



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN HEPARIN LRT

Product Code : 221013

Lot No. : F1903257

Expiration date : 2021-06-08

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	3 vials	F193U03257	2021-06-08
R2 : Bovine FXa	3 vials	F193U03257	2021-06-08

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 - R ² = 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 - R ² = 0.99
DETECTION THRESHOLD	\leq 0.05 IU/ml	$<$ 0.01 IU/ml

Calibration Curve for information

Conc. LMWH	0	0.50	1.00	1.50	1.95
OD STAR	1.657	1.158	0.815	0.584	0.440
OD CS	0.737	0.466	0.307	0.203	0.139

	Acceptance Range	MV
C3	[0.69 - 0.93]	0.84
C4	[1.06 - 1.36]	1.29

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: 2020-02-04

Quality Control Manager: S. LECOURT

