

## ANALYSIS CERTIFICATE

**BIOPHEN DABIGATRAN CONTROL PLASMA LOW (#225001) Lot : F1601249**

**QC release : 2017-01-18 Expiration date : 2019-05-27**

Components	Volume	Exp. (months)	Lot #	Exp. date
C1 : Control 1	6 vials	30	F161101249	2019-05-27
C2 : Control 2	6 vials	30	F161101249	2019-05-27

805

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Analytical data	Specifications												
<b>1. <u>Within lot reproducibility</u></b>  <div style="text-align: center;"><b><u>Mean CT (sec)</u></b></div> <table style="width: 100%; margin-top: 10px;"> <tr> <td style="width: 15%;">N= 15</td> <td style="width: 15%;">C1:</td> <td style="width: 15%;">46,05</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>72,03</td> <td>CV:</td> <td>1,8 %</td> <td></td> </tr> </table>	N= 15	C1:	46,05	CV:	1,1 %		N= 15	C2:	72,03	CV:	1,8 %		CV (CT) ≤ 3%  CV(CT) ≤ 3%
N= 15	C1:	46,05	CV:	1,1 %									
N= 15	C2:	72,03	CV:	1,8 %									

<b>2. <u>Concentration and acceptance range</u></b>  <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 10%;">Controls</th> <th style="width: 10%;">N series</th> <th style="width: 15%;">Target value [C] ng/mL</th> <th style="width: 40%;">Acceptance range (ng/mL)</th> <th style="width: 15%;">SD</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">10</td> <td style="text-align: center;">23</td> <td style="text-align: center;">13-33</td> <td style="text-align: center;">1,33</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">10</td> <td style="text-align: center;">68</td> <td style="text-align: center;">54-82</td> <td style="text-align: center;">1,89</td> </tr> </tbody> </table>	Controls	N series	Target value [C] ng/mL	Acceptance range (ng/mL)	SD	C1	10	23	13-33	1,33	C2	10	68	54-82	1,89	<b>Target value for [C]:</b>  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	10	23	13-33	1,33												
C2	10	68	54-82	1,89												

<b>3. <u>Aspect</u></b>  <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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<b>4. <u>Stability of reconstituted reagents</u></b>  <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Temp.</th> <th style="width: 15%;">C1</th> <th style="width: 15%;">C2</th> </tr> <tr> <th>ng/mL</th> <th>ng/mL</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Fresh</td> <td style="text-align: center;">/</td> <td style="text-align: center;">25</td> <td style="text-align: center;">71</td> </tr> <tr> <td style="text-align: center;">48h</td> <td style="text-align: center;">RT</td> <td style="text-align: center;">27</td> <td style="text-align: center;">76</td> </tr> <tr> <td style="text-align: center;">7 days</td> <td style="text-align: center;">2-8°C</td> <td style="text-align: center;">27</td> <td style="text-align: center;">76</td> </tr> </tbody> </table>		Temp.	C1	C2	ng/mL	ng/mL	Fresh	/	25	71	48h	RT	27	76	7 days	2-8°C	27	76	<b><u>48h at RT</u></b> Controls within the acceptance range  <b><u>7 days at 2-8°C</u></b> Controls within the acceptance range
			Temp.	C1	C2														
	ng/mL	ng/mL																	
Fresh	/	25	71																
48h	RT	27	76																
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<b>Comments :</b>  	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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Date : 2017-01-18

QC Manager :

S.LECOURT



**BIOPHEN DABIGATRAN CONTROL LOW**  
# 225001

Pour diagnostic *in vitro* exclusivement.

FRANÇAIS

Lot : F1601249 - Exp. : 2019-05-27

**BIOPHEN DABIGATRAN CONTROL LOW**  
# 225001

For *in vitro* diagnostic use only

ENGLISH

Lot : F1601249 - Exp. : 2019-05-27

**C1 (Contrôle 1)** Lot : F161101249  
[C]: 23 ng/mL  
Intervalle de confiance: 13 - 33 ng/mL

**C2 (Contrôle 2)** Lot : F161101249  
[C]: 68 ng/mL  
Intervalle de confiance: 54 - 82 ng/mL

**C1 (Control 1)** Lot : F161101249  
[C]: 23 ng/mL  
Acceptance range: 13 - 33 ng/mL

**C2 (Control 2)** Lot : F161101249  
[C]: 68 ng/mL  
Acceptance range: 54 - 82 ng/mL

Quality Control Approval  
19 JAN. 2017

S. Lecourt

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