



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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002L

Lot No. : FA10596S

Expiration date : 2023-11-13

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	FA1059AP6S	2023-11-13
R2 : Human Calcium Thrombin	3 vials	FA1059AQ6S	2023-11-17

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	47.8 sec PASS PASS
Normal Plasma	Dabigatran conc. < 10 ng / mL	PASS

Calibration Curve for information

Equipment :

STAR

Standard Range

Dabigatran Conc.-ng/mL	0	270	432
CT (Sec.)	30.4	60.7	76.3
R ²	0.999		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[84 - 126] ng/ml	107
C2	[255 - 345] ng/ml	300

Low Range

Dabigatran Conc.-ng/mL	0	43	110
CT (Sec.)	29.6	51.4	78.2
R ²	0.995		

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[13 - 33] ng/ml	23
CII	[54 - 80] ng/ml	70

* 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 : 2021-06-14

Quality Control Manager : S.LECOURT