

## ANALYSIS CERTIFICATE

**BIOPHEN FVIII:C- #221402**

**Lot : F1700013**

**QC Release : 2017-02-24**

**Expiration date : 2019-06-29**

<b>Components</b>	<b>Volume</b>	<b>Exp. (months)</b>	<b>Lot #</b>	<b>Exp. date</b>
R1 : Human Factor X	2 vials	30	F171H00013	2019-07-01
R2 : Activation Reagent	2 vials	30	F171H00013	2019-07-30
R3 : SXa-11 substrate	2 vials	30	F171H00013	2019-06-29
R4+ : Tris-BSA buffer	4 vials	30	F171H00013	2019-06-30

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Analytical data	Specifications												
<p><b>1. <u>Human Factor X</u></b></p> <p><b>a. Reproducibility (water bath)( 100 % VIII:C)</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 25%; text-align: center;">N = 20</td> <td style="width: 30%;"></td> <td style="width: 25%;">Mean (A405):</td> <td style="width: 20%; text-align: center;"><b>1,148</b></td> </tr> <tr> <td></td> <td></td> <td>CV:</td> <td style="text-align: center;"><b>1,29 %</b></td> </tr> </table> <p><b>b. Factor X concentration (water bath)</b> <span style="float: right;"><b>66 %</b></span></p>	N = 20		Mean (A405):	<b>1,148</b>			CV:	<b>1,29 %</b>	<p>≤ 2 %</p> <p>≥ 50 %</p>				
N = 20		Mean (A405):	<b>1,148</b>										
		CV:	<b>1,29 %</b>										
<p><b>2. <u>Activation Reagent (IXa - Thrombin - PLPs - calcium)</u></b></p> <p><b>a. Reproducibility (water bath)( 100 % VIII:C)</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 25%; text-align: center;">N = 20</td> <td style="width: 30%;"></td> <td style="width: 25%;">Mean (A405):</td> <td style="width: 20%; text-align: center;"><b>1,185</b></td> </tr> <tr> <td></td> <td></td> <td>CV:</td> <td style="text-align: center;"><b>1,52 %</b></td> </tr> </table>	N = 20		Mean (A405):	<b>1,185</b>			CV:	<b>1,52 %</b>	<p>≤ 2 %</p>				
N = 20		Mean (A405):	<b>1,185</b>										
		CV:	<b>1,52 %</b>										
<p><b>3. <u>SXa-11 substrate</u> (tested at 3 mg/ml for a,b)</b></p> <p><b>a. Blank value (N=10)</b> <span style="float: right;">Mean (A405): <b>0,217</b></span></p> <p><b>b. Stability of substrate blank (A405)</b></p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%; text-align: center;">Fresh</th> <th style="width: 50%; text-align: center;">7 days R.T</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">0,202</td> <td style="text-align: center;">0,204</td> </tr> </tbody> </table> <p><b>c. Reproducibility (water bath)</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 25%; text-align: center;">N = 20</td> <td style="width: 30%;"></td> <td style="width: 25%;">Mean (A405):</td> <td style="width: 20%; text-align: center;"><b>0,975</b></td> </tr> <tr> <td></td> <td></td> <td>CV:</td> <td style="text-align: center;"><b>1,14 %</b></td> </tr> </table>	Fresh	7 days R.T	0,202	0,204	N = 20		Mean (A405):	<b>0,975</b>			CV:	<b>1,14 %</b>	<p>A405 ≤ 0.30</p>   <p>A405 ≤ 0.30</p>   <p>≤ 2 %</p>
Fresh	7 days R.T												
0,202	0,204												
N = 20		Mean (A405):	<b>0,975</b>										
		CV:	<b>1,14 %</b>										

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Analytical data				Specifications		
<b>1. Calibration curve</b>						
<b>High Range:</b>						
VIII:C (%)			A405	A405	Water Bath: A405(200%) ≥ 1,60 ΔA405(100%-200%) ≥ 0.60  R <sup>2</sup> ≥ 0.98  Water Bath: A405(25%) ≥ 0.80 ΔA405(12.5%-25%) ≥ 0.30  R <sup>2</sup> ≥ 0.98	
STAR	WB	W. Bath	STAR			
0	20	0	0,016	0,07		
C/4	50	25	0,157	0,216		
C/2	100	50	0,444	0,451		
C	160	100	1,146	0,696		
2C	190	200	2,224	0,812		
Linearity:		R <sup>2</sup> =	0,9935	0,9987		
<b>Low Range:</b>						
VIII:C (%)			A405	A405		
STAR	WB	W. Bath	STAR			
0	0,9	0	0,015	0,048		
C/4	6,25	6,25	0,203	0,333		
C/2	12,5	12,5	0,515	0,660		
C	25	25	1,088	1,167		
Linearity:		R <sup>2</sup> =	0,9937	0,9948		

<b>2. Accuracy: WB</b>			
Control	TV*	MV*	
	% VIII :C	% VIII :C	
Normal Control	102	106	[ 92 -112 ]
Abnormal Control	37	39	[ 31 - 43 ]
* TV= Target Value - MV= Measured Value			

<b>3. Detection threshold</b>		Method :	CS5100
High range:	<2 %		≤ 10%
Low range:	<1 %		≤ 2%

<b>4. Performances</b>		Method :	CS5100
Normal plasmas:	N=	10	N ≥ 10
	Mean=	68 %	≥ 50 %
	Range:	51 to 84 %	About 50-150%
FVIII Deficient Plasma:	<2 % VIII:C	(high range)	< 10 %
	<1 % VIII:C	(low range)	< 2 %

<b>5. Stability of restored reagents</b>		Method :	WB			
VIII:C (%)		A405 Fresh	A405 24H RT	A405 72H 2-8°C	Δ A405 point C ≤ 15% Δ A405 point 2C ≤ 15% between fresh and 24h RT or 72H at 2-8°C  [ 92 - 112 ] [ 31 - 43 ]	
0	0	0,031	0,029	0,029		
C/4	25	0,172	0,159	0,163		
C/2	50	0,466	0,436	0,446		
C	100	1,165	1,117	1,120		
2C	200	2,316	2,227	2,250		
Linearity:		R <sup>2</sup> =	0,9964	0,9958		0,9966
Control	MV*	MV*	MV*			
	% VIII :C	% VIII :C	% VIII :C			
Normal Control	108	110	108			
Abnormal Control	37	37	38			
* MV= Measured Value						

Comments :



PASSED IN  
COMPLIANCE

Date : 2017-02-24

QC Manager : S.LECOURT