



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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002K

Lot No. : F2000024

Expiration date : 2022-07-02

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	F201600024	2022-07-02
R2 : Human Calcium Thrombin	3 vials	F201600024	2022-07-08

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 65 ± 25 sec $R^2 \geq 0.98$ Controls measured in acceptance ranges	41 0.99 Controls are in acceptance ranges
Normal Plasma	Dabigatran conc. < 10 ng / mL	< 1 ng / mL

Calibration Curve for information

Equipment :

STAR

Standard Range

Dabigatran Conc.-ng/mL	0	270	544
CT (Sec.)	28.0	54.5	77.1
R ²	0.998		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[87 - 131] ng/ml	104
C2	[286 - 388] ng/ml	334

Low Range

Dabigatran Conc.-ng/mL	0	43	85
CT (Sec.)	27.4	45.8	60.7
R ²	0.995		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[17 -37] ng/ml	28
C2	[61 - 91] ng/ml	81

* 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: 2020-02-04

Quality Control Manager: S. LECOURT