



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ FIX

Product Code : 221806

Lot No. : FF1209VX

Expiration date : 2028-11-12

Components	Quantity	Lot	Expiration Date
R1 : FX(h)-FVIII(h)	2 vials	FF1209EBVX	2028-11-13
R2 : Activator reagent	2 vials	FF1209ECVX	2028-11-20
R3 : SXa-11	2 vials	FF1209EDVX	2028-11-13
R4: Tris-BSA Buffer	4 vials	FF1209EEVX	2028-11-12

Analytical Data	Specification	Result
Calibration curve : reactivity, linearity, slope and accuracy	Water-Bath (High Range) A405 (200%) ≥ 1.2 Delta A405 (100 ; 200%) ≥ 0.30 $R^2 \geq 0.98$ Measured values for controls in acceptance ranges	1.675 0.419 0.992 PASS
Calibration curve : reactivity, linearity, and slope	Water-Bath (Low Range) A405 (20%) ≈ 1.00 Delta A405 (10; 20%) ≥ 0.25 $R^2 \geq 0.98$	1.101 0.340 0.999
Detection Threshold High Range	$\leq 5\%$	< 1%
Detection Threshold Low Range	$\leq 2\%$	< 1%

Calibration Curve for information HIGH RANGE

Conc. WB	0	12.5	25	50	100
OD WB	0.055	0.368	0.584	0.880	1.256
Conc. STAR	22	44	54	87	145
OD STAR	0.309	0.490	0.592	0.805	1.053

	Acceptance Range	MV (STAR)
NC	[77-97]	88
AC	[30-41]	36

MV = Measured value

Calibration Curve for information LOW RANGE

Conc. WB	1	2.5	5	10	20
OD WB	0.192	0.340	0.517	0.761	1.101
Conc. STAR	1	2	6	15	22
OD STAR	0.081	0.148	0.308	0.600	0.796

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

Quality Control Manager :

30 JUIN 2026

S.MONEUS