



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C

Product Code : 221406

Lot No. : FF0041TK / FF0045

Expiration date : 2028-06-02

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FF0041h8TK / FF0045	2028-06-25
R2 : Activation reagent	2 vials	FF0041h9TK / FF0045	2028-07-22
R3 : Substrate	2 vials	FF0041i1TK / FF0045	2028-07-16
R4: Buffer	4 vials	FF0041i2TK / FF0045	2028-06-02

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	2.489 1.133 0.999 PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (25%) ≥ 0.80 Delta A405 (12.5; 25%) ≥ 0.30 $R^2 \geq 0.98$	1.309 0.600 0.997

Calibration Curve for information HIGH RANGE

Conc. %	12.5	25	50	100	200
OD WB	0.121	0.263	0.603	1.356	2.489
Conc. %	18	44	88	152	183
OD STAR	0.068	0.178	0.389	0.661	0.761

	Acceptance Range	MV
NC	[84-104]	95
AC	[29-39]	33

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. %	0	3.12	6.25	12.5	25
OD WB	0.014	0.144	0.330	0.709	1.309
Conc. %	1.00	2.00	7.00	14.00	25
OD STAR	0.041	0.080	0.364	0.714	1.233

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

27 FEB. 2026

S.MONEUS