



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C

Product Code : 221406

Lot No. : FD0954K6 / FD0955K7

Expiration date : 2026-10-30

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FD0945h8K6 / FD0955K7	2026-11-02
R2 : Activation reagent	2 vials	FD0945h9K6 / FD0955K7	2026-11-14
R3 : Substrate	2 vials	FD0954i1K6/ FD0955K7	2026-11-02
R4: Buffer	4 vials	FD0954i2K6 / FD0955K7	2026-10-30

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range)	
	A405 (200%) \geq 1.60	2.271
	Delta A405 (100 ; 200%) \geq 0.60	1.152
	R ² \geq 0.98	0.999
	Measured values for controls in acceptance ranges	PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range)	
	A405 (25%) \geq 0.80	0.717
	Delta A405 (12.5; 25%) \geq 0.30	10.587
	R ² \geq 0.98	0.999
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	0,088	0,197	0,477	1,119	2,271
Conc.	20	50	100	133	200
OD STAR	0,075	0,215	0,446	0,586	0,838

	Acceptance Range	MV
NC	[79-119]	113
AC	[22-38]	33

MV = Measured value

Calibration Curve for information LOW RANGE

Conc.	0	3,12	6,25	12,5	25
OD WB	0,014	0,157	0,362	0,748	1,464
Conc.	0,83	1,25	6,25	12,5	25
OD STAR	0,042	0,061	0,330	0,630	1,207

This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.

Date of Approval :

ok - 07 - 2024

Quality Control Manager :

Claire DUNOIS
Dir. Etudes Clin. & Val.

[Signature]