HYPHEN BioMed

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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002K

Lot No. : FF1681WS / FF1746

Expiration date : 2029-01-09

Components	Quantity	Lot	Expiration Date
R1: Normal Pooled Plasma	3 vials	FF1681APWS / FF1746	2029-01-09
R2 : Human Calcium Thrombin	3 vials	FF1681AQWS / FF1746	2029-01-22

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	53.2 sec PASS PASS
Normal Plasma	Dabigatran conc. < 10 ng / mL	PASS

Calibration Curve for information

Standard Range

Dabigatran Conc.-ng/mL	0	250	503
CT (Sec.) STAR	28.6	59.6	86.9
CT (Sec.) CS	39.6	74.7	109.2

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[84-129]	99
C2	[216-292]	259

Low Range

Dabigatran Conc.-ng/mL	0	43	110
CT (Sec.) STAR	28.0	49.1	79.9
CT (Sec.) CS	38.5	55.5	83.9

QC:	TV* (ng/ml)	MV* (ng/ml)
C1	[17-37]	25
C2	[58-86]	69

* 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

25 AOUT 2026

S. LECOURT