



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN DTI

Product Code : 220202

Lot No. : FC25241F / FD001113

Expiration date : 2026-06-05

Components	Quantity	Lot	Expiration Date
R1 : Substrate	2 vials	FC2524DG1F / FD001113	2026-06-22
R2 : Thrombin	2 vials	FC2524DH1F / FD001113	2026-07-24
R3: Tris BSA Buffer	2 vials	FC2524DI1F / FD001113	2026-06-05

Analytical Data	Specification	Result
Calibration curve : linearity and accuracy	R ² ≥ 0.98 Measured values for Dabigatran Controls in acceptance ranges	PASS
Detection Threshold for Dabigatran Standard range	≤ 30 ng/ml	< 30 ng/ml
Detection Threshold for Dabigatran Low range	≤ 10 ng/ml	< 10 ng/ml

Calibration Curve for information

Equipment : STAR

Standard Range

Dabigatran Conc.-ng/mL	0	270	432
OD	1.49	1.007	0.836
R ²	0.996		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[90 - 134] ng/ml	130
C2	[286-388] ng/ml	353

Low Range

Dabigatran Conc.-ng/mL	0	70	110
OD	1.453	0.887	0.687
R ²	0.994		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[16 - 36] ng/ml	29
C2	[60 - 90] ng/ml	81

* 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 :

Sophie LEGOURT
Deputy Director Quality Control

Quality Control Approval

27 FFV. 2024