




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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002K

Lot No. : F1900695

Expiration date : 2021-11-27

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	F191500695	2021-11-27
R2: Human Calcium Thrombin	3 vials	F191500695	2021-12-03

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 65 ± 25 sec R ² ≥ 0.98	54.0 sec 0.998
	Controls measured in acceptance ranges	Controls in range
Normal Plasma	Dabigatran conc. < 10 ng / mL	< 1 ng/mL

Calibration Curve for information

Equipment :

STAR

Standard Range

Dabigatran Conc.-ng/mL	45	278	532
CT (Sec.)	43.6	81.7	118.7
R ²	0.999		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[86 - 130] ng/ml	106
C2	[263 - 355] ng/ml	322

Low Range

Dabigatran Conc.-ng/mL	0	53	106
CT (Sec.)	32.6	65.5	91.3
R ²	0.995		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[15 - 35] ng/ml	28
C2	[62 - 92] ng/ml	76

* 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 : 2019-07-01

Quality Control Manager :

S.LECOURT