



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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002L

Lot No. : FA17667Y

Expiration date : 2024-03-11

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	FA1766AP7Y	2024-03-11
R2 : Human Calcium Thrombin	3 vials	FA1766AQ7Y	2024-03-17

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 50 ± 10 sec	50.9
	$R^2 \geq 0.98$	PASS
	Controls measured in acceptance ranges	PASS
Normal Plasma	Dabigatran conc. < 10 ng / mL	PASS

Calibration Curve for information

Equipment :

STAR

Standard Range

Dabigatran Conc.-ng/mL	0	270	432
CT (Sec.)	30.2	60.0	80.4
R^2	0.999		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[82-124] ng/ml	101
C2	[257-347] ng/ml	307

Low Range

Dabigatran Conc.-ng/mL	0	43	110
CT (Sec.)	29.4	49.0	79.5
R^2	0.999		

QC:	TV* (ng/ml)	MV* (ng/ml)
CI	[17-37] ng/ml	25
CII	[64-96] ng/ml	79

* 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 : 2021-10-11

Quality Control Manager : S.LECOURT