



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C

Product Code : 221406

Lot No. : FE3461S2 / FE3460

Expiration date : 2028-02-25

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FE3461h8S2/FE3460	2028-02-25
R2 : Activation reagent	2 vials	FE3461h9S2/FE3460	2028-03-18
R3 : Substrate	2 vials	FE3461i1S2/FE3460	2028-02-27
R4: Buffer	4 vials	FE3461i2S2/FE3460	2028-03-03

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range) A405 (200%) ≥ 1.60 Delta A405 (100 ; 200%) ≥ 0.60 $R^2 \geq 0.98$ Measured values for controls in acceptance ranges	2.308 1.177 0.998 PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (25%) ≥ 0.80 Delta A405 (12.5; 25%) ≥ 0.30 $R^2 \geq 0.98$	1.372 0.686 0.996

Calibration Curve for information HIGH RANGE

Conc. %	12.5	25	50	100	200
OD WB	0.114	0.203	0.469	1.131	2.308
Conc. %	16	39	78	135	163
OD STAR	0.069	0.168	0.360	0.621	0.746

	Acceptance Range	MV
NC	[79-99]	92
AC	[29-39]	32

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. %	0	3.12	6.25	12.5	25
OD WB	0.054	0.142	0.308	0.686	1.372
Conc. %	1.00	2.00	6.00	12.00	22
OD STAR	0.079	0.114	0.371	0.705	1.257

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 Manager :

Quality Control Approval

16 OCT. 2025

S. LECOURT