



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. : FD14731C
Expiration date : 2027-01-19

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FD1473AS1C	2027-01-19
CAL 2	4 vials	FD1473AT1C	2027-01-19
CAL 3	4 vials	FD1473AU1C	2027-01-19

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 325 ng/mL 508 ng/mL(*)
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	PASS PASS

(*) NCI 2450 : Accepted under waiver

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

16 SEP. 2024

S. LECOURT