



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C

Product Code : 221402

Lot No. : FD0960K9

Expiration date : 2026-10-30

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FD0960h8K9	2026-11-02
R2 : Activation reagent	2 vials	FD0960h9K9	2026-11-14
R3 : Substrate	2 vials	FD0960i1K9	2026-11-02
R4: Buffer	4 vials	FD0960i2K9	2026-10-30

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range)	
	A405 (200%) ≥ 1.60	2.524
	Delta A405 (100 ; 200%) ≥ 0.60	1.206
	$R^2 \geq 0.98$	0.999
	Measured values for controls in acceptance ranges	PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range)	
	A405 (25%) ≥ 0.80	0.756
	Delta A405 (12.5; 25%) ≥ 0.30	11.440
	$R^2 \geq 0.98$	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	0,106	0,242	0,582	1,319	2,524
Conc.	20	50	100	133	200
OD STAR	0,076	0,224	0,468	0,612	0,879

	Acceptance Range	MV
NC	[79-119]	104
AC	[22-38]	32

MV = Measured value

Calibration Curve for information LOW RANGE

Conc.	0	3,12	6,25	12,5	25
OD WB	0,010	0,142	0,342	0,756	1,512
Conc.	0,83	1,25	6,25	12,5	25
OD STAR	0,035	0,050	0,346	0,721	1,362

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

Date of Approval :

01.07.2024

Quality Control Manager :

Claire DUNOIS
Dir. Etudes Clin. & Val.

