



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN LRT

Product Code : 221013

Lot No. : FF0604UU / FF0614

Expiration date : 2027-09-07

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	3 vials	FF0604BHUU / FF0614	2028-01-21
R2 : Bovine FXa	3 vials	FF0604BIUU / FF0614	2027-09-07

Analytical Data	Specification	Result
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON STAR	- For a same A405 (UFH/LMWH): - MV = TV ± 0.05 IU/ml for conc. ≤ 0.50 IU/ml - MV = TV ± 0.10 IU/ml for conc. > 0.50 IU/ml $R^2 \geq 0.98$	PASS PASS >0.99
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON CS	- For a same A405 (UFH/LMWH): - MV = TV ± 0.05 IU/ml for conc. ≤ 0.50 IU/ml - MV = TV ± 0.10 IU/ml for conc. > 0.50 IU/ml $R^2 \geq 0.98$	PASS PASS >0.99

Calibration Curve for information

Conc. LMWH	0.00	0.44	0.93	1.39	1.81
OD STAR	1.774	1.216	0.863	0.626	0.439
OD CS	0.743	0.476	0.314	0.213	0.145

	Acceptance Range	MV
C3	[0.67 - 0.87]	0.76
C4	[1.05 - 1.25]	1.15

MV = Measured value

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 Manager :

Quality Control Approval

29 AVR. 2026

S.MONEUS

