



A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN DTI

Product Code : 220202

Lot No. : FE25911K / FE26141B

Expiration date : 2027-11-06

Components	Quantity	Lot	Expiration Date
R1 : Substrate	2 vials	FE2591DG1K / FE26141B	2027-11-06
R2 : Thrombin	2 vials	FE2591DH1K / FE26141B	2027-11-21
R3: Tris BSA Buffer	2 vials	FE2591DI1K / FE26141B	2027-11-12

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

Calibration Curve for information

Equipment :

CN

Standard Range

Dabigatran Conc.-ng/mL	0	270	544
OD	0.906	0.643	0.469
R ²	0.999		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[82 - 124] ng/ml	115
C2	[212 - 286] ng/ml	268

Low Range

Dabigatran Conc.-ng/mL	0	43	110
OD	1.548	1.097	0.730
R ²	0.994		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[17 - 37] ng/ml	27
C2	[50 - 76] ng/ml	65

* 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 :

30 JUN 2025

S. LECOURT