



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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002L

Lot No. : FF0515UK / FF0543

Expiration date : 2028-08-14

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	FF0515APUK / FF0543	2028-08-14
R2 : Human Calcium Thrombin	3 vials	FF0515AQUK / FF0543	2028-08-20

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	48.1 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	30.0	57.8	88.6
CT (Sec.) CS	38.4	72.5	110.7

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[84-126]	103
C2	[216-292]	252

Low Range

Dabigatran Conc.-ng/mL	0	43	110
CT (Sec.) STAR	28.9	48.2	76.1
CT (Sec.) CS	38.7	54.9	80.3

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[17-37]	22
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 Manager :

Quality Control Approval

17 MARS 2026

S.MONEUS