



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN DTI

Product Code : 220202

Lot No. : F2000323

Expiration date : 2022-08-26

Components	Quantity	Lot	Expiration Date
R1 : Substrate	2 vials	F201800323	2022-08-29
R2 : Thrombin	2 vials	F201800323	2022-08-29
R3: Tris BSA Buffer	2 vials	F201800323	2022-08-26

Analytical Data	Specification	Result
Calibration curve : linearity and accuracy	R ² ≥ 0.98 Measured values for Dabigatran Controls in acceptance ranges	R ² = 0.99 Measured values for Dabigatran Controls in acceptance ranges
Detection Threshold for Dabigatran Standard range	≤ 20 ng/ml	< 7 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	43	289	552
OD	1.161	0.823	0.591
R ²	0.998		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[82 - 124] ng/ml	95
C2	[253 - 343] ng/ml	286

Low Range

Dabigatran Conc.-ng/mL	0	48	95
OD	1.272	0.854	0.620
R ²	0.996		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[17 - 37] ng/ml	30
C2	[61 - 91] ng/ml	77

* 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: 2020-03-31

Quality Control Manager: S. LECOURT