



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

## CERTIFICATE OF ANALYSIS

**Product Description:** BIOPHEN DiXal  
**Product Code:** 221030  
**Lot No.:** F2000933  
**Expiration date:** 2023-01-06

Components	Quantity	Lot	Expiration Date
R1 : Human FXa	3 vials	F201C00933	2023-01-09
R2 : Substrate	3 vials	F201C00933	2023-01-07
R3: Buffer	4 vials	F201C00933	2023-01-06

Analytical Data	Specification	Result
Calibration curve : linearity, slope and accuracy on STAR	Delta A405 (Rivaroxaban Std range) $\geq 1.0$ $R^2 \geq 0.98$ Measured values for Rivaroxaban Controls in acceptance ranges	1.6 0.99 Controls in acceptance ranges
Detection Threshold for Rivaroxaban Standard range	$\leq 50$ ng/ml	$< 1$ ng/ml
Detection Threshold for Rivaroxaban Low range	$\leq 10$ ng/ml	$< 4$ ng/ml

### Calibration Curve for information

Equipment : STAR

#### Standard Range

Rivaroxaban Conc.-ng/mL	0	275	554
OD	2.245	1.382	0.664
R <sup>2</sup>	0.994		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[ 73 - 135 ] ng/ml	102
C2	[259 - 357 ] ng/ml	318

#### Low Range

Rivaroxaban Conc.-ng/mL	0	53	130
OD	1.979	1.123	0.522
R <sup>2</sup>	0.998		

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[ 14 - 34 ] ng/ml	24
CII	[ 64 - 96 ] ng/ml	82

\* 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: 2020-07-29

Quality Control Manager: S. LECOURT

