



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN RIVAROXABAN CALIBRATOR LOW

Product Code : 226001

Lot No. : FC17451D

Expiration date : 2026-01-20

Components	Quantity	Lot	Expiration Date
CAL I	4 vials	FC1745DJ1D	2026-01-20
CAL II	4 vials	FC1745DK1D	2026-01-20
CAL III	4 vials	FC1745DL1D	2026-01-20

Analytical Data	Specification	Result
Concentration	CAL I : < 20 ng/ml CAL II : 40 -60 ng/ml CAL III : 80 -100 ng/ml	0 ng/ml 50 ng/ml 94 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 : 2023-11-02 Quality Control Manager :

Sophie LECOURT
Deputy Director Quality Control

