

ANALYSIS CERTIFICATE

BIOPHEN FVIIa- #221312

Lot : F1700960

QC release: 2017-09-18

Expiration date : 2020-02-15

Components	Volume	Exp. (months)	Lot #	Exp. date
R1 : Human Factor X	2 vials	30	F171200960	2020-02-21
R2 : FVIIa Cof-PIps	2 vials	30	F171200960	2020-02-24
R3 : SXXa-11 substrate	2 vials	30	F171200960	2020-02-15
R4 : Tris-BSA buffer	2 vials	30	F171200960	2020-02-23

SK

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Lot : F1700960

QC release: 2017-09-18

Expiration date : 2020-02-15

Analytical data	Specifications									
<p>1. <u>Human Factor X</u></p> <p>a. Reproducibility (water bath)</p> <p style="margin-left: 40px;">N = 5 Mean (A405): 2,423</p> <p style="margin-left: 80px;">CV: 0,4 %</p> <p>b. Factor X concentration (water bath)</p> <p style="margin-left: 40px;">2,5 µg/ml</p>	<p>≤ 2 %</p> <p>≥ 2 µg/ml</p>									
<p>2. <u>FVIIa Cof-Pips</u></p> <p>a. Reproducibility (water bath)</p> <p style="margin-left: 40px;">N = 5 Mean (A405): 2,347</p> <p style="margin-left: 80px;">CV: 0,7 %</p>	<p>≤ 2 %</p>									
<p>3. <u>SXa-11 substrate</u></p> <p>a. Blank value (N=10) Mean (A405): 0,129</p> <p>b. Stability of substrate blank (A405)</p> <table border="1" style="margin-left: 40px; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>Time</th> <th>Fresh</th> <th>1 week</th> </tr> </thead> <tbody> <tr> <td>2-8°C</td> <td>0,124</td> <td>0,123</td> </tr> <tr> <td>R.T.</td> <td>0,124</td> <td>0,129</td> </tr> </tbody> </table> <p>c. Reproducibility (water bath)</p> <p style="margin-left: 40px;">N = 5 Mean (A405): 2,340</p> <p style="margin-left: 80px;">CV: 0,4 %</p>	Time	Fresh	1 week	2-8°C	0,124	0,123	R.T.	0,124	0,129	<p>A405 (2mg/mL) ≤ 0.30</p> <p>A405 (2mg/mL) 24h at RT ≤ 0.30 72h at 2-8°C ≤ 0.30</p> <p>≤ 2 %</p>
Time	Fresh	1 week								
2-8°C	0,124	0,123								
R.T.	0,124	0,129								

SPC

ANALYSIS CERTIFICATE

BIOPHEN FVIIa- #221312

Lot : F1700960

QC release: 18/09/2017

Expiration date : 2020-02-15

Analytical data	Specifications																																				
<p>4. Calibration curve</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th colspan="2">VIIa (mUI/ml)</th> <th>A405</th> <th>A405</th> </tr> <tr> <th>W. Bath</th> <th>STAR</th> <th>W. Bath</th> <th>STAR</th> </tr> </thead> <tbody> <tr> <td>500</td> <td></td> <td>2,362</td> <td>...</td> </tr> <tr> <td>250</td> <td></td> <td>1,589</td> <td>...</td> </tr> <tr> <td>125</td> <td>NA</td> <td>0,927</td> <td>...</td> </tr> <tr> <td>62,5</td> <td></td> <td>0,499</td> <td>NA</td> </tr> <tr> <td>31,25</td> <td></td> <td>0,255</td> <td>...</td> </tr> <tr> <td>0</td> <td></td> <td>0,001</td> <td>...</td> </tr> <tr> <td colspan="2">Linearity: R2 =</td> <td>0,9908</td> <td>...</td> </tr> </tbody> </table>	VIIa (mUI/ml)		A405	A405	W. Bath	STAR	W. Bath	STAR	500		2,362	...	250		1,589	...	125	NA	0,927	...	62,5		0,499	NA	31,25		0,255	...	0		0,001	...	Linearity: R2 =		0,9908	...	<p>Water Bath: A405 (C mUI/ml) ≥ 1.80 A405 (0 mUI/mL) ≤ 0.010</p> <p style="text-align: center; margin-top: 20px;">R2 ≥ 0.98</p>
VIIa (mUI/ml)		A405	A405																																		
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<p>5. Detection threshold</p> <p style="text-align: center; margin-top: 10px;"><1 mUI/ml</p>	<p>≤ 25 mUI/ml</p>
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<p>6. Stability of restored reagents (about 500 mUI/mL FVIIa)</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th></th> <th>Fresh</th> <th>24 hrs RT</th> <th>72 hrs 2-8°C</th> </tr> </thead> <tbody> <tr> <td>A405</td> <td>2,342</td> <td>2,290</td> <td>2,417</td> </tr> </tbody> </table>		Fresh	24 hrs RT	72 hrs 2-8°C	A405	2,342	2,290	2,417	<p>Δ A405 ≤ 0.20</p>
	Fresh	24 hrs RT	72 hrs 2-8°C						
A405	2,342	2,290	2,417						

Comments :



PASSED IN COMPLIANCE

Date : 2017-09-18

QC Manager :

S.LECOURT

