



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

CERTIFICATE OF ANALYSIS

Product Description: BIOPHEN HEPARIN LRT
Product Code: 221011
Lot No.: F2001453
Expiration date: 2022-05-10

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	F204F01453	2022-05-10
R2 : Bovine FXa	4 vials	F204F01453	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 • $R^2 \geq 0.98$ 	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 • $R^2 \geq 0.98$ 	PASS
DETECTION THRESHOLD	≤ 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	1.684	1.205	0.879	0.648	0.474
OD CS	0.739	0.489	0.329	0.225	0.159

	Acceptance Range	MV
C3	[0.69 - 0.93]	0,79
C4	[1.06 - 1.44]	1,24

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

