

# ANALYSIS CERTIFICATE

**BIOPHEN® APIXABAN CONTROL - #225301**

**Lot : F1600453**

**QC release : 05/07/2016**

**Expiration date : 2018-10-28**

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
C1 : Control 1	6 vials	30	F161200453	F161200453	2018-10-28
C2 : Control 2	6 vials	30	F161200453	F161200453	2018-10-28

*905*

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Analytical data	Specifications
<b>1. <u>Within lot reproducibility (N ≥ 10)</u></b>  N= 20                      CV:    0,5 %  N= 20                      CV:    0,6 %	OD : CV ≤ 2%  OD : CV ≤ 2%

<b>2. <u>Concentration and acceptance range</u></b>  <table border="1" style="margin-left: auto; margin-right: 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;">191</td> <td style="text-align: center;">162-220</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">385</td> <td style="text-align: center;">327-443</td> </tr> </tbody> </table>	Controls	[C] ng/mL	Acceptance range (ng/mL)	C1	191	162-220	C2	385	327-443	<b>Target value:</b>  C1: 140 to 260 ng/mL  C2: 340 to 460 ng/mL
Controls	[C] ng/mL	Acceptance range (ng/mL)								
C1	191	162-220								
C2	385	327-443								

<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
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<b>4. <u>Stability of reconstituted reagents</u></b>  <table border="1" style="margin-left: auto; margin-right: 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;">189</td> <td style="text-align: center;">392</td> </tr> <tr> <td style="text-align: center;">48h</td> <td style="text-align: center;">RT</td> <td style="text-align: center;">202</td> <td style="text-align: center;">394</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;">204</td> <td style="text-align: center;">401</td> </tr> </tbody> </table>		Temp.	C1	C2	ng/mL	ng/mL	Fresh	/	189	392	48h	RT	202	394	7 days	2-8°C	204	401	<b>48h at RT</b> Controls within the acceptance range  <b>7 days at 2-8°C</b> Controls within the acceptance range
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	ng/mL	ng/mL																	
Fresh	/	189	392																
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<b>Comments :</b>  	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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**Date : 05/07/2016**

**QC Manager : S.LECOURT**



BIOPHEN® APIXABAN CONTROL  
# 225301

Pour diagnostic *in vitro* exclusivement

FRANCAIS

Lot : F1600453 - Exp. : 2018-10-28

C1 (Contrôle 1) Lot : F161200453  
[C]: 191 ng/mL  
Intervalle de confiance: 162 - 220 ng/mL

C2 (Contrôle 2) Lot : F161200453  
[C]: 385 ng/mL  
Intervalle de confiance: 327 - 443 ng/mL

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For *in vitro* diagnostic use only.

ENGLISH

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Quality Control Approval  
11 JUL. 2016

S. Lecourt

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