



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

## CERTIFICATE OF ANALYSIS

**Product Description:** BIOPHEN FVIII:C  
**Product Code:** 221406  
**Lot No.:** FB03999H/FB04009J  
**Expiration date:** 2024-08-16

Components	Quantity	Lot	Expiration Date
R1: Human FX	2 vials	FB0399h89H/FB04009J	2024-10-21
R2: Activation reagent	2 vials	FB0399h99H/FB04009J	2024-10-27
R3: Substrate	2 vials	FB0399i19H/FB04009J	2024-08-17
R4: Buffer	4 vials	FB0399i29H/FB04009J	2024-08-16

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	2.248 0.994 PASS PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (25%) $\geq 0.80$ Delta A405 (12.5; 25%) $\geq 0.30$ $R^2 \geq 0.98$	1.286 0.607 PASS
Detection Threshold High Range	$\leq 10\%$	$< 2\%$
Detection Threshold Low Range	$\leq 2\%$	$< 1\%$

### Calibration Curve for information HIGH RANGE

Conc.	200%	100%	50%	25%	12.5%
OD WB	2.248	1.254	0.599	0.266	0.121
Conc.	200%	133%	100%	50%	20%
OD STAR	0.731	0.531	0.403	0.191	0.095

	Acceptance Range	MV (STAR)
NC	[ 91 - 111 ]	106
AC	[ 29 - 40 ]	38

MV = Measured value

### Calibration Curve for information LOW RANGE

Conc.	25%	12.5%	6.25%	3.12%
OD WB	1.286	0.679	0.328	0.128
Conc.	25%	12.5%	6.25%	1.56%
OD STAR	1.098	0.593	0.319	0.080

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

Date of Approval: 2022-06-07

Quality Control Manager: S.LECOURT