

ANALYSIS CERTIFICATE

BIOPHEN FXIa - #220412

Lot : F1700716

QC Release : 2017-09-22

Expiration date : 2019-12-13

Components	Volume	Exp. (months)	Lot #	Exp. date
R1A : Human Factor X -FVIII:C	2 vials	30	F171100716	2020-01-19
R1B : Human Factor IX	2 vials	30	F171100716	2020-02-10
R2 : "Activation" Reagent	2 vials	30	F171100716	2020-02-10
R3 : Sxa-11 substrate	2 vials	30	F171100716	2019-12-24
R4 : Tris-BSA buffer	2 vials	30	F171100716	2020-01-24
Cal : FXIa Calibrator	2 vials	30	F171100716	2019-12-13

ANALYSIS CERTIFICATE

BIOPHEN FXIa - #220412

Lot : F1700716

QC Release : 2017-09-22

Expiration date : 2019-12-13

Analytical data	Specifications									
<p>1. <u>Human Factor X-VIII:C</u></p> <p>a. Reproducibility :</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 20%;">N = 10</div> <div style="width: 40%;">Mean (A405) : 1,825 CV : 1,7 %</div> <div style="width: 40%; text-align: right;">≤ 2 %</div> </div> <p>b. Factor X concentration 88 %</p> <p>c. Factor VIII:C concentration 214 % = 2,14 UI/ml</p>	<p>≤ 2 %</p> <p>≥ 50 %</p> <p>≥ 190 % or 1.90IU/ml or 5.7 IU/vial</p>									
<p>2. <u>Human Factor IX</u></p> <p>a. Reproducibility :</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 20%;">N = 10</div> <div style="width: 40%;">Mean (A405) : 1,711 CV : 1,5 %</div> <div style="width: 40%; text-align: right;">≤ 2 %</div> </div> <p>c. Factor IX (h) concentration 96 % = 4,85 µg/ml</p>	<p>≤ 2 %</p> <p>≥ 4µg/ml or 12 µg/vial</p>									
<p>3. <u>"Activation" Reagent (Thrombin - PLPs - calcium)</u></p> <p>Reproducibility :</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 20%;">N = 10</div> <div style="width: 40%;">Mean (A405) : 1,767 CV : 1,5 %</div> <div style="width: 40%; text-align: right;">≤ 2 %</div> </div>	<p>≤ 2 %</p>									
<p>4. <u>SXa-11 substrate</u></p> <p>a. Blank value (N=10) Mean (A405) : 0,199</p> <p>b. Stability of substrate blank (A405)</p> <table border="1" style="margin: 5px auto; border-collapse: collapse;"> <thead> <tr> <th>Time</th> <th>Fresh</th> <th>7 days</th> </tr> </thead> <tbody> <tr> <td>2-8°C</td> <td style="text-align: center;">0,200</td> <td style="text-align: center;">0,201</td> </tr> <tr> <td>R.T.</td> <td style="background-color: #cccccc;"></td> <td style="text-align: center;">0,201</td> </tr> </tbody> </table> <p>c. Reproducibility :</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 20%;">N = 10</div> <div style="width: 40%;">Mean (A405) : 1,912 CV : 1,7 %</div> <div style="width: 40%; text-align: right;">≤ 2 %</div> </div>	Time	Fresh	7 days	2-8°C	0,200	0,201	R.T.		0,201	<p>A405 ≤ 0.30</p> <p>A405</p> <p>7 days ≤ 0.30</p> <p>≤ 2 %</p>
Time	Fresh	7 days								
2-8°C	0,200	0,201								
R.T.		0,201								
<p>4. <u>FXIa calibrator</u></p> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 35%;">N = 18</div> <div style="width: 30%;">FXIa conc. = 47</div> <div style="width: 30%;">N ≥ 18</div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 35%;">CV : 9,3</div> <div style="width: 30%;">50 ± 10 mIU/ml</div> <div style="width: 30%; text-align: right;">≤ 10 %</div> </div>										

SOS

ANALYSIS CERTIFICATE

BIOPHEN FXIa - #220412

Lot : F1700716

QC Release : 2017-09-22

Expiration date : 2019-12-13

Analytical data	Specifications																								
<p>1. Calibration curve</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">FXIa</th> <th style="width: 20%;">A405 W. Bath</th> <th style="width: 20%;">A405 STAR</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">0</td> <td style="text-align: center;">0,078</td> <td style="text-align: center;">NA</td> </tr> <tr> <td style="text-align: center;">C/16</td> <td style="text-align: center;">0,174</td> <td style="text-align: center;">0,085</td> </tr> <tr> <td style="text-align: center;">C/8</td> <td style="text-align: center;">0,278</td> <td style="text-align: center;">0,171</td> </tr> <tr> <td style="text-align: center;">C/4</td> <td style="text-align: center;">0,492</td> <td style="text-align: center;">0,389</td> </tr> <tr> <td style="text-align: center;">C/2</td> <td style="text-align: center;">0,960</td> <td style="text-align: center;">0,682</td> </tr> <tr> <td style="text-align: center;">C</td> <td style="text-align: center;">1,758</td> <td style="text-align: center;">1,340</td> </tr> <tr> <td>Linearity : R² =</td> <td style="text-align: center;">0,9927</td> <td style="text-align: center;">0,994</td> </tr> </tbody> </table>	FXIa	A405 W. Bath	A405 STAR	0	0,078	NA	C/16	0,174	0,085	C/8	0,278	0,171	C/4	0,492	0,389	C/2	0,960	0,682	C	1,758	1,340	Linearity : R² =	0,9927	0,994	<p>Water Bath: A405(C) ≥ 1.50 A405 (0) ≤ 0.100</p> <p>ΔA405(C-C/2) ≥ 0.30</p> <p>R² ≥ 0.98</p>
FXIa	A405 W. Bath	A405 STAR																							
0	0,078	NA																							
C/16	0,174	0,085																							
C/8	0,278	0,171																							
C/4	0,492	0,389																							
C/2	0,960	0,682																							
C	1,758	1,340																							
Linearity : R² =	0,9927	0,994																							

<p>2. Accuracy</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Control</th> <th style="width: 20%;">TV*</th> <th style="width: 20%;">MV*</th> </tr> </thead> <tbody> <tr> <td>Normal Control</td> <td style="text-align: center;">11</td> <td style="text-align: center;">12</td> </tr> <tr> <td>Abnormal Control</td> <td style="text-align: center;">38</td> <td style="text-align: center;">42</td> </tr> </tbody> </table> <p><small>* TV= Target Value - MV= Measured Value</small></p>	Control	TV*	MV*	Normal Control	11	12	Abnormal Control	38	42	<p>[9 - 13] [30 - 46]</p>
Control	TV*	MV*								
Normal Control	11	12								
Abnormal Control	38	42								

<p>3. Detection threshold</p> <p style="text-align: center;">2,4 mIU/ml</p>	<p>≤ 2,5 mIU/ml</p>
--	---------------------

<p>4. Stability of restored reagents (for the C FXIa concentration)</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;"></th> <th style="width: 20%;">Fresh</th> <th style="width: 20%;">8hrs RT</th> <th style="width: 20%;">24 hrs 2-8°C</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">A405 (point C)</td> <td style="text-align: center;">1,632</td> <td style="text-align: center;">1,696</td> <td style="text-align: center;">1,488</td> </tr> </tbody> </table>		Fresh	8hrs RT	24 hrs 2-8°C	A405 (point C)	1,632	1,696	1,488	<p>Δ A405 ≤ 0.20</p>
	Fresh	8hrs RT	24 hrs 2-8°C						
A405 (point C)	1,632	1,696	1,488						

<p>Comments :</p>	<div style="display: flex; align-items: center; justify-content: center;"> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;"> <input checked="" type="checkbox"/> </div> <div> <p>PASSED IN COMPLIANCE</p> </div> </div>
-------------------	---

Date : 22.09.2017

QC Manager : S. LECOURT



BIOPHEN® Factor Xla

Chromogenic assay for the quantitative determination of FXla activity in purified milieu/
Dosage fonctionnel du Facteur Xla sur milieu purifié par méthode colorimétrique

REF 220412

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

LOT F1700716

 2019-12-13

Factor Xla Concentration [C] in the calibrator /
Concentration [C] en Facteur Xla dans le calibrateur

<u>Factor Xla Calibrator / Calibrateur Facteur Xla</u>	LOT : F171100716
[C] :	47 mIU/mL / mUI/mL

Standardization / *Standardisation* : Calibrator is calibrated against international standard from NIBSC 13/100

Approved Date / *Date d'Approbation* : 2017-09-22

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

