



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. : FA184217
Expiration date : 2024-03-26

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FA1842CG17	2024-03-26
CAL 2	4 vials	FA1842CH17	2024-03-26
CAL 3	4 vials	FA1842CI17	2024-03-26
CAL 4	4 vials	FA1842CJ17	2024-03-26
CAL 5	4 vials	FA1842CK17	2024-03-26

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 0.40 0.79 1.19 1.64
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 : 2021-10-21

Quality Control Manager : S.LECOURT

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