

## ANALYSIS CERTIFICATE

**DABIGATRAN CONTROL PLASMA (#224701)**

**Lot : F1800034**

**QC release : 2018-02-06**

**Expiration date : 2020-07-04**

<b>Components</b>	<b>Volume</b>	<b>Exp. (months)</b>	<b>Lot #</b>	<b>Exp. date</b>
C1 : Control 1	6 vials	30	F181500034	2020-07-04
C2 : Control 2	6 vials	30	F181500034	2020-07-04

*Jco.*

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Analytical data	Specifications												
<b>1. <u>Within lot reproducibility</u></b>  <div style="text-align: center;"><b>Mean CT (sec)</b></div> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N= 25</td> <td style="width: 15%;">C1:</td> <td style="width: 15%; text-align: center;">56,8</td> <td style="width: 15%;">CV:</td> <td style="width: 15%; text-align: center;">0,9 %</td> <td style="width: 20%;"></td> </tr> <tr> <td>N= 25</td> <td>C2:</td> <td style="text-align: center;">81,7</td> <td>CV:</td> <td style="text-align: center;">1,8 %</td> <td style="text-align: center;">CV(CT) ≤ 3%</td> </tr> </table>	N= 25	C1:	56,8	CV:	0,9 %		N= 25	C2:	81,7	CV:	1,8 %	CV(CT) ≤ 3%	CV(CT) ≤ 3%  CV(CT) ≤ 3%
N= 25	C1:	56,8	CV:	0,9 %									
N= 25	C2:	81,7	CV:	1,8 %	CV(CT) ≤ 3%								

<b>2. <u>Concentration and acceptance range</u></b>  <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="width: 15%;">Controls</th> <th style="width: 15%;">N series</th> <th style="width: 15%;">Target value [C] ng/mL</th> <th style="width: 25%;">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;">9</td> <td style="text-align: center;">103</td> <td style="text-align: center;">82-124</td> <td style="text-align: center;">3,7</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">10</td> <td style="text-align: center;">298</td> <td style="text-align: center;">253-343</td> <td style="text-align: center;">7,9</td> </tr> </tbody> </table>	Controls	N series	Target value [C] ng/mL	Acceptance range (ng/mL)	SD	C1	9	103	82-124	3,7	C2	10	298	253-343	7,9	<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	9	103	82-124	3,7												
C2	10	298	253-343	7,9												

<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 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;">107</td> <td style="text-align: center;">323</td> </tr> <tr> <td style="text-align: center;">48h</td> <td style="text-align: center;">RT</td> <td style="text-align: center;">108</td> <td style="text-align: center;">311</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;">107</td> <td style="text-align: center;">311</td> </tr> </tbody> </table>		Temp.	C1	C2	ng/mL	ng/mL	Fresh	/	107	323	48h	RT	108	311	7 days	2-8°C	107	311	<b>48h at RT</b> Measured Values within the acceptance ranges  <b>7 days at 2-8°C</b> Measured Values within the acceptance ranges
			Temp.	C1	C2														
	ng/mL	ng/mL																	
Fresh	/	107	323																
48h	RT	108	311																
7 days	2-8°C	107	311																

<b>Comments :</b>  	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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**Date : 2018-02-06**

**QC Manager :**

**S.LECOURT**  




## DABIGATRAN CONTROL PLASMA

Human plasmas at two levels of Dabigatran for the quality control of Dabigatran measurements with anti-IIa method //  
*Plasmas humains à deux niveaux Dabigatran pour le contrôle de qualité des dosages Dabigatran par méthode anti-IIa*

**REF** 224701

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

**LOT** F1800034

2020-07-04

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

<b>Control / Contrôle C1</b>	LOT : <b>F181500034</b>
Target value / <i>Valeur cible</i> :	<b>103</b> ng/mL / ng/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[ <b>82 - 124</b> ] ng/mL / ng/mL

<b>Control / Contrôle C2</b>	LOT : <b>F181500034</b>
Target value / <i>Valeur cible</i> :	<b>298</b> ng/mL / ng/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[ <b>253 - 343</b> ] ng/mL / ng/mL

Standardization / *Standardisation* : **NA**

Approved Date / *Date d'Approbation* :2018-02-06

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