



A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C

Product Code : 221406

Lot No. : FC2261GX

Expiration date : 2026-04-24

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FC2261GX	2026-04-24
R2 : Activation reagent	2 vials	FC2261GX	2026-05-02
R3 : Substrate	2 vials	FC2261GX	2026-04-28
R4: Buffer	4 vials	FC2261GX	2026-04-24

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	2.512 1.077 0.996 PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (25%) ≥ 0.80 Delta A405 (12.5; 25%) ≥ 0.30 $R^2 \geq 0.98$	1.429 0.664 0.999
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	0.018	0.333	0.732	1.436	2.512
Conc.	0	50	100	133	200
OD STAR	0.000	0.201	0.406	0.539	0.730

	Acceptance Range	MV
NC	[89 - 109]	101
AC	[27 - 38]	35

MV = Measured value

Calibration Curve for information LOW RANGE

Conc.	0	6.25	12.5	25
OD WB	0.021	0.380	0.765	1.429
Conc.	0.83	6.25	12.5	25
OD STAR	0.041	0.320	0.616	1.170

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

Date of Approval : 2023-12-07

Quality Control Manager : S.LECOURT