

## ANALYSIS CERTIFICATE

**BIOPHEN™ FIX - #221806**

**Lot : F1701219 / F1701220**

**QC Release : 27/11/2017**

**Expiration date : 2020-04-06**

<b>Components</b>	<b>Volume</b>	<b>Exp. (months)</b>	<b>Lot #</b>	<b>Exp Date</b>
R1 : Human Factor X -FVIII:C	2 vials	30	F171Y01219 F171Z01220	2020-04-06
R2 : Activation Reagent (XIa)	2 vials	30	F171Y01219 F171Z01220	2020-04-13
R3 : Sxa-11 substrate	2 vials	30	F171Y01219 F171Z01220	2020-04-11
R4 : Tris-BSA buffer	4 vials	30	F171Y01219 F171Z01220	2020-04-12

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Analytical data	Specifications																				
<p><b>1. <u>Human Factor X-VIII:C</u></b></p> <p><b>a. Reproducibility ( 100 % FIX)</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N =</td> <td style="width: 15%; text-align: center;"><b>10</b></td> <td style="width: 20%;">Mean (A405):</td> <td style="width: 50%; text-align: right;"><b>1,076</b></td> </tr> <tr> <td></td> <td></td> <td>CV:</td> <td style="text-align: right;"><b>1,4 %</b></td> </tr> </table> <p><b>b. Factor X concentration</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;"></td> <td style="width: 20%; text-align: right;"><b>122 %</b></td> <td style="width: 20%;"></td> </tr> </table>	N =	<b>10</b>	Mean (A405):	<b>1,076</b>			CV:	<b>1,4 %</b>		<b>122 %</b>		<p><b>≤ 2 %</b></p> <p><b>≥ 50 %</b></p>									
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<p><b>2. <u>Activation Reagent (XIIa - Thrombin - PLPs - calcium)</u></b></p> <p><b>a. Reproducibility ( 100 % FIX)</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N =</td> <td style="width: 15%; text-align: center;"><b>10</b></td> <td style="width: 20%;">Mean (A405):</td> <td style="width: 50%; text-align: right;"><b>1,078</b></td> </tr> <tr> <td></td> <td></td> <td>CV:</td> <td style="text-align: right;"><b>1,2 %</b></td> </tr> </table>	N =	<b>10</b>	Mean (A405):	<b>1,078</b>			CV:	<b>1,2 %</b>	<p><b>≤ 2 %</b></p>												
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<p><b>3. <u>SXa-11 substrate</u> (tested at 2.5 mg/ml for a,b)</b></p> <p><b>a. Blank value (N=10)</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 40%;"></td> <td style="width: 20%; text-align: right;"><b>Mean (A405):</b></td> <td style="width: 40%; text-align: right;"><b>0,158</b></td> </tr> </table> <p><b>b. Stability of substrate blank (A405)</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin: 5px 0;"> <thead> <tr> <th style="width: 20%;">Time</th> <th style="width: 30%;">Fresh</th> <th style="width: 50%;">7 days</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"><b>2-8°C</b></td> <td style="text-align: center;">0,158</td> <td style="text-align: center;">0,157</td> </tr> <tr> <td style="text-align: center;"><b>R.T.</b></td> <td style="background-color: black;"></td> <td style="text-align: center;">0,163</td> </tr> </tbody> </table> <p><b>c. Reproducibility ( 100 % FIX)</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N =</td> <td style="width: 15%; text-align: center;"><b>10</b></td> <td style="width: 20%;">Mean (A405):</td> <td style="width: 50%; text-align: right;"><b>1,068</b></td> </tr> <tr> <td></td> <td></td> <td>CV:</td> <td style="text-align: right;"><b>0,6 %</b></td> </tr> </table>		<b>Mean (A405):</b>	<b>0,158</b>	Time	Fresh	7 days	<b>2-8°C</b>	0,158	0,157	<b>R.T.</b>		0,163	N =	<b>10</b>	Mean (A405):	<b>1,068</b>			CV:	<b>0,6 %</b>	<p><b>A405 ≤ 0.30</b></p> <p><b>A405</b></p> <p><b>7 days ≤ 0.30</b></p> <p><b>≤ 2 %</b></p>
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QC Manager :

S. LECOURT

