CE IVD

Precision in Hemostasis

Behnk Elektronik

BE TT Thrombin Time

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

REF 771400: RE (12 x 2 mL)

INTENDED USE

This reagent is designated for professional use in laboratory (semi-automated or automated method). It is used for the chronometric determination of Thrombin Time in human plasma to investigate the formation of fibrin prior to further specific tests in case of unexplained prolongation of the clotting time.

PRINCIPLE [1]

In the presence of a standardised amount of thrombin, normal plasma coagulates in a specific and constant time.

GENERALITIES [1] [2]

It is recommended to determine the Thrombin Time (TT) before any dosing is performed based on analyses if an unexplained prolongation of the global tests (PT, APTT) is detected.
The Thrombin Time (TT) remains normal in the presence of a deficiency of Factor XIII (a factor that causes fibrin stabilisation).
Prolongation of Thrombin Time may indicate the following:

- A qualitative (dysfibrinogenaemia) or quantitative (severe hypofibrinogenaemia or congenital afibrinogenaemia, acquired hypofibrinogenaemia (DIC, fibrinolysis, liver disease)) abnormality of fibrinogen.
- The presence of antithrombins, whether therapeutic (heparin, hirudin, argatroban...) or abnormal (myelomatic proteins that inhibit the polymerisation of fibrin monomers...).

| REAGENTS

RE **TT** Thrombin Reagent
Lyophilised calcified thrombin (bovine origin)
Approx. 1.5 NIH/mL after reconstitution.
According to 1272/2008 regulation, this reagent is not classified as dangerous.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.behnk.de
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

PREPARATION OF REAGENTS

RE: Reconstitute the lyophilisate with the amount of demineralised water indicated on the label of the bottle.
Close the bottle and let stand at room temperature for 20 min.
Invert carefully before use to homogenise the content, avoiding the formation of bubbles.

STABILITY AND STORAGE

Unopened vials, stored away from light at 2-8 °C are stable until the expiry date stated on the label.
Stability after reconstitution:

- 2-8 °C 7 days
- On board Stability (OBS)* 2 days
- 15-25 °C 2 days

* 18-22 °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 (sodium 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 samples that have been partially coagulated (microclots).
Do not test samples that may have been contaminated with heparin (by sampling material, tubes, syringes, etc. ...).
When using thrombin of bovine origin, TT prolongations due to immunological antithrombin or abnormal antibodies cannot be detected.
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 the reagents.

REFERENCE RANGE [3]

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

QUALITY CONTROL

REF 773100: BE Trol 1; REF 773101: BE Trol 2
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.

PROCEDURE

Manual method on semi-automated systems
Pre-incubate 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.

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Made in France

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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 [6]

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 reference plasma.
Reference plasma: use normal human plasma from healthy individuals, men or women aged between 18 and 55, who are not taking any medication and blood donors.

PERFORMANCES

The studies were performed on Thrombolyzer Compact X.
Precision:

Within run *(n = 30)*	Level 1
Mean (sec)	20.0
S.D. (sec)	0.41
C.V. %	2.0

Between run *(n = 16)*	Level 1
Mean (sec)	20.0
S.D. (sec)	0.56
C.V. %	2.8

Comparison with commercially available reagent:
23 plasmas located between 15 sec and 40 sec were tested.
y = 0.8548 x + 2.2008 r= 0.9960

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)

REFERENCES

(1) *Caen J., Larrieu MJ, Samama M: « L'hémostase. Méthodes d'exploration et diagnostic pratique » Paris : L'Expension Scientifique, 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 Numéro spécial STV Recommandations variables pré analytiques en Hémostase, p19-21, p 40 (1998)*

| = Significant modifications

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Manufacturer | Expiry date | In Vitro Diagnostic | Temperature limitation | Catalogue number | See insert | Batch number | Store away from light | Sufficient for | Dilute with | Demineralized water | Biological hazard

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