



A Sysmex Group Company



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ BIVALIRUDIN CALIBRATOR
Product Code : 226701
Lot No. : FE052212
Expiration date : 2027-04-13

Components	Quantity	Lot	Expiration Date
CAL 1	2 vials	FD21021A	2027-04-13
CAL 2	2 vials	FD21021A	2027-04-13
CAL 3	2 vials	FD21021A	2027-04-13
CAL 4	2 vials	FD21021A	2027-04-13
CAL 5	2 vials	FD21021A	2027-04-13

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 µg/mL 1.12 µg/mL 2.17 µg/mL 3.60 µg/mL 4.41 µg/mL
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.

Quality Control Approval

Date of Approval : 20 FEB. 2025

Quality Control Manager :

S. LECOURT