

## ANALYSIS CERTIFICATE

**PLASMA ARGATROBAN® CALIBRATOR - #SC030K**

**Lot : 54301**

**QC release: 17/11/2015**

**Expiration date : 2018-04**

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	151023A	54301-1	2018-04
CAL2 : Calibrator 2	4 vials	30	151023B	54301-2	2018-04
CAL3 : Calibrator 3	4 vials	30	151023C	54301-3	2018-04
CAL4 : Calibrator 4	4 vials	30	151023D	54301-4	2018-04
CAL5 : Calibrator 5	4 vials	30	151023E	54301-5	2018-04

*SOB*

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Analytical data	Specifications
<b>1. <u>Within lot reproducibility</u> (N ≥ 10)</b>	
<b>Mean CT</b>	
N= 10      CAL1: 33,6    sec      CV: 1,1 %	CV (CT) ≤ 3%
N= 10      CAL2: 53,2    sec      CV: 1,1 %	CV (CT) ≤ 3%
N= 10      CAL3: 68,8    sec      CV: 1,8 %	CV (CT) ≤ 3%
N= 10      CAL4: 84,2    sec      CV: 1,2 %	CV (CT) ≤ 3%
N= 10      CAL5: 96,4    sec      CV: 2,2 %	CV (CT) ≤ 3%

2. <u>Concentration [C] and Standard Deviation (SD)</u>																									
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Controls</th> <th>N series</th> <th>[C] µg/mL</th> <th>SD</th> </tr> </thead> <tbody> <tr> <td><b>CAL1</b></td> <td>13</td> <td>0,00</td> <td>0,004</td> </tr> <tr> <td><b>CAL2</b></td> <td>13</td> <td>0,54</td> <td>0,02</td> </tr> <tr> <td><b>CAL3</b></td> <td>13</td> <td>1,03</td> <td>0,03</td> </tr> <tr> <td><b>CAL4</b></td> <td>13</td> <td>1,49</td> <td>0,03</td> </tr> <tr> <td><b>CAL5</b></td> <td>13</td> <td>1,88</td> <td>0,05</td> </tr> </tbody> </table>	Controls	N series	[C] µg/mL	SD	<b>CAL1</b>	13	0,00	0,004	<b>CAL2</b>	13	0,54	0,02	<b>CAL3</b>	13	1,03	0,03	<b>CAL4</b>	13	1,49	0,03	<b>CAL5</b>	13	1,88	0,05	CAL1: ≤ 0.05 µg/ml CAL2: 0.35-0.65µg/mL CAL3: 0.85-1.15 µg/mL CAL4: 1.30-1.65 µg/mL CAL5: 1.80-2.10 µg/mL
Controls	N series	[C] µg/mL	SD																						
<b>CAL1</b>	13	0,00	0,004																						
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<b>CAL4</b>	13	1,49	0,03																						
<b>CAL5</b>	13	1,88	0,05																						

3. <u>Aspect</u>	
a) :            Slightly opalescent to clear	a) Slightly opalescent to clear
b) :            No coagulum	b) No coagulum
c) :            Stable solution	c) Stable solution

4. <u>Stability of reconstituted reagents</u>				
		Fresh	48h	7 days
		/	RT	2-8°C
<b>CAL1</b>	µg/mL	0	0	0
	Δ %	NA	0	0
<b>CAL2</b>	µg/mL	0,54	0,53	0,53
	Δ %	NA	1,9	1,9
<b>CAL3</b>	µg/mL	1,05	1,04	1,03
	Δ %	NA	1,0	1,9
<b>CAL4</b>	µg/mL	1,48	1,50	1,47
	Δ %	NA	1,4	0,7
<b>CAL5</b>	µg/mL	1,86	1,85	1,88
	Δ %	NA	0,5	1,1

**48 hours at RT:**  
 Δ [C] ≤ 10%

**7 days at 2-8°C:**  
 Δ [C] ≤ 10%

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Analytical data	Specifications																		
<p><b>5. Calibration curve</b></p> <p style="text-align: center;"> <input checked="" type="checkbox"/> <b>STAR</b> <span style="margin-left: 150px;"><input type="checkbox"/> <b>ACL</b></span> </p> <p style="text-align: center;"> <b>Hemoclot Thrombin Inhibitors</b> <span style="margin-left: 100px;"><b>Lot: 52803</b></span> </p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse; text-align: center;"> <thead> <tr> <th></th> <th>µg/ml</th> <th>CT (sec)</th> </tr> </thead> <tbody> <tr> <td>Cal 1</td> <td>0,00</td> <td>31,1</td> </tr> <tr> <td>Cal 2</td> <td>0,54</td> <td>44,8</td> </tr> <tr> <td>Cal 3</td> <td>1,03</td> <td>57,1</td> </tr> <tr> <td>Cal 4</td> <td>1,49</td> <td>68,0</td> </tr> <tr> <td>Cal 5</td> <td>1,88</td> <td>78,0</td> </tr> </tbody> </table>		µg/ml	CT (sec)	Cal 1	0,00	31,1	Cal 2	0,54	44,8	Cal 3	1,03	57,1	Cal 4	1,49	68,0	Cal 5	1,88	78,0	
	µg/ml	CT (sec)																	
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<p><b>6. Linearity</b></p> <p style="text-align: center;"><math>r^2</math> <span style="margin-left: 150px;">1,000</span></p>	<p><math>r^2 \geq 0.98</math></p>
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<p><b>7. Accuracy</b></p> <p style="text-align: center;"> <input checked="" type="checkbox"/> <b>STAR</b> <span style="margin-left: 150px;"><input type="checkbox"/> ...</span> </p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse; text-align: center;"> <thead> <tr> <th colspan="2">CONTROLS</th> <th>TV*</th> <th>MV*</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td>Lot 35104-1</td> <td>0,79</td> <td>0,83</td> </tr> <tr> <td>C2</td> <td>Lot 35104-2</td> <td>1,38</td> <td>1,40</td> </tr> </tbody> </table> <p style="text-align: center; font-size: small;">*TV: Target Value      *MV: Measured Value</p>	CONTROLS		TV*	MV*	C1	Lot 35104-1	0,79	0,83	C2	Lot 35104-2	1,38	1,40	<p>MV* within the acceptance range</p>
CONTROLS		TV*	MV*										
C1	Lot 35104-1	0,79	0,83										
C2	Lot 35104-2	1,38	1,40										

<p>Comments :</p>	<p><input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b></p>
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**Date : 17/11/2015**

**QC Manager : S. LECOURT**

**ARGATROBAN® PLASMA CALIBRATOR**  
Référence SC030K

Pour diagnostic *in vitro* exclusivement

FRANÇAIS

**Lot : 54301 - Exp. : 2018-04**

Concentration [C] en ARGATROBAN® dans les calibrateurs

<u>Cal 1</u>	Lot : 54301-1	[C] : 0	µg/mL
<u>Cal 2</u>	Lot : 54301-2	[C] : 0,54	µg/mL
<u>Cal 3</u>	Lot : 54301-3	[C] : 1,03	µg/mL
<u>Cal 4</u>	Lot : 54301-4	[C] : 1,49	µg/mL
<u>Cal 5</u>	Lot : 54301-5	[C] : 1,88	µg/mL

**ARGATROBAN® PLASMA CALIBRATOR**  
# SC030K

For *in vitro* diagnostic use only

ENGLISH

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ARGATROBAN® concentration [C] in the calibrators

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<u>Cal 5</u>	Lot : 54301-5	[C] : 1,88	µg/mL

*Handwritten signature and date:*  
17-11-15