

## ANALYSIS CERTIFICATE

**DABIGATRAN PLASMA CALIBRATOR - #222801**

**Lot : F1600113**

**QC release : 05/04/2016**

**Expiration date : 2018-08-21**

<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	F161100113	F161100113	2018-08-21
CAL2 : Calibrator 2	4 vials	30	F161100113	F161100113	2018-08-21
CAL3 : Calibrator 3	4 vials	30	F161100113	F161100113	2018-08-21

*SOS*

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Analytical data				Specifications																
<b>1. <u>Within lot reproducibility (N ≥ 10)</u></b>																				
<b><u>Mean CT (sec)</u></b>																				
N= 15	CAL1: 36,9	CV: 1,2 %		CV (CT) ≤ 3%																
N= 15	CAL2: 63,8	CV: 1,3 %		CV (CT) ≤ 3%																
N= 15	CAL3: 90,2	CV: 1,5 %		CV (CT) ≤ 3%																
<b>2. <u>Concentration [C] and Standard Deviation (SD)</u></b>																				
<table border="1" style="width: 100%; border-collapse: collapse;"> <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 style="text-align: center;">CAL1</td> <td style="text-align: center;">10</td> <td style="text-align: center;">43</td> <td style="text-align: center;">3,8</td> </tr> <tr> <td style="text-align: center;">CAL2</td> <td style="text-align: center;">10</td> <td style="text-align: center;">297</td> <td style="text-align: center;">7,9</td> </tr> <tr> <td style="text-align: center;">CAL3</td> <td style="text-align: center;">10</td> <td style="text-align: center;">553</td> <td style="text-align: center;">20,6</td> </tr> </tbody> </table>				Controls	N series	[C] ng/mL	SD	CAL1	10	43	3,8	CAL2	10	297	7,9	CAL3	10	553	20,6	CAL1: ≤ 100 ng/ml CAL2: 150-350ng/mL CAL3: 400-600 ng/mL
Controls	N series	[C] ng/mL	SD																	
CAL1	10	43	3,8																	
CAL2	10	297	7,9																	
CAL3	10	553	20,6																	
<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>																				
		Fresh	48h	7 days																
		/	RT	2-8°C																
<b>CAL1</b>	ng/mL	41	42	43																
	Δ	NA	1	2																
<b>CAL2</b>	ng/mL	306	303	308																
	Δ	NA	3	2																
<b>CAL3</b>	ng/mL	556	554	561																
	Δ	NA	2	5																
				<b><u>48 hours at RT:</u></b> Δ [C] ≤ 30ng/ml  <b><u>7 days at 2-8°C:</u></b> Δ [C] ≤ 30ng/ml																

505



DABIGATRAN PLASMA CALIBRATOR  
Référence 222801

Pour diagnostic *in vitro* exclusivement

FRANÇAIS

Lot : F1600113 - Exp. : 2018-08-21

Concentration [C] en DABIGATRAN dans les calibrateurs

Cal 1 Lot : F161100113  
[C] : 43 ng/mL

Cal 2 Lot : F161100113  
[C] : 297 ng/mL

Cal 3 Lot : F161100113  
[C] : 553 ng/mL

DABIGATRAN PLASMA CALIBRATOR  
# 222801

For *in vitro* diagnostic use only

ENGLISH

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*Speed  
Stewart  
07/24/16*

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