



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

## CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN™ FXIa

Product Code : 220412

Lot No. : FD19991A

Expiration date : 2027-03-28

| Components              | Quantity | Lot      | Expiration Date |
|-------------------------|----------|----------|-----------------|
| R1A : Human FX- FVIII:C | 2 vials  | FD19991A | 2027-04-02      |
| R1B : Human FIX         | 2 vials  | FD19991A | 2027-06-28      |
| R2 : Activation Reagent | 2 vials  | FD19991A | 2027-06-28      |
| R3 : Substrate          | 2 vials  | FD19991A | 2027-04-17      |
| R4: Buffer              | 2 vials  | FD19991A | 2027-04-23      |
| Cal : FXIa Calibrator   | 2 vials  | FD19991A | 2027-03-28      |

| Analytical Data                                               | Specification                                                                                                                                                   | Result                                  |
|---------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| Calibration curve : reactivity, linearity, slope and accuracy | Water-Bath<br>A405 (C) $\geq 1.50$<br>A405 (0) $\leq 0.100$<br>Delta A405 (C/2; C) $\geq 0.30$<br>$R^2 \geq 0.98$<br>Controls measured within acceptance ranges | 1.753<br>0.047<br>0.742<br>PASS<br>PASS |
| Detection Threshold                                           | $\leq 2.5$ mIU/ml                                                                                                                                               | < 1 mIU/ml                              |

### Calibration Curve for information

|         |       |       |       |       |       |
|---------|-------|-------|-------|-------|-------|
| Conc.   | 2.625 | 5.25  | 10.5  | 21    | 42    |
| OD WB   | 0.144 | 0.272 | 0.526 | 1.011 | 1.753 |
| Conc.   | 2.625 | 5.25  | 10.5  | 21    | 42    |
| OD STAR | 0.078 | 0.184 | 0.432 | 0.848 | 1.594 |

|    | Acceptance Range | MV |
|----|------------------|----|
| C1 | [ 10 - 16 ]      | 16 |
| C2 | [ 28 - 38 ]      | 34 |

MV = Measured value

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

Date of Approval : 23 JAN. 2025

Quality Control Manager : P.O. Resp. Labo CQ

Isabelle CORNUEJOLS