



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN FIX

Product Code : 221806

Lot No. : F1900969 - F1900970

Expiration date : 2022-01-21

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	F193K00969-F193L00970	2022-03-21
R2 : Xla	2 vials	F193K00969-F193L00970	2022-03-25
R3 : Substrate	2 vials	F193K00969-F193L00970	2022-01-25
R4: Buffer	4 vials	F193K00969-F193L00970	2022-01-21

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 $R^2 \geq 0.98$ Measured values for controls in acceptance ranges	1.506 0.432 $R^2 > 0.99$ Measured values for controls in acceptance ranges
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≥ 0.4 Delta A405 (10; 20%) ≥ 0.15 $R^2 \geq 0.98$	0.889 0.308 $R^2 > 0.99$
Detection Threshold High Range	$\leq 5\%$	< 1 %
Detection Threshold Low Range	$\leq 2\%$	< 1 %

Calibration Curve for information HIGH RANGE

Conc. WB	12.5%	25%	50%	100%	200%
OD WB	0.267	0.447	0.718	1.074	1.506
Conc. STAR	25%	50%	63%	100%	167%
OD STAR	0.237	0.405	0.494	0.640	0.923

	Acceptance Range	MV (STAR)
NC	[84 - 104]	94
AC	[27 - 37]	35

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	1%	5%	10%	20%
OD WB	0.115	0.366	0.581	0.889
Conc. STAR	0.8%	2%	10%	29%
OD STAR	0.046	0.110	0.368	0.660

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

Date of Approval : 2019-11-06

Quality Control Manager : **S. LECOURT**