



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C

Product Code : 221406

Lot No. : FE2062N7 / FE2121ND

Expiration date : 2027-09-07

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FE2062h8N7 / FE2121ND	2027-09-10
R2 : Activation reagent	2 vials	FE2062h9N7 / FE2121ND	2027-09-27
R3 : Substrate	2 vials	FE2062i1N7 / FE2121ND	2027-09-07
R4: Buffer	4 vials	FE2062i2N7 / FE2121ND	2027-09-17

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range) A405 (200%) ≥ 1.60 Delta A405 (100 ; 200%) ≥ 0.60 $R^2 \geq 0.98$ Measured values for controls in acceptance ranges	2.363 1.034 0.998 PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (25%) ≥ 0.80 Delta A405 (12.5; 25%) ≥ 0.30 $R^2 \geq 0.98$	1.341 0.620 0.998
Detection Threshold High Range	$\leq 10\%$	$< 2\%$
Detection Threshold Low Range	$\leq 2\%$	$< 1\%$

Calibration Curve for information HIGH RANGE

Conc.	12.5	25	50	100	200
OD WB	0.121	0.267	0.590	1.328	2.363
Conc.	18	44	88	152	183
OD STAR	0.062	0.168	0.359	0.601	0.718

	Acceptance Range	MV
NC	[79-99]	89
AC	[29-39]	35

MV = Measured value

Calibration Curve for information LOW RANGE

Conc.	0	3.12	6.25	12.5	25
OD WB	0.017	0.156	0.347	0.721	1.341
Conc.	0.83	1.72	13.75	25	
OD STAR	0.039	0.077	0.659	1.125	

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 Manager :

Quality Control Approval

06 MAI 2025

S. LECOURT