

ANALYSIS CERTIFICATE

BIOPHEN FXIa CONTROL SET - #224801

Lot : F1700715

QC release : 02/08/2017

Expiration date : 2019-12-13

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
C1 : Control 1	3 vials	30	F171200715	F171200715	2019-12-13
C2 : Control 2	3 vials	30	F171200715	F171200715	2019-12-13

SRS

ANALYSIS CERTIFICATE

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Lot : F1700715

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Analytical data				Specifications
1. <u>Within lot reproducibility</u>				
		<u>mean OD</u>		
C1:	N= 5	0,354	CV: 0,7 %	OD : CV ≤ 5%
C2:	N= 5	1,237	CV: 1,7 %	OD : CV ≤ 5%

2. <u>Concentration and acceptance range</u>				Target value: C1: 5 to 15 mIU/mL C2: 35 to 45 mIU/mL
Controls	[C]	SD	Acceptance range	
C1	11 mIU/ml	1,3	9 - 13 mIU/ml	
C2	38 mIU/ml	3,6	30 - 46 mIU/ml	

3. <u>Aspect</u> <input checked="" type="checkbox"/> Clear, Stable solution, no coagulum	Clear, stable solution, no coagulum
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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; text-align: center;"> <thead> <tr> <th></th> <th>8 h at RT</th> <th>24h at 2-8°C</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">12,5 mIU/ml</td> <td style="text-align: center;">12,6 mIU/ml</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">37,9 mIU/ml</td> <td style="text-align: center;">39,6 mIU/ml</td> </tr> </tbody> </table>		8 h at RT	24h at 2-8°C	C1	12,5 mIU/ml	12,6 mIU/ml	C2	37,9 mIU/ml	39,6 mIU/ml	
	8 h at RT	24h at 2-8°C								
C1	12,5 mIU/ml	12,6 mIU/ml								
C2	37,9 mIU/ml	39,6 mIU/ml								

Comments : See NCI N° 1619 : lot accepted under waiver	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 02/08/2017

QC Manager :

S. Lecourt





BIOPHEN® FXIa CONTROL SET

Two levels of FXIa controls for the quality control of FXIa measurements with chromogenic FXIa assay (Biophen® FXIa) /
Deux niveaux de contrôles FXIa pour le contrôle de qualité des dosages de FXIa par méthode chromogène (Biophen® FXIa)

REF 224801

For in vitro use only. For research use only. / *Pour utilisation in vitro exclusive. Uniquement à usage de recherche.*

LOT

F1700715



2019-12-13

Factor XIa Concentration in the controls / *Concentration en Facteur XIa dans les contrôles*

Control / <i>Contrôle</i> C1	LOT : F171200715
Target value / <i>Valeur cible</i> :	11 mIU/mL / <i>mUI/mL</i>
Acceptance range / <i>Intervalle d'acceptation</i> :	[9 – 13] mIU/mL / <i>mUI/mL</i>

Control / <i>Contrôle</i> C2	LOT : F171200715
Target value / <i>Valeur cible</i> :	38 mIU/mL / <i>mUI/mL</i>
Acceptance range / <i>Intervalle d'acceptation</i> :	[30 – 46] mIU/mL / <i>mUI/mL</i>

Standardization / *Standardisation* : **Controls are qualified against International Standard NIBSC 13/100**

Approved Date / *Date d'Approbation* : 02/08/2017

Quality Control Manager / *Responsable Contrôle Qualité* : S. LECOURT