

ANALYSIS CERTIFICATE

BIOPHEN RIVAROXABAN® CONTROL PLASMA - #224501

Lot : F1600888

QC release : 03/10/2016

Expiration date : 2019-02-26

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
C1 : Control 1	6 vials	30	F161100888	F161100888	2019-02-26
C2 : Control 2	6 vials	30	F161100888	F161100888	2019-02-26

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Analytical data	Specifications
1. <u>Within lot reproducibility (N ≥ 10)</u> N= 35 C1(OD): 1,774 CV: 1,3 % N= 35 C2(OD): 1,314 CV: 0,5 %	OD : CV ≤ 2% OD : CV ≤ 2%

2. <u>Concentration and acceptance range</u> <table border="1" style="margin: 10px auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Controls</th> <th style="width: 20%;">[C] ng/mL</th> <th style="width: 60%;">Acceptance range (ng/mL)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">104</td> <td style="text-align: center;">73-135</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">316</td> <td style="text-align: center;">265-367</td> </tr> </tbody> </table>	Controls	[C] ng/mL	Acceptance range (ng/mL)	C1	104	73-135	C2	316	265-367	Target value: C1: 50 to 150 ng/mL C2: 250 to 350 ng/mL
Controls	[C] ng/mL	Acceptance range (ng/mL)								
C1	104	73-135								
C2	316	265-367								

3. <u>Aspect</u> <ul style="list-style-type: none"> <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="margin: 10px auto; border-collapse: collapse;"> <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 style="text-align: center;">Fresh</td> <td style="text-align: center;">/</td> <td style="text-align: center;">104</td> <td style="text-align: center;">320</td> </tr> <tr> <td style="text-align: center;">48h</td> <td style="text-align: center;">RT</td> <td style="text-align: center;">104</td> <td style="text-align: center;">320</td> </tr> <tr> <td style="text-align: center;">7 days</td> <td style="text-align: center;">2-8°C</td> <td style="text-align: center;">102</td> <td style="text-align: center;">323</td> </tr> </tbody> </table>		Temp.	C1	C2	ng/mL	ng/mL	Fresh	/	104	320	48h	RT	104	320	7 days	2-8°C	102	323	48h at RT Controls within the acceptance range 7 days at 2-8°C Controls within the acceptance range
			Temp.	C1	C2														
	ng/mL	ng/mL																	
Fresh	/	104	320																
48h	RT	104	320																
7 days	2-8°C	102	323																

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 03/10/2016

QC Manager : S.LECOURT



BIOPHEN RIVAROXABAN® CONTROL PLASMA
Référence 224501

Pour diagnostic *in vitro* exclusivement

FRANÇAIS

Lot : F1600888 - Exp. : 2019-02-26

C1 (Contrôle 1) Lot : F161100888
[C]: 104 ng/mL
Intervalle de confiance: 73 - 135 ng/mL

C2 (Contrôle 2) Lot : F161100888
[C]: 316 ng/mL
Intervalle de confiance: 265 - 367 ng/mL

BIOPHEN RIVAROXABAN® CONTROL PLASMA
224501

For *in vitro* diagnostic use only

ENGLISH

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Acceptance range: 265 - 367 ng/mL

Quality Control Approval

05 OCT. 2016

S. Lecourt

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Approved
