CE
In Vitro
Diagnostic

Behnk Elektronik

BE TT Thrombin Time

REF 771400: RE (12 x 2 mL)

Reagent for determination of Thrombin Time (TT) in human plasma

PRINCIPLE [4]

In the presence of a standardised quantity of thrombin, a normal plasma will coagulate in a specific and constant time.

CLINICAL SIGNIFICANCE [1] [2]

The Thrombin Time is a simple and rapid test which allows exploring the fibrin formation. However, the TT remains normal in deficiencies of factor XIII (fibrin stabilising factor). It is recommended to perform TT before any specific assays are attempted, when an increase time of the overall tests cannot be explained (PT, APTT).
Increased Thrombin Time may indicate:
• An abnormality of the fibrinogen: qualitative (dysfibrinogenaemia), quantitative (severe hypofibrinogenaemia or congenital afibrinogenaemia, acquired hypofibrinogenaemia (DIC, fibrinolysis, liver disease)
• The presence of antithrombins which may be therapeutic (heparin, hirudin, argatroban…) or abnormal (myeloma proteins inhibiting the polimerization of fibrin monomers)

REAGENTS

RE **TT** Thrombin Reagent
Calcic freeze-dried thrombin (Bovin Origin)
Approx. 1.5 NIH/mL once reconstituted

SAFETY CAUTIONS

Behnk reagent kits are designated for professional in vitro diagnostic use.
Good Laboratory Practices must be applied during use of reagents, reference or control plasmas, and human samples and should be handled as potentially infectious.
For further information, Material Safety datasheet is available upon request.
Dispose of waste in accordance with the local regulations.

PREPARATION OF REAGENTS

RE: Reconstitute the lyophilisate with 2 mL of demineralised water.
Allow to stand at room temperature for 20 minutes.
Then, well mix the reagent by swirling the vial without creating bubbles.

STABILITY AND STORAGE

Unopened vials stored at 2-8 °C are stable until the expiry date stated on the label.
RE: After reconstitution the working reagent is stable 2 days at room temperature, or 7 days at 2-8 °C.
Do not use any reagent after expiry date.

SAMPLES COLLECTION AND HANDLING [3] [5]

Plasma from careful venipuncture with anticoagulant ratio of 1/10 (trisodium citrate solution 0.109 M). Mix immediately the blood with anticoagulant.
Avoid drawing with a syringe that could result in the formation of micro-clots.
Centrifuge 10 minutes at 2500 g.
The specimen is stable 4 hours after collection, at room temperature (15-25 °C).

LIMITS [4]

Do not test any samples that have been partially coagulated (micro-clots).
Do not test any specimen which may have been contaminated by heparin (in collection tubes, syringes, etc …).
The use of bovine thrombin does not allow the detection of increased TT due to immunological antithrombin or exceptional antibodies.
For a more comprehensive review of factors affecting this assay, refer to the publication of Young D.S.

MATERIAL REQUIRED BUT NOT PROVIDED

Basic medical analysis laboratory equipment
Automated or semi-automated Coagulation analyzer
Demineralised water for reconstitution of reagent

PROCEDURE

Manual method on semi-automated systems:
Pre-incubate TT reagent 15 min to reach a temperature of 37 °C and mix gently before use:

- Plasma: 150 µL

Incubate for 120 sec at 37 °C

- TT Reagent (37°C): 150 µL

The automatic Countdown timer will start immediately after addition of TT reagent and stop when the clot is formed.

Automated method on Behnk Thrombolyzer series
Refer to the full detailed application specific to the automated system.
Note:

- Performances and stability data have been validated on Thrombolyzer Compact X (available on request).
- With manual procedure and on other automated coagulation analyzer, performances and stability data must be validated by user.
- Other validated applications or proposal applications are available on request.

CALIBRATION

Results are expressed in seconds or ratio. The validity of the result depends on the accuracy of the time counting, the respect of reagent/specimen ratio and temperature.

CALCULATION

Results may be expressed as follows:

- In seconds (Patient time and Reference normal plasma time).
- In ratio Patient time/Reference normal plasma time

Each laboratory should determine its Reference normal plasma time using a pool of normal patient specimens.

QUALITY CONTROL

REF 773100: BE Trol 1
Controls are required for checking the accuracy and reproducibility of the results.
The control intervals should be adapted to each laboratory's individual requirements.
Values obtained should fall within the defined limits.
Follow the applicable government regulations and local guidelines for quality control.

EXPECTED VALUES [3]

Normal TT: between 17 and 23 seconds
(Variable, depending on the reagent-instruments combination)
Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

The within run and between run studies were performed with normal and abnormal plasma on Thrombolyzer Compact X:

Within run *(n= 30)*	Plasma level 1
Mean (sec)	14.2
S.D. (sec)	0.28
C.V. %	1.97

Between run *(n=16)*	Plasma level 1
Mean (sec)	14.0
S.D. (sec)	0.20
C.V. %	1.44

Comparison with commercially available reagent (same method):
23 plasmas located between 15 sec and 40 sec were tested:
y = 0.8535 +2.1038 r= 0.9904

Interferences:

Total bilirubin	Positive interference from 2.50 mg/dL
Turbidity	No interference up to 10.3 mmol/L of triglycerides
Hemoglobin	No interference up to 246 µmol/L

Other substances may interfere with the results (see § Limits)
On the board stability: 17 days when kept 8 hours per days on board

REFERENCES

(1) *Caen J., Larrieu MJ, Samama M : « L'hémostase. Méthodes d'exploration et diagnostic pratique » Paris : L'Expension Scientfique, p.208-209, p.348-351 (1975).*
(2) *Samama M., Conard J., Horellou M.H., Lecompte T.: "Physiologie et exploration de l'hémostase"Paris : Doin, p.155-156 (1990)*
(3) *Clinical guide to laboratory Test 4th edition, p.1028-1029 (2006)*
(4) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p.3-554 à 3-55*
(5) *GEHT Numero spécial STV Recommandations variables préanalytiques en Hémostase, p19-21 ,p 40 (1998)*

Manufacturer	Use by	IVD	Temperature limitation	REF	See insert	LOT	Store away from light	Sufficient for	→	Dilute with	H2O	Demineralized water	Biological hazard

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