



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN FIX

Product Code : 221802
Lot No. : F1900790-F1900791
Expiration date : 2021-12-17

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	F193F00790/F193G00791	2022-01-07
R2 : Xla	2 vials	F193F00790/F193G00791	2022-01-10
R3 : Substrate	2 vials	F193F00790/F193G00791	2021-12-21
R4: Buffer	2 vials	F193F00790/F193G00791	2021-12-17

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 $R^2 \geq 0.98$ Measured values for controls in acceptance ranges	1.395 0.341 $R^2=0.99$ 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 $R^2 \geq 0.98$	0.831 0.254 $R^2=0.99$
Detection Threshold High Range	$\leq 5\%$	< 1 %
Detection Threshold Low Range	$\leq 2\%$	< 1 %

Calibration Curve for information HIGH RANGE

Conc. WB	200%	100%	50%	25%	12.5%
OD WB	1.395	1.054	0.758	0.518	0.336
Conc. STAR	167%	100%	63%	50%	25%
OD STAR	1.126	0.877	0.663	0.577	0.344

	Acceptance Range	MV (STAR)
NC	[88 - 108]	93
AC	[22 - 34]	31

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	20%	10%	5%	2.5%
OD WB	0.831	0.577	0.395	0.255
Conc. STAR	29%	10%	7%	2%
OD STAR	0.624	0.378	0.288	0.112

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

Date of Approval : 2019-09-03

Quality Control Manager : S. LECOURT

