



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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002K

Lot No. : F2001655

Expiration date : 2023-05-27

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	F204R01655	2023-05-27
R2 : Human Calcium Thrombin	3 vials	F204R01655	2023-05-29

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 50 ± 10 sec R ² ≥ 0.98 Controls measured in acceptance ranges	45.2 0.99 Controls in compliance range
Normal Plasma	Dabigatran conc. < 10 ng / mL	<10

Calibration Curve for information

Equipment :

STAR

Standard Range

Dabigatran Conc.-ng/mL	0	270	432
CT (Sec.)	28.9	55.6	71.8
R ²	0.99		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[87-131] ng/ml	111
C2	[258-348] ng/ml	297

Low Range

Dabigatran Conc.-ng/mL	0	43	85
CT (Sec.)	28.0	47.2	64.6
R ²	0.99		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[17-37] ng/ml	27
C2	[64-96] ng/ml	84

* 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 : 2020-12-22

Quality Control Manager : S.LECOURT

P. Lecourt