



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

### CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX

Product Code : 221806

Lot No. : FA04235A

Expiration date : 2023-08-08

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FA0423EB5A	2023-08-11
R2 : Xla	2 vials	FA0423EC5A	2023-08-13
R3 : Substrate	2 vials	FA0423ED5A	2023-08-08
R4: Buffer	4 vials	FA0423EE5A	2023-08-18

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range)	
	A405 (200%) $\geq 1.2$	1.645
	Delta A405 (100 ; 200%) $\geq 0.30$	0.460
	$R^2 \geq 0.98$	0.99
	Measured values for controls in acceptance ranges	PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range)	
	A405 (20%) $\approx 1.00$	0.847
	Delta A405 (10; 20%) $\geq 0.25$	0.276
	$R^2 \geq 0.98$	0.99
Detection Threshold High Range	$\leq 5\%$	< 1%
Detection Threshold Low Range	$\leq 2\%$	< 1%

#### Calibration Curve for information HIGH RANGE

Conc. WB	200%	100%	50%	25%	12.5%
OD WB	1.645	1.185	0.789	0.485	0.274
Conc. STAR	167%	100%	63%	50%	25%
OD STAR	0.962	0.713	0.508	0.449	0.223

	Acceptance Range	MV (STAR)
NC	[ 82 - 102 ]	94
AC	[ 27 - 37 ]	34

MV = Measured value

#### Calibration Curve for information LOW RANGE

Conc. WB	20%	10%	5%	2.5%
OD WB	0.847	0.571	0.312	0.210
Conc. STAR	29%	10%	7%	2%
OD STAR	0.634	0.321	0.234	0.092

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

Date of Approval : 2021-03-18

Quality Control Manager : S.LECOURT

*P.O. Duvet*