



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN DABIGATRAN PLASMA CALIBRATOR LOW
Product Code : 222901
Lot No. : FE25831B / FE261311
Expiration date : 2027-11-08

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FE2583DA1B / FE261311	2027-11-08
CAL 2	4 vials	FE2583DB1B / FE261311	2027-11-08
CAL 3	4 vials	FE2583DC1B / FE261311	2027-11-08

Analytical Data	Specification	Result
Concentration	CAL 1 : < 20 ng/ml CAL 2 : 40 -60 ng/ml CAL 3 : 80 -110 ng/ml	0 ng/mL 51 ng/mL 97 ng/mL
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	PASS PASS

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

Date of Approval :

06 JUIN 2025

Quality Control Manager :

Sophie LECOURT
Deputy Director Quality Control