



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

## CERTIFICATE OF ANALYSIS

**Product Description : BIOPHEN HEPARIN 3**

**Product Code : 221003**

**Lot No. : FA10886V**

**Expiration date : 2023-11-20**

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	3 vials	FA1088BF6V	2023-11-20
R2 : Bovine FXa	3 vials	FA1088BG6V	2023-11-26

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 ±0.05 IU/ml for conc. ≤ 0.50 IU/ml</li> <li>MV = TV ±0.10 IU/ml for conc. &gt; 0.50 IU/ml</li> <li>• R<sup>2</sup> ≥ 0.98</li> </ul>	PASS
DETECTION THRESHOLD	≤ 0.05 IU/ml	< 0.01 IU/ml

### Calibration Curve for information

Conc. LMWH	0	0.45	0.92	1.36	1.80
OD STAR	1.394	0.948	0.655	0.434	0.306
OD CS	0.638	0.427	0.289	0.203	0.142

	Acceptance Range	MV
C3	[ 0.70 - 0.90 ]	0.79
C4	[ 1.10 - 1.40 ]	1.21

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 : 2021-06-24

Quality Control Manager : S.LECOURT

