

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN LRT (#221013)

Lot : F1700494
F1700495

QC Release: 2017-06-22

Expiration date : 2018-10-24

| Components | Qty | Exp. (months) | Lot # | Exp. date |
|-----------------------|---------|------------------|--------------------------|--------------|
| R1 : Sxa-11 substrate | 3 vials | 18 | F171L00494 F171M00495 | 2018-10-24 |
| R2 : Bovine FXa | 3 vials | 18 | F171L00494 F171M00495 | 2018-10-24 |

Sas

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| Analytical data | Specifications |
|--|---------------------------------|
| <p>1. <u>Xa substrate</u></p> <p>a. Blank value (N=10) Mean (A405): 0,175</p> <p>b. Reproducibility (water bath)</p> <p style="padding-left: 150px;">Mean (A405): 1,208</p> <p style="padding-left: 150px;">CV: 1,3 %</p> | <p>A405 ≤ 0.30</p> <p>≤ 2 %</p> |
| <p>2. <u>Bovine Factor Xa</u></p> <p>a. Reproducibility (water bath)</p> <p style="padding-left: 150px;">Mean (A405): 1,242</p> <p style="padding-left: 150px;">CV: 0,8 %</p> <p>b. Factor Xa reactivity (water bath)</p> <p style="padding-left: 150px;">A405 : 1,279</p> | <p>≤ 2 %</p> <p>≥ 0.80</p> |

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| 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 style="color: red;">0</td> <td style="color: red;">0,753</td> <td style="color: red;">0</td> <td style="color: red;">0,746</td> </tr> <tr> <td>CAL2</td> <td style="color: red;">0,46</td> <td style="color: red;">0,495</td> <td style="color: red;">0,47</td> <td style="color: red;">0,475</td> </tr> <tr> <td>CAL3</td> <td style="color: red;">0,88</td> <td style="color: red;">0,328</td> <td style="color: red;">0,94</td> <td style="color: red;">0,312</td> </tr> <tr> <td>CAL4</td> <td style="color: red;">1,33</td> <td style="color: red;">0,224</td> <td style="color: red;">1,47</td> <td style="color: red;">0,197</td> </tr> <tr> <td>CAL5</td> <td style="color: red;">1,76</td> <td style="color: red;">0,145</td> <td style="color: red;">1,93</td> <td style="color: red;">0,132</td> </tr> </tbody> </table> <p>Linearity: R² = 0,9994 0,9996</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 style="color: red;">53903-1</td> <td style="color: red;">0,24</td> <td style="color: red;">0,21</td> </tr> <tr> <td>C2/UFH</td> <td style="color: red;">53903-2</td> <td style="color: red;">0,49</td> <td style="color: red;">0,46</td> </tr> <tr> <td>C3/LMWH</td> <td style="color: red;">52605-1</td> <td style="color: red;">0,80</td> <td style="color: red;">0,77</td> </tr> <tr> <td>C4/LMWH</td> <td style="color: red;">F1600910</td> <td style="color: red;">1,16</td> <td style="color: red;">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 style="color: red;">0</td> <td style="color: red;">1,750</td> <td style="color: red;">0</td> <td style="color: red;">1,745</td> </tr> <tr> <td>CAL2</td> <td style="color: red;">0,46</td> <td style="color: red;">1,260</td> <td style="color: red;">0,47</td> <td style="color: red;">1,212</td> </tr> <tr> <td>CAL3</td> <td style="color: red;">0,88</td> <td style="color: red;">0,918</td> <td style="color: red;">0,94</td> <td style="color: red;">0,856</td> </tr> <tr> <td>CAL4</td> <td style="color: red;">1,33</td> <td style="color: red;">0,667</td> <td style="color: red;">1,47</td> <td style="color: red;">0,589</td> </tr> <tr> <td>CAL5</td> <td style="color: red;">1,76</td> <td style="color: red;">0,469</td> <td style="color: red;">1,93</td> <td style="color: red;">0,439</td> </tr> </tbody> </table> <p>Linearity: R² = 0,9994 0,9988</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 style="color: red;">53903-1</td> <td style="color: red;">0,24</td> <td style="color: red;">0,19</td> </tr> <tr> <td>C2/UFH</td> <td style="color: red;">53903-2</td> <td style="color: red;">0,49</td> <td style="color: red;">0,48</td> </tr> <tr> <td>C3/LMWH</td> <td style="color: red;">52605-1</td> <td style="color: red;">0,80</td> <td style="color: red;">0,82</td> </tr> <tr> <td>C4/LMWH</td> <td style="color: red;">F1600910</td> <td style="color: red;">1,16</td> <td style="color: red;">1,20</td> </tr> </tbody> </table> <p>*TV: Target Value **MV: Measured value</p> | | | UFH UI/ml | A405 | LMWH UI/ml | A405 | CAL1 | 0 | 0,753 | 0 | 0,746 | CAL2 | 0,46 | 0,495 | 0,47 | 0,475 | CAL3 | 0,88 | 0,328 | 0,94 | 0,312 | CAL4 | 1,33 | 0,224 | 1,47 | 0,197 | CAL5 | 1,76 | 0,145 | 1,93 | 0,132 | | Lot | TV* | MV** | C1/UFH | 53903-1 | 0,24 | 0,21 | C2/UFH | 53903-2 | 0,49 | 0,46 | 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 | 1,750 | 0 | 1,745 | CAL2 | 0,46 | 1,260 | 0,47 | 1,212 | CAL3 | 0,88 | 0,918 | 0,94 | 0,856 | CAL4 | 1,33 | 0,667 | 1,47 | 0,589 | CAL5 | 1,76 | 0,469 | 1,93 | 0,439 | | Lot | TV* | MV** | C1/UFH | 53903-1 | 0,24 | 0,19 | C2/UFH | 53903-2 | 0,49 | 0,48 | C3/LMWH | 52605-1 | 0,80 | 0,82 | C4/LMWH | F1600910 | 1,16 | 1,20 | <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> |
| | UFH UI/ml | A405 | LMWH UI/ml | A405 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL1 | 0 | 0,753 | 0 | 0,746 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL2 | 0,46 | 0,495 | 0,47 | 0,475 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL3 | 0,88 | 0,328 | 0,94 | 0,312 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL4 | 1,33 | 0,224 | 1,47 | 0,197 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL5 | 1,76 | 0,145 | 1,93 | 0,132 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Lot | TV* | MV** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C1/UFH | 53903-1 | 0,24 | 0,21 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C2/UFH | 53903-2 | 0,49 | 0,46 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | 1,750 | 0 | 1,745 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL2 | 0,46 | 1,260 | 0,47 | 1,212 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL3 | 0,88 | 0,918 | 0,94 | 0,856 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL4 | 1,33 | 0,667 | 1,47 | 0,589 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL5 | 1,76 | 0,469 | 1,93 | 0,439 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Lot | TV* | MV** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C1/UFH | 53903-1 | 0,24 | 0,19 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C2/UFH | 53903-2 | 0,49 | 0,48 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C3/LMWH | 52605-1 | 0,80 | 0,82 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C4/LMWH | F1600910 | 1,16 | 1,20 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

SPS

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|--|--------------|----------------|----------------|--------------|----------------|------------------------|--|--|------|-------|-------|---------------------------------|--|--|------|-------|-------|------|-------|-------|------|-------|-------|------|-------|-------|------|-------|-------|---|--|--|--------|------|------|--------|------|------|---------|------|------|---------|------|------|---|
| <p>c. Stability of reagents <i>Method : CS</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>0,159</td> <td>0,166</td> </tr> <tr> <td colspan="3">A405 (calibration curve)</td> </tr> <tr> <td>CAL1</td> <td>0,766</td> <td>0,763</td> </tr> <tr> <td>CAL2</td> <td>0,520</td> <td>0,520</td> </tr> <tr> <td>CAL3</td> <td>0,355</td> <td>0,353</td> </tr> <tr> <td>CAL4</td> <td>0,251</td> <td>0,250</td> </tr> <tr> <td>CAL5</td> <td>0,181</td> <td>0,178</td> </tr> <tr> <td colspan="3">Measured values for controls (IU/ml)</td> </tr> <tr> <td>C1/UFH</td> <td>0,20</td> <td>0,21</td> </tr> <tr> <td>C2/UFH</td> <td>0,47</td> <td>0,47</td> </tr> <tr> <td>C3/LMWH</td> <td>0,80</td> <td>0,80</td> </tr> <tr> <td>C4/LMWH</td> <td>1,18</td> <td>1,19</td> </tr> </tbody> </table> <p>d. Detection threshold A405 (0 IU/ml) - 3SD = 1,626 Detection threshold: <0,01 IU/ml</p> | | | | 7 days 2-8°C | 7 days 18-25°C | Substrate blank | | | A405 | 0,159 | 0,166 | A405 (calibration curve) | | | CAL1 | 0,766 | 0,763 | CAL2 | 0,520 | 0,520 | CAL3 | 0,355 | 0,353 | CAL4 | 0,251 | 0,250 | CAL5 | 0,181 | 0,178 | Measured values for controls (IU/ml) | | | C1/UFH | 0,20 | 0,21 | C2/UFH | 0,47 | 0,47 | C3/LMWH | 0,80 | 0,80 | C4/LMWH | 1,18 | 1,19 | <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] [0,34 — 0,64] [0,68 — 0,92] [1,01 — 1,31]</p> <p>≤ 0.05 IU/ml</p> |
| | 7 days 2-8°C | 7 days 18-25°C | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Substrate blank | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| A405 | 0,159 | 0,166 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| A405 (calibration curve) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL1 | 0,766 | 0,763 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL2 | 0,520 | 0,520 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL3 | 0,355 | 0,353 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL4 | 0,251 | 0,250 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CAL5 | 0,181 | 0,178 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Measured values for controls (IU/ml) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C1/UFH | 0,20 | 0,21 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C2/UFH | 0,47 | 0,47 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C3/LMWH | 0,80 | 0,80 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| C4/LMWH | 1,18 | 1,19 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Comments :



**PASSED
 IN COMPLIANCE**

Date : **2017-06-22**

QC Manager :

S. LECOURT