



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

CERTIFICATE OF ANALYSIS
Product Description : BIOPHEN™ Heparin LRT
Product Code : 221015
Lot No. : FE3186RD / FE3196
Expiration date : 2027-02-17

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FE3186BHRD / FE3196	2027-07-03
R2 : Bovine FXa	4 vials	FE3186BIRD / FE3196	2027-02-17

Analytical Data	Specification	Result
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON STAR	<ul style="list-style-type: none"> For a same A405 (UFH/LMWH): MV = TV \pm0.05 IU/ml for conc. \leq 0.50 IU/ml MV = TV \pm0.10 IU/ml for conc. $>$ 0.50 IU/ml $R^2 \geq 0.98$ 	PASS PASS >0.99
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON CS	<ul style="list-style-type: none"> For a same A405 (UFH/LMWH): MV = TV \pm0.05 IU/ml for conc. \leq 0.50 IU/ml MV = TV \pm0.10 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	1.800	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
