

ANALYSIS CERTIFICATE

BIOPHEN FXIa - #220412

Lot : 53403

QC Release : 05/11/2015

Expiration date : 2018-02

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
R1A : Human Factor X -FVIII:C	2 vials	30	150904B	53403-1A	2018-03
R1B : Human Factor IX	2 vials	30	150922B	53403-1B	2018-03
R2 : "Activation" Reagent	2 vials	30	150922C	53403-2	2018-03
R3 : SXa-11 substrate	2 vials	30	150903G	53403-3	2018-03
R4 : Tris-BSA buffer	2 vials	30	150902B	53403-4	2018-03
Cal : FXIa Calibrator	2 vials	30	150820A	53403-5	2018-02

SOS

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Analytical data	Specifications									
<p>1. <u>Human Factor X-VIII:C</u></p> <p>a. Reproducibility :</p> <p style="padding-left: 40px;">N = 20 Mean (A405) : 1,652</p> <p style="padding-left: 80px;">CV : 1,57 %</p> <p>b. Factor X concentration 86 %</p> <p>c. Factor VIII : c concentration 268 % = 2,68 UI/mL</p>	<p style="text-align: center;">N ≥ 10</p> <p style="text-align: center;">≤ 2 %</p> <p style="text-align: center;">≥ 50 %</p> <p style="text-align: center;">≥ 190 % ou 1.90UI/ml ou 5.7 UI/flacon</p>									
<p>2. <u>Human Factor IX</u></p> <p>a. Reproducibility :</p> <p style="padding-left: 40px;">N = 20 Mean (A405) : 1,544</p> <p style="padding-left: 80px;">CV : 1,89 %</p> <p>c. Factor IX (h) concentration 120 % = 6 µg/mL</p>	<p style="text-align: center;">N ≥ 10</p> <p style="text-align: center;">≤ 2 %</p> <p style="text-align: center;">≥ 4µg/ml ou 12 µg/flacon</p>									
<p>2. <u>"Activation" Reagent (Thrombin - PLPs - calcium)</u></p> <p>Reproducibility :</p> <p style="padding-left: 40px;">N = 20 Mean (A405) : 1,510</p> <p style="padding-left: 80px;">CV : 1,26 %</p>	<p style="text-align: center;">N ≥ 10</p> <p style="text-align: center;">≤ 2 %</p>									
<p>3. <u>SXa-11 substrate</u></p> <p>a. Blank value (N=10) Mean (A405) : 0,212</p> <p>b. Stability of substrate blank (A405)</p> <table border="1" style="width: 100%; margin: 5px 0; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Time</th> <th style="width: 40%;">Fresh</th> <th style="width: 40%;">7 days</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">2-8°C</td> <td style="text-align: center;">0,198</td> <td style="text-align: center;">0,173</td> </tr> <tr> <td style="text-align: center;">R.T.</td> <td style="background-color: #cccccc;"></td> <td style="text-align: center;">0,199</td> </tr> </tbody> </table> <p>c. Reproducibility :</p> <p style="padding-left: 40px;">N = 25 Mean (A405) : 1,395</p> <p style="padding-left: 80px;">CV : 1,33 %</p>	Time	Fresh	7 days	2-8°C	0,198	0,173	R.T.		0,199	<p style="text-align: center;">A405 ≤ 0.30</p> <p style="text-align: center;">A405</p> <p style="text-align: center;">7 days ≤ 0.30</p> <p style="text-align: center;">N ≥ 10</p> <p style="text-align: center;">≤ 2 %</p>
Time	Fresh	7 days								
2-8°C	0,198	0,173								
R.T.		0,199								
<p>4. <u>FXIa calibrator</u></p> <p style="padding-left: 40px;">N = 18</p> <p style="padding-left: 40px;">FXIa conc. = 5,1 ng/ml</p> <p style="padding-left: 80px;">51 mIU/ml</p> <p style="padding-left: 40px;">CV : 8,6 %</p>	<p style="text-align: center;">N ≥ 9</p> <p style="text-align: center;">5,0 ± 1,0 ng/ml</p> <p style="text-align: center;">50 ± 10 mIU/ml</p> <p style="text-align: center;">≤ 10 %</p>									

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Analytical data	Specifications																								
<p>1. <u>Calibration curve</u></p> <table border="1" style="margin-left: 20px; border-collapse: collapse; width: 80%;"> <thead> <tr> <th style="width: 25%;">FXIa</th> <th style="width: 25%;">A405 W. Bath</th> <th style="width: 25%;">A405 STAR</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">0</td> <td style="text-align: center;">0,086</td> <td style="text-align: center;">NA</td> </tr> <tr> <td style="text-align: center;">C/16</td> <td style="text-align: center;">0,219</td> <td style="text-align: center;">0,080</td> </tr> <tr> <td style="text-align: center;">C/8</td> <td style="text-align: center;">0,351</td> <td style="text-align: center;">0,186</td> </tr> <tr> <td style="text-align: center;">C/4</td> <td style="text-align: center;">0,620</td> <td style="text-align: center;">0,336</td> </tr> <tr> <td style="text-align: center;">C/2</td> <td style="text-align: center;">1,074</td> <td style="text-align: center;">0,711</td> </tr> <tr> <td style="text-align: center;">C</td> <td style="text-align: center;">1,800</td> <td style="text-align: center;">1,413</td> </tr> <tr> <td>Linearity : r2 =</td> <td style="text-align: center;">0,9988</td> <td style="text-align: center;">0,998</td> </tr> </tbody> </table>	FXIa	A405 W. Bath	A405 STAR	0	0,086	NA	C/16	0,219	0,080	C/8	0,351	0,186	C/4	0,620	0,336	C/2	1,074	0,711	C	1,800	1,413	Linearity : r2 =	0,9988	0,998	<p style="text-align: center;">Water Bath: A405(C) ≥ 1.5 A405 (0) < 0.100</p> <p style="text-align: center;">ΔA405(C-C/2) ≥ 0.30</p> <p style="text-align: center;">r2 ≥ 0.98</p>
FXIa	A405 W. Bath	A405 STAR																							
0	0,086	NA																							
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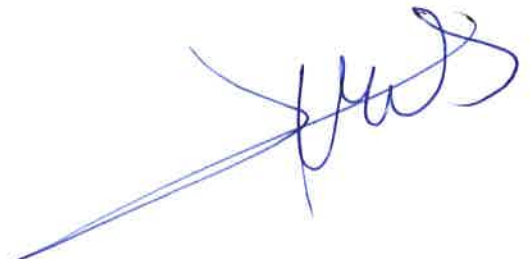
<p>2. <u>Detection threshold</u></p> <p style="text-align: center;"><0,1 ng/ml <1 mIU/ml</p>	<p style="text-align: center;">≤ 0.25 ng/ml ≤ 2,5 mIU/ml</p>
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<p>3. <u>Stability of restored reagents (for the C FXIa concentration)</u></p> <table border="1" style="margin-left: 20px; border-collapse: collapse; width: 80%;"> <thead> <tr> <th style="width: 15%;"></th> <th style="width: 15%;">Fresh</th> <th style="width: 15%;">8hrs RT</th> <th style="width: 15%;">24 hrs 2-8°C</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">A405</td> <td style="text-align: center;">1,800</td> <td style="text-align: center;">1,717</td> <td style="text-align: center;">1,746</td> </tr> </tbody> </table>		Fresh	8hrs RT	24 hrs 2-8°C	A405	1,800	1,717	1,746	<p style="text-align: center;">Δ A405 ≤ 0.20</p>
	Fresh	8hrs RT	24 hrs 2-8°C						
A405	1,800	1,717	1,746						

<p>Comments : CoA updated regarding availability of WHO International standard FXIa (cf DCC 74)</p>	<div style="display: flex; align-items: center; justify-content: center;"> <div style="border: 1px solid black; width: 30px; height: 30px; margin-right: 10px; display: flex; align-items: center; justify-content: center;"> X </div> <div> <p>PASSED IN COMPLIANCE</p> </div> </div>
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Date : 08.02.2016

QC Manager : S. LECOURT



BIOPHEN Factor Xla
Référence 220412

Pour recherche *in vitro* exclusivement

FRANÇAIS

Lot : 53403 - Exp. : 2018-02

Calibrateur Facteur Xla

Lot : 53403-5

C= 5,1 ng/ml

C= 51 mUI/ml

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Référence 220412

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Calibrateur Facteur Xla

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C= 5,1 ng/ml

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220412

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Factor Xla Calibrator

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D. Lecourt
S. LECOURT
09 FEV. 2016