

ANALYSIS CERTIFICATE

BIOPHEN FACTOR X - #221705

Lot : F1700758

QC Release : 08/08/2017

Expiration date : 2019-12-24

Components	Volume	Exp. Months	Lot #	Exp. date
R1 : Substrate	4 vials	30	F171300758	2019-12-24
R2 : RVV	4 vials	30	F171300758	2020-01-12
R3 : Buffer	4 vials	30	F171300758	2020-01-05



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Analytical data	Specifications												
<p>1. <u>R1: SXa-11 substrate</u></p> <p>a. Blank value (N=10) Mean (A405): 0,173</p> <p>b. Stability of substrate blank (A405)</p> <table border="1" style="margin: 5px auto; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="padding: 2px;">Time</th> <th style="padding: 2px;">Fresh</th> <th style="padding: 2px;">72 hrs</th> <th style="padding: 2px;">7 days</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">2-8°C</td> <td style="padding: 2px;">0,165</td> <td style="padding: 2px;">[REDACTED]</td> <td style="padding: 2px;">0,167</td> </tr> <tr> <td style="padding: 2px;">18-25°C</td> <td style="padding: 2px;">[REDACTED]</td> <td style="padding: 2px;">0,173</td> <td style="padding: 2px;">[REDACTED]</td> </tr> </tbody> </table> <p>c. Reproducibility (water bath)(100% X)</p> <p style="margin-left: 40px;">N = 15 Mean (A405): 0,869</p> <p style="margin-left: 100px;">CV: 0,64 %</p>	Time	Fresh	72 hrs	7 days	2-8°C	0,165	[REDACTED]	0,167	18-25°C	[REDACTED]	0,173	[REDACTED]	<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>
Time	Fresh	72 hrs	7 days										
2-8°C	0,165	[REDACTED]	0,167										
18-25°C	[REDACTED]	0,173	[REDACTED]										
<p>2. <u>R2: Activation Reagent (RVV)</u></p> <p>a. Reproducibility (water bath)(100% X)</p> <p style="margin-left: 40px;">N = 15 Mean (A405): 0,869</p> <p style="margin-left: 100px;">CV: 0,94 %</p>	<p style="text-align: center;">≤ 2 %</p>												

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<p>1. Calibration curve</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th colspan="2" style="text-align: center;">X (%)</th> <th style="text-align: center;">A405</th> </tr> <tr> <th colspan="2"></th> <th style="text-align: center;">STAR</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0,001</td> </tr> <tr> <td style="text-align: center;">1:40</td> <td style="text-align: center;">25</td> <td style="text-align: center;">0,121</td> </tr> <tr> <td style="text-align: center;">1:20</td> <td style="text-align: center;">50</td> <td style="text-align: center;">0,250</td> </tr> <tr> <td style="text-align: center;">1:10</td> <td style="text-align: center;">100</td> <td style="text-align: center;">0,510</td> </tr> <tr> <td style="text-align: center;">1:5</td> <td style="text-align: center;">200</td> <td style="text-align: center;">0,988</td> </tr> <tr> <td colspan="2">Linearity: R² =</td> <td style="text-align: center;">1,000</td> </tr> </tbody> </table>	X (%)		A405			STAR	0	0	0,001	1:40	25	0,121	1:20	50	0,250	1:10	100	0,510	1:5	200	0,988	Linearity: R ² =		1,000	<p style="text-align: center;">A405(1:5) ≥ 0.75 ΔA405(1:5-1:10) ≥ 0.35</p> <p style="text-align: center;">R² ≥ 0.98</p>
X (%)		A405																							
		STAR																							
0	0	0,001																							
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Linearity: R ² =		1,000																							
<p>2. Detection threshold</p> <p style="text-align: center;"><1 %</p>	<p>≤ 5%</p>																								
<p>3. Accuracy:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 5px;"> <thead> <tr> <th style="text-align: left;">Control</th> <th style="text-align: center;">TV* (%X)</th> <th style="text-align: center;">MV* (%X)</th> </tr> </thead> <tbody> <tr> <td>Normal Control</td> <td style="text-align: center;">84</td> <td style="text-align: center;">87</td> </tr> <tr> <td>Abnormal Control</td> <td style="text-align: center;">35</td> <td style="text-align: center;">37</td> </tr> </tbody> </table> <p>* TV= Target Value - MV= Measured Value</p>	Control	TV* (%X)	MV* (%X)	Normal Control	84	87	Abnormal Control	35	37	<p>[74 - 94] [30 - 40]</p>															
Control	TV* (%X)	MV* (%X)																							
Normal Control	84	87																							
Abnormal Control	35	37																							
<p>4. Performances</p> <p>Normal plasmas: N= 7 Mean= 107 % Range: 92 to 129 %</p> <p>FX Deficient Plasma: <1 %</p>	<p>N ≥ 5 60 to 130 % ≤ 5%</p>																								
<p>5. Stability of restored reagents (for the 100% X concentration)</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th></th> <th style="text-align: center;">Fresh</th> <th style="text-align: center;">72 hrs 18-25°C</th> <th style="text-align: center;">7 days 2-8°C</th> <th style="text-align: center;">Frozen</th> </tr> </thead> <tbody> <tr> <td style="text-align: left;">A405</td> <td style="text-align: center;">0,539</td> <td style="text-align: center;">0,532</td> <td style="text-align: center;">0,532</td> <td style="text-align: center;">0,530</td> </tr> </tbody> </table>		Fresh	72 hrs 18-25°C	7 days 2-8°C	Frozen	A405	0,539	0,532	0,532	0,530	<p>Δ A405 ≤ 10%</p>														
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A405	0,539	0,532	0,532	0,530																					
<p>Comments :</p>	<p><input checked="" type="checkbox"/> PASSED IN COMPLIANCE</p>																								

Date : 08/08/2017

QC Manager : Anne-Marie VISSAC

Technical Director