



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C
Product Code : 221402
Lot No. : FC1115E4 / FC1114E3
Expiration date : 2025-10-06

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FC1115h8E4 / FC1114E3	2025-10-10
R2 : Activation reagent	2 vials	FC1115h9E4 / FC1114E3	2025-10-19
R3 : Substrate	2 vials	FC1115i1E4 / FC1114E3	2025-10-06
R4: Buffer	4 vials	FC1115i2E4 / FC1114E3	2025-10-18

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	2.720 1.154 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	1.559 0.69 PASS
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	0.191	0.345	0.752	1.565	2.720
Conc.	20%	50%	100%	133%	200%
OD STAR	0.075	0.203	0.431	0.581	0.835

	Acceptance Range	MV
NC	[80 - 100]	94
AC	[27 - 38]	35

MV = Measured value

Calibration Curve for information LOW RANGE

Conc.	3.12%	6.25%	12.5%	25%	
OD WB	0.265	0.467	0.869	1.559	
Conc.	1.25%	1.56%	6.25%	12.5%	25%
OD STAR	0.074	0.087	0.342	0.671	1.266

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

Date of Approval : 2023-05-31

Quality Control Manager : **S.LECOURT**

