



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

## CERTIFICATE OF ANALYSIS

**Product Description:** BIOPHEN™ Heparin LRT

**Product Code:** 221015

**Lot No.:** FB020498

**Expiration date:** 2023-08-08

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FB0204BH98	2023-08-08
R2 : Bovine FXa	4 vials	FB0204BI98	2023-08-08

Analytical Data	Specification	Result
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON STAR	<ul style="list-style-type: none"> <li>For a same A405 (UFH/LMWH): MV = TV <math>\pm</math>0.05 IU/ml for conc. <math>\leq</math> 0.50 IU/ml MV = TV <math>\pm</math>0.10 IU/ml for conc. <math>&gt;</math> 0.50 IU/ml • R<sup>2</sup> <math>\geq</math> 0.98</li> </ul>	PASS
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON CS	<ul style="list-style-type: none"> <li>For a same A405 (UFH/LMWH): MV = TV <math>\pm</math>0.05 IU/ml for conc. <math>\leq</math> 0.50 IU/ml MV = TV <math>\pm</math>0.10 IU/ml for conc. <math>&gt;</math> 0.50 IU/ml • R<sup>2</sup> <math>\geq</math> 0.98</li> </ul>	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	1.759	1.205	0.867	0.621	0.451
OD CS	0.797	0.516	0.338	0.228	0.158

	Acceptance Range	MV
C3	[ 0.68 -0.92 ]	0.82
C4	[ 0.99 - 1.35 ]	1.19

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: 2021-04-12

Quality Control Manager: S.LECOURT