



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN HEPARIN LRT

**Product Code :** 221011

**Lot No. :** FD1465LN

**Expiration date :** 2026-02-03

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FD1465BHLN	2026-07-03
R2 : Bovine FXa	4 vials	FD1465BILN	2026-02-03

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</li> <li>• R<sup>2</sup> <math>\geq</math> 0.98</li> </ul>	PASS PASS >0,99
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</li> <li>• R<sup>2</sup> <math>\geq</math> 0.98</li> </ul>	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	1.802	1.252	0.904	0.651	0.465
OD CS	0.763	0.497	0.325	0.219	0.152

	Acceptance Range	MV
C3	[0,68 - 0,88]	0.74
C4	[1,02 - 1,22]	1.12

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 :

30 SEP. 2024

S. LECOURT