

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN 6 - # 221006

F1700344
Lot : F1700346

QC Release:

2017-05-02

Expiration date : 2019-09-20

Components	Volume	Exp. (months)	Lot #	Exp. date
R1 : Sxa-11 substrate	4 vials of 15 mg	30	F171200344 F171100346	2019-09-20
R2 : Bovine FXa	4 vials of 15 µg	30	F171200344 F171100346	2019-09-28

905

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F1700344

F1700346

QC Release: 2017-05-02

Expiration date : 2019-09-20

Analytical data	Specifications
1. <u>SXa-11 substrate</u>	
a. Blank value (N=10) Mean (A405): 0,185	A405 ≤ 0.30
b. Reproducibility (water bath)	
N= 20 Mean (A405): 1,978	
CV(DO): 0,4 %	≤ 2 %

2. <u>Bovine Factor Xa</u>	
a. Reproducibility (water bath)	
N= 20 Mean (A405): 1,973	
CV(DO): 0,9 %	≤ 2 %
b. Factor Xa reactivity (water bath)	
A405 : 2,069	≥ 1.50

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<p>3. <u>Assay method</u></p> <p><u>a. STAR method</u></p> <p style="text-align: center;"><u>Calibration curves</u></p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th>UFH IU/ml</th> <th>A405</th> <th>LMWH IU/ml</th> <th>A405</th> </tr> </thead> <tbody> <tr> <td>CAL1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1,679</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1,674</td> </tr> <tr> <td>CAL2</td> <td style="text-align: center;">0,46</td> <td style="text-align: center;">1,133</td> <td style="text-align: center;">0,47</td> <td style="text-align: center;">1,108</td> </tr> <tr> <td>CAL3</td> <td style="text-align: center;">0,88</td> <td style="text-align: center;">0,738</td> <td style="text-align: center;">0,94</td> <td style="text-align: center;">0,730</td> </tr> <tr> <td>CAL4</td> <td style="text-align: center;">1,33</td> <td style="text-align: center;">0,483</td> <td style="text-align: center;">1,47</td> <td style="text-align: center;">0,422</td> </tr> <tr> <td>CAL5</td> <td style="text-align: center;">1,76</td> <td style="text-align: center;">0,310</td> <td style="text-align: center;">1,93</td> <td style="text-align: center;">0,293</td> </tr> </tbody> </table> <p style="text-align: center; margin-top: 20px;"><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="text-align: center;">53903-1</td> <td style="text-align: center;">0,24</td> <td style="text-align: center;">0,22</td> </tr> <tr> <td>C2/UFH</td> <td style="text-align: center;">53903-2</td> <td style="text-align: center;">0,49</td> <td style="text-align: center;">0,47</td> </tr> <tr> <td>C3/LMWH</td> <td style="text-align: center;">44202-1</td> <td style="text-align: center;">0,79</td> <td style="text-align: center;">0,75</td> </tr> <tr> <td>C4/LMWH</td> <td style="text-align: center;">F1600910</td> <td style="text-align: center;">1,16</td> <td style="text-align: center;">1,12</td> </tr> </tbody> </table> <p style="font-size: small; margin-top: 5px;">*TV: Target Value **MV: Measured value</p> <p style="margin-top: 20px;"><u>b. 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Analytical data	Specifications																																										
4. <u>Stability of reconstituted reagents</u>																																											
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;"></th> <th style="width: 35%;">Fresh</th> <th style="width: 50%;">7 days RT (18-25°C)</th> </tr> </thead> <tbody> <tr> <td colspan="3" style="text-align: center;"><i>Substrate blank</i></td> </tr> <tr> <td>A405</td> <td style="text-align: center;">0,133</td> <td style="text-align: center;">0,190</td> </tr> <tr> <td colspan="3" style="text-align: center;"><i>A405 (LMWH calibration curve)</i></td> </tr> <tr> <td>CAL1</td> <td style="text-align: center;">0,690</td> <td style="text-align: center;">0,718</td> </tr> <tr> <td>CAL2</td> <td style="text-align: center;">0,482</td> <td style="text-align: center;">0,500</td> </tr> <tr> <td>CAL3</td> <td style="text-align: center;">0,344</td> <td style="text-align: center;">0,344</td> </tr> <tr> <td>CAL4</td> <td style="text-align: center;">0,237</td> <td style="text-align: center;">0,250</td> </tr> <tr> <td>CAL5</td> <td style="text-align: center;">0,187</td> <td style="text-align: center;">0,192</td> </tr> <tr> <td colspan="3" style="text-align: center;"><i>Measured values for controls (IU/ml)</i></td> </tr> <tr> <td>C1/UFH</td> <td style="text-align: center;">0,17</td> <td style="text-align: center;">0,21</td> </tr> <tr> <td>C2/UFH</td> <td style="text-align: center;">0,43</td> <td style="text-align: center;">0,48</td> </tr> <tr> <td>C3/LMWH</td> <td style="text-align: center;">0,73</td> <td style="text-align: center;">0,79</td> </tr> <tr> <td>C4/LMWH</td> <td style="text-align: center;">1,12</td> <td style="text-align: center;">1,17</td> </tr> </tbody> </table>		Fresh	7 days RT (18-25°C)	<i>Substrate blank</i>			A405	0,133	0,190	<i>A405 (LMWH calibration curve)</i>			CAL1	0,690	0,718	CAL2	0,482	0,500	CAL3	0,344	0,344	CAL4	0,237	0,250	CAL5	0,187	0,192	<i>Measured values for controls (IU/ml)</i>			C1/UFH	0,17	0,21	C2/UFH	0,43	0,48	C3/LMWH	0,73	0,79	C4/LMWH	1,12	1,17	<p style="text-align: center;">A405 ≤ 0.30</p> <p style="text-align: center;">Δ A405 ≤ 0.10 7 days at RT (18-25°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;">[0,68 - 0,92]</p> <p style="text-align: center;">[1,00 - 1,36]</p>
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A405 (0 IU/ml) - 3SD =	0,795																																										
Detection threshold:	<0,01 IU/ml																																										
	≤ 0.05 IU/ml																																										

Comments :

**PASSED
 IN COMPLIANCE**

Date : 2017-05-02

QC Manager : S.LECOURT

