



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN FVIII:C

Product Code : 221402

Lot No. : F2001709

Expiration date : 2023-06-03

| Components | Quantity | Lot | Expiration Date |
|-------------------------|----------|------------|-----------------|
| R1 : Human FX | 2 vials | F201A01709 | 2023-07-07 |
| R2 : Activation reagent | 2 vials | F201A01709 | 2023-07-16 |
| R3 : Substrate | 2 vials | F201A01709 | 2023-06-03 |
| R4: Buffer | 4 vials | F201A01709 | 2023-06-09 |

| Analytical Data | Specification | Result |
|---|---|---|
| Calibration curve : reactivity, linearity, slope and accuracy | Water-Bath (High Range) A405 (200%) \geq 1.60 Delta A405 (100 ; 200%) \geq 0.60 $R^2 \geq$ 0.98 Measured values for controls in acceptance ranges | 2.33 1.04 0.99 Controls are in acceptance ranges |
| Calibration curve : reactivity, linearity, and slope | Water-Bath (Low Range) A405 (25%) \geq 0.80 Delta A405 (12.5; 25%) \geq 0.30 $R^2 \geq$ 0.98 | 1.38 0.64 0.99 |
| Detection Threshold High Range | \leq 10% | < 1 % |
| Detection Threshold Low Range | \leq 2 % | < 1 % |

Calibration Curve for information HIGH RANGE

| | | | | | |
|---------|-------|-------|-------|-------|-------|
| Conc. | 12.5 | 25 | 50 | 100 | 200 |
| OD WB | 0.129 | 0.274 | 0.613 | 1.289 | 2.332 |
| Conc. | 20 | 50 | 100 | 133 | 200 |
| OD STAR | 0.081 | 0.234 | 0.455 | 0.580 | 0.815 |

| | Acceptance Range | MV |
|----|------------------|-----|
| NC | [96 - 116] | 108 |
| AC | [28 - 38] | 34 |

MV = Measured value

Calibration Curve for information LOW RANGE

| | | | | |
|---------|-------|-------|-------|-------|
| Conc. | 3.12 | 6.25 | 12.5 | 25 |
| OD WB | 0.164 | 0.350 | 0.742 | 1.384 |
| Conc. | 1.25 | 6.25 | 12.5 | 25 |
| OD STAR | 0.069 | 0.348 | 0.693 | 1.270 |

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

Date of Approval : 2021-02-10

Quality Control Manager : S.LECOURT

