



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN LRT

Product Code : 221013

Lot No. : FE2169NN / FE2193NR

Expiration date : 2026-09-29

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	3 vials	FE2169BHNN / FE2193NR	2027-02-12
R2 : Bovine FXa	3 vials	FE2169BINN / FE2193NR	2026-09-29

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	1.804	1.242	0.871	0.618	0.457
OD CS	0.756	0.495	0.328	0.222	0.153

	Acceptance Range	MV
C3	[0.67 - 0.87]	0.75
C4	[1.05 - 1.25]	1.14

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 : **27 MAI 2025**
S. LECOURT

Quality Control Manager :

