



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

CERTIFICATE OF ANALYSIS

Product Description : DABIGATRAN CONTROL PLASMA
Product Code : 224701
Lot No. : F1800832
Expiration date : 2020-11-07

Components	Quantity	Lot	Expiration Date
C1	6 vials	F181600832	2020-11-07
C2	6 vials	F181600832	2020-11-07

Analytical Data	Specification	Result
Concentration	C1 : 50 -200 ng/ml C2 : 200 -400 ng/ml	104 ng/mL 321 ng/mL

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

Date of Approval : 2018-06-21

Quality Control Manager :

M.PEYRAFITTE



DABIGATRAN CONTROL PLASMA

Human plasmas at two levels of Dabigatran for the quality control of Dabigatran measurements with anti-IIa method //
Plasmas humains à deux niveaux Dabigatran pour le contrôle de qualité des dosages Dabigatran par méthode anti-IIa

REF 224701

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

LOT F1800832



2020-11-07

Dabigatran Concentration in the controls / *Concentration en Dabigatran dans les contrôles*

Control / Contrôle C1	LOT : F181600832
Target value / <i>Valeur cible</i> :	104 ng/mL / ng/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[83 - 125] ng/mL / ng/mL

Control / Contrôle C2	LOT : F181600832
Target value / <i>Valeur cible</i> :	321 ng/mL / ng/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[273 - 369] ng/mL / ng/mL

Standardization / *Standardisation* : **N/A**

Approved Date / *Date d'Approbation* : 2018-06-21

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