



HYPHEN BioMed  
155 rue d'Eragny  
95000 Neuville-sur-Oise  
France

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN FVIII:C

**Product Code :** 221406

**Lot No. :** FB1313AX

**Expiration date :** 2025-02-01

| Components              | Quantity | Lot        | Expiration Date |
|-------------------------|----------|------------|-----------------|
| R1 : Human FX           | 2 vials  | FB1313h8AX | 2025-02-23      |
| R2 : Activation reagent | 2 vials  | FB1313h9AX | 2025-03-16      |
| R3 : Substrate          | 2 vials  | FB1313i1AX | 2025-02-15      |
| R4: Buffer              | 4 vials  | FB1313i2AX | 2025-02-01      |

| Analytical Data   | Specification                       | Result |
|---|-------------------------------------|--------|
| Calibration curve : reactivity, linearity, slope and accuracy | Water-Bath (High Range)             | 2.386  |
|   | A405 (200%) $\geq 1.60$             | 1.084  |
|   | Delta A405 (100 ; 200%) $\geq 0.60$ | 0.998  |
|   | $R^2 \geq 0.98$                     | PASS   |
| Measured values for controls in acceptance ranges             |                                     |        |
| Calibration curve : reactivity, linearity, and slope          | Water-Bath (Low Range)              | 1.313  |
|   | A405 (25%) $\geq 0.80$              | 0.651  |
|   | Delta A405 (12.5; 25%) $\geq 0.30$  | 0.996  |
|   | $R^2 \geq 0.98$                     |        |
| Detection Threshold High Range                                | $\leq 10\%$                         | < 2 %  |
| Detection Threshold Low Range                                 | $\leq 2\%$                          | < 1 %  |

### Calibration Curve for information HIGH RANGE

|         |       |       |       |       |       |
|---------|-------|-------|-------|-------|-------|
| Conc.   | 200%  | 100%  | 50%   | 25%   | 12.5% |
| OD WB   | 2.386 | 1.302 | 0.626 | 0.285 | 0.133 |
| Conc.   | 200%  | 133%  | 100%  | 50%   | 20%   |
| OD STAR | 0.778 | 0.534 | 0.409 | 0.203 | 0.070 |

|    | Acceptance Range | MV |
|----|------------------|----|
| NC | [ 80 - 100 ]     | 98 |
| AC | [ 29 - 40 ]      | 38 |

MV = Measured value

### Calibration Curve for information LOW RANGE

|         |       |       |       |       |
|---------|-------|-------|-------|-------|
| Conc.   | 25%   | 12.5% | 6.25% | 3.12% |
| OD WB   | 1.313 | 0.662 | 0.289 | 0.136 |
| Conc.   | 25%   | 12.5% | 6.25% | 1.56% |
| OD STAR | 1.234 | 0.649 | 0.323 | 0.075 |

*This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.*

Date of Approval : 2022-11-14

Quality Control Manager : **S. LECOURT**