



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX

Product Code : 221802

Lot No. : FE05603M / FE05613N

Expiration date : 2027-08-23

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FE0560EB3M/FE05613N	2027-08-23
R2 : Xla	2 vials	FE0560EC3M/FE05613N	2027-09-20
R3 : Substrate	2 vials	FE0560ED3M/FE05613N	2027-09-07
R4: Buffer	2 vials	FE0560EE3M/FE05613N	2027-09-12

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	1.773 0.486 0.99 PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≈ 1.00 Delta A405 (10; 20%) ≥ 0.25 $R^2 \geq 0.98$	1.307 0.511 0.998
Detection Threshold High Range	$\leq 5\%$	< 1%
Detection Threshold Low Range	$\leq 2\%$	< 1%

Calibration Curve for information HIGH RANGE

Conc. WB	0	12.5	25	50	100
OD WB	0.013	0.318	0.548	0.869	1.287
Conc. STAR	25	50	63	100	167
OD STAR	0.147	0.326	0.401	0.640	0.962

	Acceptance Range	MV (STAR)
NC	[75-95]	84
AC	[29-39]	34

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	1	2.5	5	10	20
OD WB	0.135	0.289	0.496	0.797	1.307
Conc. STAR	1	2	7	10	29
OD STAR	0.025	0.058	0.255	0.569	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 : **Quality Control Approval**

Quality Control Manager :