



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN™ Heparin LRT

**Product Code :** 221015

**Lot No. :** FD0805JY

**Expiration date :** 2025-11-04

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FD0805BHJY	2026-03-22
R2 : Bovine FXa	4 vials	FD0805BIJY	2025-11-04

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 ±0.05 IU/ml for conc. ≤ 0.50 IU/ml MV = TV ±0.10 IU/ml for conc. &gt; 0.50 IU/ml • R<sup>2</sup> ≥ 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 ±0.05 IU/ml for conc. ≤ 0.50 IU/ml MV = TV ±0.10 IU/ml for conc. &gt; 0.50 IU/ml • R<sup>2</sup> ≥ 0.98</li> </ul>	PASS PASS >0.99
DETECTION THRESHOLD	≤ 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	1.747	1.230	0.859	0.641	0.456
OD CS	0.784	0.507	0.332	0.223	0.152

	Acceptance Range	MV
C3	[0.68 - 0.88]	0.79
C4	[1.02 - 1.22]	1.13

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 :

13 JUN 2024

S. LECOURT

