



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX

Product Code : 221802

Lot No. : FC2405HD

Expiration date : 2026-05-15

Components	Quantity	Lot	Expiration Date
R1 : Human FX- FVIII:C	2 vials	FC2405EBHD	2026-07-17
R2 : Xla	2 vials	FC2405ECHD	2026-07-27
R3 : Substrate	2 vials	FC2405EDHD	2026-05-23
R4: Buffer	2 vials	FC2405EEHD	2026-05-15

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	1.384 0.387 0.987 PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≈ 1.00 Delta A405 (10; 20%) ≥ 0.25 $R^2 \geq 0.98$	0.851 0.280 0.987
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	0.009	0.207	0.382	0.640	0.997
Conc. STAR	0	25	50	63	100
OD STAR	LIN	0.174	0.339	0.394	0.595

	Acceptance Range	MV (STAR)
NC	[77-97]	88
AC	[27-37]	31

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	1	2.5	5	10	20
OD WB	0.082	0.205	0.359	0.572	0.851
Conc. STAR	0.8	1	2	7	10
OD STAR	0.036	0.039	0.085	0.230	0.303

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 :

04 MARS 2024

S. LECOURT