



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. : FC23921B
Expiration date : 2026-05-16

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FC2392AS1B	2026-05-16
CAL 2	4 vials	FC2392AT1B	2026-05-16
CAL 3	4 vials	FC2392AU1B	2026-05-16

Analytical Data	Specification	Result
Concentration	CAL 1 : < 20 ng/ml CAL 2 : 150 -350 ng/ml CAL 3 : 400 -500 ng/ml	0 267 460
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 :

Quality Control Manager :

Quality Control Approval

18 JAN. 2024

S. LECOURT