



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

## CERTIFICATE OF ANALYSIS

**Product Description : BIOPHEN HEPARIN LRT**

**Product Code : 221013**

**Lot No. : FC1350EC**

**Expiration date : 2024-12-04**

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	3 vials	FC1350BHEC	2025-05-03
R2 : Bovine FXa	3 vials	FC1350BIEC	2024-12-04

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 <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 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 • 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	1.748	1.222	0.861	0.633	0.466
OD CS	0.735	0.476	0.313	0.211	0.145

	Acceptance Range	MV
C3	[0.68 - 0.88]	0.75
C4	[1.07 - 1.27]	1.17

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 Manager :

Quality Control Approval

18 JUL. 2023

S. LECOURT