



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. : FD1633M8
Expiration date : 2027-02-13

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FD1633BSM8	2027-02-13
CAL 2	4 vials	FD1633BTM8	2027-02-13
CAL 3	4 vials	FD1633BUM8	2027-02-13
CAL 4	4 vials	FD1633BVM8	2027-02-13
CAL 5	4 vials	FD1633BWM8	2027-02-13

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 IU/mL 0.33 IU/mL 0.67 IU/mL 0.99 IU/mL 1.30 IU/mL
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 : **Quality Control Approval** Quality Control Manager :

17 SEP. 2024

S. LECOURT