



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

## CERTIFICATE OF ANALYSIS

### Product Description BIOPHEN DTI

**Product Code :** 220202

**Lot No. :** FA09681C

**Expiration date :** 2023-10-27

| Components          | Quantity | Lot          | Expiration Date |
|---------------------|----------|--------------|-----------------|
| R1 : Substrate      | 2 vials  | FA0968DG1C   | 2023-10-28      |
| R2 : Thrombin       | 2 vials  | FA0968DH1C   | 2023-11-06      |
| R3: Tris BSA Buffer | 2 vials  | FA09681C (*) | 2023-10-27      |

| Analytical Data                                   | Specification   | Result       |
|---|---|--------------|
| Calibration curve : linearity and accuracy        | R <sup>2</sup> ≥ 0.98<br>Measured values for Dabigatran Controls in acceptance ranges | PASS<br>PASS |
| Detection Threshold for Dabigatran Standard range | ≤ 20 ng/ml  | < 1 ng/ml    |
| Detection Threshold for Dabigatran Low range      | ≤ 20 ng/ml  | < 3 ng/ml    |

### Calibration Curve for information

Equipment : STAR

#### Standard Range

| Dabigatran Conc.-ng/mL | 0     | 270   | 432   |
|------------------------|-------|-------|-------|
| OD                     | 1.435 | 1.057 | 0.890 |
| R <sup>2</sup>         | 1.000 |       |       |

| QC: | TV* (ng/ml)         | MV* (ng/ml) |
|-----|---------------------|-------------|
| C1  | [ 84 - 126 ] ng/ml  | 92          |
| C2  | [ 255 - 345 ] ng/ml | 266         |

#### Low Range

| Dabigatran Conc.-ng/mL | 0     | 43    | 85    |
|------------------------|-------|-------|-------|
| OD                     | 1.488 | 1.090 | 0.850 |
| R <sup>2</sup>         | 0.994 |       |       |

| QC: | TV* (ng/ml)       | MV* (ng/ml) |
|-----|-------------------|-------------|
| C1  | [ 13 - 33 ] ng/ml | 24          |
| C2  | [ 54 - 80 ] ng/ml | 71          |

\* 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 : 2021-06-02

Quality Control Manager : S.LECOURT

(\*) NCI 1923 : R3 lot number FA09681C will be readed DI1C on CS analyser using barcode functionality

