

ANALYSIS CERTIFICATE

BIOPHEN FVIII:C (6) - #221406

**Lot : F1700962-
F1700963**

QC Release : 2017/10/09

Expiration date : 2020-02-15

Components	Volume	Exp. (months)	Lot #	Exp. date
R1 : Human Factor X	2 vials	30	F171R00962- F171S00963	2020-03-02
R2 : Activation Reagent	2 vials	30	F171R00962- F171S00963	2020-03-07
R3 : SXa-11 substrate	2 vials	30	F171R00962- F171S00963	2020-02-15
R4+ : Tris-BSA buffer	4 vials	30	F171R00962- F171S00963	2020-02-23

SJS

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Analytical data	Specifications				
<p>1. <u>Human Factor X</u></p> <p>a. Reproducibility (water bath)(100 % VIII:C)</p> <p style="margin-left: 40px;">N = 15 Mean (A405): 1,191</p> <p style="margin-left: 80px;">CV: 1,3 %</p> <p>b. Factor X concentration (water bath) 68 %</p>	<p style="text-align: center;">≤ 2 %</p> <p style="text-align: center;">≥ 50 %</p>				
<p>2. <u>Activation Reagent (IXa - Thrombin - PLPs - calcium)</u></p> <p>a. Reproducibility (water bath)(100 % VIII:C)</p> <p style="margin-left: 40px;">N = 15 Mean (A405): 1,285</p> <p style="margin-left: 80px;">CV: 1,8 %</p>	<p style="text-align: center;">≤ 2 %</p>				
<p>3. <u>SXa-11 substrate</u> (tested at 3 mg/ml for a,b)</p> <p>a. Blank value (N=10) Mean (A405): 0,19</p> <p>b. Stability of substrate blank (A405)</p> <table border="1" style="margin-left: 40px; margin-bottom: 20px;"> <thead> <tr> <th style="padding: 5px;">Fresh</th> <th style="padding: 5px;">7 days R.T</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; padding: 5px;">0,16</td> <td style="text-align: center; padding: 5px;">0,19</td> </tr> </tbody> </table> <p>c. Reproducibility (water bath)</p> <p style="margin-left: 40px;">N = 15 Mean (A405): 1,282</p> <p style="margin-left: 80px;">CV: 1,5 %</p>	Fresh	7 days R.T	0,16	0,19	<p style="text-align: center;">A405 ≤ 0.30</p> <p style="text-align: center;">A405 ≤ 0.30</p> <p style="text-align: center;">≤ 2 %</p>
Fresh	7 days R.T				
0,16	0,19				

SNS

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Analytical data				Specifications
1. Calibration curve				
High Range:				
VIII:C (%)		A405 W. Bath	A405 STAR	Water Bath: A405(200%) ≥ 1,60 ΔA405(100%-200%) ≥ 0.60 R ² ≥ 0.98
0	0	0,022	0	
C/4	25	0,287	0,082	
C/2	50	0,629	0,233	
C	100	1,263	0,474	
2C	200	2,173	0,812	
Linearity: R ² =		0,995	0,996	
Low Range:				
VIII:C (%)		A405 W. Bath	A405 STAR	Water Bath: A405(25%) ≥ 0.80 ΔA405(12.5%-25%) ≥ 0.30 R ² ≥ 0.98
0	0	0,025	0,047	
C/4	6,25	0,398	0,361	
C/2	12,5	0,761	0,699	
C	25	1,323	1,249	
2C	50	2,646	2,498	
Linearity: R ² =		0,995	0,995	

2. Accuracy:			
Control	TV* % VIII :C	MV* % VIII :C	
Normal Control	102	110	[92 - 112]
Abnormal Control	29	32	[25 - 33]
* TV= Target Value - MV= Measured Value			

3. Detection threshold	Method :	CS 5100	
High range:	< 2 %		≤ 10%
Low range:	< 0,1 %		≤ 2%

4. Performances	Method :	CS 5100	
Normal plasmas:	N=	12	N ≥ 10
	Mean=	94 %	≥ 50 %
	Range:	80 to 120 %	About 50-150%
FVIII Deficient Plasma:	< 2 % VIII:C	(high range)	< 10 %
	0,2 % VIII:C	(low range)	< 2 %

5. Stability of restored reagents		Method : water batch			
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
C/B	12,1	0,106	0,075	0,099	
C/4	24,3	0,268	0,205	0,265	
C/2	48,5	0,618	0,550	0,635	
C	97	1,322	1,234	1,309	
2C	194	2,296	2,262	2,302	
Linearity: R ² =		0,992	0,990	0,990	
Control		MV* % VIII :C	MV* % VIII :C	MV* % VIII :C	
Normal Control		104	103	101	[92 - 112]
Abnormal Control		21	30	24	[21 - 31]
* MV= Measured Value					

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-10-09

S.LECOURT

