

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002K

Lot No. : FE3477S4 / FE3476

Expiration date : 2028-02-26

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	FE3477APS4 / FE3476	2028-02-26
R2 : Human Calcium Thrombin	3 vials	FE3477AQS4 / FE3476	2028-03-03

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 50 ± 10 sec	55.8 sec
	R ² ≥ 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	28.6	61.7	96.3
CT (Sec.) CS	41.4	80.1	127.0

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[82-124]	100
C2	[212-286]	240

Low Range

Dabigatran Conc.-ng/mL	0	43	110
CT (Sec.) STAR	27.6	50.3	82.9
CT (Sec.) CS	40.5	60.8	93.8

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[17-37]	24
C2	[50-76]	60

* 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 :

29 SEP. 2025

S. LECOURT

