



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

## CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ FIX

Product Code : 221806

Lot No. : FF0031TG / FE4226

Expiration date : 2028-05-26

| Components             | Quantity | Lot                | Expiration Date |
|------------------------|----------|--------------------|-----------------|
| R1 : FX(h)-FVIII(h)    | 2 vials  | FF0031EBTG/ FE4226 | 2028-06-30      |
| R2 : Activator reagent | 2 vials  | FF0031ECTG/ FE4226 | 2028-07-10      |
| R3 : Sxa-11            | 2 vials  | FF0031EDTG/ FE4226 | 2028-05-29      |
| R4 : Tris-BSA Buffer   | 4 vials  | FF0031EETG/ FE4226 | 2028-05-26      |

| 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 | 1.541<br>0.416<br>0.989<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>$R^2 \geq 0.98$                                                       | 0.996<br>0.333<br>0.996         |
| 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 | 0.291 | 0.493 | 0.777 | 1.125 |
| Conc. STAR | 22    | 44    | 54    | 87    | 145   |
| OD STAR    | 0.226 | 0.399 | 0.480 | 0.663 | 0.890 |

|    | Acceptance Range | MV (STAR) |
|----|------------------|-----------|
| NC | [77-97]          | 86        |
| AC | [29-39]          | 36        |

MV = Measured value

### Calibration Curve for information LOW RANGE

|            |       |       |       |       |       |
|------------|-------|-------|-------|-------|-------|
| Conc. WB   | 1     | 2.5   | 5     | 10    | 20    |
| OD WB      | 0.136 | 0.276 | 0.440 | 0.663 | 0.996 |
| Conc. STAR | 1     | 2     | 6     | 9     | 25    |
| OD STAR    | 0.050 | 0.104 | 0.258 | 0.352 | 0.685 |

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 :

23 FEB. 2026

p/b S.MONEUS