

BioMed-Liquiplastin for P.Tdetermination

Prothrombin Time (ISI - 1.05)

REF: PT200150 (6x5 ml)



INTENDED FOR USE:

For quantitative determination of Thromboplastin activity in plasma

PRINCIPLE:

Tissue Thromboplastin in the presence of calcium activates the extrinsic pathway of human blood coagulation mechanism. When **LIQUIPLASTIN** reagent is added to normal citrated plasma, the clotting mechanism is initiated, forming a solid gel clot within a specified period of time. The time required for clot formation would be prolonged if there is acquired or congenital deficiency of factors/ factor activity in the extrinsic pathway of the coagulation mechanism or reduction in the activity of Vitamin **K** dependent clotting factors during oral anticoagulant therapy

SPECIMEN COLLECTION:

The arrest of bleeding depends upon primary platelet plug formed along with the formation of stable fibrin clot. Formation of this clot involves the sequential interaction of series of plasma proteins in a highly ordered and complex manner and also the interaction of these complexes with blood platelets and materials released from the tissues.

Tissue Thromboplastin, in the presence of calcium, is an activator, which initiates the extrinsic pathway of coagulation factors **VII, X, V**, Prothrombin and Fibrinogen.

During oral anticoagulant therapy most of the Vitamin **K** dependent factors such as **II, VII, IX, X**, Protein S are depressed, as also during the deficiencies of clotting factor activity which may be hereditary or acquired.

Prothrombin Time determination is the preferred method for presurgical screening, as a liver function test, determination of congenital deficiency of factors **II, V, VII** and **X** and for monitoring of patients on oral anticoagulant therapy

REAGENT COMPOSITIONS :

LIQUIPLASTIN is a novel, highly sensitive, low opacity, ready to use liquid Calcified liquiplastin Reagent, which is derived from rabbit brain.

Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its sensitivity and performance.

PACKAGE: Collection and storage.

- Store the reagent at **2-8°C**. **DO NOT FREEZE**.

- The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label. The uncontaminated reagent is stable at **2-8°C** up to the expiration date.

PRECAUTIONS & WARNING :

Avoid pipetting with mouth.

The preparation, according to current regulation, is classified as not dangerous.

The total concentration of non active components (preservatives, detergents, stabilizers) is below the minimum required for citation.

Anyway handle with care, avoid ingestion, avoid contact with eyes, skin and mucous membranes.

The samples must be handle as potentially infected from HIV or Hepatitis.

REAGENT PREPARATION & STABILITY :

- Use freshly collected blood taken into **0.11** mol/L trisodium citrate in the ratio **9** parts blood to **1** part anticoagulant.

- Centrifuge immediately for **5** minutes at **RCF 1500-2000** g and separate plasma into a clean test tube.

- Plasma should be tested within **3** hours (keep refrigerated).

REQUIRED MATERIALS NOT PROVIDED:

General Laboratory Equipment and instrumentations

PROCEDURE:

Manual method

- Patients samples should be tested in parallel with pooled fresh normal plasma (**FNP**) and suitable controls.

1. Bring the reagent vial to room temperature (**20-30°C**). Mix the contents of the vial to homogenise the suspension completely.

2. Aspirate from the reagent vial enough reagents for immediate testing requirements in a thoroughly clean and dry test tube. (Plastic test tubes are preferred).

3. Prewarm the reagent and bring to **37°C** before use in test procedure (**5-10** minutes may be required depending on the reagent volume to attain **37°C** before testing).

4. Recap the reagent vial and replace immediately to **2-8°C**.

5. To a **12 x 75** mm tube add **0.1** ml of plasma (**PPP**) and place the tube in a waterbath for **3** to **5** minutes at **37°C**.

6. To the tube forcibly add **0.2** ml of **BioMed- LIQUIPLASTIN** reagent (prewarmed at **37°C** for at least **0** minutes) and simultaneously start a stopwatch. Shake the tube gently to mix contents.

7. Gently tilte the tube back and forth and stop the stopwatch as soon as the first fibrin strand is visible and the gel / clot formation begins record the time in seconds.

8. Repeat steps from **4** to **6** for a duplicate test on the same sample.

9. Find the average of the duplicate test values. This is the Prothrombin time (**PT**).

CALCULATION:

Manual Method

The results may be reported directly in terms of the mean of the double determination of **PT** of the test plasma in seconds.

Mean of the patient plasma PT in seconds

Or as a ratio 'R': $R = \frac{\text{Mean of the patient plasma PT in seconds}}{\text{MNPT for the reagent}}$

MNPT for the reagent

Or as International Normalized Ratio (**INR**), $INR = (R)ISI$, where **ISI** = International Sensitivity Index of the reagent.

It is recommended by the **WHO** that **MNPT** should be established for each lot of **PT** reagents by each laboratory, since **PT** result are dependent on the combination of reagent lot, instrument and technique followed at each laboratory.

Usually plasma from at least **20** normal healthy individuals should be used to establish the **MNPT**. The average of such **PT** results in seconds = **MNPT**.

EXPECTED VALUE:

Normal values using **BioMed-LIQUIPLASTIN** are between **11-15** seconds. Between manual and Turbo densitometric instrument results a variation of **1-2** seconds may be expected. For photo optical instruments, it is recommended that each laboratory must establish its own **MNPT** for each lot of **BioMed- LIQUIPLASTIN**.

Oral Anticoagulant Therapeutic range: **INR = 2.0 - 3.5**

WASTE DISPOSAL:

The disposal of the product must be in accordance with local regulation concerning waste disposal.

REFERENCES:

1. Biggs R. and R.G. McFarlane: Human Blood Coagulation and its Disorders, Blackwell Scientific Publications, Oxford, 1962.
2. Hirsh J., Dalen J.E., Deykin D., Poller L.: Oral Anticoagulants: Mechanism of Action, Clinical Effectiveness and Optimal Therapeutic Range, Chest: 1995: 108 (Suppl.): 231S-246S.

PERFORMANCE:



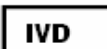


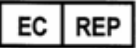

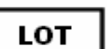

1. It is recommended that controls (**PLASMATROL H-I/II**) with known factor activity should be run simultaneously with each test series to validate test run.
2. Incorrect mixture of blood and tri-sodium citrate, insufficient prewarming of plasma and reagent, contaminated reagents, glassware etc. are potential source of errors.
3. Oxalated plasma may induce prolonged clotting times.
4. Since the PT test functions correctly only at **37+ 0.5°C**, temperature of all equipment must be calibrated daily.
5. Clotting time of patients on anticoagulant and also the time lag between the specimen collected and the last dose.
6. Turbid, icteric, lipemic, or grossly hemolysed samples may generate erroneous **PT** results.
7. Glasswares and cuvettes used in the test must be scrupulously clean and free from even traces of acids /alkalies or detergents.
8. Plasma samples held at **4-8°C** may undergo 'cold activation' leading to marked shortening of the **PT**.
9. The **PT** may be shortened during acute inflammatory conditions, which are accompanied by increase in Fibrinogen levels and also by agents such as antihistamines, butabarbital, Phenobarbital, caffeine, oral contraceptives and vitamin **K**. The **PT** may be prolonged by corticosteroids, **EDTA**, asparaginase, clofibrate, erythromycin, ethanol, tetracycline, aspirin and anticoagulants such as heparin and warfarin.
10. It is important that each laboratory express the results in terms of **INR** for patients on oral anticoagulant therapy for the clinician to adjust the dosage based on **INR**.
11. Since the test uses platelet poor plasma, each laboratory must calibrate the necessary force and time required during centrifugation to yield the **PPP**. Contamination of plasma with excess platelets could falsely elevated levels of some of the factors.
12. Homogenisation of **LIQUIPLASTIN** reagent suspension before use is important to achieve accurate and consistent results.

LIMITATIONS :

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. **BioMed-LIQUIPLASTIN** reagent is not from human source hence contamination due to **HbsAg** and **HIV** is practically excluded.
3. It is very important that scrupulously clean and dry micropipette tips be used to aspirate / dispense the reagent.

4. Avoid exposure of the **LIQUIPLASTIN** reagent to elevated temperatures, contamination and undue stress due to high and low temperature exposure cycles. Immediately replace reagent cap after use and store at recommended temperatures only.

5. On prolonged storage at **2-8°C** the Thromboplastin suspension has a tendency to settle down. Homogenize the reagent by resuspending before use.

	Consult Instructions for Use
	Caution, consult accompanying Documents
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Manufacturer
	Authorized Representative in the European Community
	Catalogue number
	Batch code
	Use by

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