



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

## CERTIFICATE OF ANALYSIS

**Product Description** BIOPHEN DTI

**Product Code :** 220202

**Lot No. :** FE38491L / FE3850

**Expiration date :** 2028-04-07

Components	Quantity	Lot	Expiration Date
R1 : Substrate	2 vials	FE3849DG1L / FE3850	2028-04-08
R2 : Thrombin	2 vials	FE3849DH1L / FE3850	2028-05-01
R3: Tris BSA Buffer	2 vials	FE3849DI1L / FE3850	2028-04-07

Analytical Data	Specification	Result
Calibration curve : linearity and accuracy	R <sup>2</sup> ≥ 0.98 Measured values for Dabigatran Controls in acceptance ranges	PASS PASS

### Calibration Curve for information

Equipment :

#### Standard Range

Dabigatran Conc.-ng/mL	0	270	432
OD	0.873	0.621	0.512
R <sup>2</sup>	0.998		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[ 84 - 126 ] ng/mL	113
C2	[ 216 - 292 ] ng/mL	275

#### Low Range

Dabigatran Conc.-ng/mL	0	43	110
OD	0.743	0.552	0.382
R <sup>2</sup>	0.997		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[ 17 - 37 ] ng/mL	20
C2	[ 50 - 76 ] ng/mL	68

\* 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 Approval**

Quality Control Manager :

11 DEC. 2025  
S. LECOURT

