



# TriniCLOT™ PT Excel S

REF	T1103	5 x 20 ml
REF	T1104	10 x 6 ml

Pour d'autres langues  
Für andere Sprachen  
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## INTENDED USE

TriniCLOT PT Excel S is a tissue thromboplastin reagent (rabbit brain) for use in the determination of Prothrombin Time (PT) tests.

## SUMMARY AND PRINCIPLE

The Prothrombin Time test is used predominantly as a presurgical screen to detect potential bleeding problems. An abnormal or extended PT test is usually indicative of a decreased level of one or more of the factors in the extrinsic or common path of blood coagulation. This condition could be caused by hereditary coagulation disorders, vitamin K deficiency, liver disease, or drug administration.

The PT is also the most common laboratory assay used to monitor oral anticoagulant therapy since it is sensitive to Factors II, VII, and X.<sup>1</sup> The PT may be used to perform factor assays for the extrinsic system (i.e. Factors II, V, VII, X).

The PT is not sensitive to deficiencies in the intrinsic coagulation system (Factors VIII, IX, XI, and XII) or platelet dysfunctions, nor can it be used to monitor heparin therapy. An Activated Partial Thromboplastin Time (APTT) determination is recommended for monitoring heparin therapy,<sup>2</sup> and a bleeding time test is recommended for identifying platelet dysfunctions.<sup>3</sup>

## REAGENT

For *in vitro* diagnostic use.

## REAGENT DESCRIPTION

TriniCLOT PT Excel S Reagent, 5 x 20 ml, T1103A

TriniCLOT PT Excel S Reagent, 10 x 6 ml, T1104A

Tissue thromboplastin from rabbit brain, calcium ions and buffer.

TriniCLOT PT Excel S Diluent, 5 x 20 ml, T1103B

TriniCLOT PT Excel S Diluent, 10 x 6 ml, T1104B

Stabilizers and preservatives. Contains 0.05% sodium azide as a preservative.

## REAGENT PREPARATION

Reconstitute one vial of TriniCLOT PT Excel S Reagent with one vial of Diluent. Both components must be of the same kit lot. Restopper the vial and gently invert several times to ensure complete rehydration. Allow to stand for 30 minutes at room temperature (18-25°C). Invert gently before use to ensure homogeneity and run at least two (2) levels of quality control immediately.

**Caution:** This product contains sodium azide (NaN<sub>3</sub>) as a preservative. When discarding into sewerage, always flush with copious quantities of water. This helps prevent formation of metallic azides which, when highly concentrated in metal plumbing, may be potentially explosive.

## ADDITIONAL MATERIALS REQUIRED

Disposable tip micropipette.  
Anticoagulant: Use commercially available evacuated collection tubes containing sodium citrate at 3.2% concentration.

## MATERIALS AVAILABLE

- Control reagents
- Coagulation instrumentation

## INSTRUMENTS

Applications/method adaptations for individual analyzers are available upon request; please contact your local representative.

## STORAGE AND STABILITY

Store TriniCLOT PT Excel S Reagent and Diluent at 2-8°C when not in use. Expiration date printed on the vial indicates unreconstituted limits of stability. The reagent is stable for four days if kept in the original (tightly capped) vial and stored at 2-8°C. Add four days to the date of reconstitution and record on the vial label.

## SPECIMEN COLLECTION AND STORAGE

Nine volumes of blood are to be collected in one volume of 3.2% (0.109 M) sodium citrate. Immediately after blood collection, samples are centrifuged at 1500 x g for 15 minutes. Storage at 2-8°C is not recommended as it may result in cold activation of Factor VII. Please refer to the most recent version of the CLSI document H21 for further instructions regarding specimen collection and storage.<sup>4</sup>

## PROCEDURE

### WARNINGS AND PRECAUTIONS

- Do not pipette any of the materials by mouth. Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Use disposable gloves and handle all blood specimens used in the test cautiously as though capable of transmitting infectious agents. Consult a physician immediately in the event that blood materials are ingested or come in contact with open lacerations, lesions, or other breaks in the skin.
- Immediately clean up any spillage of specimens with a 1:10 dilution of 5% sodium hypochlorite. Dispose of the cleaning material by an acceptable method.
- Treatment of blood products prior to disposal:
  - Autoclave for 60 minutes at 121°C.
  - Incinerate disposable materials.
  - Mix liquid waste with 5% sodium hypochlorite solution so that the final concentration is approximately 1% sodium hypochlorite. Allow to stand 30 minutes before disposal.

### TEST PROCEDURE

- Pre-warm a sufficient volume of reconstituted TriniCLOT PT Excel S to 37°C (0.2 ml needed per test). Take precautions to prevent evaporation and do not hold at 37°C uncapped for longer than 60 minutes. Discard reagent that has been held at 37°C for 60 minutes or longer. On OPTION Plus only, do not hold the reagent on the instrument at 37°C for longer than 8 hours and discard reagent that has been held at 37°C for 8 hours or longer.
- Label a test tube for each sample (patient and control) to be tested.
- Pipette 0.1 ml of sample or control into the appropriate tube.
- Incubate each sample and control at 37°C for 3 to 10 minutes.
- Forcibly add 0.2 ml of pre-warmed TriniCLOT PT Excel S and simultaneously begin timing for clot formation.
- Record the time, in seconds, required for clot detection.

### PROCEDURAL NOTES AND PRECAUTIONS

- Use of clean glassware (or plasticware) is important. Container surface and surface area may affect activation of samples. Consistent technique is recommended for all coagulation procedures. Duplicate determinations are recommended.
- The following sequence for performing a one-stage prothrombin time test is suitable for manual techniques. Automated determinations should be performed according to the specific instructions accompanying the instrument used.  
**Note:** When using TriniCLOT PT Excel S with an automated instrument, a "maximum time" greater than 50 seconds should be used.
- The use of control plasmas (TriniCHECK Level 1, 2 and 3 or TriniCHECK Control 1, 2 and 3 (assayed)) is recommended for monitoring coagulation tests.

### QUALITY CONTROL

- The use of control plasmas (TriniCHECK Level 1, 2 and 3 or TriniCHECK Control 1, 2 and 3 (assayed)) is recommended for monitoring coagulation assays following established laboratory quality control procedures. CLSI recommends controls be assayed at the initiation of testing, at least once each shift, or with each group of assays. In high volume laboratories, controls should be tested at least every 40 samples.<sup>5</sup>
- If control values are out of range, do not report patient results. Determine which part of the instrument/reagent/control system is not functioning properly and correct it. After corrective measures are implemented and documented following good laboratory practice, retest the controls. If they are within range, patient samples can be tested and reported.

## RESULTS

The Prothrombin Time obtained may be converted to percent of normal activity (Quick %), prothrombin time ratio, or International Normalized Ratio (INR).

### Prothrombin Time Ratio

The Prothrombin Time (PT) ratio is calculated by dividing the patient's PT by the mean PT of the laboratory's normal range.

$$PT \text{ Ratio} = \frac{\text{Patient PT}}{\text{Normal PT } \bar{X}}$$

### INTERPRETATION OF RESULTS

Although most manual or automated methods for clot detection may be used with TriniCLOT PT Excel S, different methods may detect slightly different endpoints. Caution must be used when comparing results from different methods.

### EXPECTED RESULTS

Clotting times are contingent upon numerous factors including temperature, water quality, pH, ionic strength, test system, specimen collection and preservation, and patient population. Specific normal ranges for the PT test should be established by each laboratory. As a guide for the user, PT data were obtained on 24 normal adults, using photo-optical instruments, in order to establish a normal range. Based on these results, the normal range was determined to be 12-18 seconds, corresponding to a Quick % value of ≥70% or a PT ratio value ≤1.2.

### CALCULATION OF RESULTS

The test result (in seconds) is converted to percent of normal activity through the use of a reference curve. The reference curve can be determined by (1) preparation and testing dilutions of a normal citrated plasma pool or of a reference material or (2) use of an assigned Quick % calibration plasma set such as TriniCAL INR & Quick (T5101).

- The reference curve is prepared by testing dilutions of a normal citrated plasma pool or of a reference material. Dilutions are made in Owren's Veronal Buffer according to the scheme below.

Percentage	100%	50%	25%	12.5%
Dilution	undiluted	1:2	1:4	1:8
Plasma	0.5 ml	0.5 ml	0.5 ml	0.5 ml
Veronal Buffer	0.0 ml	0.5 ml	1.5 ml	3.5 ml

- (2) TriniCAL INR & Quick (T5101) refer to the TriniCAL INR & Quick package insert when utilizing this product.

OPTION/OPTION Plus Instrument series customers may alternatively refer to the enclosed lot-specific Prothrombin Time Conversion Chart to determine the patient's Quick % activity.

**International Normalized Ratio (INR)**

The INR is calculated using the International Sensitivity Index (ISI):

$$\text{INR} = \text{PT Ratio}^{\text{ISI}}$$

For every lot of **TriniCLOT PT Excel S**, an ISI value is determined by calibration against an International Reference Preparation and is provided on the enclosed INR value chart. Using the calculated PT ratio and the assigned ISI value for the particular lot of **TriniCLOT PT Excel S**, the INR can be determined from the accompanying table.

**PERFORMANCE CHARACTERISTICS**

In representative studies performed with **TriniCLOT PT Excel S**, the average clotting time for normal pooled plasma was 14.6 seconds with a coefficient of variation (CV) of 0.4%.

In representative studies using photo-optical instruments and **TriniCLOT PT Excel S**, the interassay coefficient of variation (CV) for TriniCHECK Level 1 was less than 2.0%, TriniCHECK Level 2 was less than 3.0%, and TriniCHECK Level 3 was less than 4.0%.

The results presented above should be used only as a guide. Each laboratory should establish its own control values based on the endpoint detection method employed and test conditions within that laboratory.

For technical assistance in the U.S.A., contact **Tcoag** Customer Service at 888 291 0415. Outside the U.S.A., contact your local **Tcoag** Representative.

**REFERENCES**

- Hirsh J, Hull RD: *Venous Thromboembolism: Natural History, Diagnosis and Management*, Boca Raton, FL, CRC Press Inc., 1987.
- Brandt JT, Triplett DA: *Laboratory monitoring of heparin. Effect of reagents and instruments on the activated partial thromboplastin time*. Am J Clin Pathol 1981; 76:530.
- Kumar R, Ansell JE, Canoso R, Deykin D: *Clinical trial of a new bleeding time device*. Am J Clin Pathol 1978; 70:642.
- Clinical and Laboratory Standards Institute (CLSI). *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline - Fifth Edition*. CLSI document H21-A5 Vol. 28, No. 5, 2008.
- Clinical and Laboratory Standards Institute (CLSI). *One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline - Second Edition*. CLSI document H47-A2, Vol. 28 No. 20.

**ORDERING INFORMATION**

KIT		TriniCLOT PT Excel S
Kit Content	Item	Quantity
T1103	TriniCLOT PT Excel S	5 x 20 ml
T1104	TriniCLOT PT Excel S	10 x 6 ml
ADDITIONAL PRODUCTS AVAILABLE		
Catalogue No.	Item	Quantity
T4111	TriniCHECK Level 1 (un-assayed)	10 x 1 ml
T4112	TriniCHECK Level 2 (un-assayed)	10 x 1 ml
T4113	TriniCHECK Level 3 (un-assayed)	10 x 1 ml
T4101	TriniCHECK Control 1 (assayed)	10 x 1 ml
T4102	TriniCHECK Control 2 (assayed)	10 x 1 ml
T4103	TriniCHECK Control 3 (assayed)	10 x 1 ml
T5101	TriniCAL INR & Quick	4 x 1 ml



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