



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN LRT

Product Code : 221011

Lot No. : FE2869QV / FE2885

Expiration date : 2027-01-02

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FE2869BHQV / FE2885	2027-05-18
R2 : Bovine FXa	4 vials	FE2869BIQV / FE2885	2027-01-02

Analytical Data	Specification	Result
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON STAR	- For a same A405 (UFH/LMWH): - MV = TV $\pm$ 0.05 IU/ml for conc. $\leq$ 0.50 IU/ml - MV = TV $\pm$ 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 $\pm$ 0.05 IU/ml for conc. $\leq$ 0.50 IU/ml - MV = TV $\pm$ 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	1.881	1.300	0.907	0.649	0.489
OD CS	0.873	0.555	0.368	0.243	0.168

	Acceptance Range	MV
C3	[0.67 - 0.87]	0.75
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 Approval

Quality Control Manager :

08 SEP. 2025

S. LECOURT