

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN LRT (#221011)

Lot : F1700922

QC Release: 2017-09-28

Expiration date : 2019-01-30

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : SXa-11 substrate	4 vials	18	F171900922	2019-01-30
R2 : Bovine FXa	4 vials	18	F171900922	2019-01-30

825

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN LRT (#221011)

Lot : F1700922

QC Release: 2017-09-28

Expiration date : 2019-01-30

Analytical data	Specifications
1. <u>Xa substrate</u>	
a. Blank value (N=10) Mean (A405): 0,156	A405 ≤ 0.30
b. Reproducibility (water bath) Mean (A405): 1,197 CV: 1,49 %	
	≤ 2 %
2. <u>Bovine Factor Xa</u>	
a. Reproducibility (water bath) Mean (A405): 1,223 CV: 0,86 %	≤ 2 %
b. Factor Xa reactivity (water bath) A405 : 1,213	
	≥ 0.80

825

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN LRT (#221011)

Lot : F1700922

QC Release: 2017-09-28

Expiration date : 2019-01-30

Analytical data	Specifications																																																																																																					
<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>0,740</td> </tr> <tr> <td>CAL2</td> <td>0,46</td> <td>0,484</td> <td>0,47</td> <td>0,467</td> </tr> <tr> <td>CAL3</td> <td>0,88</td> <td>0,323</td> <td>0,94</td> <td>0,301</td> </tr> <tr> <td>CAL4</td> <td>1,33</td> <td>0,217</td> <td>1,47</td> <td>0,186</td> </tr> <tr> <td>CAL5</td> <td>1,76</td> <td>0,139</td> <td>1,93</td> <td>0,125</td> </tr> </tbody> </table> <p>Linearity: $R^2 =$ 0,9996 0,9994</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>0,19</td> </tr> <tr> <td>C2/UFH</td> <td>53903-2</td> <td>0,49</td> <td>0,45</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>1,708</td> <td>0</td> <td>1,717</td> </tr> <tr> <td>CAL2</td> <td>0,46</td> <td>1,228</td> <td>0,47</td> <td>1,183</td> </tr> <tr> <td>CAL3</td> <td>0,88</td> <td>0,882</td> <td>0,94</td> <td>0,839</td> </tr> <tr> <td>CAL4</td> <td>1,33</td> <td>0,649</td> <td>1,47</td> <td>0,569</td> </tr> <tr> <td>CAL5</td> <td>1,76</td> <td>0,442</td> <td>1,93</td> <td>0,407</td> </tr> </tbody> </table> <p>Linearity: $R^2 =$ 0,9984 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>0,47</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>1,17</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	0,740	CAL2	0,46	0,484	0,47	0,467	CAL3	0,88	0,323	0,94	0,301	CAL4	1,33	0,217	1,47	0,186	CAL5	1,76	0,139	1,93	0,125		Lot	TV*	MV**	C1/UFH	53903-1	0,24	0,19	C2/UFH	53903-2	0,49	0,45	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	1,708	0	1,717	CAL2	0,46	1,228	0,47	1,183	CAL3	0,88	0,882	0,94	0,839	CAL4	1,33	0,649	1,47	0,569	CAL5	1,76	0,442	1,93	0,407		Lot	TV*	MV**	C1/UFH	53903-1	0,24	0,21	C2/UFH	53903-2	0,49	0,47	C3/LMWH	52605-1	0,80	0,82	C4/LMWH	F1600910	1,16	1,17	<p style="text-align: center;">For a same A405 (UFH/LMWH)</p> <p>MV = TV \pm 0.05 IU/ml for rate \leq 0.50 IU/ml MV = TV \pm 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 \pm 0.05 IU/ml MV = TV \pm 0.05 IU/ml MV = TV \pm 0.10 IU/ml MV = TV \pm 0.10 IU/ml</p> <p style="text-align: center;">For a same A405 (UFH/LMWH)</p> <p>MV = TV \pm 0.05 IU/ml for rate \leq 0.50 IU/ml MV = TV \pm 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 \pm 0.05 IU/ml MV = TV \pm 0.05 IU/ml MV = TV \pm 0.10 IU/ml MV = TV \pm 0.10 IU/ml</p>
	UFH UI/ml	A405	LMWH UI/ml	A405																																																																																																		
CAL1	0	0,749	0	0,740																																																																																																		
CAL2	0,46	0,484	0,47	0,467																																																																																																		
CAL3	0,88	0,323	0,94	0,301																																																																																																		
CAL4	1,33	0,217	1,47	0,186																																																																																																		
CAL5	1,76	0,139	1,93	0,125																																																																																																		
	Lot	TV*	MV**																																																																																																			
C1/UFH	53903-1	0,24	0,19																																																																																																			
C2/UFH	53903-2	0,49	0,45																																																																																																			
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	1,708	0	1,717																																																																																																		
CAL2	0,46	1,228	0,47	1,183																																																																																																		
CAL3	0,88	0,882	0,94	0,839																																																																																																		
CAL4	1,33	0,649	1,47	0,569																																																																																																		
CAL5	1,76	0,442	1,93	0,407																																																																																																		
	Lot	TV*	MV**																																																																																																			
C1/UFH	53903-1	0,24	0,21																																																																																																			
C2/UFH	53903-2	0,49	0,47																																																																																																			
C3/LMWH	52605-1	0,80	0,82																																																																																																			
C4/LMWH	F1600910	1,16	1,17																																																																																																			

SAB

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN LRT (#221011)

Lot : F1700922

QC Release: 2017-09-28

Expiration date : 2019-01-30

Analytical data	Specifications																																										
<p>c. Stability of reagents</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">Substrate blank</td> </tr> <tr> <td style="text-align: center;">A405</td> <td style="text-align: center;">0,170</td> <td style="text-align: center;">0,170</td> </tr> <tr> <td colspan="3">A405 (calibration curve)</td> </tr> <tr> <td style="text-align: center;">CAL1</td> <td style="text-align: center;">0,747</td> <td style="text-align: center;">0,738</td> </tr> <tr> <td style="text-align: center;">CAL2</td> <td style="text-align: center;">0,505</td> <td style="text-align: center;">0,503</td> </tr> <tr> <td style="text-align: center;">CAL3</td> <td style="text-align: center;">0,345</td> <td style="text-align: center;">0,338</td> </tr> <tr> <td style="text-align: center;">CAL4</td> <td style="text-align: center;">0,243</td> <td style="text-align: center;">0,240</td> </tr> <tr> <td style="text-align: center;">CAL5</td> <td style="text-align: center;">0,170</td> <td style="text-align: center;">0,167</td> </tr> <tr> <td colspan="3">Measured values for controls (IU/ml)</td> </tr> <tr> <td style="text-align: center;">C1/UFH</td> <td style="text-align: center;">0,21</td> <td style="text-align: center;">0,22</td> </tr> <tr> <td style="text-align: center;">C2/UFH</td> <td style="text-align: center;">0,48</td> <td style="text-align: center;">0,48</td> </tr> <tr> <td style="text-align: center;">C3/LMWH</td> <td style="text-align: center;">0,80</td> <td style="text-align: center;">0,80</td> </tr> <tr> <td style="text-align: center;">C4/LMWH</td> <td style="text-align: center;">1,13</td> <td style="text-align: center;">1,13</td> </tr> </tbody> </table> <p>d. Detection threshold</p> <p>A405 (0 UI/ml) - 3SD = 0,801</p> <p>Detection threshold: <0,01 UI/ml</p>		7 days 2-8°C	7 days 18-25°C	Substrate blank			A405	0,170	0,170	A405 (calibration curve)			CAL1	0,747	0,738	CAL2	0,505	0,503	CAL3	0,345	0,338	CAL4	0,243	0,240	CAL5	0,170	0,167	Measured values for controls (IU/ml)			C1/UFH	0,21	0,22	C2/UFH	0,48	0,48	C3/LMWH	0,80	0,80	C4/LMWH	1,13	1,13	<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] [0,32 - 0,62] [0,68 - 0,92] [0,97 - 1,31]</p> <p style="text-align: center;">≤ 0.05 UI/ml</p>
	7 days 2-8°C	7 days 18-25°C																																									
Substrate blank																																											
A405	0,170	0,170																																									
A405 (calibration curve)																																											
CAL1	0,747	0,738																																									
CAL2	0,505	0,503																																									
CAL3	0,345	0,338																																									
CAL4	0,243	0,240																																									
CAL5	0,170	0,167																																									
Measured values for controls (IU/ml)																																											
C1/UFH	0,21	0,22																																									
C2/UFH	0,48	0,48																																									
C3/LMWH	0,80	0,80																																									
C4/LMWH	1,13	1,13																																									

Comments :



**PASSED
IN COMPLIANCE**

Date : 2017-09-28

QC Manager : S.LECOURT

