



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

CERTIFICATE OF ANALYSIS

Product Description BIOPHEN DTI

Product Code : 220202

Lot No. : FA09671B

Expiration date : 2023-10-27

Components	Quantity	Lot	Expiration Date
R1 : Substrate	2 vials	FA0967DG1B	2023-10-28
R2 : Thrombin	2 vials	FA0967DH1B	2023-11-06
R3: Tris BSA Buffer	2 vials	FA09671B (*)	2023-10-27

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	< 2 ng/ml

Calibration Curve for information

Equipment :

STAR

Standard Range

Dabigatran Conc.-ng/mL	0	270	432
OD	1.401	1.016	0.842
R ²	0.998		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[84 - 126] ng/ml	99
C2	[255 - 345] ng/ml	282

Low Range

Dabigatran Conc.-ng/mL	0	43	85
OD	1.426	1.023	0.800
R ²	0.992		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[13 - 33] ng/ml	22
C2	[54 - 80] ng/ml	71

* 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 : 2021-06-02

Quality Control Manager : S.LECOURT

(*) NCI 1923 : R3 lot number FA09671B will be readed D11B on CS analyser using barcode functionality

