

TECHNOCLOT[®] DTI






For research use only



REF 5100025 TECHNOCLOT DTI

2 x 20 T.

Symbols key

| | | | |
|---|-----------------------|---|------------------------------|
|  | Manufacturer |  | Expiry date |
|  | Storage temperature / |  | Consult instructions for use |
| RUO | For research use only |  | Determinations |
| AQUA | Distilled water | LOT | Lot |
| BUF | Reaction buffer | MTP | Microtiter plate |
| CAL | Calibrator | REF | Catalogue number |
| CONJ | Conjugate | RTU | Ready to use |
| CONT | Control | STOP | Stop solution |
| DIL | Dilute or dissolve in | SUB | Substrate |
| INC | Incubation buffer | WASH | Washing solution concentrate |



TECHNOCLOT® DTI

PRODUCT DESCRIPTION

INTENDED USE

TECHNOCLOT DTI is used for the determination of anticoagulant activity of the direct thrombin inhibitor (DTI) Dabigatran in human citrated plasma. Dabigatran is the active component of the oral anticoagulant pro-drug, Dabigatran Etxilate which has been approved for various applications under the tradename Pradaxa. To measure Dabigatran in plasma, the diluted sample is mixed with normal human plasma (R1). Clotting is then initiated by adding the thrombin reagent (R2). The clotting time measured is directly related to the concentration of the Dabigatran in the sample plasma.

COMPOSITION

| | |
|---------|---|
| vial | Reagents |
| 2 x 2mL | Reagent 1 (R1): Normal Plasma, lyophilized |
| 2 x 2mL | Reagent 2 (R2): Bovine Thrombin, stabilizer, polybrene, lyophilized |

MATERIAL REQUIRED (not supplied with the kit)

- Pipette: 200 µL
- Distilled water
- Diluent, Sodium Chloride solution 0.9 %
- Calibration plasma

REF 5090210 TECHNOVIEW Dabigatran Calibrators 1-4 4 x 1 mL

- Control plasma

REF 5090214 TECHNOVIEW Dabigatran Control Low 5 x 1 mL

REF 5090212 TECHNOVIEW Dabigatran Control High 5 x 1 mL

WARNING AND PRECAUTIONS

- RUO for *research use only*.
- All blood and plasma samples and products have to be regarded as potentially infectious and handled with appropriate care and in compliance with the biosafety regulations in force and must be disposed of in the same way as hospital waste.

STABILITY AND STORAGE

The expiry date printed on the labels applies to storage of the unopened bottles at +2...8 °C.

Stability after reconstitution:

| | | |
|---------|---------|---------|
| | RT* | -20 °C |
| R1 & R2 | 8 hours | 1 month |

*=room temperature

The vials can be frozen up to two freeze/thaw cycles. Upon storage, caps should be screwed tightly

TEST PROCEDURE

PREPARATION OF PLASMA SAMPLES

Plasma separation:

Mix 9 parts of venous blood and 1 part of Sodium Citrate Solution (0.11 mol/L) and centrifuge for 15 min at a RCF of at least 2500 g (corresponding to DIN 58905). Store the plasma at room temperature.

PREPARATION OF REAGENT

Carefully open the vial and reconstitute the lyophilised reagent in the volume of distilled water indicated on the vial label. Slowly rotate the vial. Allow the reconstituted reagent to stand for 10 minutes at room temperature. For standardisation a reconstitution time of 30 min is recommended.

PERFORMANCE OF THE TEST

CEVERON ALPHA AND OTHER ANALYZERS

Technoclone provides application sheets for Ceveron alpha. The application sheets contain analyzer/assay specific handling and performance information, which may differ from that provided in this instruction for use. In this case the information contained in the application sheet supersedes the information in this instruction for use. Please consult the instruction manual of the Ceveron alpha. Application sheets for other analyzers are available on request.

MANUAL

The assay is calibrated with the Dabigatran Calibrators.

Calibrators, controls and specimen samples are diluted 1:8 with 0.9 % sodium chloride solution.

Pipetting scheme:

| |
|---|
| 0.05 mL diluted calibrator, control, specimen plasma (room temperature) |
| + 0.10 mL TECHNOCLOT DTI Reagent 1 (room temperature) |
| Incubate for 2 minutes at 37°C |
| + 0.10 mL TECHNOCLOT DTI Reagent 2 (room temperature) |
| determine the point of coagulation |

LIMITATION OF THE TEST

The values found when testing control plasma should be compared to the value given on the control batch table for the corresponding lot of control plasma. If the results obtained are outside the recommended range, avoid measuring specimen samples until the problem is solved.

Blood activation, during specimen collection and plasma preparation, may interfere in the assay. No significant interference of excess or deficiency of other plasma factors was identified in compliance with the test principle using diluted test plasma and a substrate plasma in excess. However special caution is recommended for plasmas presenting a constitutional or acquired hypocoagulability. In order to get the optimal assay performances, the working instructions must be carefully followed. Incubation times indicated have to be followed strictly.

ANALYSES OF RESULTS

EVALUATION USING A REFERENCE CURVE (example using Ceveron)

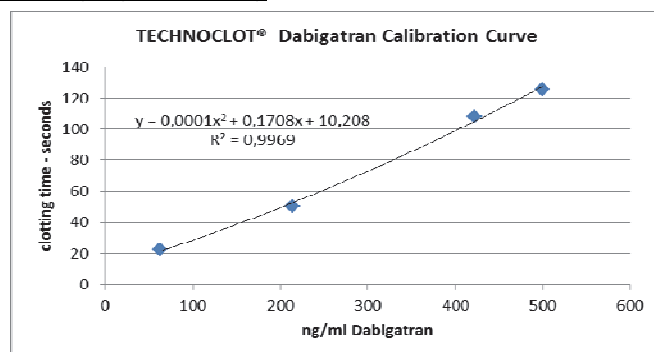
Setting up a reference curve:

X axis: Concentration ng/mL (Dabigatran)

Y axis: Seconds

Draw the best-fit calibration line with linear axis

Example (using Ceveron alpha):



Measuring concentration of samples

All samples diluted 1:8 can be read off directly from the appropriate reference curve. For other dilutions the value read off from the calibration curve has to be multiplied by the additional dilution factor. It is recommended to run controls with every test in order to ensure accuracy and reproducibility of the results.

REFERENCE RANGE

Pradaxa does not in general require routine anticoagulant testing. Please refer to the local product information or Summary of Product Characteristics (SmPC) for Pradaxa for more information.

ASSAY RANGE

The assay range for Dabigatran is 40 – 500 ng/ml.

The limit of detection (LoD) for Dabigatran is 50 ng/ml.

PERFORMANCE CHARACTERISTICS

Performance data are given below. Results obtained in individual laboratories may differ.

PRECISION

Reproducibility was determined with different samples (in series and day to day). The following results were obtained:

| Sample | Intra assay | | Inter assay | |
|------------|-------------|----------|-------------|----------|
| | Sample 1 | Sample 2 | Sample 1 | Sample 2 |
| n | 21 | 21 | 16 | 16 |
| Mean ng/mL | 114 | 326 | 132 | 347 |
| CV (%) | 6.7 | 4.2 | 7.7 | 7.1 |

COMPARISON OF METHODS OR CORRELATION

Following correlation was obtained in comparing TECHNOCLOT DTI (Technoclone) with HEMOCLOT TI (Hyphen) Dabigatran method:

Dabigatran samples: n=27 R² = 0.986

INTERFERENCES

Heparin: no interference up to 1.2 IU/mL UFH or LMW

LITERATURE

Please contact Technoclone or your local distributor.