



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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002K

Lot No. : FC0081CQ

Expiration date : 2025-06-28

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	FC0081APCQ	2025-06-28
R2 : Human Calcium Thrombin	3 vials	FC0081AQCQ	2025-07-04

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 50 ± 10 sec	52 sec
	R ² ≥ 0.98	PASS
	Controls measured in acceptance ranges	PASS
Normal Plasma	Dabigatran conc. < 10 ng / mL	PASS

Calibration Curve for information

Equipment :

STAR

Standard Range

Dabigatran Conc.-ng/mL	0	270	544
CT (Sec.)	28.5	58.0	91.1
R ²	0.99		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[82- 124] ng/ml	103
C2	[257- 347] ng/ml	300

Low Range

Dabigatran Conc.-ng/mL	0	70	110
CT (Sec.)	27.7	57.7	78.3
R ²	0.99		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[13- 33] ng/ml	23
C2	[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 : 2023-02-06

Quality Control Manager :

S. LECOURT