

## ANALYSIS CERTIFICATE

DABIGATRAN CONTROL PLASMA (#224701)

Lot : F1600526

QC release : 07.07.2016

Expiration date : 2018-11-06

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
C1 : Control 1	6 vials	30	F161100526	F161100526	2018-11-06
C2 : Control 2	6 vials	30	F161100526	F161100526	2018-11-06



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Analytical data	Specifications														
<b>1. <u>Within lot reproducibility (N ≥ 10)</u></b>  <div style="text-align: center;"><b><u>Mean CT (sec)</u></b></div> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N= 35</td> <td style="width: 15%;">C1:</td> <td style="width: 15%;">49,5</td> <td style="width: 15%;">CV:</td> <td style="width: 15%;">0,4 %</td> <td style="width: 20%;"></td> <td style="width: 20%; text-align: center;">CV (CT) ≤ 3%</td> </tr> <tr> <td>N= 35</td> <td>C2:</td> <td>70,9</td> <td>CV:</td> <td>0,6 %</td> <td></td> <td style="text-align: center;">CV(CT) ≤ 3%</td> </tr> </table>		N= 35	C1:	49,5	CV:	0,4 %		CV (CT) ≤ 3%	N= 35	C2:	70,9	CV:	0,6 %		CV(CT) ≤ 3%
N= 35	C1:	49,5	CV:	0,4 %		CV (CT) ≤ 3%									
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<b>2. <u>Concentration and acceptance range</u></b>  <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <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 style="text-align: center;">C1</td> <td style="text-align: center;">11</td> <td style="text-align: center;">112</td> <td style="text-align: center;">90-134</td> <td style="text-align: center;">4,2</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">10</td> <td style="text-align: center;">302</td> <td style="text-align: center;">257-347</td> <td style="text-align: center;">11,0</td> </tr> </tbody> </table>	Controls	N series	Target value [C] ng/mL	Acceptance range (ng/mL)	SD	C1	11	112	90-134	4,2	C2	10	302	257-347	11,0	<b>Target value for [C]:</b>  <b>C1: 50 to 200 ng/mL</b>  <b>C2: 200 to 400 ng/mL</b>
Controls	N series	Target value [C] ng/mL	Acceptance range (ng/mL)	SD												
C1	11	112	90-134	4,2												
C2	10	302	257-347	11,0												

<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-bottom: 10px;"> <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 style="text-align: center;">Fresh</td> <td style="text-align: center;">/</td> <td style="text-align: center;">114</td> <td style="text-align: center;">302</td> </tr> <tr> <td style="text-align: center;">48h</td> <td style="text-align: center;">RT</td> <td style="text-align: center;">116</td> <td style="text-align: center;">302</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;">116</td> <td style="text-align: center;">304</td> </tr> </tbody> </table>		Temp.	C1	C2	ng/mL	ng/mL	Fresh	/	114	302	48h	RT	116	302	7 days	2-8°C	116	304	<b><u>48h at RT</u></b> C1: TV±20 ng/ml  C2 : TV ±30 ng/ml  <b><u>7 days at 2-8°C</u></b>  C1: TV±20 ng/ml C2 : TV ±30 ng/ml
			Temp.	C1	C2														
	ng/mL	ng/mL																	
Fresh	/	114	302																
48h	RT	116	302																
7 days	2-8°C	116	304																

<b>Comments :</b>  	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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Date : 07.07.2016

QC Manager :

S. LECOURT

DABIGATRAN CONTROL PLASMA  
Référence 224701

Pour diagnostic *in vitro* exclusivement

FRANÇAIS

Lot : F1600526 - Exp. : 2018-11-06

**C1 (Contrôle 1)** Lot : F161100526  
[C] : 112 ng/mL  
Intervalle de confiance : 90-134 ng/mL

**C2 (Contrôle 2)** Lot : F161100526  
[C] : 302 ng/mL  
Intervalle de confiance : 257-347 ng/mL

DABIGATRAN CONTROL PLASMA  
# 224701

For *in vitro* diagnostic use only

ENGLISH

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Acceptance range: 257-347 ng/mL

Quality Control Approval

04 JAN. 2017

S. Lecourt

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