



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN LRT

Product Code : 221011

Lot No. : FC2314H4

Expiration date : 2025-05-20

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FC2314BHH4	2025-10-17
R2 : Bovine FXa	4 vials	FC2314BIH4	2025-05-20

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 $R^2 \geq 0.98$ 	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
DETECTION THRESHOLD	\leq 0.05 IU/ml	<0.01 IU/mL

Calibration Curve for information

Conc. LMWH	0.00	0.44	0.93	1.39	1.81
OD STAR	1.740	1.220	0.872	0.636	0.469
OD CS	0.746	0.485	0.321	0.220	0.148

	Acceptance Range	MV
C3	[0.68 - 0.88]	0.76
C4	[1.02 - 1.22]	1.15

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 :

08 JAN. 2024

S. LECOURT

