



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN DABIGATRAN CONTROL PLASMA  
LOW  
**Product Code :** 225001  
**Lot No. :** F1900830  
**Expiration date :** 2021-12-28

Components	Quantity	Lot	Expiration Date
C1	6 vials	F191300830	2021-12-28
C2	6 vials	F191300830	2021-12-28

Analytical Data	Specification	Result
Concentration	C1 : 15 -35 ng/ml C2 : 45 -105 ng/ml	27 ng/mL 76 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 : 2019-07-24

Quality Control Manager : S.LECOURT

**BIOPHEN® DABIGATRAN CONTROL LOW**

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

**REF** 225001For in vitro diagnostic use only / *Pour diagnostic in vitro exclusivement***LOT** F1900830 2021-12-28**Dabigatran Concentration in the controls /  
Concentration en Dabigatran dans les contrôles**

<b>Control / Contrôle C1</b>	<b>LOT : F191300830</b>
Target value / <i>Valeur cible</i> :	<b>27</b> ng/mL / <i>ng/mL</i>
Acceptance range / <i>Intervalle d'acceptation</i> :	<b>[ 17 – 37 ]</b> ng/mL / <i>ng/mL</i>

<b>Control / Contrôle C2</b>	<b>LOT : F191300830</b>
Target value / <i>Valeur cible</i> :	<b>76</b> ng/mL / <i>ng/mL</i>
Acceptance range / <i>Intervalle d'acceptation</i> :	<b>[ 61 – 91 ]</b> ng/mL / <i>ng/mL</i>

Standardization / *Standardisation* : **NA**Approved Date / *Date d'Approbation* : 2019-07-24Quality Control Manager / *Responsable Contrôle Qualité* : S.LECOURT