



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN FVIII:C  
**Product Code :** 221402  
**Lot No. :** FD0257HY/FD0262HZ  
**Expiration date :** 2026-07-24

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FD0257h8HY/FD0262HZ	2026-08-09
R2 : Activation reagent	2 vials	FD0257h9HY/FD0262HZ	2026-08-15
R3 : Substrate	2 vials	FD0257i1HY/FD0262HZ	2026-08-03
R4 : Buffer	4 vials	FD0257i2HY/FD0262HZ	2026-07-24

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range) A405 (200%) $\geq$ 1.60 Delta A405 (100 ; 200%) $\geq$ 0.60 $R^2 \geq$ 0.98 Measured values for controls in acceptance ranges	2.366 0.988 0.994 PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (25%) $\geq$ 0.80 Delta A405 (12.5; 25%) $\geq$ 0.30 $R^2 \geq$ 0.98	1.292 0.567 0.994
Detection Threshold High Range	$\leq$ 10%	< 2 %
Detection Threshold Low Range	$\leq$ 2 %	< 1 %

### Calibration Curve for information HIGH RANGE

Conc.	12.5	25	50	100	200
OD WB	0.135	0.302	0.681	1.379	2.366
Conc.	20	50	100	133	200
OD STAR	0.068	0.194	0.386	0.548	0.779

	Acceptance Range	MV
NC	[ 89 - 109 ]	103
AC	[ 26 - 35 ]	33

MV = Measured value

### Calibration Curve for information LOW RANGE

Conc.	0	3.12	6.25	12.5	25
OD WB	0.010	0.160	0.363	0.725	1.292
Conc.	0.83	1.25	6.25	12.5	25
OD STAR	0.039	0.050	0.306	0.603	1.133

*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**

28 MARS 2024

S. LECOURT

