



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN FVIII:C

**Product Code :** 221406

**Lot No. :** FF1092VJ / FF1093

**Expiration date :** 2028-10-29

| Components              | Quantity | Lot                 | Expiration Date |
|-------------------------|----------|---------------------|-----------------|
| R1 : Human FX           | 2 vials  | FF1092h8VJ / FF1093 | 2028-11-13      |
| R2 : Activation reagent | 2 vials  | FF1092h9VJ / FF1093 | 2028-11-18      |
| R3 : Substrate          | 2 vials  | FF1092i1VJ / FF1093 | 2028-10-29      |
| R4: Buffer              | 4 vials  | FF1092i2VJ / FF1093 | 2028-11-12      |

| 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 | 2.489<br>1.171<br>0.999<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>$R^2 \geq 0.98$                                                        | 1.415<br>0.654<br>0.998         |

### Calibration Curve for information HIGH RANGE

|         |       |       |       |       |       |
|---------|-------|-------|-------|-------|-------|
| Conc. % | 12.5  | 25    | 50    | 100   | 200   |
| OD WB   | 0.115 | 0.244 | 0.589 | 1.318 | 2.489 |
| Conc. % | 18    | 44    | 88    | 152   | 183   |
| OD STAR | 0.059 | 0.161 | 0.341 | 0.582 | 0.727 |

|    | Acceptance Range | MV |
|----|------------------|----|
| NC | [84-104]         | 99 |
| AC | [29-39]          | 35 |

MV = Measured value

### Calibration Curve for information LOW RANGE

|         |       |       |       |       |       |
|---------|-------|-------|-------|-------|-------|
| Conc. % | 0     | 3.12  | 6.25  | 12.5  | 25    |
| OD WB   | 0.026 | 0.174 | 0.379 | 0.761 | 1.415 |
| Conc. % | 1.00  | 2.00  | 7.00  | 14.00 | 25    |
| OD STAR | 0.044 | 0.078 | 0.336 | 0.670 | 1.202 |

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

Date of Approval :

Quality Control Approval

Quality Control Manager :

26 JUN 2026

S.MONEUS