



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN LRT

Product Code : 221011

Lot No. : FE3187RE / FE3197

Expiration date : 2027-02-17

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FE3187BHRE / FE3197	2027-07-03
R2 : Bovine FXa	4 vials	FE3187BIRE / FE3197	2027-02-17

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

Calibration Curve for information

Conc. LMWH	0.00	0.44	0.93	1.39	1.81
OD STAR	1.800	1.226	0.882	0.649	0.465
OD CS	0.746	0.486	0.323	0.214	0.150

	Acceptance Range	MV
C3	[0.67 - 0.87]	0.77
C4	[1.05 - 1.25]	1.16

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 :

23 OCT. 2025

S. LECOURT

