

## 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									
<b>1. <u>Human Factor X-VIII:C</u></b>  <b>a. Reproducibility ( 100 % FIX)</b> <div style="display: flex; justify-content: space-between; width: 80%;"> <span>N = <b>10</b></span> <span>Mean (A405): <b>1,076</b></span> </div> <div style="display: flex; justify-content: space-between; width: 80%;"> <span></span> <span>CV: <b>1,4 %</b></span> </div> <b>b. Factor X concentration</b> <span style="float: right;"><b>122 %</b></span>	   ≤ 2 %   ≥ 50 %									
<b>2. <u>Activation Reagent (XIIa - Thrombin - PLPs - calcium)</u></b>  <b>a. Reproducibility ( 100 % FIX)</b> <div style="display: flex; justify-content: space-between; width: 80%;"> <span>N = <b>10</b></span> <span>Mean (A405): <b>1,078</b></span> </div> <div style="display: flex; justify-content: space-between; width: 80%;"> <span></span> <span>CV: <b>1,2 %</b></span> </div>	   ≤ 2 %									
<b>3. <u>SXa-11 substrate</u> (tested at 2.5 mg/ml for a,b)</b>  <b>a. Blank value (N=10)</b> <span style="float: right;">Mean (A405): <b>0,158</b></span>  <b>b. Stability of substrate blank (A405)</b> <table border="1" style="width: 100%; text-align: center; margin-bottom: 10px;"> <thead> <tr> <th style="padding: 2px;">Time</th> <th style="padding: 2px;">Fresh</th> <th style="padding: 2px;">7 days</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;"><b>2-8°C</b></td> <td style="padding: 2px;">0,158</td> <td style="padding: 2px;">0,157</td> </tr> <tr> <td style="padding: 2px;"><b>R.T.</b></td> <td style="background-color: black; color: black; padding: 2px;">[REDACTED]</td> <td style="padding: 2px;">0,163</td> </tr> </tbody> </table> <b>c. Reproducibility ( 100 % FIX)</b> <div style="display: flex; justify-content: space-between; width: 80%;"> <span>N = <b>10</b></span> <span>Mean (A405): <b>1,068</b></span> </div> <div style="display: flex; justify-content: space-between; width: 80%;"> <span></span> <span>CV: <b>0,6 %</b></span> </div>	Time	Fresh	7 days	<b>2-8°C</b>	0,158	0,157	<b>R.T.</b>	[REDACTED]	0,163	A405 ≤ 0.30   A405 7 days ≤ 0.30   ≤ 2 %
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<b>2-8°C</b>	0,158	0,157								
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<p>Method: BME</p> <table border="1" style="width:100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th></th> <th>Fresh</th> <th>8hrs RT</th> <th>24 hrs 2-8°C</th> </tr> </thead> <tbody> <tr> <td>A405</td> <td style="text-align:center;">1,528</td> <td style="text-align:center;">1,406</td> <td style="text-align:center;">1,486</td> </tr> </tbody> </table>		Fresh	8hrs RT	24 hrs 2-8°C	A405	1,528	1,406	1,486	<p style="text-align:center;">Δ A405 ≤ 0.20</p>																																																																																									
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Date : 27/11/2017

QC Manager :

S. LECOURT

