

## ANALYSIS CERTIFICATE

BIOPHEN HEPARIN LRT (#221013)

Lot : F1700494  
F1700495

QC Release: 2017-06-22

Expiration date : 2018-10-24

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : SXa-11 substrate	3 vials	18	F171L00494 F171M00495	2018-10-24
R2 : Bovine FXa	3 vials	18	F171L00494 F171M00495	2018-10-24

*Sas*

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Analytical data	Specifications
<p><b>1. <u>Xa substrate</u></b></p> <p>a. Blank value (N=10)      Mean (A405): <b>0,175</b></p> <p>b. Reproducibility (water bath)</p> <p style="padding-left: 150px;">Mean (A405): <b>1,208</b></p> <p style="padding-left: 150px;">CV: <b>1,3 %</b></p>	<p>A405 ≤ 0.30</p> <p>≤ 2 %</p>
<p><b>2. <u>Bovine Factor Xa</u></b></p> <p>a. Reproducibility (water bath)</p> <p style="padding-left: 150px;">Mean (A405): <b>1,242</b></p> <p style="padding-left: 150px;">CV: <b>0,8 %</b></p> <p>b. Factor Xa reactivity (water bath)</p> <p style="padding-left: 150px;">A405 : <b>1,279</b></p>	<p>≤ 2 %</p> <p>≥ 0.80</p>

SAS

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<p><b>3. Assay method</b></p> <p><b>a. CS :</b></p> <p style="text-align: center;"><u>Calibration curves and linearity</u></p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th>UFH UI/ml</th> <th>A405</th> <th>LMWH UI/ml</th> <th>A405</th> </tr> </thead> <tbody> <tr> <td>CAL1</td> <td style="color: red;">0</td> <td style="color: red;">0,753</td> <td style="color: red;">0</td> <td style="color: red;">0,746</td> </tr> <tr> <td>CAL2</td> <td style="color: red;">0,46</td> <td style="color: red;">0,495</td> <td style="color: red;">0,47</td> <td style="color: red;">0,475</td> </tr> <tr> <td>CAL3</td> <td style="color: red;">0,88</td> <td style="color: red;">0,328</td> <td style="color: red;">0,94</td> <td style="color: red;">0,312</td> </tr> <tr> <td>CAL4</td> <td style="color: red;">1,33</td> <td style="color: red;">0,224</td> <td style="color: red;">1,47</td> <td style="color: red;">0,197</td> </tr> <tr> <td>CAL5</td> <td style="color: red;">1,76</td> <td style="color: red;">0,145</td> <td style="color: red;">1,93</td> <td style="color: red;">0,132</td> </tr> </tbody> </table> <p>Linearity: R<sup>2</sup> = <span style="color: red;">0,9994</span> <span style="color: red;">0,9996</span></p> <p style="text-align: center;"><u>Controls</u></p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th>Lot</th> <th>TV*</th> <th>MV**</th> </tr> </thead> <tbody> <tr> <td>C1/UFH</td> <td style="color: red;">53903-1</td> <td style="color: red;">0,24</td> <td style="color: red;">0,21</td> </tr> <tr> <td>C2/UFH</td> <td style="color: red;">53903-2</td> <td style="color: red;">0,49</td> <td style="color: red;">0,46</td> </tr> <tr> <td>C3/LMWH</td> <td style="color: red;">52605-1</td> <td style="color: red;">0,80</td> <td style="color: red;">0,77</td> </tr> <tr> <td>C4/LMWH</td> <td style="color: red;">F1600910</td> <td style="color: red;">1,16</td> <td style="color: red;">1,13</td> </tr> </tbody> </table> <p>*TV: Target Value      **MV: Measured value</p> <p><b>b. 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<p><b>c. Stability of reagents</b>    <i>Method : CS</i></p> <table border="1"> <thead> <tr> <th></th> <th>7 days 2-8°C</th> <th>7 days 18-25°C</th> </tr> </thead> <tbody> <tr> <td colspan="3"><b>Substrate blank</b></td> </tr> <tr> <td>A405</td> <td>0,159</td> <td>0,166</td> </tr> <tr> <td colspan="3"><b>A405 (calibration curve)</b></td> </tr> <tr> <td>CAL1</td> <td>0,766</td> <td>0,763</td> </tr> <tr> <td>CAL2</td> <td>0,520</td> <td>0,520</td> </tr> <tr> <td>CAL3</td> <td>0,355</td> <td>0,353</td> </tr> <tr> <td>CAL4</td> <td>0,251</td> <td>0,250</td> </tr> <tr> <td>CAL5</td> <td>0,181</td> <td>0,178</td> </tr> <tr> <td colspan="3"><b>Measured values for controls (IU/ml)</b></td> </tr> <tr> <td>C1/UFH</td> <td>0,20</td> <td>0,21</td> </tr> <tr> <td>C2/UFH</td> <td>0,47</td> <td>0,47</td> </tr> <tr> <td>C3/LMWH</td> <td>0,80</td> <td>0,80</td> </tr> <tr> <td>C4/LMWH</td> <td>1,18</td> <td>1,19</td> </tr> </tbody> </table> <p><b>d. Detection threshold</b>            A405 (0 IU/ml) - 3SD = <b>1,626</b>            Detection threshold: <b>&lt;0,01 IU/ml</b></p>				7 days 2-8°C	7 days 18-25°C	<b>Substrate blank</b>			A405	0,159	0,166	<b>A405 (calibration curve)</b>			CAL1	0,766	0,763	CAL2	0,520	0,520	CAL3	0,355	0,353	CAL4	0,251	0,250	CAL5	0,181	0,178	<b>Measured values for controls (IU/ml)</b>			C1/UFH	0,20	0,21	C2/UFH	0,47	0,47	C3/LMWH	0,80	0,80	C4/LMWH	1,18	1,19	<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 : **2017-06-22**

QC Manager :

**S. LECOURT**