



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

## CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX

Product Code : 221802

Lot No. : FE3007R3 / FE3008

Expiration date : 2028-01-01

| Components             | Quantity | Lot                 | Expiration Date |
|------------------------|----------|---------------------|-----------------|
| R1 : Human FX- FVIII:C | 2 vials  | FE3007EBR3 / FE3008 | 2028-01-10      |
| R2 : Xla               | 2 vials  | FE3007ECR3 / FE3008 | 2028-01-24      |
| R3 : Substrate         | 2 vials  | FE3007EDR3 / FE3008 | 2028-01-01      |
| R4: Buffer             | 2 vials  | FE3007EER3 / FE3008 | 2028-01-01      |

| Analytical Data                                               | Specification                                                                                                                                                    | Result                          |
|---------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Calibration curve : reactivity, linearity, slope and accuracy | Water-Bath (High Range)<br>A405 (200%) $\geq 1.2$<br>Delta A405 (100 ; 200%) $\geq 0.30$<br>$R^2 \geq 0.98$<br>Measured values for controls in acceptance ranges | 1.415<br>0.386<br>0.993<br>PASS |
| Calibration curve : reactivity, linearity, and slope          | Water-Bath (Low Range)<br>A405 (20%) $\approx 1.00$<br>Delta A405 (10; 20%) $\geq 0.25$<br>$R^2 \geq 0.98$                                                       | 0.900<br>0.265<br>0.995         |
| Detection Threshold High Range                                | $\leq 5\%$                                                                                                                                                       | $< 1\%$                         |
| Detection Threshold Low Range                                 | $\leq 2\%$                                                                                                                                                       | $< 1\%$                         |

### Calibration Curve for information HIGH RANGE

|            |       |       |       |       |       |
|------------|-------|-------|-------|-------|-------|
| Conc. WB   | 0     | 12.5  | 25    | 50    | 100   |
| OD WB      | 0.021 | 0.275 | 0.451 | 0.701 | 1.030 |
| Conc. STAR | 0     | 25    | 50    | 63    | 100   |
| OD STAR    | 0.007 | 0.261 | 0.438 | 0.544 | 0.714 |

|    | Acceptance Range | MV (STAR) |
|----|------------------|-----------|
| NC | [75-95]          | 82        |
| AC | [29-39]          | 38        |

MV = Measured value

### Calibration Curve for information LOW RANGE

|            |       |       |       |       |       |
|------------|-------|-------|-------|-------|-------|
| Conc. WB   | 1     | 2.5   | 5     | 10    | 20    |
| OD WB      | 0.139 | 0.267 | 0.422 | 0.635 | 0.900 |
| Conc. STAR | 0.8   | 1     | 2     | 7     | 10    |
| OD STAR    | 0.046 | 0.064 | 0.120 | 0.302 | 0.400 |

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 Manager :

Quality Control Approval

21 AOUT 2025

S. LECOURT