



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN DiXal  
**Product Code :** 221030  
**Lot No. :** FD17531L  
**Expiration date :** 2027-02-26

Components	Quantity	Lot	Expiration Date
R1 : Human FXa	3 vials	FD1753AX1L	2027-04-09
R2 : Substrate	3 vials	FD1753AY1L	2027-03-15
R3: Buffer	4 vials	FD1753AZ1L	2027-02-26

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	1.85 PASS PASS
Detection Threshold for Rivaroxaban Standard range	$\leq 50$ ng/ml	<15 ng/mL
Detection Threshold for Rivaroxaban Low range	$\leq 10$ ng/ml	<3 ng/mL

### Calibration Curve for information

Equipment :

CS

#### Standard Range

Rivaroxaban Conc.-ng/mL	0	263	547
OD	1.843	1.226	0.720
R <sup>2</sup>	0.992		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[ 67 - 125 ] ng/mL	84
C2	[ 258 - 356 ] ng/mL	302

#### Low Range

Rivaroxaban Conc.-ng/mL	0	52	128
OD	1.209	0.815	0.485
R <sup>2</sup>	0.997		

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[ 15 - 35 ] ng/mL	25
CII	[ 49 - 73 ] ng/mL	61

\* 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**

14 NOV. 2024  
S. LECOURT

