



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. : FF1161VP / FF1172
Expiration date : 2028-11-06

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FF1161BSVP / FF1172	2028-11-06
CAL 2	4 vials	FF1161BTVP / FF1172	2028-11-06
CAL 3	4 vials	FF1161BUVP / FF1172	2028-11-06
CAL 4	4 vials	FF1161BVVP / FF1172	2028-11-06
CAL 5	4 vials	FF1161BWVP / FF1172	2028-11-06

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 0.36 IU/ml 0.70 IU/ml 1.03 IU/ml 1.37 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

Quality Control Manager :

02 JUIN 2026

S.MONEUS