

## ANALYSIS CERTIFICATE

**DABIGATRAN PLASMA CALIBRATOR - #222801**

**Lot : F1600663**

**QC release : 04/08/2016**

**Expiration date : 2018-12-15**

<b>Components</b>	<b>Volume</b>	<b>Exp. (months)</b>	<b>Int. Ref.</b>	<b>Lot #</b>	<b>Exp. date</b>
CAL1 : Calibrator 1	4 vials	30	F161300663	F161300663	2018-12-15
CAL2 : Calibrator 2	4 vials	30	F161300663	F161300663	2018-12-15
CAL3 : Calibrator 3	4 vials	30	F161300663	F161300663	2018-12-15

SQS

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Analytical data	Specifications																																					
<p><b>1. <u>Within lot reproducibility (N ≥ 10)</u></b></p> <p style="text-align: center;"><b><u>Mean CT (sec)</u></b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">N= 20</td> <td style="width: 40%;">CAL1: 38,1</td> <td style="width: 15%;">CV: 0,7 %</td> <td style="width: 30%; text-align: right;">CV (CT) ≤ 3%</td> </tr> <tr> <td>N= 20</td> <td>CAL2: 62,1</td> <td>CV: 1,6 %</td> <td style="text-align: right;">CV (CT) ≤ 3%</td> </tr> <tr> <td>N= 20</td> <td>CAL3: 87,3</td> <td>CV: 1,3 %</td> <td style="text-align: right;">CV (CT) ≤ 3%</td> </tr> </table>		N= 20	CAL1: 38,1	CV: 0,7 %	CV (CT) ≤ 3%	N= 20	CAL2: 62,1	CV: 1,6 %	CV (CT) ≤ 3%	N= 20	CAL3: 87,3	CV: 1,3 %	CV (CT) ≤ 3%																									
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<p><b>2. <u>Concentration [C] and Standard Deviation (SD)</u></b></p> <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: 20%;">[C] ng/mL</th> <th style="width: 10%;">SD</th> </tr> </thead> <tbody> <tr> <td>CAL1</td> <td style="text-align: center;">10</td> <td style="text-align: center;">43</td> <td style="text-align: center;">4,68</td> </tr> <tr> <td>CAL2</td> <td style="text-align: center;">10</td> <td style="text-align: center;">257</td> <td style="text-align: center;">9,90</td> </tr> <tr> <td>CAL3</td> <td style="text-align: center;">10</td> <td style="text-align: center;">489</td> <td style="text-align: center;">12,78</td> </tr> </tbody> </table>		Controls	N series	[C] ng/mL	SD	CAL1	10	43	4,68	CAL2	10	257	9,90	CAL3	10	489	12,78																					
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<p><b>3. <u>Aspect</u></b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 60%;">Slightly opalescent to clear</td> <td style="width: 30%; text-align: right;">a) Slightly opalescent to clear</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>No coagulum</td> <td style="text-align: right;">b) No coagulum</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Stable solution</td> <td style="text-align: right;">c) Stable solution</td> </tr> </table>		<input checked="" type="checkbox"/>	Slightly opalescent to clear	a) Slightly opalescent to clear	<input checked="" type="checkbox"/>	No coagulum	b) No coagulum	<input checked="" type="checkbox"/>	Stable solution	c) Stable solution																												
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<p><b>4. <u>Stability of reconstituted reagents</u></b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th colspan="2"></th> <th style="width: 10%;">Fresh</th> <th style="width: 10%;">48h</th> <th style="width: 10%;">7 days</th> </tr> <tr> <th colspan="2"></th> <th style="text-align: center;">/</th> <th style="text-align: center;">RT</th> <th style="text-align: center;">2-8°C</th> </tr> </thead> <tbody> <tr> <td rowspan="2" style="width: 10%; text-align: center;">CAL1</td> <td style="width: 10%;">ng/mL</td> <td style="text-align: center;">45</td> <td style="text-align: center;">43</td> <td style="text-align: center;">46</td> </tr> <tr> <td style="text-align: center;">Δ</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">2</td> <td style="text-align: center;">1</td> </tr> <tr> <td rowspan="2" style="text-align: center;">CAL2</td> <td>ng/mL</td> <td style="text-align: center;">253</td> <td style="text-align: center;">261</td> <td style="text-align: center;">255</td> </tr> <tr> <td style="text-align: center;">Δ</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">8</td> <td style="text-align: center;">2</td> </tr> <tr> <td rowspan="2" style="text-align: center;">CAL3</td> <td>ng/mL</td> <td style="text-align: center;">491</td> <td style="text-align: center;">492</td> <td style="text-align: center;">490</td> </tr> <tr> <td style="text-align: center;">Δ</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">1</td> <td style="text-align: center;">1</td> </tr> </tbody> </table>				Fresh	48h	7 days			/	RT	2-8°C	CAL1	ng/mL	45	43	46	Δ	NA	2	1	CAL2	ng/mL	253	261	255	Δ	NA	8	2	CAL3	ng/mL	491	492	490	Δ	NA	1	1
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<p><b><u>48 hours at RT:</u></b></p> <p>Δ [C] ≤ 30ng/ml</p> <p><b><u>7 days at 2-8°C:</u></b></p> <p>Δ [C] ≤ 30ng/ml</p>																																						

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Analytical data	Specifications															
<p><b>5. <u>Calibration curve</u></b></p> <p><b>Instrument: STAR</b></p> <p><b>Hemoclot Thrombin Inhibitors Lot: 52803</b></p> <table border="1" style="margin-left: 20px; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 20%;">ng/ml</th> <th style="width: 20%;">CT (sec)</th> </tr> </thead> <tbody> <tr> <td><b>Cal 1</b></td> <td style="text-align: center;">43</td> <td style="text-align: center;">34,5</td> </tr> <tr> <td><b>Cal 2</b></td> <td style="text-align: center;">257</td> <td style="text-align: center;">53,6</td> </tr> <tr> <td><b>Cal 3</b></td> <td style="text-align: center;">489</td> <td style="text-align: center;">74,6</td> </tr> </tbody> </table>		ng/ml	CT (sec)	<b>Cal 1</b>	43	34,5	<b>Cal 2</b>	257	53,6	<b>Cal 3</b>	489	74,6				
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<p><b>6. <u>Linearity</u></b></p> <p style="margin-left: 40px;"><math>r^2</math>                      1,000</p>	<p><math>r^2 \geq 0.98</math></p>															
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	CONTROLS		TV*	MV*												
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<p><b><u>Comments :</u></b></p>	<p><input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b></p>															

**Date : 04/08/2016**

**QC Manager :**

**S. LECOURT**



**DABIGATRAN PLASMA CALIBRATOR**  
Référence 222801

Pour diagnostic *in vitro* exclusivement

FRANÇAIS

Lot : F1600663 - Exp. : 2018-12-15

Concentration [C] en DABIGATRAN dans les calibrateurs

Cal 1 Lot : F161300663  
[C] : 43 ng/mL

Cal 2 Lot : F161300663  
[C] : 257 ng/mL

Cal 3 Lot : F161300663  
[C] : 489 ng/mL

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*Approved  
N. P. Ray of the  
05/08/2016  
APC*

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