

ANALYSIS CERTIFICATE

BIOPHEN FXIa CONTROL SET - #224801

Lot : F1600111

QC release : 18/03/2016

Expiration date : 2018-08-21

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
C1 : Control 1	3 vials	30	F161100111	F161100111	2018-08-21
C2 : Control 2	3 vials	30	F161100111	F161100111	2018-08-21

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Analytical data	Specifications
1. <u>Within lot reproducibility</u>	
<u>mean OD</u>	
C1: N= 5 0,435 CV: 2,7 %	OD : CV ≤ 5%
C2: N= 5 1,412 CV: 2,5 %	OD : CV ≤ 5%

2. <u>Concentration and acceptance range</u>	Target value:												
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Controls</th> <th style="width: 20%;">[C]</th> <th style="width: 15%;">SD</th> <th style="width: 50%;">Acceptance range</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">10 mIU/ml</td> <td style="text-align: center;">0,94</td> <td style="text-align: center;">8,5 - 11,5 mIU/ml</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">41 mIU/ml</td> <td style="text-align: center;">2,33</td> <td style="text-align: center;">33 - 49 mIU/ml</td> </tr> </tbody> </table>	Controls	[C]	SD	Acceptance range	C1	10 mIU/ml	0,94	8,5 - 11,5 mIU/ml	C2	41 mIU/ml	2,33	33 - 49 mIU/ml	C1: 5 to 15 mIU/mL C2: 35 to 45 mIU/mL
Controls	[C]	SD	Acceptance range										
C1	10 mIU/ml	0,94	8,5 - 11,5 mIU/ml										
C2	41 mIU/ml	2,33	33 - 49 mIU/ml										

3. <u>Aspect</u>	
<input checked="" type="checkbox"/> Clear, Stable solution, no coagulum	Clear, stable solution, no coagulum

4. <u>Stability of reconstituted reagents</u>	8h at RT or 24 h at 2-8°C: In acceptance range									
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;"></th> <th style="width: 30%;">8 h at RT</th> <th style="width: 30%;">24h at 2-8°C</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">9,7 mIU/ml</td> <td style="text-align: center;">9,5 mIU/ml</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">42 mIU/ml</td> <td style="text-align: center;">44 mIU/ml</td> </tr> </tbody> </table>		8 h at RT	24h at 2-8°C	C1	9,7 mIU/ml	9,5 mIU/ml	C2	42 mIU/ml	44 mIU/ml	
	8 h at RT	24h at 2-8°C								
C1	9,7 mIU/ml	9,5 mIU/ml								
C2	42 mIU/ml	44 mIU/ml								

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 18/03/2016

QC Manager :

S. LECOURT

BIOPHEN FXIa CONTROL SET
Référence 224801

Pour recherche *in vitro* exclusivement

FRANÇAIS

Lot : F1600111 - Exp. : 2018-08-21

C1 (Contrôle 1)

Lot : F161100111

[C] : 10 mUI/mL

Intervalle de confiance : 8,5 – 11,5 mUI/mL

C2 (Contrôle 2)

Lot : F161100111

[C] : 41 mUI/mL

Intervalle de confiance : 33 - 49 mUI/mL

BIOPHEN FXIa CONTROL SET
Référence 224801

For *in vitro* research use only

ENGLISH

Lot : F1600111 - Exp. : 2018-08-21

C1 (Control 1)

Lot : F161100111

[C]: 10 mIU/mL

Acceptance range: 8,5 – 11,5 mIU/mL

C2 (Control 2)

Lot : F161100111

[C]: 41 mIU/mL

Acceptance range: 33 - 49 mIU/mL

BIOPHEN FXIa CONTROL SET
Référence 224801

Pour recherche *in vitro* exclusivement

FRANÇAIS

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[C]: 41 mIU/mL

Acceptance range: 33 - 49 mIU/mL

Approved
S. LECOURT
21 MARS 2016