



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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002L

Lot No. : FC2448HJ/FC2449HK

Expiration date : 2026-05-25

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	FC2448HJ/FC2449APHK	2026-05-25
R2 : Human Calcium Thrombin	3 vials	FC2448HJ/FC2449AQHK	2026-06-01

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 50 ± 10 sec $R^2 \geq 0.98$ Controls measured in acceptance ranges	54.1 sec PASS 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	62.6	96.5
CT (Sec.) CS	41.9	80.6	123.4

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[90-134]	102
C2	[286-388]	317

Low Range

Dabigatran Conc.-ng/mL	0	43	110
CT (Sec.) STAR	29.6	50.1	80.9
CT (Sec.) CS	41.0	59.0	88.3

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[16-36]	21
CII	[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.

Date of Approval :

Quality Control Manager :

Quality Control Approval

05 JAN. 2024

S. LECOURT