

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

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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

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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: 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>
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Comments :



**PASSED
IN COMPLIANCE**

Date : 2017-09-28

QC Manager : S.LECOURT

