

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN FIX

Product Code : 221806

Lot No. : F1900619-F1900620

Expiration date : 2021-11-06

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	F193A00619 / F193B00620	2021-11-13
R2 : Xla	2 vials	F193A00619 / F193B00620	2021-11-19
R3 : Substrate	2 vials	F193A00619 / F193B00620	2021-11-06
R4: Buffer	4 vials	F193A00619 / F193B00620	2021-11-19

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	1.450 0.360 0.99 controls are in acceptance range
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≥ 0.4 Delta A405 (10; 20%) ≥ 0.15 $R^2 \geq 0.98$	0.907 0.297 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	1.450	1.090	0.742	0.459	0.271
Conc. STAR	167%	100%	63%	50%	25%
OD STAR	0.973	0.717	0.526	0.419	0.224

	Acceptance Range	MV (STAR)
NC	[88 - 108]	97%
AC	[24 - 32]	29%

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	20%	10%	5%	2.5%
OD WB	0.907	0.610	0.395	0.238
Conc. STAR	29%	10%	7%	2%
OD STAR	0.689	0.370	0.247	0.090

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

Date of Approval : 2019-06-20

Quality Control Manager : **S.LECOURT**