



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

CERTIFICATE OF ANALYSIS

Product Description : HEMOCLOT THROMBIN INHIBITORS

Product Code : CK002L

Lot No. : F2001656-F2001666

Expiration date : 2023-05-27

| Components | Quantity | Lot | Expiration Date |
|-----------------------------|----------|-----------------------|-----------------|
| R1: Normal Pooled Plasma | 3 vials | F204S01656-F201501666 | 2023-05-27 |
| R2 : Human Calcium Thrombin | 3 vials | F204S01656-F201501666 | 2023-05-29 |

| Analytical Data | Specification | Result |
|---|--|--|
| Dabigatran standard calibration curve on STAR | Delta CT (50-500 ng / mL) : 50 ± 10 sec R ² ≥ 0.98 Controls measured in acceptance ranges | 51.3 0.99 Controls in compliance range |
| 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 | 59.8 | 78.0 |
| R ² | 0.99 | | |

| QC: | TV* (ng/ml) | MV* (ng/ml) |
|-----|-------------------|-------------|
| C1 | [87-131] ng/ml | 102 |
| C2 | [258-348] ng/ml | 292 |

Low Range

| | | | |
|------------------------|------|------|------|
| Dabigatran Conc.-ng/mL | 0 | 43 | 85 |
| CT (Sec.) | 28.2 | 48.8 | 68.3 |
| R ² | 0.99 | | |

| QC: | TV* (ng/ml) | MV* (ng/ml) |
|-----|-----------------|-------------|
| CI | [17-37] ng/ml | 24 |
| CII | [64-96] ng/ml | 84 |

* 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 : 2020-12-22

Quality Control Manager : S.LECOURT