



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C

Product Code : 221402

Lot No. : F1801710

Expiration date : 2021-06-20

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	F183201710	2021-06-20
R2 : Activation reagent	2 vials	F183201710	2021-07-03
R3 : Substrate	2 vials	F183201710	2021-06-28
R4: Buffer	4 vials	F183201710	2021-06-27

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range) A405 (200%) ≥ 1.60 Delta A405 (100 ; 200%) ≥ 0.60 $R^2 \geq 0.98$ Measured values for controls in acceptance ranges	2.584 1.111 0.994 Controls in range
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (25%) ≥ 0.80 Delta A405 (12.5; 25%) ≥ 0.30 $R^2 \geq 0.98$	1.498 0.751 0.997
Detection Threshold High Range	$\leq 10\%$	< 2 %
Detection Threshold Low Range	$\leq 2\%$	< 2 %

Calibration Curve for information HIGH RANGE

Conc.	200	100	50	25	12.5
OD WB	2.584	1.473	0.669	0.277	0.119
Conc.	200	133	100	50	20
OD STAR	0.825	0.579	0.430	0.213	0.075

	Acceptance Range	MV
NC	[92 - 112]	103
AC	[23 - 31]	28

MV = Measured value

Calibration Curve for information LOW RANGE

Conc.	25	12.5	6.25	3.12
OD WB	1.498	0.747	0.321	0.120
Conc.	25	12.5	6.25	1.56
OD STAR	1.358	0.668	0.321	0.072

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

Date of Approval : 2019-02-11

Quality Control Manager : **S.LECOURT**