



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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002L

Lot No. : F2001041

Expiration date : 2023-01-23

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	F201701041	2023-01-23
R2 : Human Calcium Thrombin	3 vials	F201701041	2023-03-10

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 50 ± 10 sec $R^2 \geq 0.98$ Controls measured in acceptance ranges	52.0 sec 0.99 Controls in acceptance range
Normal Plasma	Dabigatran conc. < 10 ng / mL	< 1 ng / mL

Calibration Curve for information

Equipment :

STAR

Standard Range

Dabigatran Conc.-ng/mL	0	270	432
CT (Sec.)	28.9	59.9	77.5
R ²	0.99		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[87-131] ng/ml	102
C2	[258-348] ng/ml	279

Low Range

Dabigatran Conc.-ng/mL	0	70	110
CT (Sec.)	28.4	59.2	76.3
R ²	0.999		

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[17-37] ng/ml	26
CII	[61-91] ng/ml	75

* 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 : 2020-10-01

Quality Control Manager : S.LECOURT