



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN™ FIX

Product Code : 221802

Lot No. : FD2046N5

Expiration date : 2027-04-02

| Components | Quantity | Lot | Expiration Date |
|------------------------|----------|------------|-----------------|
| R1 : Human FX- FVIII:C | 2 vials | FE0521EB3E | 2027-08-13 |
| R2 : Xla | 2 vials | FD2046ECN5 | 2027-04-25 |
| R3 : Substrate | 2 vials | FD2046EDN5 | 2027-04-03 |
| R4: Buffer | 2 vials | FD2046EEN5 | 2027-04-02 |

| Analytical Data | Specification | Result |
|---|--|---------------------------------|
| Calibration curve : reactivity, linearity, slope and accuracy | Water-Bath (High Range) A405 (200%) ≥ 1.2 Delta A405 (100 ; 200%) ≥ 0.30 R ² ≥ 0.98 Measured values for controls in acceptance ranges | 1.519 0.367 0.993 PASS |
| Calibration curve : reactivity, linearity, and slope | Water-Bath (Low Range) A405 (20%) ≈ 1.00 Delta A405 (10; 20%) ≥ 0.25 R ² ≥ 0.98 | 0.957 0.299 0.999 |
| Detection Threshold High Range | ≤ 5% | < 1% |
| Detection Threshold Low Range | ≤ 2% | < 1% |

Calibration Curve for information HIGH RANGE

| | | | | | |
|------------|-------|-------|-------|-------|-------|
| Conc. WB | 0 | 12.5 | 25 | 50 | 100 |
| OD WB | 0.072 | 0.333 | 0.518 | 0.791 | 1.151 |
| Conc. STAR | 0 | 25 | 50 | 63 | 100 |
| OD STAR | 0.034 | 0.246 | 0.451 | 0.539 | 0.719 |

| | Acceptance Range | MV (STAR) |
|----|------------------|-----------|
| NC | [75-95] | 86 |
| AC | [29-39] | 36 |

MV = Measured value

Calibration Curve for information LOW RANGE

| | | | | | |
|------------|-------|-------|-------|-------|-------|
| Conc. WB | 1 | 2.5 | 5 | 10 | 20 |
| OD WB | 0.171 | 0.302 | 0.443 | 0.658 | 0.957 |
| Conc. STAR | 1 | 2 | 7 | 10 | 29 |
| OD STAR | 0.098 | 0.150 | 0.311 | 0.405 | 0.823 |

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 :

04 MARS 2025

S. LECOURT