

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

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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 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: R² = 0,9994 0,9996</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. 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 style="color: red;">0</td> <td style="color: red;">1,750</td> <td style="color: red;">0</td> <td style="color: red;">1,745</td> </tr> <tr> <td>CAL2</td> <td style="color: red;">0,46</td> <td style="color: red;">1,260</td> <td style="color: red;">0,47</td> <td style="color: red;">1,212</td> </tr> <tr> <td>CAL3</td> <td style="color: red;">0,88</td> <td style="color: red;">0,918</td> <td style="color: red;">0,94</td> <td style="color: red;">0,856</td> </tr> <tr> <td>CAL4</td> <td style="color: red;">1,33</td> <td style="color: red;">0,667</td> <td style="color: red;">1,47</td> <td style="color: red;">0,589</td> </tr> <tr> <td>CAL5</td> <td style="color: red;">1,76</td> <td style="color: red;">0,469</td> <td style="color: red;">1,93</td> <td style="color: red;">0,439</td> </tr> </tbody> </table> <p>Linearity: R² = 0,9994 0,9988</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;">0,19</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;">0,48</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;">0,82</td> </tr> <tr> <td>C4/LMWH</td> <td style="color: red;">F1600910</td> <td style="color: red;">1,16</td> <td style="color: red;">1,20</td> </tr> </tbody> </table> <p>*TV: Target Value **MV: Measured value</p>			UFH UI/ml	A405	LMWH UI/ml	A405	CAL1	0	0,753	0	0,746	CAL2	0,46	0,495	0,47	0,475	CAL3	0,88	0,328	0,94	0,312	CAL4	1,33	0,224	1,47	0,197	CAL5	1,76	0,145	1,93	0,132		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	0,77	C4/LMWH	F1600910	1,16	1,13		UFH UI/ml	A405	LMWH UI/ml	A405	CAL1	0	1,750	0	1,745	CAL2	0,46	1,260	0,47	1,212	CAL3	0,88	0,918	0,94	0,856	CAL4	1,33	0,667	1,47	0,589	CAL5	1,76	0,469	1,93	0,439		Lot	TV*	MV**	C1/UFH	53903-1	0,24	0,19	C2/UFH	53903-2	0,49	0,48	C3/LMWH	52605-1	0,80	0,82	C4/LMWH	F1600910	1,16	1,20	<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 > 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 > 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>c. Stability of reagents <i>Method : CS</i></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="width: 20%;"></th> <th style="width: 20%;">7 days 2-8°C</th> <th style="width: 20%;">7 days 18-25°C</th> </tr> </thead> <tbody> <tr> <td colspan="3">Substrate blank</td> </tr> <tr> <td>A405</td> <td style="text-align: center;">0,159</td> <td style="text-align: center;">0,166</td> </tr> <tr> <td colspan="3">A405 (calibration curve)</td> </tr> <tr> <td>CAL1</td> <td style="text-align: center;">0,766</td> <td style="text-align: center;">0,763</td> </tr> <tr> <td>CAL2</td> <td style="text-align: center;">0,520</td> <td style="text-align: center;">0,520</td> </tr> <tr> <td>CAL3</td> <td style="text-align: center;">0,355</td> <td style="text-align: center;">0,353</td> </tr> <tr> <td>CAL4</td> <td style="text-align: center;">0,251</td> <td style="text-align: center;">0,250</td> </tr> <tr> <td>CAL5</td> <td style="text-align: center;">0,181</td> <td style="text-align: center;">0,178</td> </tr> <tr> <td colspan="3">Measured values for controls (IU/ml)</td> </tr> <tr> <td>C1/UFH</td> <td style="text-align: center;">0,20</td> <td style="text-align: center;">0,21</td> </tr> <tr> <td>C2/UFH</td> <td style="text-align: center;">0,47</td> <td style="text-align: center;">0,47</td> </tr> <tr> <td>C3/LMWH</td> <td style="text-align: center;">0,80</td> <td style="text-align: center;">0,80</td> </tr> <tr> <td>C4/LMWH</td> <td style="text-align: center;">1,18</td> <td style="text-align: center;">1,19</td> </tr> </tbody> </table> <p>d. Detection threshold</p> <p>A405 (0 IU/ml) - 3SD = 1,626</p> <p>Detection threshold: <0,01 IU/ml</p>			7 days 2-8°C	7 days 18-25°C	Substrate blank			A405	0,159	0,166	A405 (calibration curve)			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	Measured values for controls (IU/ml)			C1/UFH	0,20	0,21	C2/UFH	0,47	0,47	C3/LMWH	0,80	0,80	C4/LMWH	1,18	1,19
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	<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 style="text-align: right;">≤ 0.05 IU/ml</p>																																										

Comments :



**PASSED
IN COMPLIANCE**

Date : **2017-06-22**

QC Manager :

S. LECOURT

