



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

## CERTIFICATE OF ANALYSIS

**Product Description:** BIOPHEN HEPARIN LRT  
**Product Code:** 221013  
**Lot No.:** FB0768A6  
**Expiration date:** 2023-10-31

Components	Quantity	Lot	Expiration Date
R1: Sxa-11 substrate	3 vials	FB0768BHA6	2024-03-29
R2: Bovine FXa	3 vials	FB0768BIA6	2023-10-31

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	1.716	1.171	0.826	0.596	0.451
OD CS	0.737	0.470	0.310	0.213	0.152

	Acceptance Range	MV
C3	[ 0.67 -0.91 ]	0.81
C4	[ 1.01 -1.37 ]	1.18

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: 2022-06-28

Quality Control Manager: S.LECOURT

