

## ANALYSIS CERTIFICATE

**BIOPHEN HEPARIN LRT (#221011)**

**Lot : F1700089**

**QC Release: 2017-04-12**

**Expiration date : 2018-07-13**

<b>Components</b>	<b>Qty</b>	<b>Exp. (months)</b>	<b>Lot #</b>	<b>Exp. date</b>
R1 : SXa-11 substrate	4 vials	18	F171700089	2018-07-13
R2 : Bovine FXa	4 vials	18	F171700089	2018-07-13

*205*

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Analytical data	Specifications
<b>1. <u>Xa substrate</u></b>	
a. Blank value (N=10)      Mean (A405): <b>0,140</b>	A405 ≤ 0.30
b. Reproducibility (water bath)	
Mean (A405): <b>1,412</b>	
CV: <b>1,0 %</b>	≤ 2 %
<b>2. <u>Bovine Factor Xa</u></b>	
a. Reproducibility (water bath)	
Mean (A405): <b>1,399</b>	
CV: <b>1,1 %</b>	≤ 2 %
b. Factor Xa reactivity (water bath)	
A405 : <b>1,277</b>	≥ 0.80

*SOS*

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<p><b>3. <u>Assay method</u></b></p>																															
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<p><b>c. Stability of reagents</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="width: 20%;"></th> <th style="width: 40%;">7 days 2-8°C</th> <th style="width: 40%;">7 days 18-25°C</th> </tr> </thead> <tbody> <tr> <td colspan="3"><b>Substrate blank</b></td> </tr> <tr> <td>A405</td> <td style="text-align: center;">0,151</td> <td style="text-align: center;">0,152</td> </tr> <tr> <td colspan="3"><b>A405 (calibration curve)</b></td> </tr> <tr> <td>CAL1</td> <td style="text-align: center;">1,830</td> <td style="text-align: center;">1,812</td> </tr> <tr> <td>CAL2</td> <td style="text-align: center;">1,335</td> <td style="text-align: center;">1,332</td> </tr> <tr> <td>CAL3</td> <td style="text-align: center;">1,008</td> <td style="text-align: center;">0,982</td> </tr> <tr> <td>CAL4</td> <td style="text-align: center;">0,741</td> <td style="text-align: center;">0,770</td> </tr> <tr> <td>CAL5</td> <td style="text-align: center;">0,602</td> <td style="text-align: center;">0,595</td> </tr> <tr> <td colspan="3"><b>Measured values for controls (IU/ml)</b></td> </tr> <tr> <td>C1/UFH</td> <td style="text-align: center;">0,22</td> <td style="text-align: center;">0,22</td> </tr> <tr> <td>C2/UFH</td> <td style="text-align: center;">0,48</td> <td style="text-align: center;">0,47</td> </tr> <tr> <td>C3/LMWH</td> <td style="text-align: center;">0,82</td> <td style="text-align: center;">0,82</td> </tr> <tr> <td>C4/LMWH</td> <td style="text-align: center;">1,20</td> <td style="text-align: center;">1,22</td> </tr> </tbody> </table> <p><b>d. Detection threshold</b></p> <p>A405 (0 IU/ml) - 3SD = <span style="float: right;">0,750</span></p> <p>Detection threshold: <span style="float: right;">&lt;0,01 IU/ml</span></p>		7 days 2-8°C	7 days 18-25°C	<b>Substrate blank</b>			A405	0,151	0,152	<b>A405 (calibration curve)</b>			CAL1	1,830	1,812	CAL2	1,335	1,332	CAL3	1,008	0,982	CAL4	0,741	0,770	CAL5	0,602	0,595	<b>Measured values for controls (IU/ml)</b>			C1/UFH	0,22	0,22	C2/UFH	0,48	0,47	C3/LMWH	0,82	0,82	C4/LMWH	1,20	1,22	<p>A405 ≤ 0.30</p> <p>Δ A405 ≤ 0.10 7 days at 18-25°C or at 2-8°C</p> <p>[ 0,14 - 0,34 ] [ 0,34 - 0,64 ] [ 0,68 - 0,92 ] [ 1,01 - 1,31 ]</p> <p>≤ 0.05 IU/ml</p>
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Comments :

**PASSED  
IN COMPLIANCE**

**Date :** 2017-04-12

**QC Manager :** S.LECOURT

