

ANALYSIS CERTIFICATE

BIOPHEN ANTITHROMBIN 5 - #221105

Lot : F1700836

QC release : 2017-08-09

Expiration date : 2020-01-10

Components	Volume	Exp. (months)	Lot #	Exp. date
R1 : Bov Xa - 10 µg	4 vials	30	F171100836	2020-02-03
R2 : Sxa-11 - 7.5 mg	4 vials	30	F171100836	2020-01-13
R3 : Tris Heparin Buf. - 10 ml	4 vials	30	F171100836	2020-01-10

SP5

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Analytical data	Specifications									
<p>1. <u>SXa-11 substrate</u></p> <p>a. Blank value (N=10) Mean (A405) : 0,133</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="width: 15%;">Time</th> <th style="width: 15%;">Fresh</th> <th style="width: 15%;">7 days</th> </tr> </thead> <tbody> <tr> <td>2-8°C</td> <td>0,130</td> <td>0,131</td> </tr> <tr> <td>R.T (18-25°C)</td> <td style="background-color: #cccccc;"></td> <td>0,136</td> </tr> </tbody> </table> <p>c. Reproducibility (0% AT)</p> <p style="margin-left: 100px;">Mean (A405) : 1,518</p> <p style="margin-left: 100px;">CV(OD) : 0,63 %</p> <p>d. Substrate aspect</p> <p><input checked="" type="checkbox"/> Clear <input checked="" type="checkbox"/> Transparent <input checked="" type="checkbox"/> Slightly yellow</p>	Time	Fresh	7 days	2-8°C	0,130	0,131	R.T (18-25°C)		0,136	<p>A405 ≤ 0.30</p> <p>A405:</p> <p>7 days ≤ 0.30</p> <p>A405= 1.45 ± 0.20</p> <p>≤ 2 %</p> <p>Clear, Transparent</p> <p>Slightly yellow</p>
Time	Fresh	7 days								
2-8°C	0,130	0,131								
R.T (18-25°C)		0,136								

<p>2. <u>Bovine Factor Xa</u></p> <p>a. Reproducibility (0% AT)</p> <p style="margin-left: 100px;">Mean (A405) : 1,502</p> <p style="margin-left: 100px;">CV (OD) : 1,47 %</p> <p>b. Factor Xa aspect</p> <p><input checked="" type="checkbox"/> Clear <input checked="" type="checkbox"/> Transparent</p>	<p>A405= 1.45 ± 0.20</p> <p>≤ 2 %</p> <p>Clear, Transparent</p>
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Analytical data	Specifications																									
<p>6. <u>Other Automated Method</u> Equipment NR</p> <table border="1" style="margin: 10px auto; border-collapse: collapse;"> <tr> <td style="text-align: center;">% AT</td> <td style="text-align: center;">0</td> <td style="text-align: center;">25</td> <td style="text-align: center;">50</td> <td style="text-align: center;">100</td> </tr> <tr> <td style="text-align: center;">A405</td> <td style="text-align: center;">NR</td> <td style="text-align: center;">NR</td> <td style="text-align: center;">NR</td> <td style="text-align: center;">NR</td> </tr> </table> <p style="margin: 10px auto;">R² = NR</p> <table border="1" style="margin: 10px auto; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Control</th> <th colspan="2" style="text-align: center;">TV*</th> <th colspan="2" style="text-align: center;">MV*</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Normal Control</td> <td style="text-align: center;">NR</td> <td style="text-align: center;">NR</td> <td style="text-align: center;">NR</td> <td style="text-align: center;">NR</td> </tr> <tr> <td style="text-align: center;">Abnormal Control</td> <td style="text-align: center;">NR</td> <td style="text-align: center;">NR</td> <td style="text-align: center;">NR</td> <td style="text-align: center;">NR</td> </tr> </tbody> </table> <p style="font-size: small; margin-top: 5px;">* TV= Target Value - MV= Measured Value</p>	% AT	0	25	50	100	A405	NR	NR	NR	NR	Control	TV*		MV*		Normal Control	NR	NR	NR	NR	Abnormal Control	NR	NR	NR	NR	<p style="text-align: center; margin-top: 40px;">R² ≥ 0.98</p> <p style="text-align: center; margin-top: 20px;">[NR - NR]</p> <p style="text-align: center; margin-top: 10px;">[NR - NR]</p>
% AT	0	25	50	100																						
A405	NR	NR	NR	NR																						
Control	TV*		MV*																							
Normal Control	NR	NR	NR	NR																						
Abnormal Control	NR	NR	NR	NR																						

<p><u>Comments :</u></p>	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-09-08

QC Manager :

S.LECOURT

