BIOLABO
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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

IVD

Made In France

I: corresponds to significant modifications

TECHNICAL SUPPORT AND ORDERS
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INTENDED USE

This reagent is designated for professional use in laboratory (semi-automated or automated method).
It allows the determination of Thrombin Time in human plasma to screen fibrin formation before any more specific tests in case of unexplained increased coagulation time.

GENERALITIES (1) (2)

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). However, the TT remains normal in deficiencies of factor XIII (fibrin stabilising factor).

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.

I REAGENTS

R1 BIO-TT Freeze dried Reagent

Calcic thrombin (Bovin Origin)

Approx. 1,5 NIH/mL once reconstituted

This reagent is not classified as dangerous according to regulation 1272/2008/CE

SAFETY CAUTIONS

- 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 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.

REAGENTS PREPARATION

Vial R1 : Add exactly the volume of demineralised water indicated.
Wait for 20 minutes at room temperature.

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 opened:

- Reconstitute immediately vial R1with demineralized water
- Transfer requested quantity, well recap vials and store at 2-8°C
- Working reagent 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)

Careful venipuncture.

- Blood/anticoagulant ratio: 4.5 mL of blood for 0.5 mL of sodium citrate 2 H_2O 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.

QUALITY CONTROL

REF 13961	Control Plasma Level 1	6 x 1 mL
REF 13962	Control Plasma Level 2	6 x 1 mL
REF 13963	Control Plasma Level 3	6 x 1 mL
REF 13971	Coatrol 1	6 x 1 mL
REF 13972	Coatrol 2	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 operations on the instrument

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PERFORMANCES

On automatic analyzer Thrombolyzer Compact X at 37°C:

Precision :

Within run N = 20	Level 1
Mean (sec)	20.0
S.D. (sec)	0.41
C.V. %	2 %

Between run N = 20	Level 1
Mean (sec)	20.0
S.D. (sec)	0.56
C.V. %	2.8 %

On automatic analyzer SOLEA 100 at 37°C:

Precision :

Within run N = 30	Level 1
Mean (sec)	14,2
S.D. (sec)	0,28
C.V. %	2 %

Between run N = 16	Level 1
Mean (sec)	14,0
S.D. (sec)	0,20
C.V. %	1,44 %

On board stability: at least 7 days (8h/day on board)

On BIO SOLEA 4 semi-automated analyzer, at 37°C:

Precision :

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):

Study on 23 human plasmas located between 15 sec and 40 sec :

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

Interferences:

Total bilirubin	Positive interference from 2,6 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)

REFERENCE INTERVAL (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

Semi-automated procedure:

Place reagent R1 reconstituted at room temperature (20-25°C) and homogenize.

Plasma	150 µL
Incubate for 2 minutes at 37°C	
Working Reagent (homogenized)	150 µL
The automatic countdown timer will start immediately after Working reagent addition and stop when the clot is formed.	

Automated procedure : Full detailed application available on request

- Performances and stability data have been validated on SOLEA 100 automated analyzer
- With manual procedure and on other automated coagulation analyzer, performances and stability data must be validated by user.
- Other validated applications or proposal are available on request.

CALCULATION

Results are 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)*

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with