

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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN LRT

Product Code : 221013

Lot No. : FE4042T1 / FE4050

Expiration date : 2027-05-20

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	3 vials	FE4042BHT1 / FE4050	2027-10-03
R2 : Bovine FXa	3 vials	FE4042BIT1 / FE4050	2027-05-20

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 • R² \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 • R² \geq 0.98 	PASS PASS >0.99

Calibration Curve for information

						Acceptance Range	MV
Conc. LMWH	0.00	0.44	0.93	1.39	1.81		
OD STAR	1.791	1.190	0.817	0.581	0.424	C3 [0.67 - 0.87]	0.76
OD CS	0.749	0.472	0.307	0.205	0.139	C4 [1.05 - 1.25]	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.

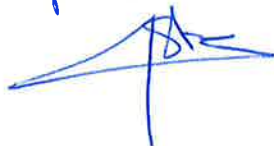
Date of Approval :

Quality Control Manager :

Quality Control Approval

09 FEV. 2026

po S.MONEUS



Sophie LECOURT
Technical Director

