



A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN UFH CALIBRATOR
Product Code : 222301
Lot No. : FC08911F
Expiration date : 2025-09-02

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FC0891BS1F	2025-09-02
CAL 2	4 vials	FC0891BT1F	2025-09-02
CAL 3	4 vials	FC0891BU1F	2025-09-02
CAL 4	4 vials	FC0891BV1F	2025-09-02
CAL 5	4 vials	FC0891BW1F	2025-09-02

Analytical Data	Specification	Result
Concentration	CAL 1 : ≤ 0.05 IU/ml CAL 2 : 0.20 -0.45 IU/ml CAL 3 : 0.50 -0.80 IU/ml CAL 4 : 0.80 -1.15 IU/ml CAL 5 : 1.15 -1.50 IU/ml	0.00 0.32 0.66 0.99 1.33
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	PASS PASS

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

Date of Approval : 2023-04-13

Quality Control Manager : **S. LECOURT**