



A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS	
Product Description :	BIOPHEN ARIXTRA CALIBRATOR
Product Code :	222501
Lot No. :	F2000539
Expiration date :	2022-10-08

Components	Quantity	Lot	Expiration Date
CAL 1	3 vials	F201400539	2022-10-08
CAL 2	3 vials	F201400539	2022-10-08
CAL 3	3 vials	F201400539	2022-10-08
CAL 4	3 vials	F201400539	2022-10-08

Analytical Data	Specification	Result
Concentration	CAL 1 : $\leq 0.05 \mu\text{g/mL}$ CAL 2 : $0.40 - 0.60 \mu\text{g/mL}$ CAL 3 : $0.90 - 1.10 \mu\text{g/mL}$ CAL 4 : $1.35 - 1.60 \mu\text{g/mL}$	0 $\mu\text{g/mL}$ 0.48 $\mu\text{g/mL}$ 0.99 $\mu\text{g/mL}$ 1.47 $\mu\text{g/mL}$
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: 2020-05-11

Quality Control Manager: S. LECOURT