



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

## CERTIFICATE OF ANALYSIS

**Product Description : BIOPHEN HEPARIN LRT**

**Product Code : 221011**

**Lot No. : F1900723**

**Expiration date : 2020-12-08**

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	F191G00723	2020-12-08
R2 : Bovine FXa	4 vials	F191G00723	2020-12-08

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  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  0.99
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	1.633	1.102	0.769	0.546	0.394
OD CS	0.727	0.453	0.294	0.195	0.137

	Acceptance Range	MV
C3	[ 0.65 - 0.85 ]	0.80
C4	[ 1.00 - 1.30 ]	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 : 2019-07-22

Quality Control Manager : **S.LECOURT**

