



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C

Product Code : 221402

Lot No. : FE2078NA/FE2068N8

Expiration date : 2027-09-06

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FE2078h8NA/FE2068N8	2027-09-12
R2 : Activation reagent	2 vials	FE2078h9NA/FE2068N8	2027-09-27
R3 : Substrate	2 vials	FE2078i1NA/FE2068N8	2027-09-06
R4: Buffer	4 vials	FE2078i2NA/FE2068N8	2027-09-17

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range) A405 (200%) $\geq$ 1.60 Delta A405 (100 ; 200%) $\geq$ 0.60 $R^2 \geq$ 0.98 Measured values for controls in acceptance ranges	2.218 1.041 0.998 PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (25%) $\geq$ 0.80 Delta A405 (12.5; 25%) $\geq$ 0.30 $R^2 \geq$ 0.98	1.281 0.604 0.997
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	0.095	0.207	0.517	1.177	2.218
Conc.	18	44	88	152	183
OD STAR	0.055	0.156	0.340	0.600	0.727

	Acceptance Range	MV
NC	[79-99]	92
AC	[29-39]	35

MV = Measured value

Calibration Curve for information LOW RANGE

Conc.	0	3.12	6.25	12.5	25
OD WB	0.013	0.128	0.299	0.677	1.281
Conc.	0.83	1.72	13.75	25	
OD STAR	0.035	0.070	0.665	1.131	

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 :

06 MAI 2025

S. LECOURT