

A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS

Product Description:

BIOPHEN EDOXABAN CALIBRATOR LOW

Product Code:

226401

Lot No.:

FC09951A

Expiration date:

2026-03-03

Components	Quantity	Lot	Expiration Date
CALI	4 vials	FC0995af1A	2026-03-03
CAL II	4 vials	FC0995ag1A	2026-03-03
CAL III	4 vials	FC0995ah1A	2026-03-03

Analytical Data	Specification	Result
Concentration	CAL II : < 15 ng/ml CAL III : 40 -60 ng/ml CAL III : 80 -120 ng/ml	0 mg/ml 48 mg/ml 105 mg/ml
Linearity and accuracy of calibration with values assigned	$\label{eq:R2} R^2 \geq 0.98$ 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: 2023-12-11

Quality Control Manager: S. LECOURT