

ANALYSIS CERTIFICATE

BIOPHEN™ FIX - #221806

Lot : F1701219 / F1701220

QC Release : 27/11/2017

Expiration date : 2020-04-06

Components	Volume	Exp. (months)	Lot #	Exp Date
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>1. <u>Human Factor X-VIII:C</u></p> <p>a. Reproducibility (100 % FIX)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N =</td> <td style="width: 15%; text-align: center;">10</td> <td style="width: 30%;">Mean (A405):</td> <td style="width: 40%; text-align: center;">1,076</td> </tr> <tr> <td></td> <td></td> <td>CV:</td> <td style="text-align: center;">1,4 %</td> </tr> </table> <p>b. Factor X concentration</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;"></td> <td style="width: 40%; text-align: center;">122 %</td> </tr> </table>	N =	10	Mean (A405):	1,076			CV:	1,4 %		122 %	<p>$\leq 2 \%$</p> <p>$\geq 50 \%$</p>									
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<p>2. <u>Activation Reagent (XIIa - Thrombin - PLPs - calcium)</u></p> <p>a. Reproducibility (100 % FIX)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N =</td> <td style="width: 15%; text-align: center;">10</td> <td style="width: 30%;">Mean (A405):</td> <td style="width: 40%; text-align: center;">1,078</td> </tr> <tr> <td></td> <td></td> <td>CV:</td> <td style="text-align: center;">1,2 %</td> </tr> </table>	N =	10	Mean (A405):	1,078			CV:	1,2 %	<p>$\leq 2 \%$</p>											
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<p>3. <u>SXa-11 substrate</u> (tested at 2.5 mg/ml for a,b)</p> <p>a. Blank value (N=10)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 40%;"></td> <td style="width: 60%; text-align: center;">Mean (A405): 0,158</td> </tr> </table> <p>b. Stability of substrate blank (A405)</p> <table border="1" style="width: 100%; border-collapse: collapse; margin: 5px 0;"> <thead> <tr> <th style="width: 20%;">Time</th> <th style="width: 40%;">Fresh</th> <th style="width: 40%;">7 days</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">2-8°C</td> <td style="text-align: center;">0,158</td> <td style="text-align: center;">0,157</td> </tr> <tr> <td style="text-align: center;">R.T.</td> <td style="background-color: black;"></td> <td style="text-align: center;">0,163</td> </tr> </tbody> </table> <p>c. Reproducibility (100 % FIX)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N =</td> <td style="width: 15%; text-align: center;">10</td> <td style="width: 30%;">Mean (A405):</td> <td style="width: 40%; text-align: center;">1,068</td> </tr> <tr> <td></td> <td></td> <td>CV:</td> <td style="text-align: center;">0,6 %</td> </tr> </table>		Mean (A405): 0,158	Time	Fresh	7 days	2-8°C	0,158	0,157	R.T.		0,163	N =	10	Mean (A405):	1,068			CV:	0,6 %	<p>A405 ≤ 0.30</p> <p>A405</p> <p>7 days ≤ 0.30</p> <p>$\leq 2 \%$</p>
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Normal plasmas: N= 12 Mean= 106 % Range: 86 to 122 % FIX Deficient Plasma: <1 % FIX Purified FIX (5µg/ml) in R4 buffer : 85 % Purified FIX (5µg/ml) in FIX Def. Plasma : 77 % Δ reactivity: 10 %	N ≥ 5 ~ 70% - 130% ≤ 2 % 75-150% 75-150% ≤ 20%																																																																																																	
5. Stability of restored reagents (for the point "C" % FIX concentration)																																																																																																		
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Date : 27/11/2017

QC Manager :

S. LECOURT

