

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN LRT (#221011)

Lot : F1601278 / F1601337

QC Release: 2017-01-23

Expiration date : 2018-06-05

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : SXa-11 substrate	4 vials	18	F161501278 / F161101337	2018-06-05
R2 : Bovine FXa	4 vials	18	F161501278 / F161101337	2018-06-05

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Analytical data	Specifications
<p>1. <u>Xa substrate</u></p> <p>a. Blank value (N=10) Mean (A405): 0,134</p> <p>b. Reproducibility (water bath)</p> <p> Mean (A405): 2,042</p> <p> CV: 0,72 %</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): 1,985</p> <p> CV: 0,72 %</p> <p>b. Factor Xa reactivity (water bath)</p> <p> A405 : 1,916</p>	<p>≤ 2 %</p> <p>≥ 0.80</p>

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<p>c. Stability of reagents</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="width: 20%;"></th> <th style="width: 40%;">7 days 2-8°C</th> <th style="width: 40%;">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;">0,147</td> <td style="text-align: center;">0,145</td> </tr> <tr> <td colspan="3">A405 (calibration curve)</td> </tr> <tr> <td style="text-align: center;">CAL1</td> <td style="text-align: center;">1,743</td> <td style="text-align: center;">1,707</td> </tr> <tr> <td style="text-align: center;">CAL2</td> <td style="text-align: center;">1,298</td> <td style="text-align: center;">1,303</td> </tr> <tr> <td style="text-align: center;">CAL3</td> <td style="text-align: center;">1,005</td> <td style="text-align: center;">0,962</td> </tr> <tr> <td style="text-align: center;">CAL4</td> <td style="text-align: center;">0,749</td> <td style="text-align: center;">0,756</td> </tr> <tr> <td style="text-align: center;">CAL5</td> <td style="text-align: center;">0,579</td> <td style="text-align: center;">0,578</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;">0,25</td> <td style="text-align: center;">0,21</td> </tr> <tr> <td style="text-align: center;">C2/UFH</td> <td style="text-align: center;">0,45</td> <td style="text-align: center;">0,47</td> </tr> <tr> <td style="text-align: center;">C3/LMWH</td> <td style="text-align: center;">0,84</td> <td style="text-align: center;">0,85</td> </tr> <tr> <td style="text-align: center;">C4/LMWH</td> <td style="text-align: center;">1,25</td> <td style="text-align: center;">1,24</td> </tr> </tbody> </table> <p>d. Detection threshold</p> <p>A405 (0 UI/ml) - 3SD = 0,829</p> <p>Detection threshold: <0,01 UI/ml</p>		7 days 2-8°C	7 days 18-25°C	Substrate blank			A405	0,147	0,145	A405 (calibration curve)			CAL1	1,743	1,707	CAL2	1,298	1,303	CAL3	1,005	0,962	CAL4	0,749	0,756	CAL5	0,579	0,578	Measured values for controls (IU/ml)			C1/UFH	0,25	0,21	C2/UFH	0,45	0,47	C3/LMWH	0,84	0,85	C4/LMWH	1,25	1,24	<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]</p> <p style="text-align: center;">[0,34 – 0,64]</p> <p style="text-align: center;">[0,67 – 0,91]</p> <p style="text-align: center;">[1,00 – 1,36]</p> <p style="text-align: center;">≤ 0.05 UI/ml</p>
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Comments :

**PASSED
IN COMPLIANCE**

Date : 2017-01-23

QC Manager : S. LECOURT

