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BIO-TT Thrombin Time

Reagent for the determination of Thrombin Time in human plasmas

REF 13980 **R1** 12 x 2 mL

CE

IN VITRO DIAGNOSTIC USE

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, TCA).
Increased Thrombin Time may indicate:

- An abnormality of the fibrinogen: qualitative (dysfibrinogenaemia), quantitative (severe hypofibrinogenemia or congenital afibrinogenemia, acquired hypofibrinogenemia (DIC, fibrinolysis, liver disease)
- The presence of antithrombins which may be therapeutic (heparin, hirudin, argatroban…) or abnormal (myeloma proteins inhibiting the polymerization of fibrin monomers)

PRINCIPLE (4)

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

REAGENTS

R1 BIO-TT Freeze dried Reagent

Calcic thrombin (Bovin Origin)

Approx. 1,5 NIH/mL once reconstituted

Once reconstituted: Working reagent is not classified as dangerous according to regulation 1272/2008/CE

SAFETY CAUTIONS

BIOLABO reagents are designated for professional, in vitro diagnostic use (do not pipette with mouth).

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.

All specimens or reagents from biological origin should be handled as potentially infectious using appropriate precautions. Respect legislation in force in the country.

REAGENTS PREPARATION

- **Reagent** (vial R1)

Use a non-sharp instrument to remove aluminium cap from the vial. Transfer the amount of distilled water stated on the label into the vial. Allow to stand at room temperature for 20 minutes. Then, mix the reagent by swirling gently.

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, and used as described, reagents are stable:

Unopened:

- Until expiry date stated on the label of the kit.

Once reconstituted:

- Transfer requested quantity, well recap vials and store at 2-8°C
- Reconstituted reagent (R1) is stable for:
  - ✓7 days at 2-8°C
  - ✓2 days at 15-25°C

Don't use the working reagent after expiry date.

SPECIMEN COLLECTION AND HANDLING (3) (5)

Plasma: Careful veinipuncture (blue top-citrate).

- Blood/anticoagulant ratio: 4.5 mL of blood for 0.5 mL of trisodium citrate 0.109 M. Avoid blood drawing with a syringe that could result in the formation of micro-clots. Centrifuge for 10 minutes at 2500 g.
- Run the assay within 4 hours after collection, storing plasma at room temperature (15-25°C).

LIMITS (4)

- Do not test any sample 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

1. Basic medical analysis laboratory equipment
2. Automatic or semi-automated coagulation analyzer
3. Demineralised water for preparation of reagent

CALIBRATION

Results are method dependent. The validity of the result depends on the accuracy of the time counting, the respect of reagent/specimen ratio and temperature.

Manufacturer | Use by | IVD In vitro diagnostic | Temperature limitation | REF Catalogue number | See insert | LOT Batch number | Store away from light | Σ sufficient for | → dilute with | H2O Demineralized water | Biological hazard

QUALITY CONTROL

REF 13961	Control Plasma Level 1	6 x 1 mL
REF 13971	Coatrol 1	6 x 1 mL

- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operation on the instrument.

When control is out of range, apply following actions:

1. Repeat the test with the same control plasma.
2. If control is still out of range, prepare a fresh control plasma and repeat the test.
3. If control is still out of range, verify with a new vial of reagent.
4. If control is still out of range, please contact BIOLABO technical support or your local Agent.

PERFORMANCES AT 37°C on BIO SOLEA 4

Precision studies realised on normal and pathological plasmas

Within run N = 20	Level 1	Level 2
Mean (sec)	16.7	28.9
S.D. (sec)	0.21	1.24
C.V. %	1.3%	4.3%

Between run N = 20	Level 1	Level 2
Mean (sec)	16.3	32.8
S.D. (sec)	0.62	1.41
C.V. %	3.8%	4.3%

Comparison with commercially available reagent (same method):

23 plasmas located between 15 sec and 40 sec were tested with the 2 reagents on BIO SOLEA 4 coagulometer:

y = 0,8548 x +2,2008 r= 0,9960

Interferences:

Total bilirubin	Positive interference from 5.85 mg/dL
Turbidity	No interference up to 10.3 mmol/L of triglycerides
Hemoglobin	No interference up to 240 µmol/L

Other substances may interfere with the results (see § Limits)

EXPECTED VALUES (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.

PROCEDURE

Manual procedure on BIO SOLEA 2 , BIO SOLEA 4 Coagulometer

Let stand the working reagent (vial R1) at room temperature (20-25°C)

Plasma	0.150 mL
Incubate for 2 minutes at 37°C	
Working Reagent (homogenized)	0.150 mL
The automatic countdown timer will start immediately after Working reagent addition and stop when the clot is formed.	

Automated Procedure on SOLEA 100

Refer to the full detailed application.

Note:

1- Performances data have been validated on BIO SOLEA 4 semi-automated analyzer

2- With manual procedure and on other automated coagulation analyzer, performances and stability data's must be validated by user

3- Other validated applications or proposal applications are available on request (SOLEA 100, Thrombolyzer Compact X...)

CALCULATION

Results may be expressed as follows:

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

REFERENCES

(1) *Caen J., Larrieu MJ, Samama M : « L'hémostase. Méthodes d'exploration et diagnostic pratique » Paris : L'Expansion 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)*