



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. : FA067319
Expiration date : 2023-09-16

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FA0673AS19	2023-09-16
CAL 2	4 vials	FA0673AT19	2023-09-16
CAL 3	4 vials	FA0673AU19	2023-09-16

Analytical Data	Specification	Result
Concentration	CAL 1 : ≤ 100 ng/ml CAL 2 : 150 -350 ng/ml CAL 3 : 400 -600 ng/ml	47 268 510
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 : 2021-04-19

Quality Control Manager : S.LECOURT