



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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002L

Lot No. : FD1046KK

Expiration date : 2026-11-16

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	FD1046APKK	2026-11-16
R2 : Human Calcium Thrombin	3 vials	FD1046AQKK	2026-11-23

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 50 ± 10 sec	55.0 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	27.7	59.4	94.3
CT (Sec.) CS	40.7	80.6	129.4

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[82-124]	96
C2	[212-286]	233

Low Range

Dabigatran Conc.-ng/mL	0	43	110
CT (Sec.) STAR	26.0	48.2	81.0
CT (Sec.) CS	40.0	59.5	93.2

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[15-35]	25
CII	[40-80]	64

* 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 :

20 JUIN 2024

Quality Control Manager :

S. LECOURT