

## ANALYSIS CERTIFICATE

**BIOPHEN™ FIX - #221806**

**Lot : F1701219 / F1701220**

**QC Release : 27/11/2017**

**Expiration date : 2020-04-06**

| <b>Components</b>             | <b>Volume</b> | <b>Exp.<br/>(months)</b> | <b>Lot #</b>             | <b>Exp Date</b> |
|-------------------------------|---------------|--------------------------|--------------------------|-----------------|
| R1 : Human Factor X -FVIII:C  | 2 vials       | 30                       | F171Y01219<br>F171Z01220 | 2020-04-06      |
| R2 : Activation Reagent (XIa) | 2 vials       | 30                       | F171Y01219<br>F171Z01220 | 2020-04-13      |
| R3 : Sxa-11 substrate         | 2 vials       | 30                       | F171Y01219<br>F171Z01220 | 2020-04-11      |
| R4 : Tris-BSA buffer          | 4 vials       | 30                       | F171Y01219<br>F171Z01220 | 2020-04-12      |

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| Analytical data  | Specifications      |                     |              |              |       |        |              |              |                     |              |  |  |     |           |              |              |  |  |     |              |  |
|--|---------------------|---------------------|--------------|--------------|-------|--------|--------------|--------------|---------------------|--------------|--|--|-----|-----------|--------------|--------------|--|--|-----|--------------|--|
| <p><b>1. <u>Human Factor X-VIII:C</u></b></p> <p><b>a. Reproducibility ( 100 % FIX)</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N =</td> <td style="width: 15%; text-align: center;"><b>10</b></td> <td style="width: 20%;">Mean (A405):</td> <td style="width: 50%; text-align: right;"><b>1,076</b></td> </tr> <tr> <td></td> <td></td> <td>CV:</td> <td style="text-align: right;"><b>1,4 %</b></td> </tr> </table> <p><b>b. Factor X concentration</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;"></td> <td style="width: 20%; text-align: right;"><b>122 %</b></td> <td style="width: 20%;"></td> </tr> </table>   | N =                 | <b>10</b>           | Mean (A405): | <b>1,076</b> |       |        | CV:          | <b>1,4 %</b> |                     | <b>122 %</b> |  | <p><b>≤ 2 %</b></p> <p><b>≥ 50 %</b></p> |     |           |              |              |  |  |     |              |  |
| N =  | <b>10</b>           | Mean (A405):        | <b>1,076</b> |              |       |        |              |              |                     |              |  |  |     |           |              |              |  |  |     |              |  |
|  |                     | CV:                 | <b>1,4 %</b> |              |       |        |              |              |                     |              |  |  |     |           |              |              |  |  |     |              |  |
|  | <b>122 %</b>        |                     |              |              |       |        |              |              |                     |              |  |  |     |           |              |              |  |  |     |              |  |
| <p><b>2. <u>Activation Reagent (XIIa - Thrombin - PLPs - calcium)</u></b></p> <p><b>a. Reproducibility ( 100 % FIX)</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N =</td> <td style="width: 15%; text-align: center;"><b>10</b></td> <td style="width: 20%;">Mean (A405):</td> <td style="width: 50%; text-align: right;"><b>1,078</b></td> </tr> <tr> <td></td> <td></td> <td>CV:</td> <td style="text-align: right;"><b>1,2 %</b></td> </tr> </table>   | N =                 | <b>10</b>           | Mean (A405): | <b>1,078</b> |       |        | CV:          | <b>1,2 %</b> | <p><b>≤ 2 %</b></p> |              |  |  |     |           |              |              |  |  |     |              |  |
| N =  | <b>10</b>           | Mean (A405):        | <b>1,078</b> |              |       |        |              |              |                     |              |  |  |     |           |              |              |  |  |     |              |  |
|  |                     | CV:                 | <b>1,2 %</b> |              |       |        |              |              |                     |              |  |  |     |           |              |              |  |  |     |              |  |
| <p><b>3. <u>SXa-11 substrate</u> (tested at 2.5 mg/ml for a,b)</b></p> <p><b>a. Blank value (N=10)</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 40%;"></td> <td style="width: 20%; text-align: right;"><b>Mean (A405):</b></td> <td style="width: 40%; text-align: right;"><b>0,158</b></td> </tr> </table> <p><b>b. Stability of substrate blank (A405)</b></p> <table border="1" style="width: 100%; border-collapse: collapse; margin: 5px 0;"> <thead> <tr> <th style="width: 20%;">Time</th> <th style="width: 30%;">Fresh</th> <th style="width: 50%;">7 days</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"><b>2-8°C</b></td> <td style="text-align: center;">0,158</td> <td style="text-align: center;">0,157</td> </tr> <tr> <td style="text-align: center;"><b>R.T.</b></td> <td style="background-color: black;"></td> <td style="text-align: center;">0,163</td> </tr> </tbody> </table> <p><b>c. Reproducibility ( 100 % FIX)</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N =</td> <td style="width: 15%; text-align: center;"><b>10</b></td> <td style="width: 20%;">Mean (A405):</td> <td style="width: 50%; text-align: right;"><b>1,068</b></td> </tr> <tr> <td></td> <td></td> <td>CV:</td> <td style="text-align: right;"><b>0,6 %</b></td> </tr> </table> |                     | <b>Mean (A405):</b> | <b>0,158</b> | Time         | Fresh | 7 days | <b>2-8°C</b> | 0,158        | 0,157               | <b>R.T.</b>  |  | 0,163                                    | N = | <b>10</b> | Mean (A405): | <b>1,068</b> |  |  | CV: | <b>0,6 %</b> | <p><b>A405 ≤ 0.30</b></p> <p><b>A405</b></p> <p><b>7 days ≤ 0.30</b></p> <p><b>≤ 2 %</b></p> |
|  | <b>Mean (A405):</b> | <b>0,158</b>        |              |              |       |        |              |              |                     |              |  |  |     |           |              |              |  |  |     |              |  |
| Time   | Fresh               | 7 days              |              |              |       |        |              |              |                     |              |  |  |     |           |              |              |  |  |     |              |  |
| <b>2-8°C</b>   | 0,158               | 0,157               |              |              |       |        |              |              |                     |              |  |  |     |           |              |              |  |  |     |              |  |
| <b>R.T.</b>  |                     | 0,163               |              |              |       |        |              |              |                     |              |  |  |     |           |              |              |  |  |     |              |  |
| N =  | <b>10</b>           | Mean (A405):        | <b>1,068</b> |              |       |        |              |              |                     |              |  |  |     |           |              |              |  |  |     |              |  |
|  |                     | CV:                 | <b>0,6 %</b> |              |       |        |              |              |                     |              |  |  |     |           |              |              |  |  |     |              |  |

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**ANALYSIS CERTIFICATE**

BIOPHEN™ FIX - #221806

Lot : F1701219 / F1701220

QC Release : 27/11/2017

Expiration date : 2020-04-06

| Analytical data  |              | Specifications  |              |              |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
|--|--------------|---|--------------|--------------|----------------|------------|-------|------------------|-------|---------------|----------------------------|---------|------|-----|-----|-------|--|-------|--|-----|----|-------|--|-------|--|----|----|-------|--|-------|--|----|----|-------|--|-------|--|------|----|-------|--|-------|--|-----------------------------|--|--------|--|-------|--|---------|--|------|--|------------|--|---------|------|---------|------|---------|------|----|----|-------|--|-------|--|----|-----|-------|--|-------|--|---|---|-------|--|-------|--|-----|-----|-------|--|-------|--|---|---|-------|--|-------|--|-----------------------------|--|--------|--|-------|--|---|
| <b>1. Calibration curve</b><br><u>High range:</u><br><table border="1"> <thead> <tr> <th colspan="2">FIX (%)</th> <th colspan="2">A405</th> <th colspan="2">Δ A405/min</th> </tr> <tr> <th>W. Bath</th> <th>STAR</th> <th>W. Bath</th> <th>STAR</th> <th>W. Bath</th> <th>STAR</th> </tr> </thead> <tbody> <tr> <td>200</td> <td>127</td> <td>1,524</td> <td></td> <td>0,658</td> <td></td> </tr> <tr> <td>100</td> <td>89</td> <td>1,027</td> <td></td> <td>0,510</td> <td></td> </tr> <tr> <td>50</td> <td>59</td> <td>0,638</td> <td></td> <td>0,362</td> <td></td> </tr> <tr> <td>25</td> <td>45</td> <td>0,351</td> <td></td> <td>0,273</td> <td></td> </tr> <tr> <td>12,5</td> <td>22</td> <td>0,163</td> <td></td> <td>0,127</td> <td></td> </tr> <tr> <td colspan="2">Linearity: R<sup>2</sup>=</td> <td>0,9826</td> <td></td> <td>0,988</td> <td></td> </tr> </tbody> </table><br><u>Low range:</u><br><table border="1"> <thead> <tr> <th colspan="2">FIX (%)</th> <th colspan="2">A405</th> <th colspan="2">Δ A405/min</th> </tr> <tr> <th>W. Bath</th> <th>STAR</th> <th>W. Bath</th> <th>STAR</th> <th>W. Bath</th> <th>STAR</th> </tr> </thead> <tbody> <tr> <td>20</td> <td>25</td> <td>0,936</td> <td></td> <td>0,616</td> <td></td> </tr> <tr> <td>10</td> <td>8,9</td> <td>0,576</td> <td></td> <td>0,278</td> <td></td> </tr> <tr> <td>5</td> <td>6</td> <td>0,336</td> <td></td> <td>0,187</td> <td></td> </tr> <tr> <td>2,5</td> <td>1,5</td> <td>0,172</td> <td></td> <td>0,039</td> <td></td> </tr> <tr> <td>1</td> <td>1</td> <td>0,060</td> <td></td> <td>0,016</td> <td></td> </tr> <tr> <td colspan="2">Linearity: R<sup>2</sup>=</td> <td>0,9882</td> <td></td> <td>0,992</td> <td></td> </tr> </tbody> </table> |              | FIX (%)   |              | A405         |                | Δ A405/min |       | W. Bath          | STAR  | W. Bath       | STAR                       | W. Bath | STAR | 200 | 127 | 1,524 |  | 0,658 |  | 100 | 89 | 1,027 |  | 0,510 |  | 50 | 59 | 0,638 |  | 0,362 |  | 25 | 45 | 0,351 |  | 0,273 |  | 12,5 | 22 | 0,163 |  | 0,127 |  | Linearity: R <sup>2</sup> = |  | 0,9826 |  | 0,988 |  | FIX (%) |  | A405 |  | Δ A405/min |  | W. Bath | STAR | W. Bath | STAR | W. Bath | STAR | 20 | 25 | 0,936 |  | 0,616 |  | 10 | 8,9 | 0,576 |  | 0,278 |  | 5 | 6 | 0,336 |  | 0,187 |  | 2,5 | 1,5 | 0,172 |  | 0,039 |  | 1 | 1 | 0,060 |  | 0,016 |  | Linearity: R <sup>2</sup> = |  | 0,9882 |  | 0,992 |  | Water Bath:<br>A405(200%) ≥ 1.2<br><br>ΔA405(100%-200%) ≥ 0.30<br><br>R <sup>2</sup> ≥ 0.98<br><br>Water Bath:<br>A405(20%) ≥ 0.4<br><br>ΔA405(10%-20%) ≥ 0.15<br><br>R <sup>2</sup> ≥ 0.98 |
| FIX (%)  |              | A405  |              | Δ A405/min   |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| W. Bath  | STAR         | W. Bath   | STAR         | W. Bath      | STAR           |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| 200  | 127          | 1,524   |              | 0,658        |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| 100  | 89           | 1,027   |              | 0,510        |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| 50   | 59           | 0,638   |              | 0,362        |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| 25   | 45           | 0,351   |              | 0,273        |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| 12,5   | 22           | 0,163   |              | 0,127        |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| Linearity: R <sup>2</sup> =  |              | 0,9826  |              | 0,988        |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| FIX (%)  |              | A405  |              | Δ A405/min   |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| W. Bath  | STAR         | W. Bath   | STAR         | W. Bath      | STAR           |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| 20   | 25           | 0,936   |              | 0,616        |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| 10   | 8,9          | 0,576   |              | 0,278        |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| 5  | 6            | 0,336   |              | 0,187        |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| 2,5  | 1,5          | 0,172   |              | 0,039        |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| 1  | 1            | 0,060   |              | 0,016        |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| Linearity: R <sup>2</sup> =  |              | 0,9882  |              | 0,992        |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| <b>2. Accuracy:</b><br><table border="1"> <thead> <tr> <th>Control</th> <th>TV*<br/>% FIX</th> <th>MV*<br/>% FIX</th> </tr> </thead> <tbody> <tr> <td>Normal Control</td> <td>88</td> <td>92</td> </tr> <tr> <td>Abnormal Control</td> <td>36</td> <td>39</td> </tr> </tbody> </table> * TV= Target Value - MV= Measured Value   |              | Control   | TV*<br>% FIX | MV*<br>% FIX | Normal Control | 88         | 92    | Abnormal Control | 36    | 39            | [ 78 - 98 ]<br>[ 31 - 41 ] |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| Control  | TV*<br>% FIX | MV*<br>% FIX  |              |              |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| Normal Control   | 88           | 92  |              |              |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| Abnormal Control   | 36           | 39  |              |              |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| <b>3. Detection threshold</b><br><br>High range < 1 %<br>Low range < 1 %   |              | ≤ 5%<br><br>≤ 2%  |              |              |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| <b>4. Performances</b><br><br>Normal plasmas: N= 12<br>Mean= 106 %<br>Range: 86 to 122 %<br>FIX Deficient Plasma: <1 % FIX<br>Purified FIX (5µg/ml) in R4 buffer : 85 %<br>Purified FIX (5µg/ml) in FIX Def. Plasma : 77 %<br>Δ reactivity: 10 %   |              | N ≥ 5<br><br>~ 70% - 130%<br><br>≤ 2 %<br><br>75-150%<br><br>75-150%<br><br>≤ 20% |              |              |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| <b>5. Stability of restored reagents (for the point "C" % FIX concentration)</b><br>Method: BME<br><table border="1"> <thead> <tr> <th></th> <th>Fresh</th> <th>8hrs RT</th> <th>24 hrs 2-8°C</th> </tr> </thead> <tbody> <tr> <td>A405</td> <td>1,528</td> <td>1,406</td> <td>1,486</td> </tr> </tbody> </table>  |              |   | Fresh        | 8hrs RT      | 24 hrs 2-8°C   | A405       | 1,528 | 1,406            | 1,486 | Δ A405 ≤ 0.20 |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
|  | Fresh        | 8hrs RT   | 24 hrs 2-8°C |              |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| A405   | 1,528        | 1,406   | 1,486        |              |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |
| <b>Comments :</b>  |              | <input checked="" type="checkbox"/> PASSED IN COMPLIANCE                          |              |              |                |            |       |                  |       |               |                            |         |      |     |     |       |  |       |  |     |    |       |  |       |  |    |    |       |  |       |  |    |    |       |  |       |  |      |    |       |  |       |  |                             |  |        |  |       |  |         |  |      |  |            |  |         |      |         |      |         |      |    |    |       |  |       |  |    |     |       |  |       |  |   |   |       |  |       |  |     |     |       |  |       |  |   |   |       |  |       |  |                             |  |        |  |       |  |   |

Date : 27/11/2017

QC Manager :

S. LECOURT

