

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN LRT (#221013)

Lot : F1700921

QC Release: 2017-09-08

Expiration date : 2019-01-30

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : SXa-11 substrate	3 vials	18	F171Q00921	2019-01-30
R2 : Bovine FXa	3 vials	18	F171Q00921	2019-01-30



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Analytical data	Specifications
<p>1. <u>Xa substrate</u></p> <p>a. Blank value (N=10) Mean (A405): 0,162</p> <p>b. Reproducibility (water bath)</p> <p> Mean (A405): 1,201</p> <p> CV: 0,97 %</p>	<p>A405 ≤ 0.30</p> <p>≤ 2 %</p>
<p>2. <u>Bovine Factor Xa</u></p> <p>a. Reproducibility (water bath)</p> <p> Mean (A405): 1,217</p> <p> CV: 1,08 %</p> <p>b. Factor Xa reactivity (water bath)</p> <p> A405 : 1,267</p>	<p>≤ 2 %</p> <p>≥ 0.80</p>

SOS

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<p>3. Assay method</p> <p>a. CS :</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>0</td> <td>0,749</td> <td>0</td> <td>0,744</td> </tr> <tr> <td>CAL2</td> <td>0,46</td> <td>0,485</td> <td>0,47</td> <td>0,468</td> </tr> <tr> <td>CAL3</td> <td>0,88</td> <td>0,324</td> <td>0,94</td> <td>0,300</td> </tr> <tr> <td>CAL4</td> <td>1,33</td> <td>0,217</td> <td>1,47</td> <td>0,190</td> </tr> <tr> <td>CAL5</td> <td>1,76</td> <td>0,139</td> <td>1,93</td> <td>0,127</td> </tr> </tbody> </table> <p>Linearity: R² = 0,9996 0,9991</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>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>52605-1</td> <td>0,80</td> <td>0,77</td> </tr> <tr> <td>C4/LMWH</td> <td>F1600910</td> <td>1,16</td> <td>1,13</td> </tr> </tbody> </table> <p>*TV: Target Value **MV: Measured value</p> <p>b. STAR</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>0</td> <td>1,699</td> <td>0</td> <td>1,711</td> </tr> <tr> <td>CAL2</td> <td>0,46</td> <td>1,225</td> <td>0,47</td> <td>1,181</td> </tr> <tr> <td>CAL3</td> <td>0,88</td> <td>0,878</td> <td>0,94</td> <td>0,844</td> </tr> <tr> <td>CAL4</td> <td>1,33</td> <td>0,651</td> <td>1,47</td> <td>0,580</td> </tr> <tr> <td>CAL5</td> <td>1,76</td> <td>0,455</td> <td>1,93</td> <td>0,412</td> </tr> </tbody> </table> <p>Linearity: R² = 0,9991 0,9997</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>53903-1</td> <td>0,24</td> <td>0,21</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>52605-1</td> <td>0,80</td> <td>0,82</td> </tr> <tr> <td>C4/LMWH</td> <td>F1600910</td> <td>1,16</td> <td>1,21</td> </tr> </tbody> </table> <p>*TV: Target Value **MV: Measured value</p>			UFH UI/ml	A405	LMWH UI/ml	A405	CAL1	0	0,749	0	0,744	CAL2	0,46	0,485	0,47	0,468	CAL3	0,88	0,324	0,94	0,300	CAL4	1,33	0,217	1,47	0,190	CAL5	1,76	0,139	1,93	0,127		Lot	TV*	MV**	C1/UFH	53903-1	0,24	0,20	C2/UFH	53903-2	0,49	0,46	C3/LMWH	52605-1	0,80	0,77	C4/LMWH	F1600910	1,16	1,13		UFH UI/ml	A405	LMWH UI/ml	A405	CAL1	0	1,699	0	1,711	CAL2	0,46	1,225	0,47	1,181	CAL3	0,88	0,878	0,94	0,844	CAL4	1,33	0,651	1,47	0,580	CAL5	1,76	0,455	1,93	0,412		Lot	TV*	MV**	C1/UFH	53903-1	0,24	0,21	C2/UFH	53903-2	0,49	0,46	C3/LMWH	52605-1	0,80	0,82	C4/LMWH	F1600910	1,16	1,21	<p style="text-align: center;">For a same A405 (UFH/LMWH)</p> <p>MV = TV ± 0.05 IU/ml for rate ≤ 0.50 IU/ml MV = TV ± 0.10 IU/ml for rate > 0.50 IU/ml</p> <p style="text-align: center;">≥ 0.98</p> <p style="text-align: center;">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 style="text-align: center;">For a same A405 (UFH/LMWH)</p> <p>MV = TV ± 0.05 IU/ml for rate ≤ 0.50 IU/ml MV = TV ± 0.10 IU/ml for rate > 0.50 IU/ml</p> <p style="text-align: center;">≥ 0.98</p> <p style="text-align: center;">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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