

ANALYSIS CERTIFICATE

BIOPHEN™ Heparin LRT (#221015)

Lot : F1701211 / F1701212

QC Release: 01-12-2017

Expiration date : 2019-04-11

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : SXa-11 substrate	4 vials	18	F171V01211 F171W01212	2019-04-11
R2 : Bovine FXa	4 vials	18	F171V01211 F171W01212	2019-04-11

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Analytical data	Specifications
1. <u>Xa substrate</u>	
a. Blank value (N=10) Mean (A405): 0,143	A405 ≤ 0.30
b. Reproducibility (water bath) Mean (A405): 1,190 CV: 1,2 %	 ≤ 2 %
2. <u>Bovine Factor Xa</u>	
a. Reproducibility (water bath) Mean (A405): 1,186 CV: 1,4 %	 ≤ 2 %
b. Factor Xa reactivity (water bath) A405 : 1,029	 ≥ 0.80

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<p>3. Assay method</p> <p><u>a. CS :</u></p> <p style="text-align: center;"><u>Calibration curves and linearity</u></p> <table border="1"> <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>0,761</td> <td>0</td> <td>0,754</td> </tr> <tr> <td>CAL2</td> <td>0,46</td> <td>0,490</td> <td>0,47</td> <td>0,476</td> </tr> <tr> <td>CAL3</td> <td>0,88</td> <td>0,326</td> <td>0,94</td> <td>0,311</td> </tr> <tr> <td>CAL4</td> <td>1,33</td> <td>0,219</td> <td>1,47</td> <td>0,192</td> </tr> <tr> <td>CAL5</td> <td>1,76</td> <td>0,142</td> <td>1,93</td> <td>0,132</td> </tr> </tbody> </table> <p>Linearity: R² = 0,9997 0,9992</p> <p style="text-align: center;"><u>Controls</u></p> <table border="1"> <thead> <tr> <th></th> <th>Lot</th> <th>TV*</th> <th>MV**</th> </tr> </thead> <tbody> <tr> <td>C1/UFH</td> <td>F1601129</td> <td>0,24</td> <td>0,20</td> </tr> <tr> <td>C2/UFH</td> <td>F1601128</td> <td>0,47</td> <td>0,45</td> </tr> <tr> <td>C3/LMWH</td> <td>52605-1</td> <td>0,80</td> <td>0,78</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"> <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>1,793</td> <td>0</td> <td>1,770</td> </tr> <tr> <td>CAL2</td> <td>0,46</td> <td>1,280</td> <td>0,47</td> <td>1,223</td> </tr> <tr> <td>CAL3</td> <td>0,88</td> <td>0,925</td> <td>0,94</td> <td>0,860</td> </tr> <tr> <td>CAL4</td> <td>1,33</td> <td>0,653</td> <td>1,47</td> <td>0,578</td> </tr> <tr> <td>CAL5</td> <td>1,76</td> <td>0,458</td> <td>1,93</td> <td>0,414</td> </tr> </tbody> </table> <p>Linearity: R² = 0,9996 0,9998</p> <p style="text-align: center;"><u>Controls</u></p> <table border="1"> <thead> <tr> <th></th> <th>Lot</th> <th>TV*</th> <th>MV**</th> </tr> </thead> <tbody> <tr> <td>C1/UFH</td> <td>F1601129</td> <td>0,24</td> <td>0,19</td> </tr> <tr> <td>C2/UFH</td> <td>F1601128</td> <td>0,47</td> <td>0,43</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>1,12</td> </tr> </tbody> </table> <p>*TV: Target Value **MV: Measured value</p>		UFH UI/ml	A405	LMWH UI/ml	A405	CAL1	0	0,761	0	0,754	CAL2	0,46	0,490	0,47	0,476	CAL3	0,88	0,326	0,94	0,311	CAL4	1,33	0,219	1,47	0,192	CAL5	1,76	0,142	1,93	0,132		Lot	TV*	MV**	C1/UFH	F1601129	0,24	0,20	C2/UFH	F1601128	0,47	0,45	C3/LMWH	52605-1	0,80	0,78	C4/LMWH	F1600910	1,16	1,13		UFH UI/ml	A405	LMWH UI/ml	A405	CAL1	0	1,793	0	1,770	CAL2	0,46	1,280	0,47	1,223	CAL3	0,88	0,925	0,94	0,860	CAL4	1,33	0,653	1,47	0,578	CAL5	1,76	0,458	1,93	0,414		Lot	TV*	MV**	C1/UFH	F1601129	0,24	0,19	C2/UFH	F1601128	0,47	0,43	C3/LMWH	52605-1	0,80	0,77	C4/LMWH	F1600910	1,16	1,12	<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 : STAR</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">Substrate blank</td> </tr> <tr> <td>A405</td> <td>0,132</td> <td>0,138</td> </tr> <tr> <td colspan="3">A405 (calibration curve)</td> </tr> <tr> <td>CAL1</td> <td>1,641</td> <td>1,668</td> </tr> <tr> <td>CAL2</td> <td>1,221</td> <td>1,215</td> </tr> <tr> <td>CAL3</td> <td>0,899</td> <td>0,903</td> </tr> <tr> <td>CAL4</td> <td>0,682</td> <td>0,688</td> </tr> <tr> <td>CAL5</td> <td>0,520</td> <td>0,522</td> </tr> <tr> <td colspan="3">Measured values for controls (IU/ml)</td> </tr> <tr> <td>C1/UFH</td> <td>0,22</td> <td>0,23</td> </tr> <tr> <td>C2/UFH</td> <td>0,48</td> <td>0,46</td> </tr> <tr> <td>C3/LMWH</td> <td>0,82</td> <td>0,81</td> </tr> <tr> <td>C4/LMWH</td> <td>1,20</td> <td>1,24</td> </tr> </tbody> </table>				7 days 2-8°C	7 days 18-25°C	Substrate blank			A405	0,132	0,138	A405 (calibration curve)			CAL1	1,641	1,668	CAL2	1,221	1,215	CAL3	0,899	0,903	CAL4	0,682	0,688	CAL5	0,520	0,522	Measured values for controls (IU/ml)			C1/UFH	0,22	0,23	C2/UFH	0,48	0,46	C3/LMWH	0,82	0,81	C4/LMWH	1,20	1,24	<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] [0,32 – 0,62] [0,68 – 0,92] [1,01 – 1,31]</p>
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<p>d. Detection threshold</p> <p>A405 (0 IU/ml) - 3SD = 1,780</p> <p>Detection threshold: <0,01 IU/ml</p>			<p>≤ 0.05 IU/ml</p>																																										

Comments :



**PASSED
IN COMPLIANCE**

Date : 01-12-2017

QC Manager :

S. LECOURT