



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN FIX

Product Code : 221806

Lot No. : F1903148

Expiration date : 2022-05-06

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	F193R03148	2022-05-20
R2 : Xla	2 vials	F193R03148	2022-06-06
R3 : Substrate	2 vials	F193R03148	2022-05-07
R4: Buffer	4 vials	F193R03148	2022-05-06

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	Water-Bath (High Range) 1.606 0.429 $R^2 > 0.98$ 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 $R^2 \geq 0.98$	Water-Bath (Low Range) 1.050 0.345 $R^2 > 0.99$
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	0.270	0.479	0.792	1.177	1.606
Conc. STAR	25	50	63	100	167
OD STAR	0.264	0.449	0.514	0.695	0.992

	Acceptance Range	MV (STAR)
NC	[84 - 104]	91
AC	[27 - 37]	33

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	2.5	5	10	20
OD WB	0.287	0.459	0.705	1.050
Conc. STAR	2	7	10	29
OD STAR	0.131	0.310	0.384	0.847

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

Date of Approval: 2020-01-15

Quality Control Manager: S. LECOURT

