



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C

Product Code : 221406

Lot No. : FD2042N4

Expiration date : 2027-04-02

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FD2042h8N4	2027-04-04
R2 : Activation reagent	2 vials	FD2042h9N4	2027-04-10
R3 : Substrate	2 vials	FD2042i1N4	2027-05-23
R4: Buffer	4 vials	FD2042i2N4	2027-04-02

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range)	
	A405 (200%) ≥ 1.60	2.321
	Delta A405 (100 ; 200%) ≥ 0.60	1.043
	R ² ≥ 0.98	0.998
	Measured values for controls in acceptance ranges	PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range)	
	A405 (25%) ≥ 0.80	1.268
	Delta A405 (12.5; 25%) ≥ 0.30	0.587
	R ² ≥ 0.98	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	0.115	0.253	0.588	1.279	2.321
Conc.	20	50	100	133	200
OD STAR	0.073	0.197	0.404	0.540	0.758

	Acceptance Range	MV
NC	[79-99]	91
AC	[26-35]	30

MV = Measured value

Calibration Curve for information LOW RANGE

Conc.	0	3.12	6.25	12.5	25
OD WB	0.017	0.151	0.324	0.681	1.268
Conc.	0.83	1.25	6.25	12.5	25
OD STAR	0.031	0.058	0.317	0.632	1.190

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 :

19 DEC. 2024

S. LECOURT

