



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

## CERTIFICATE OF ANALYSIS

**Product Description : BIOPHEN HEPARIN LRT**

**Product Code : 221011**

**Lot No. : F1900990**

**Expiration date : 2021-02-09**

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	F191H00990	2021-02-09
R2 : Bovine FXa	4 vials	F191H00990	2021-02-09

Analytical Data	Specification	Result
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON STAR	<ul style="list-style-type: none"> <li>• For a same A405 (UFH/LMWH):</li> <li>MV = TV <math>\pm</math>0.05 IU/ml for conc. <math>\leq</math> 0.50 IU/ml</li> <li>MV = TV <math>\pm</math>0.10 IU/ml for conc. <math>&gt;</math> 0.50 IU/ml</li> <li>• R<sup>2</sup> <math>\geq</math> 0.98</li> </ul>	PASS PASS
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON CS	<ul style="list-style-type: none"> <li>• For a same A405 (UFH/LMWH):</li> <li>MV = TV <math>\pm</math>0.05 IU/ml for conc. <math>\leq</math> 0.50 IU/ml</li> <li>MV = TV <math>\pm</math>0.10 IU/ml for conc. <math>&gt;</math> 0.50 IU/ml</li> <li>• R<sup>2</sup> <math>\geq</math> 0.98</li> </ul>	PASS PASS
DETECTION THRESHOLD	$\leq$ 0.05 IU/ml	$<$ 0.01 IU/ml

### Calibration Curve for information

Conc. LMWH	0	0.5	1	1.5	1.95
OD STAR	1.697	1.161	0.817	0.584	0.435
OD CS	0.749	0.470	0.310	0.208	0.145

	Acceptance Range	MV
C3	[ 0.68 - 0.88 ]	0.81
C4	[ 1.05 - 1.25 ]	1.15

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 : 2019-09-24

Quality Control Manager : **S. LECOURT**