



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN LRT

Product Code : 221013

Lot No. : FE03892X / FE044037

Expiration date : 2026-08-18

Components	Quantity	Lot	Expiration Date
R1 : Sxa-11 substrate	3 vials	FE0389BH2X / FE044037	2027-01-01
R2 : Bovine FXa	3 vials	FE0389BI2X / FE044037	2026-08-18

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
DETECTION THRESHOLD	$\leq 0.05 \text{ IU/ml}$	<0.01 IU/mL

Calibration Curve for information

Conc. LMWH	0.00	0.44	0.93	1.39	1.81
OD STAR	1.849	1.280	0.871	0.601	0.462
OD CS	0.767	0.503	0.330	0.220	0.150

	Acceptance Range	MV
C3	[0.68 - 0.88]	0.73
C4	[1.07 - 1.27]	1.13

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

01 AVR 2025

Sophie LECOURT
Dép. Dir. Qualité Control