



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

## CERTIFICATE OF ANALYSIS

**Product Description:** BIOPHEN DiXal  
**Product Code:** 221030  
**Lot No.:** FA17501G  
**Expiration date:** 2024-03-08

Components	Quantity	Lot	Expiration Date
R1 : Human FXa	3 vials	FA1750AX1G	2024-03-24
R2 : Substrate	3 vials	FA1750AY1G	2024-03-16
R3: Buffer	4 vials	FA1750AZ1G	2024-03-08

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	1.684 $R^2 = 0.998$ PASS
Detection Threshold for Rivaroxaban Standard range	$\leq 50$ ng/ml	< 3 ng/ml
Detection Threshold for Rivaroxaban Low range	$\leq 10$ ng/ml	< 1 ng/ml

### Calibration Curve for information

Equipment : STAR

#### Standard Range

Rivaroxaban Conc.-ng/mL	0	275	554
OD	2.308	1.308	0.624
R <sup>2</sup>	0.99		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[ 70 - 130 ] ng/ml	117
C2	[ 266 - 368 ] ng/ml	328

#### Low Range

Rivaroxaban Conc.-ng/mL	0	53	130
OD	2.025	1.149	0.560
R <sup>2</sup>	1.00		

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[ 14 - 34 ] ng/ml	26
CII	[ 63 - 95 ] ng/ml	89

\* 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: 2021-11-04

Quality Control Manager: S. LECOURT