



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

## CERTIFICATE OF ANALYSIS

**Product Description : BIOPHEN HEPARIN LRT**

**Product Code : 221011**

**Lot No. : FA18798C**

**Expiration date : 2023-04-20**

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FA1879BH8C	2023-04-20
R2 : Bovine FXa	4 vials	FA1879BI8C	2023-04-20

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	0.00	0.45	0.92	1.36	1.80
OD STAR	1.693	1.139	0.812	0.593	0.448
OD CS	0.809	0.503	0.328	0.225	0.161

	Acceptance Range	MV
C3	[ 0.67 - 0.91 ]	0.82
C4	[ 1.03 - 1.39 ]	1.20

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 : 2021-12-20

Quality Control Manager : S.LECOURT

