PT

Thromboplastin calcium

Quantitative determination of Prothrombin time

IVD

PACKAGING

Ref. 104-0017	Cont.: 4x4 mL

Store at 2-8º C

INTENDED USE

High-sensitivity calcium thromboplastin for determination of Prothrombin Time, for evaluation of the extrinsic coagulation pathway and monitoring Oral Anticogulant Therapy in human citrated plasma.

PRINCIPLE

Based on A. Quick's test, the assay measures the time elapsed from the mixture of plasma with Thromboplastin (a tissue extract rich in Tissue Factor, phospholipids and calcium) until clot formation. Coagulation is initiated by activation of FVII by Tissue Factor[1].

COMPOSITION

PT	Rabbit brain thromboplastin, calcium chloride, heparin inhibitor and preservatives. Freeze-dried.

PRECAUTIONS AND WARNINGS:

- Avoid contact with skin and eyes. Wear suitable protective clothing.
- The ISI value indicated for each lot of reagent is generic for photo-optical instruments. Local ISI calibration is highly recommended[1].
- Each laboratory should establish the reference value for each lot of reagent.

PREPARATION

Dissolve the contents of each vial of thromboplastin with 4,0 mL of purified water. Replace the stopper and mix gently. Avoid foaming. Let the vial stand undisturbed for 15 min at room temperature (aprox. 25º C). Mix gently before each use.

STABILITY

Unopened reagent is stable until the expiration date shown on the vial, when stored at 2-8° C. Stability after reconstitution: 30 days at 2-8° C or 24 hours at 25° C. Do not freeze redissolved product.

SAMPLES

Nine parts of freshly drawn venous blood are collected into one part trisodium citrate. Immediately after, centrifuge at 2500 x g, 15 min, and transfer the plasma into siliconized glass or plastic tubes. The samples are stable 24 hours at room temperature (15-25º C). Do not store the samples at 2-8º C to avoid cold-activation of FVII[2].

PROCEDURE

The reagent may be used with any method for end-point (clot) detection, such as manual, photo-optical or mechanical methods/instruments.

PT test procedure

1. Prewarm to 37±1º C the amount of Thromboplastin needed and the plasma samples during no more than 10 min.
2. Start the PT test by mixing two parts (example: 200µl) of prewarmed thromboplastin reagent and one part (example: 100µl) of prewarmed citrated plasma. Start a timing device the instant the reagents are mixed. Record the time from final reagent addition to clot formation.

RESULTS

Results may be given in seconds, PT rate (comparing with a reference value), percent of activity (%; with calibration curve using a reference plasma (fresh pool or freeze-dried)), or as International Normalized Ratio (INR):

$$INR = \left(\frac{PT\ (sec)}{PT\ referenc.\ (sec)} \right)^{ISI}$$

The ISI (International Sensitivity Index) is lot-specific and it depends on the clot-detection system used. Spinreact indicates for each lot a generic ISI value for photo-optical clot detection. Such value is traceable to the ISI of the reference thromboplastin RBT/05.

QUALITY CONTROL

It is convenient to test control plasmas together with the samples. If the values obtained are outside the tolerance range, the reagents and the clot-detection system should be checked.

COAGULATION CALIBRATOR	REF. 104-0021
COAGULATION CONTROL NORMAL	REF: 104-0022
COAGULATION CONTROL PATOLOGICAL	REF: 104-0023

Each laboratory should establish its own Quality Control program, including correction measures.

REFERENCE VALUES

Using the BioBas10 coagulometer and with 20 normal samples the following normal range (95% confidence) was established: 11,1 – 14,3 seconds.
Each laboratory should establish its own reference values.

PERFORMANCE CHARACTERISTICS

Precision: Precision was studied with Spinreact's BioBas1000 using lyophilized normal (level 1) and pathologic (level 2) plasma pools, during 19 days (2 runs/day) and four replicates in each run:

Level	n	Mean (secs.)	Coeficient of Variation		
			Within-Run	Between-Run	Total
1	112	13.8	1.6 %	0 %	2.2 %
2	112	37.3	1.7 %	0 %	2.5 %

Sensitivity:

FII		FV		FVII		FX	
%	PT (s)	%	PT (s)	%	PT (s)	%	PT (s)
91	13.3	89	13.2	97	13.2	94	13.5
73	13.5	71	13.8	78	13.4	75	14.1
50	14.1	49	14.7	48	14.2	52	14.8
36	14.6	40	15.1	44	14.4	42	15.8
32	14.9	31	16.0	34	14.7	33	16.5

INTERFERENCES

The reagent contains a specific heparin inhibitor. Concentrations ≤1UI/mL do not interfere with the results.
Discard hemolytic or coagulated samples. With coagulometer BioBas1000, triglycerides (Intralipid) don't interfere up to 500 mg/dL, hemoglobin does not interfere up to 100 mg/dL, and bilirubin does not interfere up to 15 mg/dL.
Some common drugs may affect the PT result [3].

BIBLIOGRAPHY

1. *Clinical and Laboratory Standards Institute (CLSI) H47: One-stage Prothrombin Time test and Activated partial Thromboplastin Time test; approved guideline*
2. *Clinical and Laboratory Standards Institute (CLSI) H21: Collection, Transport, and Processing of Blood Specimens for Testing Plasma-based Coagulation Assays and Molecular Hemostasis Assays; approved guideline*
3. *Poller L. The Prothrombin Time. WHO/LAB/98.3. 1998.*

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