HYPHEN BioMed
ZAC Neuville Université - 155 rue d'Eragny
95000 Neuville sur Oise (France)
Tel: 33.1.34.40.65.10 - Fax: 33.1.34.48.72.36

ANALYSIS CERTIFICATE

BIOPHEN DABIGATRAN CONTROL PLASMA LOW (#225001) Lot : **F1701197**
F1701198

QC release : 2017-11-24 **Expiration date : 2020-04-04**

Components	Volume	Exp. (months)	Lot #	Exp. date
C1 : Control 1	6 vials	30	F171201197 F171101198	2020-04-04
C2 : Control 2	6 vials	30	F171201197 F171101198	2020-04-04

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Analytical data						Specifications
1.	**Within lot reproducibility**					
		Mean CT (sec)				
	N= **15**	C1:	**52,8**	CV:	**1,1** %	CV (CT) ≤ 3%
	N= **15**	C2:	**72,0**	CV:	**1,3** %	CV(CT) ≤ 3%

2. Concentration and acceptance range

Controls	N series	Target value [C] ng/mL	Acceptance range (ng/mL)	SD
C1	13	25	[15 - 35]	1,6
C2	13	77	[62 - 92]	2,7

Target value for [C]:
C1: 15 to 35 ng/mL
C2: 45 to 105 ng/mL

3. Aspect

- ☑ **Slightly opalescent to clear** — a) Slightly opalescent to clear
- ☑ **No coagulum** — b) No coagulum
- ☑ **Stable solution** — c) Stable solution

4. Stability of reconstituted reagents

	Temp.	C1 ng/mL	C2 ng/mL
Fresh	/	**25**	**79**
48h	RT	**26**	**82**
7 days	2-8°C	**27**	**83**

48h at RT
Controls within the acceptance range
7 days at 2-8°C
Controls within the acceptance range

Comments :

☑ **PASSED IN COMPLIANCE**

Date : 2017-11-24 **QC Manager : S.LECOURT**

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Web site: www.hyphen-biomed.com

ENGLISH / *FRANÇAIS*

CE

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 **225001**

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

LOT F1701197 2020-04-04

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

Control / *Contrôle* C1	LOT : **F171201197**
Target value / *Valeur cible* :	**25 ng/mL / *ng/mL***
Acceptance range / *Intervalle d'acceptation* :	**[15 - 35] ng/mL / *ng/mL***

Control / *Contrôle* C2	LOT : **F171201197**
Target value / *Valeur cible* :	**77 ng/mL / *ng/mL***
Acceptance range / *Intervalle d'acceptation* :	**[62 - 92] ng/mL / *ng/mL***

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

Approved Date / *Date d'Approbation : 2017-11-24*

Quality Control Manager / *Responsable Contrôle Qualité : S.LECOURT*