

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. <u>Within lot reproducibility</u> <div style="text-align: center;"><u>Mean CT (sec)</u></div> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N= 15</td> <td style="width: 15%;">C1:</td> <td style="width: 15%;">52,8</td> <td style="width: 15%;">CV:</td> <td style="width: 15%;">1,1 %</td> <td style="width: 20%;"></td> </tr> <tr> <td>N= 15</td> <td>C2:</td> <td>72,0</td> <td>CV:</td> <td>1,3 %</td> <td></td> </tr> </table>	N= 15	C1:	52,8	CV:	1,1 %		N= 15	C2:	72,0	CV:	1,3 %		CV (CT) ≤ 3% CV(CT) ≤ 3%
N= 15	C1:	52,8	CV:	1,1 %									
N= 15	C2:	72,0	CV:	1,3 %									

2. <u>Concentration and acceptance range</u> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>Controls</th> <th>N series</th> <th>Target value [C] ng/mL</th> <th>Acceptance range (ng/mL)</th> <th>SD</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td>13</td> <td>25</td> <td>[15 - 35]</td> <td>1,6</td> </tr> <tr> <td>C2</td> <td>13</td> <td>77</td> <td>[62 - 92]</td> <td>2,7</td> </tr> </tbody> </table>	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
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												

3. <u>Aspect</u> <input checked="" type="checkbox"/> Slightly opalescent to clear <input checked="" type="checkbox"/> No coagulum <input checked="" type="checkbox"/> Stable solution	a) Slightly opalescent to clear b) No coagulum c) Stable solution
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4. <u>Stability of reconstituted reagents</u> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Temp.</th> <th>C1</th> <th>C2</th> </tr> <tr> <th>ng/mL</th> <th>ng/mL</th> </tr> </thead> <tbody> <tr> <td>Fresh</td> <td>/</td> <td>25</td> <td>79</td> </tr> <tr> <td>48h</td> <td>RT</td> <td>26</td> <td>82</td> </tr> <tr> <td>7 days</td> <td>2-8°C</td> <td>27</td> <td>83</td> </tr> </tbody> </table>		Temp.	C1	C2	ng/mL	ng/mL	Fresh	/	25	79	48h	RT	26	82	7 days	2-8°C	27	83	<u>48h at RT</u> Controls within the acceptance range <u>7 days at 2-8°C</u> Controls within the acceptance range
			Temp.	C1	C2														
	ng/mL	ng/mL																	
Fresh	/	25	79																
48h	RT	26	82																
7 days	2-8°C	27	83																

Comments : 	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-11-24

QC 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 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 / <i>Valeur cible</i> :	25 ng/mL / ng/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[15 - 35] ng/mL / ng/mL

Control / Contrôle C2	LOT : F171201197
Target value / <i>Valeur cible</i> :	77 ng/mL / ng/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[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