


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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN DTI

Product Code : 220202

Lot No. : FC00361E

Expiration date : 2025-06-21

Components	Quantity	Lot	Expiration Date
R1 : Substrate	2 vials	FC0036DG1E	2025-06-21
R2 : Thrombin	2 vials	FC0036DH1E	2025-06-29
R3: Tris BSA Buffer	2 vials	FC0036DI1E	2025-06-27

Analytical Data	Specification	Result
Calibration curve : linearity and accuracy	$R^2 \geq 0.98$ Measured values for Dabigatran Controls in acceptance ranges	PASS
Detection Threshold for Dabigatran Standard range	≤ 20 ng/ml	< 9 ng/ml
Detection Threshold for Dabigatran Low range	≤ 20 ng/ml	< 9 ng/ml

Calibration Curve for information

Equipment :

STAR

Standard Range

Dabigatran Conc.-ng/mL	0	270	432
OD	1.774	1.323	0.943
R ²	0.994		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[90 - 134] ng/ml	113
C2	[286 - 388] ng/ml	314

Low Range

Dabigatran Conc.-ng/mL	0	70	110
OD	1.842	1.193	0.920
R ²	0.994		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[13 - 33] ng/ml	20
C2	[54 - 80] ng/ml	67

* 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 : 2023-03-28

Quality Control Manager : S. LECOURT