

## ANALYSIS CERTIFICATE

**DABIGATRAN CONTROL PLASMA (#224701)**

**Lot : 51903**

**QC release : 12/06/2015**

**Expiration date : 2017-11**

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
C1 : Control 1	6 vials	30	150507A	51903-1	2017-11
C2 : Control 2	6 vials	30	150507B	51903-2	2017-11

303

# ANALYSIS CERTIFICATE

**DABIGATRAN CONTROL PLASMA (#224701)**

**Lot : 51903**

**QC release : 12/06/2015**

**Expiration date : 2017-11**

Analytical data	Specifications										
<b>1. <u>Within lot reproducibility (N ≥ 10)</u></b>  <div style="text-align: center;"><b>Mean CT (sec)</b></div> <table style="width: 100%; border: none;"> <tr> <td style="width: 20%;">N= 45</td> <td style="width: 20%;">C1:</td> <td style="width: 20%;">48,2</td> <td style="width: 20%;">CV:</td> <td style="width: 20%;">1,9 %</td> </tr> <tr> <td>N= 45</td> <td>C2:</td> <td>75,6</td> <td>CV:</td> <td>1,9 %</td> </tr> </table>	N= 45	C1:	48,2	CV:	1,9 %	N= 45	C2:	75,6	CV:	1,9 %	CV (CT) ≤ 3%  CV(CT) ≤ 3%
N= 45	C1:	48,2	CV:	1,9 %							
N= 45	C2:	75,6	CV:	1,9 %							

<b>2. <u>Concentration and acceptance range</u></b>  <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px auto;"> <thead> <tr> <th style="width: 15%;">Controls</th> <th style="width: 10%;">N series</th> <th style="width: 15%;">Target value [C] ng/mL</th> <th style="width: 30%;">Acceptance range (ng/mL)</th> <th style="width: 10%;">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;">127</td> <td style="text-align: center;">102-152</td> <td style="text-align: center;">4,6</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">10</td> <td style="text-align: center;">335</td> <td style="text-align: center;">285-385</td> <td style="text-align: center;">7,5</td> </tr> </tbody> </table>	Controls	N series	Target value [C] ng/mL	Acceptance range (ng/mL)	SD	C1	10	127	102-152	4,6	C2	10	335	285-385	7,5	<b>Target value for [C]:</b>  C1: 50 to 200 ng/mL  C2: 200 to 400 ng/mL
Controls	N series	Target value [C] ng/mL	Acceptance range (ng/mL)	SD												
C1	10	127	102-152	4,6												
C2	10	335	285-385	7,5												

<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
---	---

<b>4. <u>Stability of reconstituted reagents</u></b>  <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px auto;"> <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;">125</td> <td style="text-align: center;">336</td> </tr> <tr> <td style="text-align: center;">48h</td> <td style="text-align: center;">RT</td> <td style="text-align: center;">127</td> <td style="text-align: center;">343</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;">130</td> <td style="text-align: center;">334</td> </tr> </tbody> </table>		Temp.	C1	C2	ng/mL	ng/mL	Fresh	/	125	336	48h	RT	127	343	7 days	2-8°C	130	334	<b>48h at RT</b> C1: TV±20 ng/ml  C2 : TV ±30 ng/ml  <b>7 days at 2-8°C</b> C1: TV±20 ng/ml C2 : TV ±30 ng/ml
			Temp.	C1	C2														
	ng/mL	ng/mL																	
Fresh	/	125	336																
48h	RT	127	343																
7 days	2-8°C	130	334																

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

Date : 12/06/2015

QC Manager :

S.LECOURT



DABIGATRAN CONTROL PLASMA  
Référence 224701

Pour diagnostic *in vitro* exclusivement

FRANÇAIS

Lot : 51903 - Exp. : 2017-11

**C1 (Contrôle 1)** Lot : 51903-1  
[C] : 127 ng/mL  
Intervalle de confiance : 102-152 ng/mL

**C2 (Contrôle 2)** Lot : 51903-2  
[C] : 335 ng/mL  
Intervalle de confiance : 285-385 ng/mL

DABIGATRAN CONTROL PLASMA  
# 224701

For *in vitro* diagnostic use only

ENGLISH

Lot : 51903 - Exp. : 2017-11

**C1 (Control 1)** Lot : 51903-1  
[C]: 127 ng/mL  
Acceptance range: 102-152 ng/mL

**C2 (Control 2)** Lot : 51903-2  
[C]: 335 ng/mL  
Acceptance range: 285-385 ng/mL

DABIGATRAN CONTROL PLASMA  
Référence 224701

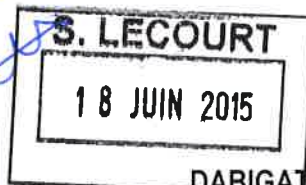
Pour diagnostic *in vitro* exclusivement

FRANÇAIS

Lot : 51903 - Exp. : 2017-11

**C1 (Contrôle 1)** Lot : 51903-1  
[C] : 127 ng/mL  
Intervalle de confiance : 102-152 ng/mL

**C2 (Contrôle 2)** Lot : 51903-2  
[C] : 335 ng/mL  
Intervalle de confiance : 285-385 ng/mL



DABIGATRAN CONTROL PLASMA  
# 224701

For *in vitro* diagnostic use only

ENGLISH

Lot : 51903 - Exp. : 2017-11

**C1 (Control 1)** Lot : 51903-1  
[C]: 127 ng/mL  
Acceptance range: 102-152 ng/mL

**C2 (Control 2)** Lot : 51903-2  
[C]: 335 ng/mL  
Acceptance range: 285-385 ng/mL