



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

CERTIFICATE OF ANALYSIS

Product Description: BIOPHEN HEPARIN LRT

Product Code: 221013

Lot No.: F2001452

Expiration date: 2022-05-10

Components	Quantity	Lot	Expiration Date
R1: Sxa-11 substrate	3 vials	F204E01452	2022-05-10
R2: Bovine FXa	3 vials	F204E01452	2022-05-10

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
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
DETECTION THRESHOLD	\leq 0.05 IU/mL	< 0.01 IU/mL

Calibration Curve for information

Conc. LMWH	0	0.45	0.92	1.36	1.80
OD STAR	1.688	1.204	0.885	0.650	0.502
OD CS	0.735	0.486	0.324	0.225	0.160

	Acceptance Range	MV
C3	[0.69 - 0.93]	0.79
C4	[1.06 - 1.44]	1.28

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: 2020-12-07

Quality Control Manager: S. LECOURT