



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

## CERTIFICATE OF ANALYSIS

**Product Description:** BIOPHEN HEPARIN LRT  
**Product Code:** 221011  
**Lot No.:** F2000404  
**Expiration date:** 2021-09-28

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	F201J00404	2021-09-28
R2 : Bovine FXa	4 vials	F201J00404	2021-09-28

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	0.50	1.00	1.50	1.95
OD STAR	1.739	1.187	0.840	0.601	0.431
OD CS	0.748	0.466	0.304	0.199	0.140

	Acceptance Range	MV (STAR)
C3	[ 0.68 - 0.92 ]	0.81
C4	[ 1.06 - 1.44 ]	1.23

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: 2020-04-24

Quality Control Manager: S. LECOURT