CHRONOLAB

CE

IVD

PT
Thromboplastin calcium

Quantitative determination of Prothrombin time

PACKAGING

Ref. 104-0017	Cont.: 4x4 mL

Store at 2-8º C

CLINICAL SIGNIFICANCE

Since its original description by Quick in 1935, the Prothrombin Time (PT) or Quick test has remained an important test for detect disorders of blood coagulation, it is the most common coagulation procedure performed in routine laboratories, apart from the APTT.

The PT is particularly sensitive to defects of the extrinsic coagulation pathway (Factors II, V, VII, X and fibrinogen) as well as its inhibitors.

It is an indicator of hepatic disease.

It is also the most commonly used test for monitoring oral anticoagulant therapy.

PT is commonly used for monitoring heparin anticoagulant therapy[1,2,3].

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

PRINCIPLE OF THE METHOD

When calcium thromboplastin is added to citrated plasma, the factors of extrinsic coagulation system are activated. The one-stage PT measures the clotting time of plasma after adding the reagent.

REAGENTS

R	Calcium thromboplastin lyophilized, extract of acetone dehydrated rabbit brain and $CaCl_2$. Buffers and stabilizers.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8º C, protected from light and contaminations prevented during their use.

Do not use reagents over the expiration date.

Do not freeze.

Signs of reagent deterioration:

- Presence of particles and turbidity.
- Quality control values outside established ranges.
- Product colour variations.

ADDITIONAL EQUIPMENT

- Coagulometer or stopwatch and bath at 37º C ± 0.5º C.
- General laboratory equipment(Note 1).

PREPARATION

Working reagent (WR): Dissolve (→) one vial of R with 4.0 mL of distilled water.

Cap the vial and mix thoroughly to dissolve contents, avoiding foam forming. Bring to room temperature for about 15 min. before use.

Stability: 7 days at 2-8ºC or 8 h at 37ºC.

SAMPLES

Plasma from venous puncture diluted 1/10 in trisodium citrate solution 3.8 %.

Mixing immediately the blood with anticoagulant. Avoid foaming the specimen.

Centrifuge the sample at 1500 x g for 15 min and transfer the supernatant (plasma) into siliconized glass or plastic containers.

Turbid, icteric, lipemic or hemolyzed samples may generate erroneous results.

The sample is stable for 2 hours at room temperature (15-25º C) or 4 hours at 2-8º C.

NOTES

1. All labware must be clean and free of trace amounts of detergents.
2. Always follow instrument manufacturer's instructions; the results must be validated by the test laboratory.

PROCEDURE

The reagent can be used by manual method, mechanical, photo-optical or other means of clot detection(Note 2).

Manual method

1. Prewarm at 37º C the Working Reagent (WR) and the sample.
2. WR: Mix gently and pipette:

WR (µL)	200

3. Incubate for 5 min. at 37º C.
4. Pipette :

Citrated plasma (µL)	100

5. Start stopwatch or timer on the coagulation analyzer and determine the coagulation time.

CALCULATIONS

It is possible to report the results as seconds, but it is recommended use Percentage of the activity (%), PT ratio (PR) or International Normalized Ratio (INR).

$$PT\ ratio\ (PR) = \frac{PT\ of\ the\ patient\ in\ \text{sec}}{PT\ of\ normal\ plasma\ (pool\ \%)\ in\ \text{sec}}$$

International Sensitivity Index (ISI)

The prothrombin ratio can be converted into internationally comparable values by means of the International Sensitivity Index (ISI). The result obtained is in International Normalized Ratio (INR):

$INR = PR^{ISI}$

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures: CONTROL NORMAL & PATHOLOGIC.

If control values are found outside the defined range, check the instrument, reagents and technique for problems.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

It is possible to report the results as seconds, in percentage of the normal, in prothrombin ratio, dividing the results of the sample (sec) by the results of COAGULATION CAL (sec) or in International Normalized Ratio (INR).

PT (seconds)	13-17 seg
PT (percentage)	70-120 %
PT (ratio)	0.9 - 1.2

These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Precision: The results is dependent on many factors, such as the instrument, technique and the reagent in use. The precision was assessed by testing a normal and abnormal plasma on several different instruments:

	Intraserie (n= 20)	
Plasma	Normal	Abnormal
CV (%)	1.95	2.9

Sensitivity:

%Factor	PT (sec)			
	Factor II	Factor V	Factor VII	Factor X
100	11.6	11.6	11.8	11.7
50	11.7	13.9	12.8	13.3
40	12.3	14.9	13.5	14.1
30	12.8	15.9	13.9	14.8
20	14.1	18.3	15.2	17.0
10	16.6	22.2	17.1	20.4

Accuracy: Results obtained using CHRONOLAB reagents did not show systematic differences when compared with other commercial reagents.

INTERFERENCES

Do not use sodium oxalate, EDTA or heparin as anticoagulant.

Oral contraceptives, corticoids or anticoagulant therapy interfere in the assay.

A list of drugs and other interfering substances with the determination has been reported[3,4].

BIBLIOGRAPHY

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