



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C

Product Code : 221406

Lot No. : FC1776FM

Expiration date : 2026-01-25

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FC1776h8FM	2026-03-06
R2 : Activation reagent	2 vials	FC1776h9FM	2026-03-21
R3 : Substrate	2 vials	FC1776i1FM	2026-02-09
R4: Buffer	4 vials	FC1776i2FM	2026-01-25

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	2.513 1.094 PASS PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (25%) ≥ 0.80 Delta A405 (12.5; 25%) ≥ 0.30 $R^2 \geq 0.98$	1.388 0.668 PASS
Detection Threshold High Range	$\leq 10\%$	< 1 %
Detection Threshold Low Range	$\leq 2\%$	< 1 %

Calibration Curve for information HIGH RANGE

Conc.	0%	25%	50%	100%	200%
OD WB	0.015	0.318	0.682	1.419	2.513
Conc.	0%	20%	50%	100%	200%
OD STAR	Lim	0.212	0.428	0.561	0.799

	Acceptance Range	MV
NC	[80 - 100]	93
AC	[27 - 38]	34

MV = Measured value

Calibration Curve for information LOW RANGE

Conc.	0%	6.25%	12.5%	25%
OD WB	0.014	0.356	0.720	1.388
Conc.	0.83%	6.25%	12.5%	25%
OD STAR	0.038	0.332	0.651	1.202

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

Date of Approval : 2023.10.23

Quality Control Manager : S.LECOURT