

ANALYSIS CERTIFICATE

BIOPHEN FACTOR X - #221705

Lot : F1600446

QC Release : 29/06/2016

Expiration date : 2018-10-29

Components	Volume	Exp. Months	Int. Ref.	Lot #	Exp. date
R1 : Substrate	4 vials	30	F161100446	F161100446	2018-10-29
R2 : RVV	4 vials	30	F161100446	F161100446	2018-11-03
R3 : Buffer	4 vials	30	F161100446	F161100446	2018-11-24

soe

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Analytical data	Specifications														
<p>1. R1: SXa-11 substrate</p> <p>a. Blank value (N=10) Mean (A405): 0,156</p> <p>b. Stability of substrate blank (A405)</p> <table border="1" style="margin-left: 20px; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="font-size: small;">Time</th> <th style="font-size: small;">Fresh</th> <th style="font-size: small;">72 hrs</th> <th style="font-size: small;">7 days</th> </tr> </thead> <tbody> <tr> <td rowspan="2" style="font-size: small;">2-8°C</td> <td style="font-size: x-small;">0,137**</td> <td style="background-color: black;"></td> <td rowspan="2" style="font-size: x-small;">0,138</td> </tr> <tr> <td style="font-size: x-small;">0,138*</td> <td style="background-color: black;"></td> </tr> <tr> <td style="font-size: small;">R.T.</td> <td style="background-color: black;"></td> <td style="font-size: x-small;">0,137</td> <td style="background-color: black;"></td> </tr> </tbody> </table> <p>c. Reproducibility (water bath)(100% X)</p> <p style="margin-left: 40px;">N = 10 Mean (A405): 0,814</p> <p style="margin-left: 80px;">CV: 1,4 %</p>	Time	Fresh	72 hrs	7 days	2-8°C	0,137**		0,138	0,138*		R.T.		0,137		<p>A405 ≤ 0.30</p> <p>A405 ≤ 0.30</p> <p>N ≥ 10</p> <p>≤ 2 %</p>
Time	Fresh	72 hrs	7 days												
2-8°C	0,137**		0,138												
	0,138*														
R.T.		0,137													
<p>2. R2: Activation Reagent (RVV)</p> <p>a. Reproducibility (water bath)(100% X)</p> <p style="margin-left: 40px;">N = 10 Mean (A405): 0,810</p> <p style="margin-left: 80px;">CV: 1,7 %</p>	<p>N ≥ 10</p> <p>≤ 2 %</p>														

* 0,138 (Fresh A405 for 72 hrs RT condition testing)

** 0,137 (Fresh A405 for 7 days 2-8 ° C condition testing)

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Analytical data	Specifications																									
<p>1. <u>Calibration curve</u></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <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;">lin</td> </tr> <tr> <td style="text-align: center;">1:40</td> <td style="text-align: center;">25</td> <td style="text-align: center;">0,119</td> </tr> <tr> <td style="text-align: center;">1:20</td> <td style="text-align: center;">50</td> <td style="text-align: center;">0,248</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;">0,997</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	lin	1:40	25	0,119	1:20	50	0,248	1:10	100	0,510	1:5	200	0,997	Linearity: r2 =		1,000	<p style="text-align: center;">A405(1:5) ≥ 0.75 ΔA405(1:5-1:10) ≥ 0.35</p> <p style="text-align: right; margin-top: 20px;">r2 ≥ 0.98</p>
X (%)		A405																								
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Linearity: r2 =		1,000																								
<p>2. <u>Detection threshold</u> STAR</p> <p style="text-align: center;">< 1,5 %</p>		≤ 5%																								
<p>3. <u>Accuracy:</u> STAR</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Control</th> <th>TV* (%X)</th> <th>MV* (%X)</th> </tr> </thead> <tbody> <tr> <td>Normal Control</td> <td style="text-align: center;">82</td> <td style="text-align: center;">89</td> </tr> <tr> <td>Abnormal Control</td> <td style="text-align: center;">35</td> <td style="text-align: center;">38</td> </tr> </tbody> </table> <p>* TV= Target Value - MV= Measured Value</p>		Control	TV* (%X)	MV* (%X)	Normal Control	82	89	Abnormal Control	35	38	<p>[72 - 92]</p> <p>[30 -40]</p>															
Control	TV* (%X)	MV* (%X)																								
Normal Control	82	89																								
Abnormal Control	35	38																								
<p>4. <u>Performances</u> STAR</p> <p>Normal plasmas: N= 7</p> <p style="margin-left: 150px;">Mean= 95 %</p> <p style="margin-left: 100px;">Range: 88 to 108 %</p> <p>FX Deficient Plasma: <1 %</p>		<p>N ≥ 5</p> <p>60 to 130 %</p> <p>≤ 5%</p>																								
<p>5. <u>Stability of restored reagents (for the 100% X concentration)</u></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Fresh</th> <th style="text-align: center;">72 hrs RT</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: center;">A405</td> <td style="text-align: center;">0,527 *</td> <td rowspan="2" style="text-align: center;">0,493</td> <td rowspan="2" style="text-align: center;">0,527</td> <td rowspan="2" style="text-align: center;">0,522</td> </tr> <tr> <td></td> <td style="text-align: center;">0,498 **</td> </tr> </tbody> </table>			Fresh	72 hrs RT	7 days 2-8°C	Frozen	A405	0,527 *	0,493	0,527	0,522		0,498 **	Δ A405 ≤ 10%												
	Fresh	72 hrs RT	7 days 2-8°C	Frozen																						
A405	0,527 *	0,493	0,527	0,522																						
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<p>Comments : * Fresh A405 for 7days 2-8 ° C and frozen ** Fresh A405 for 72 hrs RT</p>		<p><input checked="checked" type="checkbox"/> PASSED IN COMPLIANCE</p>																								

Date : 29/06/2016

QC Manager :

S.LECOURT

