



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. : FE2955

Expiration date : 2027-12-24

Components	Quantity	Lot	Expiration Date
R1 : Substrate	2 vials	FE2955	2027-12-28
R2 : Thrombin	2 vials	FE2955	2028-01-07
R3: Tris BSA Buffer	2 vials	FE2955	2027-12-24

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

Calibration Curve for information

Equipment :

CN

Standard Range

Dabigatran Conc.-ng/mL	0	270	432
OD	0.892	0.638	0.534
R ²	0.999		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[84 - 126] ng/mL	117
C2	[216 - 292] ng/mL	278

Low Range

Dabigatran Conc.-ng/mL	0	43	110
OD	0.746	0.561	0.397
R ²	0.995		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[17 - 37] ng/mL	20
C2	[50 - 76] 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 : 08 AOUT 2025

Quality Control Manager : Isabelle CORNUEJOLS
Resp. Labo CQ