



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN DiXal

Product Code : 221030

Lot No. : FE32401M / FE3366

Expiration date : 2028-02-06

Components	Quantity	Lot	Expiration Date
R1 : Human FXa	3 vials	FE3240AX1M / FE3266	2028-03-13
R2 : Substrate	3 vials	FE3240AY1M / FE3266	2028-03-06
R3: Buffer	4 vials	FE3240AZ1M / FE3266	2028-02-06

Analytical Data	Specification	Result
Calibration curve : linearity, slope and accuracy on STAR	Delta A405 (Rivaroxaban Std range) ≥ 1.0 $R^2 \geq 0.98$ Measured values for Rivaroxaban Controls in acceptance ranges	1.65 PASS PASS

Calibration Curve for information

Equipment :

CN

Standard Range

Rivaroxaban Conc.-ng/mL	0	263	547
OD	1.866	1.261	0.777
R ²	0.991		

Low Range

Rivaroxaban Conc.-ng/mL	0	52	128
OD	1.242	0.835	0.510
R ²	0.996		

* TV= Target Value - MV= Measured Value

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[70 - 130] ng/mL	101
C2	[263 - 363] ng/mL	320

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[17 - 37] ng/mL	28
CII	[52 - 78] ng/mL	66

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 Manager :

09 OCT. 2025
COLLIN Virgile
Coordinateur technique CA