



A Company of Sysmex Group



HYPHEN BioMed  
155 rue d'Eragny  
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France

## CERTIFICATE OF ANALYSIS

**Product Description:** BIOPHEN UFH CALIBRATOR  
**Product Code:** 222301  
**Lot No.:** FB10191E  
**Expiration date:** 2024-12-09

| Components | Quantity | Lot        | Expiration Date |
|------------|----------|------------|-----------------|
| CAL 1      | 4 vials  | FB1019BS1E | 2024-12-09      |
| CAL 2      | 4 vials  | FB1019BT1E | 2024-12-09      |
| CAL 3      | 4 vials  | FB1019BU1E | 2024-12-09      |
| CAL 4      | 4 vials  | FB1019BV1E | 2024-12-09      |
| CAL 5      | 4 vials  | FB1019BW1E | 2024-12-09      |

| Analytical Data  | Specification  | Result   |
|--|--|--|
| Concentration  | CAL 1: $\leq 0.05$ IU/mL<br>CAL 2: 0.20 -0.45 IU/mL<br>CAL 3: 0.50 -0.80 IU/mL<br>CAL 4: 0.80 -1.15 IU/mL<br>CAL 5: 1.15 -1.50 IU/mL | CAL 1: 0 IU/ml<br>CAL 2: 0.38 IU/ml<br>CAL 3: 0.73 IU/ml<br>CAL 4: 1.06 IU/ml<br>CAL 5: 1.41 IU/ml |
| Linearity and accuracy of calibration with values assigned | $R^2 \geq 0.98$<br>Measured values for controls in acceptance ranges   | PASS   |

*This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.*

Date of Approval: 2022-07-25

Quality Control Manager: S. LECOURT