

ANALYSIS CERTIFICATE

DABIGATRAN CONTROL PLASMA (#224701)

**Lot : F1700397
F1700398**

QC release : 2017-05-11

Expiration date : 2019-10-08

Components	Volume	Exp. (months)	Lot #	Exp. date
C1 : Control 1	6 vials	30	F171400397 F171100398	2019-10-08
C2 : Control 2	6 vials	30	F171400397 F171100398	2019-10-08

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Lot : F1700398

QC release : 2017-05-11

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Analytical data	Specifications										
1. <u>Within lot reproducibility</u> <div style="text-align: center;"><u>Mean CT (sec)</u></div> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">N= 35</td> <td style="width: 15%;">C1:</td> <td style="width: 20%;">53,0</td> <td style="width: 15%;">CV:</td> <td style="width: 35%;">0,6 %</td> </tr> <tr> <td>N= 35</td> <td>C2:</td> <td>75,3</td> <td>CV:</td> <td>1,4 %</td> </tr> </table>	N= 35	C1:	53,0	CV:	0,6 %	N= 35	C2:	75,3	CV:	1,4 %	CV (CT) ≤ 3% CV(CT) ≤ 3%
N= 35	C1:	53,0	CV:	0,6 %							
N= 35	C2:	75,3	CV:	1,4 %							

2. <u>Concentration and acceptance range</u> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>Controls</th> <th>N series</th> <th>Target value [C] ng/mL</th> <th>Acceptance range (ng/mL)</th> <th>SD</th> </tr> </thead> <tbody> <tr> <td>C1</td> <td>11</td> <td>101</td> <td>81 - 121</td> <td>5,4</td> </tr> <tr> <td>C2</td> <td>11</td> <td>300</td> <td>255 - 345</td> <td>9,7</td> </tr> </tbody> </table>	Controls	N series	Target value [C] ng/mL	Acceptance range (ng/mL)	SD	C1	11	101	81 - 121	5,4	C2	11	300	255 - 345	9,7	Target value for [C]: C1: 50 to 200 ng/mL C2: 200 to 400 ng/mL
Controls	N series	Target value [C] ng/mL	Acceptance range (ng/mL)	SD												
C1	11	101	81 - 121	5,4												
C2	11	300	255 - 345	9,7												

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
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4. <u>Stability of reconstituted reagents</u> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Temp.</th> <th>C1</th> <th>C2</th> </tr> <tr> <th>ng/mL</th> <th>ng/mL</th> </tr> </thead> <tbody> <tr> <td>Fresh</td> <td>/</td> <td>107</td> <td>313</td> </tr> <tr> <td>48h</td> <td>RT</td> <td>105</td> <td>311</td> </tr> <tr> <td>7 days</td> <td>2-8°C</td> <td>107</td> <td>308</td> </tr> </tbody> </table>		Temp.	C1	C2	ng/mL	ng/mL	Fresh	/	107	313	48h	RT	105	311	7 days	2-8°C	107	308	<u>48h at RT</u> Measured Values within the acceptance ranges <u>7 days at 2-8°C</u> Measured Values within the acceptance ranges
			Temp.	C1	C2														
	ng/mL	ng/mL																	
Fresh	/	107	313																
48h	RT	105	311																
7 days	2-8°C	107	308																

Comments : 	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-05-11

QC Manager : **S.LECOURT**





DABIGATRAN CONTROL PLASMA

Human plasmas at two levels of Dabigatran for the quality control of Dabigatran measurements with anti-IIa method //
Plasmas humains à deux niveaux Dabigatran pour le contrôle de qualité des dosages Dabigatran par méthode anti-IIa

REF 224701

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

LOT F1700397



2019-10-08

Dabigatran Concentration in the controls / *Concentration en Dabigatran dans les contrôles*

Control / Contrôle C1	LOT : F171400397
Target value / <i>Valeur cible</i> :	101 ng/mL / ng/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[81 – 121] ng/mL / ng/mL

Control / Contrôle C2	LOT : F171400397
Target value / <i>Valeur cible</i> :	300 ng/mL / ng/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[255 – 345] ng/mL / ng/mL

Standardization / *Standardisation* : NA

Approved Date / *Date d'Approbation* :2017-05-11

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