HYPHEN BioMed
A Company of Sysmex Group

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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ FVIII

Product Code : 221406

Lot No. : FF1963X2 / FF1962

Expiration date : 2029-02-16

Components	Quantity	Lot	Expiration Date
R1 : Human Factor X	2 vials	FF1963h8X2 / FF1962	2029-02-19
R2 : Activation reagent	2 vials	FF1963h9X2 / FF1962	2029-02-24
R3 : SXa-11	2 vials	FF1963i1X2 / FF1962	2029-02-18
R4: Tris-BSA Buffer	4 vials	FF1963i2X2 / FF1962	2029-02-16

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	 2.216 1.138 0.999 PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (25%) ≥ 0.80 Delta A405 (12.5; 25%) ≥ 0.30 $R^2 \geq 0.98$	 1.327 0.652 0.999

Calibration Curve for information HIGH RANGE

Conc. %	12.5	25	50	100	200
OD WB	0.094	0.185	0.456	1.079	2.216
Conc. %	18	44	88	152	183
OD STAR	0.067	0.178	0.370	0.623	0.737

	Acceptance Range	MV
NC	[84-104]	100
AC	[29-39]	38

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. %	0	3.12	6.25	12.5	25
OD WB	0.029	0.147	0.323	0.675	1.327
Conc. %	1.00	2.00	7.00	14.00	25
OD STAR	0.042	0.085	0.352	0.704	1.252

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

Date of Approval : Quality Control Approval

13 OCT. 2026

S.MONEUS

Quality Control Manager :