



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

## CERTIFICATE OF ANALYSIS

**Product Description : BIOPHEN FVIII:C**

**Product Code : 221406**

**Lot No. : FC1120E5**

**Expiration date : 2025-10-07**

| Components              | Quantity | Lot        | Expiration Date |
|-------------------------|----------|------------|-----------------|
| R1 : Human FX           | 2 vials  | FC1120h8E5 | 2025-10-12      |
| R2 : Activation reagent | 2 vials  | FC1120h9E5 | 2025-11-29      |
| R3 : Substrate          | 2 vials  | FC1120i1E5 | 2025-10-07      |
| R4: Buffer              | 4 vials  | FC1120i2E5 | 2025-10-18      |

| Analytical Data   | Specification   | Result                         |
|---|---|--------------------------------|
| Calibration curve : reactivity, linearity, slope and accuracy | Water-Bath (High Range)<br>A405 (200%) $\geq$ 1.60<br>Delta A405 (100 ; 200%) $\geq$ 0.60<br>$R^2 \geq$ 0.98<br>Measured values for controls in acceptance ranges | 2.444<br>1.016<br>PASS<br>PASS |
| Calibration curve : reactivity, linearity, and slope          | Water-Bath (Low Range)<br>A405 (25%) $\geq$ 0.80<br>Delta A405 (12.5; 25%) $\geq$ 0.30<br>$R^2 \geq$ 0.98   | 1.503<br>0.709<br>PASS         |
| 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   | 2.444 | 1.426 | 0.689 | 0.318 | 0.147 |
| Conc.   | 200%  | 133%  | 100%  | 50%   | 20%   |
| OD STAR | 0.804 | 0.574 | 0.438 | 0.210 | 0.077 |

|    | Acceptance Range | MV (STAR) |
|----|------------------|-----------|
| NC | [ 80 - 100 ]     | 94        |
| AC | [ 27 - 38 ]      | 36        |

MV = Measured value

### Calibration Curve for information LOW RANGE

|         |       |       |       |       |
|---------|-------|-------|-------|-------|
| Conc.   | 25%   | 12.5% | 6.25% | 3.12% |
| OD WB   | 1.503 | 0.795 | 0.396 | 0.181 |
| Conc.   | 25%   | 12.5% | 6.25% | 1.56% |
| OD STAR | 1.184 | 0.618 | 0.328 | 0.080 |

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

Date of Approval : 2023-06-22

Quality Control Manager : S.LECOURT

