



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

## CERTIFICATE OF ANALYSIS

**Product Description : HEMOCLOT THROMBIN INHIBITORS**

**Product Code : CK002K**

**Lot No. : F1801202 / F1801203**

**Expiration date : 2021-02-07**

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	F181401202 / F181301203	2021-03-08
R2 : Human Calcium Thrombin	3 vials	F181401202 / F181301203	2021-02-07

Analytical Data	Specification	Result
Dabigatran standard calibration curve on STAR	Delta CT (50-500 ng / mL) : 65 ± 25 sec R <sup>2</sup> ≥ 0.98	49.0 sec 0.997
	Controls measured in acceptance ranges	Controls in range
Normal Plasma	Dabigatran conc. < 10 ng / mL	< 10 ng/mL

### Calibration Curve for information

Equipment : STAR

#### Standard Range

Dabigatran Conc.-ng/mL	43	257	489
CT (Sec.)	36.2	59.2	82.7
R <sup>2</sup>	1.000		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[ 81 - 121 ] ng/ml	109
C2	[ 255 - 345 ] ng/ml	318

#### Low Range

Dabigatran Conc.-ng/mL	0	53	106
CT (Sec.)	30.2	53.6	74.3
R <sup>2</sup>	0.998		

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[ 13 - 33 ] ng/ml	29
C2	[ 54 - 82 ] 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 : 2019-06-19

Quality Control Manager :

**M.PEYRAFITTE**