



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. : F1801287 - F1801288

Expiration date : 2021-03-09

Components	Quantity	Lot	Expiration Date
CAL I	4 vials	F181301287 / F181101288	2021-03-09
CAL II	4 vials	F181301287 / F181101288	2021-03-09
CAL III	4 vials	F181301287 / F181101288	2021-03-09

Analytical Data	Specification	Result
Concentration	CAL I : < 20 ng/ml CAL II : 40 -60 ng/ml CAL III : 80 -120 ng/ml	0 ng/mL 53 ng/mL 112 ng/mL
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges

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

Date of Approval : 2018-10-15

Quality Control Manager : **M.PEYRAFITTE**





ZAC Neuville Université - 155 rue d'Eragny
 95000 Neuville sur Oise (France)
 Tel: +33.1.34.40.65.10 - Fax: +33.1.34.48.72.36
 Web site: www.hyphen-biomed.com



BIOPHEN™ Rivaroxaban Calibrator Low

REF 226001

LOT F1801287  2021-03-09

	UNIT	TARGET VALUE	WHO STD
CAL I LOT F181301287	ng/mL	0	N/A
CAL II LOT F181301287		53	
CAL III LOT F181301287		112	

P. de S. 10.18
