



A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS	
Product Description :	BIOPHEN ORGARAN CALIBRATOR
Product Code :	222201
Lot No. :	FD061719
Expiration date :	2026-09-12

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FD0617CG19	2026-09-12
CAL 2	4 vials	FD0617CH19	2026-09-12
CAL 3	4 vials	FD0617CI19	2026-09-12
CAL 4	4 vials	FD0617CJ19	2026-09-12
CAL 5	4 vials	FD0617CK19	2026-09-12

Analytical Data	Specification	Result
Concentration	CAL 1 : ≤ 0.05 U/ml CAL 2 : 0.30 -0.50 U/ml CAL 3 : 0.70 -0.90 U/ml CAL 4 : 1.10 -1.30 U/ml CAL 5 : 1.45 -1.75 U/ml	0.00 U/mL 0.40 U/mL 0.81 U/mL 1.22 U/mL 1.60 U/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.

Quality Control Approval

Date of Approval :

19 AVR. 2024

S. LECOURT

Quality Control Manager :