



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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002L

Lot No. : FC2013FY

Expiration date : 2026-03-10

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	FC2013APFY	2026-03-10
R2 : Human Calcium Thrombin	3 vials	FC2013AQFY	2026-03-15

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 50 ± 10 sec	55.8 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	27.5	60.2	94.9
CT (Sec.) CS	40.2	81.8	131.9

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[90-134]	113
C2	[286-388]	335

Low Range

Dabigatran Conc.-ng/mL	0	43	110
CT (Sec.) STAR	26.0	47.5	77.8
CT (Sec.) CS	40.2	62.0	98.6

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[16-36]	28
CII	[60-90]	74

* 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 OCT. 2023

S. LECOURT