



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

CERTIFICATE OF ANALYSIS

Product Description : BIOPHEN DiXal

Product Code : 221030

Lot No. : F2001650

Expiration date : 2023-05-28

Components	Quantity	Lot	Expiration Date
R1 : Human FXa	3 vials	F201D01650	2023-06-05
R2 : Substrate	3 vials	F201D01650	2023-06-03
R3: Buffer	4 vials	F201D01650	2023-05-28

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	1.58 0.99 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 :

CS5100

Standard Range

Rivaroxaban Conc.-ng/mL	0	255	527
OD	1.757	1.209	0.762
R ²	0.99		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[74 - 138] ng/ml	115
C2	[271 - 375] ng/ml	353

Low Range

Rivaroxaban Conc.-ng/mL	0	53	101
OD	1.139	0.754	0.536
R ²	1.00		

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[15 - 35] ng/ml	27
CII	[64 - 96] ng/ml	80

* 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 : 2020-01-07

Quality Control Manager : S.LECOURT