



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ Dabigatran Plasma Calibrator
Product Code : 222801
Lot No. : FE05931D / FE06291B
Expiration date : 2027-08-28

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FE0593AS1D / FE06291B	2027-08-28
CAL 2	4 vials	FE0593AT1D / FE06291B	2027-10-04
CAL 3	4 vials	FE0593AU1D / FE06291B	2027-10-04

Analytical Data	Specification	Result
Concentration	CAL 1 : < 20 ng/ml CAL 2 : 150 -350 ng/ml CAL 3 : 400 -500 ng/ml	0 ng/ml 257 ng/ml 453 ng/ml
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	1.00 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 MAI 2025

Quality Control Manager :

S. LECOURT