



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN DABIGATRAN PLASMA CALIBRATOR LOW
Product Code : 222901
Lot No. : F1900917
Expiration date : 2022-01-18

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	F191300917	2022-01-18
CAL 2	4 vials	F191300917	2022-01-18
CAL 3	4 vials	F191300917	2022-01-18

Analytical Data	Specification	Result
Concentration	CAL 1 : < 20 ng/ml CAL 2 : 40 -60 ng/ml CAL 3 : 80 -120 ng/ml	0 ng/mL 48 ng/mL 95 ng/mL
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	$R^2 = 0.99$ 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 : 2019-08-29

Quality Control Manager :

S. LECOURT



BIOPHEN® DABIGATRAN CALIBRATOR LOW

Set of human plasma assigned for Dabigatran intended to the calibration of the Dabigatran assays using anti-IIa method /
Gamme de plasmas humains à titre défini en Dabigatran pour l'étalonnage des dosages de Dabigatran par méthode anti-IIa

REF 222901

For in vitro diagnostic use only / Pour diagnostic in vitro exclusivement

LOT F1900917  2022-01-18

Dabigatran Concentration [C] in the calibrators /
Concentration [C] en Dabigatran dans les calibrateurs

<u>Calibrator / Calibrateur 1</u>	LOT : F191300917
[C] :	0 ng/mL / ng/mL
<u>Calibrator / Calibrateur 2</u>	LOT : F191300917
[C] :	48 ng/mL / ng/mL
<u>Calibrator / Calibrateur 3</u>	LOT : F191300917
[C] :	95 ng/mL / ng/mL

Standardization / Standardisation : **N/A**

Approved Date / Date d'Approbation : 2019-08-29

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT

