

## ANALYSIS CERTIFICATE

**BIOPHEN HEPARIN LRT (#221011)**

**Lot : F1601278 / F1601337**

**QC Release: 2017-01-23**

**Expiration date : 2018-06-05**

<b>Components</b>	<b>Qty</b>	<b>Exp. (months)</b>	<b>Lot #</b>	<b>Exp. date</b>
R1 : SXa-11 substrate	4 vials	18	F161501278 / F161101337	2018-06-05
R2 : Bovine FXa	4 vials	18	F161501278 / F161101337	2018-06-05

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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>0,134</b></p> <p>b. Reproducibility (water bath)</p> <p>   Mean (A405): <b>2,042</b></p> <p>   CV:                    <b>0,72 %</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>   Mean (A405): <b>1,985</b></p> <p>   CV:                    <b>0,72 %</b></p> <p>b. Factor Xa reactivity (water bath)</p> <p>   A405 :                <b>1,916</b></p>	<p>≤ 2 %</p> <p>≥ 0.80</p>

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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" data-bbox="204 667 663 898"> <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>0</td> <td>0,765</td> <td>0</td> <td>0,760</td> </tr> <tr> <td>CAL2</td> <td>0,46</td> <td>0,511</td> <td>0,47</td> <td>0,482</td> </tr> <tr> <td>CAL3</td> <td>0,88</td> <td>0,339</td> <td>0,94</td> <td>0,315</td> </tr> <tr> <td>CAL4</td> <td>1,33</td> <td>0,222</td> <td>1,47</td> <td>0,197</td> </tr> <tr> <td>CAL5</td> <td>1,76</td> <td>0,140</td> <td>1,93</td> <td>0,134</td> </tr> </tbody> </table> <p>Linearity: R<sup>2</sup> = 0,999                      0,999</p> <p style="text-align: center;"><u>Controls</u></p> <table border="1" data-bbox="204 1043 663 1211"> <thead> <tr> <th></th> <th>Lot</th> <th>TV*</th> <th>MV**</th> </tr> </thead> <tbody> <tr> <td>C1/UFH</td> <td>53903-1</td> <td>0,24</td> <td>0,20</td> </tr> <tr> <td>C2/UFH</td> <td>60302-1</td> <td>0,48</td> <td>0,46</td> </tr> <tr> <td>C3/LMWH</td> <td>44202-1</td> <td>0,79</td> <td>0,78</td> </tr> <tr> <td>C4/LMWH</td> <td>44202-2</td> <td>1,19</td> <td>1,19</td> </tr> </tbody> </table> <p>*TV: Target Value                      **MV: Measured value</p> <p><b>b. STAR</b></p> <p style="text-align: center;"><u>Calibration curves and linearity</u></p> <table border="1" data-bbox="204 1346 663 1576"> <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>0</td> <td>1,864</td> <td>0</td> <td>1,872</td> </tr> <tr> <td>CAL2</td> <td>0,46</td> <td>1,341</td> <td>0,47</td> <td>1,284</td> </tr> <tr> <td>CAL3</td> <td>0,88</td> <td>0,961</td> <td>0,94</td> <td>0,926</td> </tr> <tr> <td>CAL4</td> <td>1,33</td> <td>0,686</td> <td>1,47</td> <td>0,640</td> </tr> <tr> <td>CAL5</td> <td>1,76</td> <td>0,485</td> <td>1,93</td> <td>0,470</td> </tr> </tbody> </table> <p>Linearity: R<sup>2</sup> = 0,999                      0,999</p> <p style="text-align: center;"><u>Controls</u></p> <table border="1" data-bbox="204 1749 663 1917"> <thead> <tr> <th></th> <th>Lot</th> <th>TV*</th> <th>MV**</th> </tr> </thead> <tbody> <tr> <td>C1/UFH</td> <td>53903-1</td> <td>0,24</td> <td>0,20</td> </tr> <tr> <td>C2/UFH</td> <td>53903-2</td> <td>0,49</td> <td>0,46</td> </tr> <tr> <td>C3/LMWH</td> <td>44202-1</td> <td>0,79</td> <td>0,86</td> </tr> <tr> <td>C4/LMWH</td> <td>44202-2</td> <td>1,19</td> <td>1,22</td> </tr> </tbody> </table> <p>*TV: Target Value                      **MV: Measured value</p>		UFH UI/ml	A405	LMWH UI/ml	A405	CAL1	0	0,765	0	0,760	CAL2	0,46	0,511	0,47	0,482	CAL3	0,88	0,339	0,94	0,315	CAL4	1,33	0,222	1,47	0,197	CAL5	1,76	0,140	1,93	0,134		Lot	TV*	MV**	C1/UFH	53903-1	0,24	0,20	C2/UFH	60302-1	0,48	0,46	C3/LMWH	44202-1	0,79	0,78	C4/LMWH	44202-2	1,19	1,19		UFH UI/ml	A405	LMWH UI/ml	A405	CAL1	0	1,864	0	1,872	CAL2	0,46	1,341	0,47	1,284	CAL3	0,88	0,961	0,94	0,926	CAL4	1,33	0,686	1,47	0,640	CAL5	1,76	0,485	1,93	0,470		Lot	TV*	MV**	C1/UFH	53903-1	0,24	0,20	C2/UFH	53903-2	0,49	0,46	C3/LMWH	44202-1	0,79	0,86	C4/LMWH	44202-2	1,19	1,22	<p>For a same A405 (UFH/LMWH)              MV = TV ±0.05 IU/ml for rate ≤ 0.50 IU/ml              MV = TV ±0.10 IU/ml for rate &gt; 0.50 IU/ml</p> <p style="text-align: center;">≥ 0.98</p> <p>MV = TV ± 0.05 IU/ml              MV = TV ± 0.05 IU/ml              MV = TV ± 0.10 IU/ml              MV = TV ± 0.10 IU/ml</p> <p>For a same A405 (UFH/LMWH)              MV = TV ±0.05 IU/ml for rate ≤ 0.50 IU/ml              MV = TV ±0.10 IU/ml for rate &gt; 0.50 IU/ml</p> <p style="text-align: center;">≥ 0.98</p> <p>MV = TV ± 0.05 IU/ml              MV = TV ± 0.05 IU/ml              MV = TV ± 0.10 IU/ml              MV = TV ± 0.10 IU/ml</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: 30%;"></th> <th style="width: 35%;">7 days 2-8°C</th> <th style="width: 35%;">7 days 18-25°C</th> </tr> </thead> <tbody> <tr> <td colspan="3"><b>Substrate blank</b></td> </tr> <tr> <td style="text-align: center;">A405</td> <td style="text-align: center;">0,147</td> <td style="text-align: center;">0,145</td> </tr> <tr> <td colspan="3"><b>A405 (calibration curve)</b></td> </tr> <tr> <td style="text-align: center;">CAL1</td> <td style="text-align: center;">1,743</td> <td style="text-align: center;">1,707</td> </tr> <tr> <td style="text-align: center;">CAL2</td> <td style="text-align: center;">1,298</td> <td style="text-align: center;">1,303</td> </tr> <tr> <td style="text-align: center;">CAL3</td> <td style="text-align: center;">1,005</td> <td style="text-align: center;">0,962</td> </tr> <tr> <td style="text-align: center;">CAL4</td> <td style="text-align: center;">0,749</td> <td style="text-align: center;">0,756</td> </tr> <tr> <td style="text-align: center;">CAL5</td> <td style="text-align: center;">0,579</td> <td style="text-align: center;">0,578</td> </tr> <tr> <td colspan="3"><b>Measured values for controls (IU/ml)</b></td> </tr> <tr> <td style="text-align: center;">C1/UFH</td> <td style="text-align: center;">0,25</td> <td style="text-align: center;">0,21</td> </tr> <tr> <td style="text-align: center;">C2/UFH</td> <td style="text-align: center;">0,45</td> <td style="text-align: center;">0,47</td> </tr> <tr> <td style="text-align: center;">C3/LMWH</td> <td style="text-align: center;">0,84</td> <td style="text-align: center;">0,85</td> </tr> <tr> <td style="text-align: center;">C4/LMWH</td> <td style="text-align: center;">1,25</td> <td style="text-align: center;">1,24</td> </tr> </tbody> </table> <p><b>d. Detection threshold</b></p> <p>A405 (0 UI/ml) - 3SD = <span style="float: right;"><b>0,829</b></span></p> <p>Detection threshold: <span style="float: right;"><b>&lt;0,01 UI/ml</b></span></p>		7 days 2-8°C	7 days 18-25°C	<b>Substrate blank</b>			A405	0,147	0,145	<b>A405 (calibration curve)</b>			CAL1	1,743	1,707	CAL2	1,298	1,303	CAL3	1,005	0,962	CAL4	0,749	0,756	CAL5	0,579	0,578	<b>Measured values for controls (IU/ml)</b>			C1/UFH	0,25	0,21	C2/UFH	0,45	0,47	C3/LMWH	0,84	0,85	C4/LMWH	1,25	1,24	<p style="text-align: center;">A405 ≤ 0.30</p> <p style="text-align: center;">Δ A405 ≤ 0.10 7 days at 18-25°C or at 2-8°C</p> <p style="text-align: center;">[ 0,14 – 0,34 ]</p> <p style="text-align: center;">[ 0,34 – 0,64 ]</p> <p style="text-align: center;">[ 0,67 – 0,91 ]</p> <p style="text-align: center;">[ 1,00 – 1,36 ]</p> <p style="text-align: center;">≤ 0.05 UI/ml</p>
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Comments :

**PASSED  
IN COMPLIANCE**

**Date : 2017-01-23**

**QC Manager : S. LECOURT**

