

## ANALYSIS CERTIFICATE

**BIOPHEN® APIXABAN CALIBRATOR - #226201**

**Lot : F1600454**

**QC release: 06.07.2016**

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

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
CAL1 : Calibrator 1	4 vials	30	F161100454	F161100454	2018-10-28
CAL2 : Calibrator 2	4 vials	30	F161100454	F161100454	2018-10-28
CAL3 : Calibrator 3	4 vials	30	F161100454	F161100454	2018-10-28

*SAS*

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Analytical data		Specifications																																					
<b>1. <u>Within lot reproducibility</u> (N ≥ 10)</b>																																							
N= 20	CV: 0,4 %	CV (OD) ≤ 2%																																					
N= 20	CV: 0,3 %	CV (OD) ≤ 2%																																					
N= 20	CV: 1,0 %	CV (OD) ≤ 2%																																					
<b>2. <u>Concentration [C] and Standard Deviation (SD)</u></b>																																							
<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Controls</th> <th style="text-align: center;">[C] ng/mL</th> <th style="text-align: center;">SD</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">CAL1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">6,3</td> </tr> <tr> <td style="text-align: center;">CAL2</td> <td style="text-align: center;">280</td> <td style="text-align: center;">18,9</td> </tr> <tr> <td style="text-align: center;">CAL3</td> <td style="text-align: center;">558</td> <td style="text-align: center;">29,2</td> </tr> </tbody> </table>		Controls	[C] ng/mL	SD	CAL1	0	6,3	CAL2	280	18,9	CAL3	558	29,2	CAL1: < 50 ng/ml CAL2: 200-400 ng/mL CAL3: 500-700 ng/mL																									
Controls	[C] ng/mL	SD																																					
CAL1	0	6,3																																					
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<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																																					
<b>4. <u>Stability of reconstituted reagents</u></b>																																							
<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="2"></th> <th style="text-align: center;">Fresh</th> <th style="text-align: center;">48h</th> <th style="text-align: center;">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;">0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> </tr> <tr> <td style="text-align: center;">Δ [C]</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">/</td> <td style="text-align: center;">/</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;">300</td> <td style="text-align: center;">295</td> <td style="text-align: center;">291</td> </tr> <tr> <td style="text-align: center;">Δ [C]</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">5</td> <td style="text-align: center;">9</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;">569</td> <td style="text-align: center;">585</td> <td style="text-align: center;">573</td> </tr> <tr> <td style="text-align: center;">Δ [C]</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">16</td> <td style="text-align: center;">4</td> </tr> </tbody> </table>				Fresh	48h	7 days			/	RT	2-8°C	CAL1	ng/mL	0	0	0	Δ [C]	NA	/	/	CAL2	ng/mL	300	295	291	Δ [C]	NA	5	9	CAL3	ng/mL	569	585	573	Δ [C]	NA	16	4	<p style="text-align: center;"><b><u>48 hours at RT:</u></b>            Δ [C] ≤ 30 ng/ml</p> <p style="text-align: center;"><b><u>7 days at 2-8°C:</u></b>            Δ [C] ≤ 30 ng/ml</p>
		Fresh	48h	7 days																																			
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Analytical data	Specifications												
<p>5. <u>Calibration curve</u></p> <p style="text-align: center;"><input type="checkbox"/> Manual method      <input checked="" type="checkbox"/> STAR</p> <p style="text-align: center;">BIOPHEN DiXal                      Lot 53202</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%;">A<sub>405</sub></th> </tr> </thead> <tbody> <tr> <td>Cal 1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">2,381</td> </tr> <tr> <td>Cal 2</td> <td style="text-align: center;">280</td> <td style="text-align: center;">1,660</td> </tr> <tr> <td>Cal 3</td> <td style="text-align: center;">558</td> <td style="text-align: center;">1,031</td> </tr> </tbody> </table>		ng/ml	A <sub>405</sub>	Cal 1	0	2,381	Cal 2	280	1,660	Cal 3	558	1,031	
	ng/ml	A <sub>405</sub>											
Cal 1	0	2,381											
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Cal 3	558	1,031											

<p>6. <u>Linearity</u></p> <p style="text-align: center;"><math>r^2</math>                      0,998</p>	<p><math>r^2 \geq 0.98</math></p>
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<p>7. <u>Accuracy</u></p> <p style="text-align: center;"><input type="checkbox"/> Manual method      <input checked="" type="checkbox"/> STAR</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th colspan="3" style="text-align: center;">CONTROLS</th> <th style="text-align: center;">TV*</th> <th style="text-align: center;">MV*</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">44802-1</td> <td style="text-align: center;">185</td> <td style="text-align: center;">187</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">Lot</td> <td style="text-align: center;">44802-2</td> <td style="text-align: center;">388</td> <td style="text-align: center;">388</td> </tr> </tbody> </table> <p style="text-align: center; font-size: small;">*TV: Target Value      *MV: Measured Value</p>	CONTROLS			TV*	MV*	C1	Lot	44802-1	185	187	C2	Lot	44802-2	388	388	<p>MV* within the acceptance range</p> <p style="text-align: center;">[ 157 - 213 ] [ 330 - 446 ]</p>
CONTROLS			TV*	MV*												
C1	Lot	44802-1	185	187												
C2	Lot	44802-2	388	388												

<p>Comments :</p>	<p><input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b></p>
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Date : 06.07.2016

QC Manager : S. LECOURT



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Pour diagnostic *in vitro* exclusivement.

FRANCAIS

**Lot : F1600454 - Exp. : 2018-10-28**

**Concentration [C] en Apixaban dans les calibrateurs**

Cal 1 Lot : F161100454  
[C] : 0 ng/mL

Cal 2 Lot : F161100454  
[C] : 280 ng/mL

Cal 3 Lot : F161100454  
[C] : 558 ng/mL

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Quality Control Approval  
21 JUL. 2016

S. Lecourt

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