

IVD REF



Intended Use

TEClot TT reagent can be used manually or on semi-automated and automated instruments. The test is commonly applied to detect various sources of interference with normal blood coagulation. Prolongation of the thrombin clotting time can be taken as a qualitative indication of abnormal fibrinogen levels (high or low), or the presence of interfering substances such 's or heparin. Quantitative evaluation of the possible causes of prolonged thrombin clotting time should be performed as follow-up studies, such as APTT or chromogenic assay for heparin, Clauss fibrinogen, FDP determinations, heparin neutralization by protamine sulphate or polybrene¹, normal plasma mixing studies² or reptilase assay³ to distinguish between hypofibrinogenaemia and FDP effects.

A0401-020

| | Contents & Determin | ations | | | | | |
|----------------------|---------------------|------------|------------|--|--|--|--|
| | Product | TECIot TT | | | | | |
| Cat.No. A0401-020 | | | | | | | |
| TT Reagent* 10 x 2mL | | | | | | | |
| | Determinations | | | | | | |
| | Coatron M | Coatron A4 | Coatron A6 | | | | |
| | 800 | 400 | 800 | | | | |

*Each vial contains a lyophilized preparation of 26 units bovine thrombin with buffers and stabilizers. The final thrombin concentration in test application for Coatron systems is 4.33 E/mL.

Preparation

Reconstitute the reagent with 2 mL purified water. Allow to stand for 5 minutes then mix gently by inversion.

Storage & Stability

Unopened reagents are stable until the expiration date shown on the label stored at 2°-8°C. Reconstituted reagent:

| | -20 °C | 12 °C | 20-25 °C | | | | | | |
|------------------------------------|---------|----------|----------|--|--|--|--|--|--|
| TT Reagent | 1 month | 24 hours | 8 hours | | | | | | |
| The vials can be only frozen once. | | | | | | | | | |

Precautions

Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV and HCV. However products from human blood should be considered as potentially infectious.

Specimen collection and storage⁴

1. Obtain venous blood by clean vein puncture.

- 2. Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
- Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
 Separate plasma after centrifugation and store in plastic or siliconised glass tube.
- 5. Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

Stability of plasma: 4h at 18-26°C 8h at 2-8° 14d at -20°C 6m at -70°C

| Proce A. Au | Procedure A. Automated Method: Coatron A | | | | | | | | | | | | |
|----------------|---|-------|-----|------|-----|--|------------|------------|------|--|--------|----------|----|
| TT A0401-020 | | A4 | | A6 | | | | A4 | A6 | | | A4 | A6 |
| PAT | Patient | 100µl | CP1 | 50µl | CP1 | | Incubation | C |)s | | SENS | 2 | |
| BUF | - | 0µl | P00 | 0μΙ | P00 | | Maxtime | 12 | 120s | | POINTS | - | |
| CLR | - | 0μΙ | - | 0μΙ | - | | Unit | 3 | | | MIX | No | |
| DP | - | 0µl | P00 | 0μΙ | P00 | | Method | Coag | | | Clean | 0 | 2 |
| RO | - | 0µl | P00 | 0µl | P00 | | Math | Math - | | | Multi | 1 | 3 |
| R1 | - | 0μΙ | P00 | 0μΙ | P00 | | CT-Mech | CT-Mech No | | | S-Corr | 0% | |
| R2 | TT Reagent | 50µl | P27 | 25µl | P50 | | Deadtime | 5s | | | T-Corr | 20% - 3s | |

(Refer to instrument operation manual for detailed instructions)

B. Manual Method: Coatron M system

- Pipette 50 ul of sample into a test cuvette. Incubate at 37°C for 1-2 minutes
- Add 25 µl of TEClot TT reagent and simultaneously start test. 2.
- 3. Record the clotting time in seconds.

For other instrument, please refer to your instrument manual for more detailed instrument specific instructions.

Expected Results

Typical normal results are 12 - 24 s ⁶. However results are influenced by the method of clot detection and can vary from laboratory to laboratory. Each laboratory is recommended to establish its own normal range on the specific instrument used.

Quality Control

TEControl or other commercial control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory stored in closed polypropylen tubes at -20°C is stable for 30 days

Limitations

- A. Specimen Collection, AVOID:
- 1. Use only plastic tubes or siliconised glass.
- 2. Delayed mixing of blood with anticoagulant. 3. Contamination with tissue thromboplastin.
- 4. Improper ratio of anticoagulant with blood.
- 5. Hemolyzed, icteric or lipemic samples may interfere optical systems 6. Heparin below 1U/mL will not interfere results.
- B. Laboratory Techniques
 - 1. Perform tests at 37°C
 - 2. Use only high purity water.
 - 3. Optimum pH is 7.0-7.5.

As well as the cause of elongated Thrombin Clotting Times indicated above, As well as the cause of elongated that many systemic amyloidosis patients with bleeding complications may have a circulating inhibitor which prolongs the Thrombin Clotting Time⁵. Also therapeutic levels of heparin may entirely abolish clotting in the Thrombin Clotting Time test, although neutralization with protamine sulphate or polybrene should correct the Thrombin Clotting Time¹.

Performance Characteristics

| Precision: | CV% (within run) | CV% (inter-runs) | | | |
|---------------------|-------------------------|------------------|--|--|--|
| Normal control | < 3.0 | < 5.0 | | | |
| Abnormal control | < 3.0 | < 5.0 | | | |
| (Typical performanc | e on instrument Coatror | n M4) | | | |

Warranty

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

References

- Laposata et al. The Clinical Haemostasis Handbook, Yearbook Medical 1 Publishers Inc., p219, 1989.
- Thompson, A.R. and Harker, L.A. Manual of Haemostasis and Thrombosis. 3rd Ed., F.A. Davis Co., p62,1983. 2.
- DeMott, W.R., in: Laboratory Test Handbook, 2nd Ed., Jacobs D.S. et al Eds., 3. Lexi.Comp Inc., p432-433, 1990.
- 4. NCCLS: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays
- Gastineau, D.A. et al. Inhibitor of the Thrombin Time in Systemic Amyloidosis: A Common Coagulation Abnormality Blood, 1991, 77: 2637-5 2640
- 6. Lothar Thomas, Labor und Diagnose, 6.Auflage, 2005, Page846

| Symbo | ols key: | | | | | | | | |
|-------------|----------------|-----|-------------------------|-----|-------------------|-----|---------------------|--------|-----------------------------------|
| М | Expiry date | IVD | In Vitro Diagnostica | ф | Biological hazard | REF | Catalogue Number | []ii | Consult accompanying documents |
| ~~ / | Store at 2-8°C | Œ | EU conformity | *** | Manufacturer | LOT | Lot. Number | EC REP | Authorized Representative |