



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. :	FC18781G
Expiration date :	2026-02-17

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FC1878BS1G	2026-02-17
CAL 2	4 vials	FC1878BT1G	2026-02-17
CAL 3	4 vials	FC1878BU1G	2026-02-17
CAL 4	4 vials	FC1878BV1G	2026-02-17
CAL 5	4 vials	FC1878BW1G	2026-02-17

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 IU/ml 0.34 IU/ml 0.66 IU/ml 0.99 IU/ml 1.33 IU/ml
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	PASS

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**
21 SEP. 2023
S. LECOURT

Quality Control Manager :