



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

## CERTIFICATE OF ANALYSIS

### Product Description BIOPHEN DTI

**Product Code :** 220202

**Lot No. :** F1900868

**Expiration date :** 2021-12-31

Components	Quantity	Lot	Expiration Date
R1 : Substrate	2 vials	F191700868	2022-01-01
R2 : Thrombin	2 vials	F191700868	2022-01-10
R3: Tris BSA Buffer	2 vials	F191700868	2021-12-31

Analytical Data	Specification	Result
Calibration curve : linearity and accuracy	R <sup>2</sup> ≥ 0.98 Measured values for Dabigatran Controls in acceptance ranges	0.998 Controls are in acceptance range
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	1.629	1.183	0.981
R <sup>2</sup>	0.998		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[ 83 - 125 ] ng/ml	102
C2	[ 273 - 369 ] ng/ml	339

#### Low Range

Dabigatran Conc.-ng/mL	0	43	85
OD	1.641	1.207	0.950
R <sup>2</sup>	0.994		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[ 15 - 35 ] ng/ml	26
C2	[ 62 - 92 ] ng/ml	80

\* 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 : 2019-08-30

Quality Control Manager :

**S. LECOURT**