



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

CERTIFICATE OF ANALYSIS

Product Description : DABIGATRAN PLASMA CALIBRATOR
Product Code : 222801
Lot No. : F1800179-F1800180
Expiration date : 2020-08-08

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	F181200179-F181500180	2020-08-08
CAL 2	4 vials	F181200179-F181500180	2020-08-08
CAL 3	4 vials	F181200179-F181500180	2020-08-08

Analytical Data	Specification	Result
Concentration	CAL 1 : ≤ 100 ng/ml CAL 2 : 150 -350 ng/ml CAL 3 : 400 -600 ng/ml	43 ng/mL 289 ng/mL 552 ng/mL
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	1.00 Controls are in compliance

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

Date of Approval : 2018-05-22

Quality Control Manager :

M.PEYRAFITTE




DABIGATRAN PLASMA CALIBRATOR

Calibration plasma for the assay of Dabigatran with anti-IIa method /
Gamme de plasmas humains pour l'étalonnage des dosages de Dabigatran par méthode anti-IIa

REF 222801

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

LOT F1800180  2020-08-08

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

<u>Calibrator / Calibrateur 1</u>	LOT : F181500180
[C] :	43 ng/mL / ng/mL
<u>Calibrator / Calibrateur 2</u>	LOT : F181500180
[C] :	289 ng/mL / ng/mL
<u>Calibrator / Calibrateur 3</u>	LOT : F181500180
[C] :	552 ng/mL / ng/mL

Standardization / Standardisation : **N/A**

Approved Date / Date d'Approbation : 2018-05-18

Quality Control Manager / Responsable Contrôle Qualité : **M. PEYRAFITTE**