



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

## CERTIFICATE OF ANALYSIS

**Product Description:** BIOPHEN HEPARIN LRT  
**Product Code:** 221013  
**Lot No.:** F2000794  
**Expiration date:** 2021-12-14

| Components            | Quantity | Lot        | Expiration Date |
|-----------------------|----------|------------|-----------------|
| R1 : SXa-11 substrate | 3 vials  | F204700794 | 2021-12-14      |
| R2 : Bovine FXa       | 3 vials  | F204700794 | 2021-12-14      |

| Analytical Data   | Specification  | Result       |
|---|--|--------------|
| SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON STAR | <ul style="list-style-type: none"> <li>For a same A405 (UFH/LMWH):<br/>           MV = TV <math>\pm</math>0.05 IU/ml for conc. <math>\leq</math> 0.50 IU/ml<br/>           MV = TV <math>\pm</math>0.10 IU/ml for conc. &gt; 0.50 IU/ml<br/>           • 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):<br/>           MV = TV <math>\pm</math>0.05 IU/ml for conc. <math>\leq</math> 0.50 IU/ml<br/>           MV = TV <math>\pm</math>0.10 IU/ml for conc. &gt; 0.50 IU/ml<br/>           • 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     | 0.45  | 0.92  | 1.36  | 1.80  |
|------------|-------|-------|-------|-------|-------|
| OD STAR    | 1.678 | 1.190 | 0.864 | 0.620 | 0.436 |
| OD CS      | 0.736 | 0.484 | 0.321 | 0.219 | 0.154 |

|    | Acceptance Range | MV   |
|----|------------------|------|
| C3 | [ 0.70 - 0.90 ]  | 0.79 |
| C4 | [ 1.10 - 1.40 ]  | 1.23 |

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: 2020-07-16

Quality Control Manager: S. LECOURT

