



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

## CERTIFICATE OF ANALYSIS

**Product Description : HEMOCLOT THROMBIN INHIBITORS**

**Product Code : CK002K**

**Lot No. : FC2447HH**

**Expiration date : 2026-05-25**

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	FC2447HH	2026-05-25
R2 : Human Calcium Thrombin	3 vials	FC2447HH	2026-06-01

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 50 ± 10 sec	53.8 sec
	R <sup>2</sup> ≥ 0.98	PASS
	Controls measured in acceptance ranges	PASS
Normal Plasma	Dabigatran conc. < 10 ng / mL	PASS

### Calibration Curve for information

#### Standard Range

Dabigatran Conc.-ng/mL	0	270	544
CT (Sec.) STAR	30.7	62.3	95.7
CT (Sec.) CS	41.1	79.3	122.8

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[90-134]	103
C2	[286-388]	317

#### Low Range

Dabigatran Conc.-ng/mL	0	43	110
CT (Sec.) STAR	28.9	49.2	79.2
CT (Sec.) CS	41.1	57.8	87.6

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[16-36]	21
C2	[60-90]	66

\* 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.*

### Quality Control Approval

Date of Approval :

05 JAN. 2024

Quality Control Manager :

S. LECOURT