



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C
Product Code : 221402
Lot No. : FD2285NY / FD2295P3
Expiration date : 2027-05-01

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FD2285h8NY / FD2295dIP3	2027-06-04
R2 : Activation reagent	2 vials	FD2285djNY / FD2295dmP3	2027-06-05
R3 : Substrate	2 vials	FD2285dkNY / FD2295P3	2027-06-05
R4: Buffer	4 vials	FD2285i2NY / FD2295P3	2027-05-01

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range)	
	A405 (200%) ≥ 1.60	2.467
	Delta A405 (100 ; 200%) ≥ 0.60	1.237
	R ² ≥ 0.98	0.999
	Measured values for controls in acceptance ranges	PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range)	
	A405 (25%) ≥ 0.80	1.225
	Delta A405 (12.5; 25%) ≥ 0.30	0.674
Detection Threshold High Range	$\leq 10\%$	< 1%
Detection Threshold Low Range	$\leq 2\%$	< 1%

Calibration Curve for information HIGH RANGE

Conc.	12.5	25	50	100	200
OD WB	0.103	0.221	0.537	1.230	2.467
Conc.	20	50	100	133	200
OD STAR	0.080	0.238	0.471	0.633	0.912

	Acceptance Range	MV
NC	[79-99]	91
AC	[29-39]	31

MV = Measured value

Calibration Curve for information LOW RANGE

Conc.	0	3.12	6.25	12.5	25
OD WB	0.017	0.101	0.240	0.551	1.225
Conc.	0.83	1.25	6.25	12.5	25
OD STAR	0.021	0.062	0.350	0.718	1.377

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 :

14 JAN. 2025

S. LECOURT

