



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX
Product Code 221806
Lot No. F2001294
Expiration date 2023-03-17

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	F204B01294	2023-03-17
R2 : Xla	2 vials	F204B01294	2023-04-03
R3 : Substrate	2 vials	F204B01294	2023-04-10
R4: Buffer	4 vials	F204B01294	2023-04-01

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 ² ≥ 0.98 Measured values for controls in acceptance ranges	1.53 0.41 R ² = 0.99 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 ² ≥ 0.98	0.95 0.31 R ² = 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	0.294	0.494	0.769	1.125	1.531
Conc. STAR %	25	50	63	100	167
OD STAR	0.231	0.409	0.480	0.682	0.883

	Acceptance Range	MV (STAR)
NC	[82 - 102]	89
AC	[27 - 37]	33

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	2.5	5	10	20
OD WB	0.258	0.415	0.634	0.948
Conc. STAR	2	7	10	29
OD STAR	0.096	0.243	0.330	0.681

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

Date of Approval: 2020-11-09

Quality Control Manager: S. LECOURT