



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN DiXal

**Product Code :** 221030

**Lot No. :** FC12251H

**Expiration date :** 2024-11-01

Components	Quantity	Lot	Expiration Date
R1 : Human FXa	3 vials	FB0859AX1H	2024-11-09
R2 : Substrate	3 vials	FB0859AY1H	2024-11-04
R3: Buffer	4 vials	FB0859AZ1H	2024-11-01

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	1.7 0.99 PASS
Detection Threshold for Rivaroxaban Standard range	$\leq 50$ ng/ml	< 1 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	263	547
OD	2.478	1.521	0.757
R <sup>2</sup>	0.99		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[ 70 - 130 ] ng/ml	117
C2	[ 266 - 368 ] ng/ml	315

#### Low Range

Rivaroxaban Conc.-ng/mL	0	52	128
OD	2.167	1.315	0.656
R <sup>2</sup>	0.99		

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[ 17 - 37 ] ng/ml	29
CII	[ 66 - 98 ] ng/ml	87

\* 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 : 2023-05-02

Quality Control Manager : S. LECOURT

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