

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

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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>																				
		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																

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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%;">ng/ml</th> <th style="width: 20%;">CT (sec)</th> </tr> </thead> <tbody> <tr> <td>Cal 1</td> <td style="text-align: center;">44</td> <td style="text-align: center;">38,0</td> </tr> <tr> <td>Cal 2</td> <td style="text-align: center;">286</td> <td style="text-align: center;">66,5</td> </tr> <tr> <td>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> R^2 1,000</p>	$R^2 \geq 0.98$												
<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: 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 F1600528</td> <td style="text-align: center;">112</td> <td style="text-align: center;">118</td> </tr> <tr> <td>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] [257 - 347]</p>
	CONTROLS	TV*	MV*										
C1	Lot F1600528	112	118										
C2	Lot F1600526	302	322										
<p>Comments :</p>	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE												

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