



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 $R^2 \geq 0.98$	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 ²	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 ²	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