



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN FVIII:C

**Product Code :** 221402

**Lot No. :** FE3401RW / FE3402

**Expiration date :** 2028-02-21

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FE3401h8RW/FE3402	2028-03-12
R2 : Activation reagent	2 vials	FE3401h9RW/FE3402	2028-03-18
R3 : Substrate	2 vials	FE3401i1RW/FE3402	2028-02-21
R4: Buffer	4 vials	FE3401i2RW/FE3402	2028-03-03

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range)	
	A405 (200%) $\geq$ 1.60	2.284
	Delta A405 (100 ; 200%) $\geq$ 0.60	1.186
	R <sup>2</sup> $\geq$ 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	1.300
	Delta A405 (12.5; 25%) $\geq$ 0.30	0.657
	R <sup>2</sup> $\geq$ 0.98	0.995

### Calibration Curve for information HIGH RANGE

Conc. %	12.5	25	50	100	200
OD WB	0.098	0.189	0.455	1.098	2.284
Conc. %	16	39	78	135	163
OD STAR	0.060	0.159	0.335	0.585	0.704

	Acceptance Range	MV
NC	[79-99]	95
AC	[29-39]	35

MV = Measured value

### Calibration Curve for information LOW RANGE

Conc. %	0	3.12	6.25	12.5	25
OD WB	0.043	0.121	0.273	0.643	1.300
Conc. %	1.00	2.00	6.00	12.00	22
OD STAR	0.064	0.094	0.332	0.684	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 Manager :

Quality Control Approval

16 OCT. 2025

S. LECOUMT