



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ BIVALIRUDIN CALIBRATOR
Product Code : 226701
Lot No. : FC113315 / FC113213
Expiration date : 2025-10-07

| Components | Quantity | Lot | Expiration Date |
|------------|----------|-----------------------|-----------------|
| CAL 1 | 2 vials | FC1133cz15 / FC113213 | 2025-10-07 |
| CAL 2 | 2 vials | FC1133da15 / FC113213 | 2025-10-07 |
| CAL 3 | 2 vials | FC1133db15 / FC113213 | 2025-10-07 |
| CAL 4 | 2 vials | FC1133dc15 / FC113213 | 2025-10-07 |
| CAL 5 | 2 vials | FC1133dd15 / FC113213 | 2025-10-07 |

| Analytical Data | Specification | Result |
|--|--|--------------------------------------|
| Concentration | CAL 1 : < 0.25 µg/mL CAL 2 : 0.8 -1.2 µg/mL CAL 3 : 1.6 -2.4 µg/mL CAL 4 : 3.0 - 4.0 µg/mL CAL 5 : 4.0 - 5.0 µg/mL | 0.00 1.08 2.16 3.57 4.83 |
| Accuracy of calibration with values assigned | 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 : 2023-05-09

Quality Control Manager : **S.LECOURT**

