



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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002L

Lot No. : FE3994

Expiration date : 2028-05-09

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	FE3994	2028-05-09
R2 : Human Calcium Thrombin	3 vials	FE3994	2028-05-14

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 50 ± 10 sec	52.2 sec
	$R^2 \geq 0.98$	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	27.1	57.2	90.3
CT (Sec.) CS	39.5	75.8	117.0

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[82-122]	92
C2	[213-289]	233

Low Range

Dabigatran Conc.-ng/mL	0	43	110
CT (Sec.) STAR	25.9	46.4	77.7
CT (Sec.) CS	39.4	56.3	85.6

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[17-37]	23
CII	[50-76]	59

* 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 Approval

Quality Control Manager :

11 DEC. 2025
S. LECOURT