THROMBIN TIME

DIAGNOSTIC KIT FOR DETERMIANTION OF THROMBIN TIME

Kit name	Kit size	Cat. No
THROMBIN TIME	10 x 1 ml	K-560

INTRODUCTION
Fibrinogen (Factor I) is a soluble plasma protein that is instrumental in the normal coagulation process. Following trauma or injury, fibrinogen is converted to an insoluble fibrin clot by a two-stage process. In stage one, thrombin cleaves fibrinogen to form a fibrin monomer. In stage two, these fibrin monomers aggregate to form the insoluble fibrin polymers that are recognized as the end point in thrombin clotting assays.
The TT may be prolonged when any of the following conditions exist:

- decreased fibrinogen levels,
- dysfunctional fibrinogen molecules (dysfibrinogenemina),
- heparin therapy,
- increased Fibrinogen Degradation Products (FDP),
- presence of abnormal serum globulins or increased immunoglobulins.

METHOD PRINCIPLE
A low potency thrombin is added to undiluted plasma and clot formation is timed.

REAGENTS
Package

	THROMBIN TIME
THROMBIN TIME-REAGENT	10 x 1 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package.

Reagents preparation and stability
Reconstitute with 1 ml distilled water. Agitate gently until solution is complete. The reconstituted material is stable for 4 hours when stored in original glass container at 2-8°C. Reconstituted material is stable for 8 hours when stored in plastic at 2-8°C.

Concentrations in the test

bovine thrombin	< 1.0 %
BSA fraction V	1.0 %
sodium chloride	0.9 %
calcium chloride	0.222 %

Warnings and notes

- Product for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

ADDITIONAL EQUIPMENT

- a mechanical or photo-optical means of clot detection;
- general laboratory equipment.

SPECIMEN
A. Anticoagulant- sodium citrate - 3.2% (0.105M).
B. Specimen collection:

1. Obtain venous blood.
2. Immediately mix 9 parts blood with 1 part anticoagulant, mix well by inversion of tube.
3. Centrifuge the specimen at 1000 rcf for 15 min.
4. Remove plasma from the tube within 60 min using a plastic pipette and store in a plastic tube.
5. Test plasma sample within 2 hours, otherwise store frozen and thaw just prior to use.

PROCEDURE
Kit is suitable for use with manual, mechanical or automated instrument for clot detection. See instrument manufacturers instructions for full details.

Manual assay

1. Add 0.2 ml test plasma to cuvette and prewarm to 37°C for 3 minutes.
2. Add 0.2 ml THROMBIN TIME-REAGENT to the test plasma. Mix and start timer.
3. Note time for clot formation.
4. Perform duplicate determinations.

Calculation
Calculate the mean clotting time of duplicate determinations (to the nearest 0.1 second) for each sample.

REFERENCE VALUES
Generally, the normal reference interval for thrombin time is 8-14 seconds.
Laboratories should establish a normal reference interval for thrombin time measurements.

LIMITATIONS
A. Plasma samples with hematocrits outside the range of 20-55% may be improperly anticoagulated and should be adjusted appropriately.
B. Freezing and thawing plasma can affect results.

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. Bick, R.L., et al. Hematology: Clinical and Laboratory Practice. Mosby: 1993.
2. NCCLS. 1991. Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays; Approved Guideline 3rd Edition. NCCLS document H21-A3. NCCLS, Wayne, PA, 1998.
3. Powers, L.W. Diagnostic Hematology: Clinical and Technical Principles. Mosby: 1989.

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