



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN DTI

Product Code : 220202

Lot No. : FE02341J / FE02851A

Expiration date : 2027-07-16

Components	Quantity	Lot	Expiration Date
R1 : Substrate	2 vials	FE0234DG1J / FE02851A	2027-07-27
R2 : Thrombin	2 vials	FE0234DH1J / FE02851A	2027-08-06
R3: Tris BSA Buffer	2 vials	FE0234DI1J / FE02851A	2027-07-16

Analytical Data	Specification	Result
Calibration curve : linearity and accuracy	$R^2 \geq 0.98$ Measured values for Dabigatran Controls in acceptance ranges	PASS PASS
Detection Threshold for Dabigatran Standard range	≤ 30 ng/ml	< 19 ng/ml
Detection Threshold for Dabigatran Low range	≤ 10 ng/ml	< 3 ng/ml

Calibration Curve for information

Equipment :

STAR

Standard Range

Dabigatran Conc.-ng/mL	0	270	544
OD	1.550	1.113	0.830
R^2	0.998		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[82 - 124] ng/ml	109
C2	[212 - 286] ng/ml	245

Low Range

Dabigatran Conc.-ng/mL	0	43	110
OD	1.569	1.105	0.745
R^2	0.990		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[16 - 36] ng/ml	26
C2	[54 - 82] ng/ml	72

* 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 MARS 2025

S. LECOURT

