



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

CERTIFICATE OF ANALYSIS	
Product Description :	BIOPHEN RIVAROXABAN CALIBRATOR
Product Code :	222701
Lot No. :	F1801053 - F1801054
Expiration date :	2020-12-29

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	F181201053 - F181201054	2020-12-29
CAL 2	4 vials	F181201053 - F181201054	2020-12-29
CAL 3	4 vials	F181201053 - F181201054	2020-12-29

Analytical Data	Specification	Result
Concentration	CAL 1 : ≤ 50 ng/ml CAL 2 : 200 -300 ng/ml CAL 3 : 400 -600 ng/ml	CAL 1 = 0 ng/mL CAL 2 = 262 ng/mL CAL 3 = 516 ng/mL
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	$R^2 > 0.98$ 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 : 2018-08-03

Quality Control Manager :

C.DUNOIS

BIOPHEN™ Rivaroxaban Plasma Calibrator

REF 222701

LOT F1801054  2020-12-29

	UNIT	TARGET VALUE	WHO STD
<p>CAL 1</p> <p>LOT F181201054</p>	ng/mL	0	N/A
<p>CAL 2</p> <p>LOT F181201054</p>		262	
<p>CAL 3</p> <p>LOT F181201054</p>		516	