

## ANALYSIS CERTIFICATE

**BIOPHEN FIX (6) - #221806**

**Lot : F1600815**

**QC Release : 09/09/2016**

**Expiration date : 2019-01-28**

<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	F161B00815	2019-02-02
R2 : Activation Reagent (Xla)	2 vials	30	F161B00815	2019-02-10
R3 : Sxa-11 substrate	2 vials	30	F161B00815	2019-01-28
R4 : Tris-BSA buffer	4 vials	30	F161B00815	2019-02-03

SOS

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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> <p style="margin-left: 40px;">N = 15                      Mean (A405): <b>1,359</b></p> <p style="margin-left: 100px;">CV: <b>1,88 %</b></p> <p style="margin-left: 40px;"><b>b. Factor X concentration</b>                      <b>87 %</b></p>		<p>≤ 2 %</p> <p>≥ 50 %</p>									
<p><b>2. <u>Activation Reagent (Xla - Thrombin - PLPs - calcium)</u></b></p> <p><b>a. Reproducibility ( 100 % FIX)</b></p> <p style="margin-left: 40px;">N = 15                      Mean (A405): <b>1,274</b></p> <p style="margin-left: 100px;">CV: <b>1,94 %</b></p>		<p>≤ 2 %</p>									
<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>                      Mean (A405): <b>0,165</b></p> <p><b>b. Stability of substrate blank (A405)</b></p> <table border="1" style="margin-left: 40px; border-collapse: collapse; width: 150px;"> <thead> <tr> <th style="width: 30%;">Time</th> <th style="width: 30%;">Fresh</th> <th style="width: 30%;">7 days</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"><b>2-8°C</b></td> <td style="text-align: center;">0,186</td> <td style="text-align: center;">0,181</td> </tr> <tr> <td style="text-align: center;"><b>R.T.</b></td> <td style="background-color: black;"></td> <td style="text-align: center;">0,180</td> </tr> </tbody> </table> <p><b>c. Reproducibility ( 100 % FIX)</b></p> <p style="margin-left: 40px;">N = 15                      Mean (A405): <b>1,341</b></p> <p style="margin-left: 100px;">CV: <b>1,39 %</b></p>		Time	Fresh	7 days	<b>2-8°C</b>	0,186	0,181	<b>R.T.</b>		0,180	<p>A405 ≤ 0.30</p> <p>A405</p> <p>7 days ≤ 0.30</p> <p>≤ 2 %</p>
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*sp3*

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<b>1. Calibration curve</b> <u>High range:</u> <table border="1"> <thead> <tr> <th colspan="2">FIX (%)</th> <th colspan="2">A405</th> <th colspan="2">Δ A405/min</th> </tr> <tr> <th>W. Bath</th> <th>STAR</th> <th>W. Bath</th> <th>STAR</th> <th>W. Bath</th> <th>STAR</th> </tr> </thead> <tbody> <tr> <td>200</td> <td>143</td> <td>1,930</td> <td></td> <td>0,932</td> <td></td> </tr> <tr> <td>100</td> <td>100</td> <td>1,439</td> <td></td> <td>0,749</td> <td></td> </tr> <tr> <td>50</td> <td>67</td> <td>0,904</td> <td></td> <td>0,541</td> <td></td> </tr> <tr> <td>25</td> <td>50</td> <td>0,572</td> <td></td> <td>0,434</td> <td></td> </tr> <tr> <td>12,5</td> <td>25</td> <td>0,337</td> <td></td> <td>0,209</td> <td></td> </tr> <tr> <td colspan="2">Linearity:</td> <td>R<sup>2</sup>=</td> <td>0,991</td> <td>0,986</td> <td></td> </tr> </tbody> </table> <u>Low range:</u> <table border="1"> <thead> <tr> <th colspan="2">FIX (%)</th> <th colspan="2">A405</th> <th colspan="2">Δ A405/min</th> </tr> <tr> <th>W. Bath</th> <th>STAR</th> <th>W. Bath</th> <th>STAR</th> <th>W. Bath</th> <th>STAR</th> </tr> </thead> <tbody> <tr> <td>20</td> <td>29</td> <td>1,069</td> <td></td> <td>0,676</td> <td></td> </tr> <tr> <td>10</td> <td>10</td> <td>0,728</td> <td></td> <td>0,347</td> <td></td> </tr> <tr> <td>5</td> <td>7</td> <td>0,471</td> <td></td> <td>0,232</td> <td></td> </tr> <tr> <td>2,5</td> <td>2</td> <td>0,276</td> <td></td> <td>0,059</td> <td></td> </tr> <tr> <td>1</td> <td>1</td> <td>0,112</td> <td></td> <td>0,023</td> <td></td> </tr> <tr> <td colspan="2">Linearity:</td> <td>R<sup>2</sup>=</td> <td>0,985</td> <td>0,988</td> <td></td> </tr> </tbody> </table>		FIX (%)		A405		Δ A405/min		W. Bath	STAR	W. Bath	STAR	W. Bath	STAR	200	143	1,930		0,932		100	100	1,439		0,749		50	67	0,904		0,541		25	50	0,572		0,434		12,5	25	0,337		0,209		Linearity:		R <sup>2</sup> =	0,991	0,986		FIX (%)		A405		Δ A405/min		W. Bath	STAR	W. Bath	STAR	W. Bath	STAR	20	29	1,069		0,676		10	10	0,728		0,347		5	7	0,471		0,232		2,5	2	0,276		0,059		1	1	0,112		0,023		Linearity:		R <sup>2</sup> =	0,985	0,988		Water Bath: A405(200%) ≥ 1.2  ΔA405(100%-200%) ≥ 0.30  R <sup>2</sup> ≥ 0.98  Water Bath: A405(20%) ≥ 0.4  ΔA405(10%-20%) ≥ 0.15  R <sup>2</sup> ≥ 0.98
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<b>4. Performances STAR</b> Normal plasmas: N= 11 Mean= 115 % Range: 99 to 127 % FIX Deficient Plasma: <1 % FIX Purified FIX (5µg/ml) in R4 buffer : 80 % Purified FIX (5µg/ml) in FIX Def. Plasma : 83 % Δ reactivity: 3,6 %		N ≥ 5 - 70% - 130% ≤ 2 % 75-150% 75-150% ≤ 20%																																																																																																
<b>5. Stability of restored reagents (for the point "C" % FIX concentration)</b> Method: Water Bath <table border="1"> <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>1,174</td> <td>1,130</td> <td>1,140</td> </tr> </tbody> </table>			Fresh	8hrs RT	24 hrs 2-8°C	A405	1,174	1,130	1,140	Δ A405 ≤ 0.20																																																																																								
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<b>Comments :</b> CoA Retranscription following NCI 1508		<input checked="" type="checkbox"/> PASSED IN COMPLIANCE																																																																																																

Date : 2016-12-14

QC Manager :

S.LECOURT

