



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

CERTIFICATE OF ANALYSIS

Product Description: BIOPHEN DTI

Product Code: 220202

Lot No.: F2001479

Expiration date: 2023-04-29

Components	Quantity	Lot	Expiration Date
R1 : Substrate	2 vials	F201901479	2023-04-29
R2 : Thrombin	2 vials	F201901479	2023-05-08
R3: Tris BSA Buffer	2 vials	F201901479	2023-05-05

Analytical Data	Specification	Result
Calibration curve: linearity and accuracy	R ² ≥ 0.98 Measured values for Dabigatran Controls in acceptance ranges	PASS PASS
Detection Threshold for Dabigatran Standard range	≤ 20 ng/ml	< 1 ng/ml
Detection Threshold for Dabigatran Low range	≤ 20 ng/ml	< 1 ng/ml

Calibration Curve for information

Equipment: STAR

Standard Range

Dabigatran Conc.-ng/mL	0	270	432
OD	1.436	1.057	0.875
R ²	1.000		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[84 - 126] ng/ml	110
C2	[255 - 345] ng/ml	305

Low Range

Dabigatran Conc.-ng/mL	0	43	85
OD	1.300	0.919	0.709
R ²	0.990		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[13 - 33] ng/ml	22
C2	[54 - 80] ng/ml	68

* 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: 2020-11-26

Quality Control Manager: S. LECOURT