

ANALYSIS CERTIFICATE

BIOPHEN FIX - #221802

Lot : F1600683

QC Release : 14/09/2016

Expiration date : 2018-12-15

Components	Volume	Exp. (months)	Lot #	Exp. Date
R1 : Human Factor X -FVIII:C	2 vials	30	F161A00683	2018-12-24
R2 : Activation Reagent (XIa)	2 vials	30	F161A00683	2018-12-30
R3 : Sxa-11 substrate	2 vials	30	F161A00683	2018-12-18
R4 : Tris-BSA buffer	2 vials	30	F161A00683	2018-12-15

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Analytical data	Specifications																																																																																																	
<p>1. Calibration curve</p> <p style="margin-left: 20px;"><u>High range:</u></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-left: 20px;"> <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>2,075</td> <td></td> <td>0,973</td> <td></td> </tr> <tr> <td>100</td> <td>100</td> <td>1,397</td> <td></td> <td>0,729</td> <td></td> </tr> <tr> <td>50</td> <td>67</td> <td>0,935</td> <td></td> <td>0,602</td> <td></td> </tr> <tr> <td>25</td> <td>50</td> <td>0,577</td> <td></td> <td>0,502</td> <td></td> </tr> <tr> <td>12,5</td> <td>25</td> <td>0,324</td> <td></td> <td>0,289</td> <td></td> </tr> <tr> <td colspan="2">Linearity: R² =</td> <td>0,993</td> <td></td> <td>0,988</td> <td></td> </tr> </tbody> </table> <p style="margin-left: 20px;"><u>Low range:</u></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-left: 20px;"> <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>1,210</td> <td></td> <td>0,742</td> <td></td> </tr> <tr> <td>10</td> <td>10</td> <td>0,833</td> <td></td> <td>0,419</td> <td></td> </tr> <tr> <td>5</td> <td>7</td> <td>0,546</td> <td></td> <td>0,277</td> <td></td> </tr> <tr> <td>2,5</td> <td>2</td> <td>0,331</td> <td></td> <td>0,084</td> <td></td> </tr> <tr> <td>1</td> <td>1</td> <td>0,144</td> <td></td> <td>0,032</td> <td></td> </tr> <tr> <td colspan="2">Linearity: R² =</td> <td>0,9874</td> <td></td> <td>0,984</td> <td></td> </tr> </tbody> </table>		FIX (%)		A405		Δ A405/min		W. Bath	STAR	W. Bath	STAR	W. Bath	STAR	200	143	2,075		0,973		100	100	1,397		0,729		50	67	0,935		0,602		25	50	0,577		0,502		12,5	25	0,324		0,289		Linearity: R ² =		0,993		0,988		FIX (%)		A405		Δ A405/min		W. Bath	STAR	W. Bath	STAR	W. Bath	STAR	20	29	1,210		0,742		10	10	0,833		0,419		5	7	0,546		0,277		2,5	2	0,331		0,084		1	1	0,144		0,032		Linearity: R ² =		0,9874		0,984		<p style="text-align: center;">Water Bath: A405(200%) ≥ 1.2</p> <p style="text-align: center;">ΔA405(100%-200%) ≥ 0.30</p> <p style="text-align: center;">R² ≥ 0.98</p> <p style="text-align: center;">Water Bath: A405(20%) ≥ 0.4</p> <p style="text-align: center;">ΔA405(10%-20%) ≥ 0.15</p> <p style="text-align: center;">R² ≥ 0.98</p>
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Date : 14.09.2016

QC Manager : S. LECOURT