



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C

Product Code : 221402

Lot No. : F1900485

Expiration date : 2021-10-02

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	F193900485	2021-10-09
R2 : Activation reagent	2 vials	F193900485	2021-10-16
R3 : Substrate	2 vials	F193900485	2021-10-02
R4: Buffer	4 vials	F193900485	2021-10-04

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	2.35 1.10 0.99 Controls in compliance
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	1.20 0.59 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	0.081	0.206	0.518	1.245	2.347
Conc.	20	50	100	133	200
OD STAR	0.072	0.203	0.414	0.546	0.767

	Acceptance Range	MV
NC	[92 - 112]	102
AC	[23 - 31]	28

MV = Measured value

Calibration Curve for information LOW RANGE

Conc.	3.12	6.25	12.5	25
OD WB	0.100	0.267	0.612	1.200
Conc.	1.56	6.25	12.5	25
OD STAR	0.069	0.307	0.598	1.101

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

Date of Approval : 2019-05-27

Quality Control Manager : **S.LECOURT**