

ANALYSIS CERTIFICATE

DABIGATRAN PLASMA CALIBRATOR - #222801

Lot : F1700199-F1700225

QC release : 2017-03-22

Expiration date : 2019-08-11

Components	Volume	Exp. (months)	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F171400199 F171100225	2019-08-11
CAL2 : Calibrator 2	4 vials	30	F171400199 F171100225	2019-08-11
CAL3 : Calibrator 3	4 vials	30	F171400199 F171100225	2019-08-11

825

ANALYSIS CERTIFICATE

DABIGATRAN PLASMA CALIBRATOR - #222801

Lot : F1700199-F1700225

QC release : 2017-03-22

Expiration date : 2019-08-11

Analytical data				Specifications																																					
1. <u>Within lot reproducibility</u>																																									
<u>Mean CT (sec)</u>																																									
N= 25	CAL1: 39,9	CV: 2,3 %		CV (CT) ≤ 3%																																					
N= 25	CAL2: 81,2	CV: 2,1 %		CV (CT) ≤ 3%																																					
N= 25	CAL3: 120,8	CV: 1,5 %		CV (CT) ≤ 3%																																					
2. <u>Concentration [C] and Standard Deviation (SD)</u>																																									
<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;">11</td> <td style="text-align: center;">44</td> <td style="text-align: center;">3,2</td> </tr> <tr> <td style="text-align: center;">CAL2</td> <td style="text-align: center;">11</td> <td style="text-align: center;">286</td> <td style="text-align: center;">8,5</td> </tr> <tr> <td style="text-align: center;">CAL3</td> <td style="text-align: center;">11</td> <td style="text-align: center;">550</td> <td style="text-align: center;">21,6</td> </tr> </tbody> </table>				Controls	N series	[C] ng/mL	SD	CAL1	11	44	3,2	CAL2	11	286	8,5	CAL3	11	550	21,6	CAL1: ≤ 100 ng/ml CAL2: 150-350ng/mL CAL3: 400-600 ng/mL																					
Controls	N series	[C] ng/mL	SD																																						
CAL1	11	44	3,2																																						
CAL2	11	286	8,5																																						
CAL3	11	550	21,6																																						
3. <u>Aspect</u>																																									
<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																																					
4. <u>Stability of reconstituted reagents</u>																																									
<table border="1" style="width: 100%; border-collapse: collapse;"> <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="text-align: center;">CAL1</td> <td style="text-align: center;">ng/mL</td> <td style="text-align: center;">40</td> <td style="text-align: center;">51</td> <td style="text-align: center;">44</td> </tr> <tr> <td style="text-align: center;">Δ</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">11</td> <td style="text-align: center;">4</td> </tr> <tr> <td rowspan="2" style="text-align: center;">CAL2</td> <td style="text-align: center;">ng/mL</td> <td style="text-align: center;">278</td> <td style="text-align: center;">287</td> <td style="text-align: center;">281</td> </tr> <tr> <td style="text-align: center;">Δ</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">9</td> <td style="text-align: center;">3</td> </tr> <tr> <td rowspan="2" style="text-align: center;">CAL3</td> <td style="text-align: center;">ng/mL</td> <td style="text-align: center;">535</td> <td style="text-align: center;">540</td> <td style="text-align: center;">542</td> </tr> <tr> <td style="text-align: center;">Δ</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">5</td> <td style="text-align: center;">7</td> </tr> </tbody> </table>						Fresh	48h	7 days			/	RT	2-8°C	CAL1	ng/mL	40	51	44	Δ	NA	11	4	CAL2	ng/mL	278	287	281	Δ	NA	9	3	CAL3	ng/mL	535	540	542	Δ	NA	5	7	<u>48 hours at RT:</u> Δ [C] ≤ 30ng/ml <u>7 days at 2-8°C:</u> Δ [C] ≤ 30ng/ml
		Fresh	48h	7 days																																					
		/	RT	2-8°C																																					
CAL1	ng/mL	40	51	44																																					
	Δ	NA	11	4																																					
CAL2	ng/mL	278	287	281																																					
	Δ	NA	9	3																																					
CAL3	ng/mL	535	540	542																																					
	Δ	NA	5	7																																					

ANALYSIS CERTIFICATE

DABIGATRAN PLASMA CALIBRATOR - #222801

Lot : F1700199-F1700225

QC release : 2017-03-22

Expiration date : 2019-08-11

Analytical data	Specifications												
<p>5. <u>Calibration curve</u> Instrument: STAR</p> <p>Hemoclot Thrombin Inhibitors Lot: F1600598</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 20%; text-align: center;">ng/ml</th> <th style="width: 20%; text-align: center;">CT (sec)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Cal 1</td> <td style="text-align: center;">44</td> <td style="text-align: center;">38,0</td> </tr> <tr> <td style="text-align: center;">Cal 2</td> <td style="text-align: center;">286</td> <td style="text-align: center;">66,5</td> </tr> <tr> <td style="text-align: center;">Cal 3</td> <td style="text-align: center;">550</td> <td style="text-align: center;">96,6</td> </tr> </tbody> </table>		ng/ml	CT (sec)	Cal 1	44	38,0	Cal 2	286	66,5	Cal 3	550	96,6	
	ng/ml	CT (sec)											
Cal 1	44	38,0											
Cal 2	286	66,5											
Cal 3	550	96,6											
<p>6. <u>Linearity</u></p> <p style="text-align: center;">R^2 1,000</p>	<p>$R^2 \geq 0.98$</p>												
<p>7. <u>Accuracy</u> Instrument: STAR</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 40%; text-align: center;">CONTROLS</th> <th style="width: 15%; text-align: center;">TV*</th> <th style="width: 15%; text-align: center;">MV*</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">Lot F1600528</td> <td style="text-align: center;">112</td> <td style="text-align: center;">118</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">Lot F1600526</td> <td style="text-align: center;">302</td> <td style="text-align: center;">322</td> </tr> </tbody> </table> <p style="text-align: center; font-size: small;">*TV: Target Value *MV: Measured Value</p>		CONTROLS	TV*	MV*	C1	Lot F1600528	112	118	C2	Lot F1600526	302	322	<p>MV* within the acceptance range</p> <p style="text-align: center;">[90 - 134]</p> <p style="text-align: center;">[257 - 347]</p>
	CONTROLS	TV*	MV*										
C1	Lot F1600528	112	118										
C2	Lot F1600526	302	322										
<p>Comments :</p>	<p><input checked="" type="checkbox"/> PASSED IN COMPLIANCE</p>												

Date : 2017-03-22

QC Manager :

S.LECOURT





DABIGATRAN PLASMA CALIBRATOR

Calibration plasma for the assay of Dabigatran with anti-IIa method /
Gamme de plasmas humains pour l'étalonnage des dosages de Dabigatran par méthode anti-IIa

REF 222801

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

LOT F1700199  2019-08-11

Dabigatran Concentration [C] in the calibrators /
Concentration [C] en Dabigatran dans les calibrateurs

<u>Calibrator / Calibrateur 1</u>	LOT : F171400199
[C] :	44 ng/mL / ng/mL
<u>Calibrator / Calibrateur 2</u>	LOT : F171400199
[C] :	286 ng/mL / ng/mL
<u>Calibrator / Calibrateur 3</u>	LOT : F171400199
[C] :	550 ng/mL / ng/mL

Standardization / *Standardisation* : NA

Approved Date / *Date d'Approbation* : 2017-03-22

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