

## ANALYSIS CERTIFICATE

**BIOPHEN FIXa - #221812**

**Lot : 54205**

**QC Release : 2016-01-06**

**Expiration date : 2018-02-05**

| Components                   | Volume  | Exp.<br>(months) | Int. Ref. | Lot #      | Exp.<br>date |
|------------------------------|---------|------------------|-----------|------------|--------------|
| R1 : Human Factor X -FVIII:C | 2 vials | 30               | 151029A   | 54205-1    | 2018-04      |
| R2 : "Activation" Reagent    | 2 vials | 30               | 151110A   | 54205-2    | 2018-05      |
| R3 : Sxa-11 substrate        | 2 vials | 30               | 151020C   | 54205-3    | 2018-04      |
| R4 : Tris-BSA buffer         | 2 vials | 30               | 151013D   | 54205-4    | 2018-04      |
| Cal : FIXa Calibrator        | 2 vials | 30               | 150820B   | F151100088 | 2018-02-05   |

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| Analytical data  | Specifications                   |        |        |              |       |       |             |  |       |  |
|--|----------------------------------|--------|--------|--------------|-------|-------|-------------|--|-------|--|
| <b>1. <u>Human Factor X-VIII:C</u></b>   |                                  |        |        |              |       |       |             |  |       |  |
| <b>a. Reproducibility:</b><br><div style="display: flex; justify-content: space-between; width: 80%; margin-left: 40px;"> <span>N = 15</span> <span>Mean (A405): <b>2,403</b></span> </div> <div style="display: flex; justify-content: space-between; width: 80%; margin-left: 40px; margin-top: 5px;"> <span>CV:</span> <span><b>1,74 %</b></span> </div>  | N ≥ 10<br>≤ 2 %                  |        |        |              |       |       |             |  |       |  |
| <b>b. Factor X concentration (water bath)</b>  | ≥ 50 %                           |        |        |              |       |       |             |  |       |  |
| <b>2. <u>"Activation" Reagent (Thrombin - PLPs - calcium)</u></b>  |                                  |        |        |              |       |       |             |  |       |  |
| <b>a. Reproducibility (FIXa, C/2)</b><br><div style="display: flex; justify-content: space-between; width: 80%; margin-left: 40px;"> <span>N = 15</span> <span>Mean (A405): <b>2,406</b></span> </div> <div style="display: flex; justify-content: space-between; width: 80%; margin-left: 40px; margin-top: 5px;"> <span>CV:</span> <span><b>0,67 %</b></span> </div>   | N ≥ 10<br>≤ 2 %                  |        |        |              |       |       |             |  |       |  |
| <b>3. <u>SXa-11 substrate</u> (tested at 2.5 mg/ml for a,b)</b>  |                                  |        |        |              |       |       |             |  |       |  |
| <b>a. Blank value (N=10)</b>   | A405 ≤ 0.30                      |        |        |              |       |       |             |  |       |  |
| <b>b. Stability of substrate blank (A405)</b>  | A405<br>7 days ≤ 0.30            |        |        |              |       |       |             |  |       |  |
| <table border="1" style="margin-left: 40px; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="padding: 2px;">Time</th> <th style="padding: 2px;">Fresh</th> <th style="padding: 2px;">7 days</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;"><b>2-8°C</b></td> <td style="padding: 2px;">0,140</td> <td style="padding: 2px;">0,172</td> </tr> <tr> <td style="padding: 2px;"><b>R.T.</b></td> <td style="padding: 2px; background-color: black;"></td> <td style="padding: 2px;">0,186</td> </tr> </tbody> </table> | Time                             | Fresh  | 7 days | <b>2-8°C</b> | 0,140 | 0,172 | <b>R.T.</b> |  | 0,186 |  |
| Time   | Fresh                            | 7 days |        |              |       |       |             |  |       |  |
| <b>2-8°C</b>   | 0,140                            | 0,172  |        |              |       |       |             |  |       |  |
| <b>R.T.</b>  |                                  | 0,186  |        |              |       |       |             |  |       |  |
| <b>c. Reproducibility</b><br><div style="display: flex; justify-content: space-between; width: 80%; margin-left: 40px;"> <span>N = 15</span> <span>Mean (A405): <b>2,366</b></span> </div> <div style="display: flex; justify-content: space-between; width: 80%; margin-left: 40px; margin-top: 5px;"> <span>CV:</span> <span><b>1,16 %</b></span> </div>   | N ≥ 10<br>≤ 2 %                  |        |        |              |       |       |             |  |       |  |
| <b>4. <u>FIXa calibrator</u></b>   |                                  |        |        |              |       |       |             |  |       |  |
| N =  | <b>24</b>                        |        |        |              |       |       |             |  |       |  |
| FIXa conc. =   | <b>23 mIU/ml</b>                 |        |        |              |       |       |             |  |       |  |
| CV:  | <b>10 %</b>                      |        |        |              |       |       |             |  |       |  |
|  | N ≥ 9<br>25 ± 5 mIU/ml<br>≤ 10 % |        |        |              |       |       |             |  |       |  |

PS

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| Analytical data             |                |               | Specifications   |
|-----------------------------|----------------|---------------|--|
| <b>1. Calibration curve</b> |                |               | <p style="text-align: center;">Water Bath:<br/> <b>A405(C/2) ≥ 1.5</b></p> <p style="text-align: center;"><b>A405 (0)&lt;0.100</b></p><br><p style="text-align: center;"><b>ΔA405(C/2-C/4) ≥ 0.30</b></p><br><br><br><p style="text-align: center;"><b>r2 ≥ 0.98</b></p> |
| <b>FIXa (mIU/ml)</b>        | <b>A405</b>    | <b>Δ A405</b> |  |
|                             | <b>W. Bath</b> | <b>STAR</b>   |  |
| 0                           | 0,006          | 0,005         |  |
| C/40                        | 0,272          | 0,049         |  |
| C/20                        | 0,524          | 0,112         |  |
| C/8 or C/10                 | 1,203          | 0,236         |  |
| C/4                         | 1,909          | 0,557         |  |
| C/2                         | 2,684          | 0,935         |  |
| <b>Linearity: r2 =</b>      | <b>0,987</b>   | <b>0,992</b>  |  |

|                               |              |
|-------------------------------|--------------|
| <b>2. Detection threshold</b> |              |
| <0,1 mUI/ml                   | ≤ 0.2 mUI/ml |

| <b>3. Stability of restored reagents (for the C/2 FIXa concentration)</b>   |       |         |              |              |      |       |       |       |               |
|---|-------|---------|--------------|--------------|------|-------|-------|-------|---------------|
| <table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 20%;">Fresh</th> <th style="width: 20%;">8hrs RT</th> <th style="width: 20%;">24 hrs 2-8°C</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">A405</td> <td style="text-align: center;">0,901</td> <td style="text-align: center;">0,803</td> <td style="text-align: center;">0,785</td> </tr> </tbody> </table> |       | Fresh   | 8hrs RT      | 24 hrs 2-8°C | A405 | 0,901 | 0,803 | 0,785 | Δ A405 ≤ 0.20 |
|   | Fresh | 8hrs RT | 24 hrs 2-8°C |              |      |       |       |       |               |
| A405  | 0,901 | 0,803   | 0,785        |              |      |       |       |       |               |

|                   |   |
|-------------------|---|
| <b>Comments :</b> | <input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b> |
|-------------------|---|

**Date : 06/01/2016**

**QC Manager :**

**S. LECOURT**



**BIOPHEN Factor IXa (ACT. FIX)**  
Référence 221812

Pour recherche *in vitro* exclusivement

FRANÇAIS

Lot : 54205 - Exp. : 2018-02-05

**Calibrateur Facteur IXa**

Lot : F151100088

**C= 23 mUI/ml\***

(\* 1 mUI/ml est proche de 1 ng/ml)

**BIOPHEN Factor IXa (ACT. FIX)**  
# 221812

For *in vitro* research use only

ENGLISH

Lot : 54205 - Exp. : 2018-02-05

**Factor IXa Calibrator**

Lot : F151100088

**C= 23 mIU/ml\***

(\* 1 mIU/ml is close to 1 ng/ml)

**BIOPHEN Factor IXa (ACT. FIX)**  
Référence 221812

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**Factor IXa Calibrator**

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*Approché  
sans*

