

## ANALYSIS CERTIFICATE

**BIOPHEN FIXa CONTROL SET - #224601**

**Lot : F1500032**

**QC release : 15.01.2016**

**Expiration date : 28.05.2018**

<b>Components</b>	<b>Volume</b>	<b>Exp. (months)</b>	<b>Int. Ref.</b>	<b>Lot #</b>	<b>Exp. date</b>
C1 : Control 1	6 vials	30	F151100032	F151100032	2018-05-28
C2 : Control 2	6 vials	30	F151100032	F151100032	2018-05-28

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Analytical data	Specifications										
<b>1. <u>Within lot reproducibility (N ≥ 10)</u></b>  <div style="text-align: center;"><b>mean OD</b></div> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">C1:</td> <td style="width: 15%;">N= 5</td> <td style="width: 25%; text-align: center;">1,738</td> <td style="width: 15%;">CV:</td> <td style="width: 30%; text-align: center;">1,6 %</td> </tr> <tr> <td>C2:</td> <td>N= 5</td> <td style="text-align: center;">2,669</td> <td>CV:</td> <td style="text-align: center;">0,3 %</td> </tr> </table>	C1:	N= 5	1,738	CV:	1,6 %	C2:	N= 5	2,669	CV:	0,3 %	OD : CV ≤ 5%  OD : CV ≤ 5%
C1:	N= 5	1,738	CV:	1,6 %							
C2:	N= 5	2,669	CV:	0,3 %							

<b>2. <u>Concentration and acceptance range</u></b>  <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px auto;"> <thead> <tr> <th style="width: 15%;">Controls</th> <th style="width: 15%;">[C] mIU/mL</th> <th style="width: 15%;">SD</th> <th style="width: 55%;">Acceptance range (mIU/mL)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">10,4</td> <td style="text-align: center;">0,43</td> <td style="text-align: center;">8,3 - 12,5</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">18,4</td> <td style="text-align: center;">0,71</td> <td style="text-align: center;">15,6 - 21,2</td> </tr> </tbody> </table>	Controls	[C] mIU/mL	SD	Acceptance range (mIU/mL)	C1	10,4	0,43	8,3 - 12,5	C2	18,4	0,71	15,6 - 21,2	<b>Target value:</b>  C1: 5 to 15 mIU/mL  C2: 15 to 25 mIU/mL
Controls	[C] mIU/mL	SD	Acceptance range (mIU/mL)										
C1	10,4	0,43	8,3 - 12,5										
C2	18,4	0,71	15,6 - 21,2										

<b>3. <u>Aspect</u></b>  <div style="text-align: center;">Clear, stable solution</div>	Clear, stable solution
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<b>4. <u>Stability of reconstituted reagents</u></b>  <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px auto;"> <thead> <tr> <th style="width: 15%;"></th> <th style="width: 15%;">Fresh</th> <th style="width: 15%;">8 h at RT</th> <th style="width: 55%;">24h at 2-8°C</th> </tr> <tr> <td></td> <td style="text-align: center;">mIU/mL</td> <td style="text-align: center;">mIU/mL</td> <td style="text-align: center;">mIU/mL</td> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">10,4</td> <td style="text-align: center;">10,2</td> <td style="text-align: center;">10,5</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">18,3</td> <td style="text-align: center;">18,7</td> <td style="text-align: center;">18,7</td> </tr> </tbody> </table>		Fresh	8 h at RT	24h at 2-8°C		mIU/mL	mIU/mL	mIU/mL	C1	10,4	10,2	10,5	C2	18,3	18,7	18,7	<b>8h at RT or 24 h at 2-8°C:</b> <b>In compliance:</b>  <div style="text-align: center;">[ 8,3 - 12,5 ]</div>  <div style="text-align: center;">[ 15,6 - 21,2 ]</div>
	Fresh	8 h at RT	24h at 2-8°C														
	mIU/mL	mIU/mL	mIU/mL														
C1	10,4	10,2	10,5														
C2	18,3	18,7	18,7														

<b>Comments :</b>	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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**Date : 15/01/2016**

**QC Manager :**

**S. LECOURT**



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Référence 224601

Pour recherche *in vitro* exclusivement

FRANÇAIS

**Lot : F1500032 - Exp. : 2018-05-28**

**BIOPHEN FIXa CONTROL SET**  
# 224601

For *in vitro* research use only

ENGLISH

**Lot : F1500032 - Exp. : 2018-05-28**

**C1 (Contrôle 1)** Lot : F151100032  
[C] : 10,4 mIU/mL  
Intervalle de confiance : 8,3 – 12,5 mIU/mL

**C2 (Contrôle 2)** Lot : F151100032  
[C] : 18,4 mIU/mL  
Intervalle de confiance : 15,6 – 21,2 mIU/mL

**C1 (Control 1)** Lot : F151100032  
[C]: 10.4 mIU/mL  
Acceptance range: 8.3 – 12.5 mIU/mL

**C2 (Control 2)** Lot : F151100032  
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Acceptance range: 15.6 – 21.2 mIU/mL

*Approved  
S. L. Kolb  
13.01.2016*

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