



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN FVIII:C  
**Product Code :** 221402  
**Lot No. :** F1903149 - F1903150  
**Expiration date :** 2022-05-06

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	F193S03149 - F193T03150	2022-05-13
R2 : Activation reagent	2 vials	F193S03149 - F193T03150	2022-05-21
R3 : Substrate	2 vials	F193S03149 - F193T03150	2022-05-07
R4: Buffer	4 vials	F193S03149 - F193T03150	2022-05-06

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	2.79 1.27 0.99 Measured values for controls in acceptance ranges
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	1.44 0.73 0.99
Detection Threshold High Range	$\leq$ 10%	< 1 %
Detection Threshold Low Range	$\leq$ 2 %	< 1 %

### Calibration Curve for information HIGH RANGE

Conc.	12.5	25	50	100	200
OD WB	0.12	0.27	0.67	1.51	2.79
Conc.	20	50	100	133	200
OD STAR	0.08	0.23	0.50	0.65	0.90

	Acceptance Range	MV
NC	[ 96 -116 ]	106
AC	[ 28 - 38 ]	30

MV = Measured value

### Calibration Curve for information LOW RANGE

Conc.	3.12	6.25	12.5	25
OD WB	0.12	0.31	0.72	1.44
Conc.	1.56	6.25	12.5	25
OD STAR	0.08	0.36	0.74	1.41

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

Date of Approval: 2019-12-24

Quality Control Manager: S. LECOURT

