



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN FIX

Product Code : 221806

Lot No. : F1801225

Expiration date : 2021-02-15

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	F182S01225	2021-02-15
R2 : Xla	2 vials	F182S01225	2021-02-22
R3 : Substrate	2 vials	F182S01225	2021-02-19
R4: Buffer	4 vials	F182S01225	2021-02-21

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	A405 (200%) =1,864 Delta A405 (100 ; 200%) =0,544 $R^2 =0,989$ 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 $R^2 \geq 0.98$	A405 (20%) =1,232 Delta A405 (10; 20%) =0,458 $R^2 =0,998$
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	0,292	0,526	0,873	1,320	1,864
Conc. STAR	25%	50%	67%	100%	143%
OD STAR	0,268	0,502	0,583	0,788	1,021

	Acceptance Range	MV (STAR)
NC	[88-108]	98
AC	[24-32]	28

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	2,5%	5%	10%	20%
OD WB	0,250	0,414	0,774	1,232
Conc. STAR	2%	7%	10%	29%
OD STAR	0,089	0,288	0,435	0,827

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

Date of Approval : 2018-10-05

Quality Control Manager : C.DUNOIS

