

ANALYSIS CERTIFICATE

DABIGATRAN PLASMA CALIBRATOR - #222801

Lot : F1600663

QC release : 04/08/2016

Expiration date : 2018-12-15

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
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>1. <u>Within lot reproducibility (N ≥ 10)</u></p> <p style="text-align: center;"><u>Mean CT (sec)</u></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>2. <u>Concentration [C] and Standard Deviation (SD)</u></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>3. <u>Aspect</u></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>4. <u>Stability of reconstituted reagents</u></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><u>48 hours at RT:</u></p> <p>Δ [C] ≤ 30ng/ml</p> <p><u>7 days at 2-8°C:</u></p> <p>Δ [C] ≤ 30ng/ml</p>																																						

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<p>5. <u>Calibration curve</u></p> <p>Instrument: STAR</p> <p>Hemoclot Thrombin Inhibitors Lot: 52803</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>Cal 1</td> <td style="text-align: center;">43</td> <td style="text-align: center;">34,5</td> </tr> <tr> <td>Cal 2</td> <td style="text-align: center;">257</td> <td style="text-align: center;">53,6</td> </tr> <tr> <td>Cal 3</td> <td style="text-align: center;">489</td> <td style="text-align: center;">74,6</td> </tr> </tbody> </table>		ng/ml	CT (sec)	Cal 1	43	34,5	Cal 2	257	53,6	Cal 3	489	74,6	
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<p>6. <u>Linearity</u></p> <p style="margin-left: 40px;">r^2 1,000</p>	<p>$r^2 \geq 0.98$</p>												
<p>7. <u>Accuracy</u></p> <p>Instrument: STAR</p> <table border="1" style="margin-left: 20px; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 30%;">CONTROLS</th> <th style="width: 10%;">TV*</th> <th style="width: 10%;">MV*</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td style="text-align: center;">Lot 51903-1</td> <td style="text-align: center;">127</td> <td style="text-align: center;">126</td> </tr> <tr> <td>C2</td> <td style="text-align: center;">Lot 51903-2</td> <td style="text-align: center;">335</td> <td style="text-align: center;">344</td> </tr> </tbody> </table> <p style="margin-left: 40px;">*TV: Target Value *MV: Measured Value</p>		CONTROLS	TV*	MV*	C1	Lot 51903-1	127	126	C2	Lot 51903-2	335	344	<p>MV* within the acceptance range</p> <p style="margin-left: 40px;">[102 - 152]</p> <p style="margin-left: 40px;">[285 - 385]</p>
	CONTROLS	TV*	MV*										
C1	Lot 51903-1	127	126										
C2	Lot 51903-2	335	344										
<p><u>Comments :</u></p>	<p><input checked="" type="checkbox"/> PASSED IN COMPLIANCE</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

DABIGATRAN PLASMA CALIBRATOR
222801

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*Approved
N. Payer of the
05/08/2016
APC*

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