



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. : FE05891B / FE062814
Expiration date : 2027-08-28

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FE0589CG1B / FE062814	2027-08-28
CAL 2	4 vials	FE0589CH1B / FE062814	2027-08-28
CAL 3	4 vials	FE0589CI1B / FE062814	2027-08-28
CAL 4	4 vials	FE0589CJ1B / FE062814	2027-08-28
CAL 5	4 vials	FE0589CK1B / FE062814	2027-08-28

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 0.41 U/ml 0.84 U/ml 1.24 U/ml 1.66 U/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 :

28 MARS 2025

S. LECOURT