



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

## CERTIFICATE OF ANALYSIS

**Product Description** BIOPHEN™ FIX

**Product Code :** 221802

**Lot No. :** F2001292

**Expiration date :** 2023-03-17

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	F204A01292	2023-04-03
R2 : XIa	2 vials	F204A01292	2023-04-10
R3 : Substrate	2 vials	F204A01292	2023-03-20
R4: Buffer	2 vials	F204A01292	2023-03-17

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range) A405 (200%) ≥ 1.2 Delta A405 (100 ; 200%) ≥ 0.30 R <sup>2</sup> ≥ 0.98 Measured values for controls in acceptance ranges	1.76 0.42 0.98 Controls in acceptance ranges
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≈ 1.00 Delta A405 (10; 20%) ≥ 0.25 R <sup>2</sup> ≥ 0.98	1.14 0.34 0.99
Detection Threshold High Range	≤ 5%	< 1%
Detection Threshold Low Range	≤ 2%	< 1%

### Calibration Curve for information HIGH RANGE

Conc. WB %	12.5	25	50	100	200
OD WB	0.357	0.600	0.931	1.338	1.759
Conc. STAR %	25	50	63	100	167
OD STAR	0.287	0.535	0.639	0.841	1.117

	Acceptance Range	MV (STAR)
NC	[ 82 - 102 ]	90
AC	[ 27 - 37 ]	35

MV = Measured value

### Calibration Curve for information LOW RANGE

Conc. WB %	2.5	5	10	20
OD WB	0.333	0.528	0.793	1.135
Conc. STAR %	2	7	10	29
OD STAR	0.123	0.323	0.431	0.826

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

Date of Approval : 2020-11-12

Quality Control Manager :