



HYPHEN BioMed  
155 rue d'Eragny  
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France

## CERTIFICATE OF ANALYSIS

**Product Description : HEMOCLOT THROMBIN INHIBITORS**

**Product Code : CK002K**

**Lot No. : FA10616U**

**Expiration date : 2023-11-13**

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	FA1061AP6U	2023-11-13
R2 : Human Calcium Thrombin	3 vials	FA1061AQ6U	2023-11-17

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : $50 \pm 10$ sec $R^2 \geq 0.98$ Controls measured in acceptance ranges	44.5 1 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.)	29.2	56.5	73.3
R <sup>2</sup>	0.99		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[ 84 - 126 ] ng/ml	112
C2	[ 255 - 345 ] ng/ml	312

#### Low Range

Dabigatran Conc.-ng/mL	0	43	110
CT (Sec.)	28.5	48.4	74.5
R <sup>2</sup>	0.99		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[ 13 - 33 ] ng/ml	24
C2	[ 54 - 80 ] ng/ml	72

\* 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 : 2021-06-14

Quality Control Manager : S.LECOURT