



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN HEPARIN LRT

**Product Code :** 221011

**Lot No. :** FF0329U2 / FF0341

**Expiration date :** 2027-08-03

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	4 vials	FF0329BHU2 / FF0341	2027-12-17
R2 : Bovine FXa	4 vials	FF0329BIU2 / FF0341	2027-08-03

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>	<p>PASS</p> <p>PASS</p> <p><math>&gt;</math>0.99</p>
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>	<p>PASS</p> <p>PASS</p> <p><math>&gt;</math>0.99</p>

### Calibration Curve for information

Conc. LMWH	0.00	0.44	0.93	1.39	1.81
OD STAR	1.827	1.254	0.881	0.639	0.450
OD CS	0.759	0.489	0.323	0.216	0.148

	Acceptance Range	MV
C3	[0.63 - 0.83]	0.72
C4	[1.08 - 1.28]	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 :

Quality Control Manager :

Quality Control Approval

19 MARS 2026

S.MONEUS