



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. : FD0429J7 / FD0428J6
Expiration date : 2026-08-17

Components	Quantity	Lot	Expiration Date
R1 : Human FX	2 vials	FD0429h8J7 / FD0428J6	2026-08-17
R2 : Activation reagent	2 vials	FD0429h9J7 / FD0428J6	2026-09-05
R3 : Substrate	2 vials	FD0429i1J7 / FD0428J6	2026-08-17
R4: Buffer	4 vials	FD0429i2J7 / FD0428J6	2026-08-23

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range)	
	A405 (200%) \geq 1.60	2.470
	Delta A405 (100 ; 200%) \geq 0.60	0.988
	R ² \geq 0.98	0.995
	Measured values for controls in acceptance ranges	PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range)	
	A405 (25%) \geq 0.80	1.339
	Delta A405 (12.5; 25%) \geq 0.30	0.580
	R ² \geq 0.98	0.996
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	0.139	0.310	0,674	1,357	2,47
Conc.	20	50	100	133	200
OD STAR	0.075	0.207	0,409	0,525	0,745

	Acceptance Range	MV
NC	[89 - 109]	94
AC	[27 - 38]	34

MV = Measured value

Calibration Curve for information LOW RANGE

Conc.	0	3,12	6,25	12,5	25
OD WB	0,011	0,180	0,390	0,756	1,339
Conc.	0,83	1,25	6,25	12,5	25
OD STAR	0,032	0,053	0,306	0,603	1,060

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

Date of Approval :

Stefano Dall'...

Quality Control Manager :

Claire DUNOIS
Dir. Etudes Clin. & Val

Claire Dunois