



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN DiXal

Product Code : 221030

Lot No. : FC25701K

Expiration date : 2026-08-11

Components	Quantity	Lot	Expiration Date
R1 : Human FXa	3 vials	FC2570AX1K	2026-08-14
R2 : Substrate	3 vials	FC2570AY1K	2026-08-11
R3: Buffer	4 vials	FC2570AZ1K	2026-08-21

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	1.72 PASS PASS
Detection Threshold for Rivaroxaban Standard range	≤ 50 ng/ml	<1 ng/mL
Detection Threshold for Rivaroxaban Low range	≤ 10 ng/ml	<1 ng/mL

Calibration Curve for information

Equipment :

CS

Standard Range

Rivaroxaban Conc.-ng/mL	0	263	547
OD	1.753	1.167	0.716
R ²	0.99		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[67 - 125] ng/mL	93
C2	[258 - 356] ng/mL	314

Low Range

Rivaroxaban Conc.-ng/mL	0	52	128
OD	1.146	0.769	0.475
R ²	0.994		

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[15 - 35] ng/mL	24
CII	[49 - 73] ng/mL	62

* TV= Target Value - MV= Measured Value

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 :

Quality Control Approval

25 MARS 2024

S. LECOURT