



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. : F2000609
Expiration date : 2022-10-16

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	F201400609	2022-10-16
CAL 2	4 vials	F201400609	2022-10-16
CAL 3	4 vials	F201400609	2022-10-16
CAL 4	4 vials	F201400609	2022-10-16
CAL 5	4 vials	F201400609	2022-10-16

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 U/mL 0.39 U/mL 0.79 U/mL 1.17 U/mL 1.53 U/mL
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	$R^2 > 0.99$ Measured values for controls in acceptance ranges

This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.

Date of Approval : 2020-05-15

Quality Control Manager : S.LECOURT

F820-11/BI/2201 -v10