



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN FIX

Product Code : 221806

Lot No. : F1800319 / F1800318

Expiration date : 2020-08-28

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	F182900319	2020-08-28
		F182800318	
R2 : Xla	2 vials	F182900319	2020-09-14
		F182800318	
R3 : Substrate	2 vials	F182900319	2020-09-01
		F182800318	
R4: Buffer	4 vials	F182900319	2020-08-29
		F182800318	

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	1,67 0,48 0,99 controls in acceptance ranges
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≥ 0.4 Delta A405 (10; 20%) ≥ 0.15 $R^2 \geq 0.98$	1,22 0,45 0,99
Detection Threshold High Range	$\leq 5\%$	< 0,5 %
Detection Threshold Low Range	$\leq 2\%$	< 0,2 %

Calibration Curve for information HIGH RANGE

Conc. WB	200%	100%	50%	25%	0%
OD WB	1,665	1,184	0,778	0,451	0,003
Conc. STAR	167%	100%	63%	50%	0%
OD STAR	1,199	0,866	0,645	0,537	0,004

	Acceptance Range	MV (STAR)
NC	[78 - 98]	95
AC	[22 - 34]	34

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	20%	10%	5%	1%
OD WB	1,223	0,775	0,473	0,107
Conc. STAR	29%	10%	7%	1%
OD STAR	1,023	0,479	0,309	0,065

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

Date of Approval : 2018-04-20

Quality Control Manager : C.DUNOIS


 P/b C. Dunois