MARS 2025

S. LECOURT