

ANALYSIS CERTIFICATE

FIXa CALIBRATOR - #CM103

Lot : F1500051P1

QC release: 15/01/2016

Expiration date : 2018-05-28

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
Calibrator IXa	1 vial	30	F1500051	F1500051	2018-05-28

305

ANALYSIS CERTIFICATE

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Analytical data	Specifications												
<p>1. <u>Within lot reproducibility</u> (N ≥ 10)</p> <p>N= 5 OD= 2,214 CV: 0,6 %</p>	<p>OD : CV ≤ 2%</p>												
<p>2. <u>Concentration and acceptance range</u></p> <table border="1" style="margin: 10px auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">Calibrator IXa</th> <th style="width: 25%;">[C] mIU/mL</th> <th style="width: 25%;">SD</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">[C]</td> <td style="text-align: center;">29</td> <td style="text-align: center;">3,7</td> </tr> </tbody> </table>	Calibrator IXa	[C] mIU/mL	SD	[C]	29	3,7	<p>Target value: [C]: 25 to 30 mIU/mL</p>						
Calibrator IXa	[C] mIU/mL	SD											
[C]	29	3,7											
<p>3. <u>Aspect</u></p> <p style="text-align: center;">Clear, stable solution</p>	<p>Clear, stable solution</p>												
<p>4. <u>Stability of reconstituted reagents</u></p> <table border="1" style="margin: 10px auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;"></th> <th style="width: 20%;">Fresh</th> <th style="width: 20%;">8 h at RT</th> <th style="width: 20%;">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;">Cal</td> <td style="text-align: center;">24</td> <td style="text-align: center;">23</td> <td style="text-align: center;">22</td> </tr> </tbody> </table>		Fresh	8 h at RT	24h at 2-8°C		mIU/mL	mIU/mL	mIU/mL	Cal	24	23	22	<p><u>8h at RT</u> <u>or 24 h at 2-8°C:</u> In compliance: ΔC ≤ 10 %</p>
	Fresh	8 h at RT	24h at 2-8°C										
	mIU/mL	mIU/mL	mIU/mL										
Cal	24	23	22										

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

QC Manager :

S. LECOURT



Factor IXa Calibrator (ACT. FIX)
Référence CM103

Pour recherche *in vitro* exclusivement

FRANÇAIS

Lot : F1500051P1 - Exp. : 2018-05-28

Calibrateur Facteur IXa

Lot : F1500051

C= 29 mUI/ml*

(* 1 mUI/ml est proche de 1 ng/ml)

Factor IXa Calibrator (ACT. FIX)
CM103

For *in vitro* research use only

ENGLISH

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*Après
15.01.2016
Sleight*