



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ Heparin LRT

Product Code : 221015

Lot No. : FE03862U / FE043936

Expiration date : 2026-08-18

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FE0386BH2U / FE043936	2027-01-01
R2 : Bovine FXa	4 vials	FE0386BI2U / FE043936	2026-08-18

Analytical Data	Specification	Result
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON STAR	<ul style="list-style-type: none"> • 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 • R² ≥ 0.98 	PASS PASS >0.99
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON CS	<ul style="list-style-type: none"> • 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 • R² ≥ 0.98 	PASS PASS >0.99
DETECTION THRESHOLD	≤ 0.05 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.

Quality Control Approval

Date of Approval :

01 AVR. 2025

S. LECOURT

Quality Control Manager :

