



TriniCLOT PT Excel S

REF T1103 5 x 20 ml

REF T1104 10 x 6 ml

INTENDED USE

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

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. The PT may be used to perform factor assays for the extrinsic system (i.e., Factors II, VII, XI, XII). The PT is not sensitive to deficiencies in the intrinsic coagulation system (Factors VIII, IX, XI, XII) or platelet dysfunction, nor can it be used to monitor heparin therapy. An Activated Partial Thromboplastin Time (APTT) determination is recommended for monitoring heparin therapy and a bleeding time test is recommended for identifying platelet dysfunction.¹

REAGENT

REAGENT DESCRIPTION
6 mL kit 20 mL kit
10 vials 5 vials
TriniCLOT PT Excel S Reagent – Tissue thromboplastin from rabbit brain, calcium chloride, and buffer.
10 vials 5 vials
TriniCLOT PT Excel S Diluent – Stabilizers and preservatives. Contains 0.05% sodium azide as a preservative.

STORAGE AND STABILITY
Reconstitute one vial of TriniCLOT PT Excel S Reagent with one vial of Diluent. Both components must be of the same lot. Restopper the vial and gently invert several times to ensure complete rehydration. Allow to stand 30 minutes at room temperature. Invert gently several times to ensure homogeneity and mix until two clear, colorless layers of equal clarity immediately.

CAUTION: This product contains sodium azide (NaN₃) 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, may be potentially explosive.

ADDITIONAL MATERIALS REQUIRED
Disposable tip micropipet.
Anticoagulant: Use commercially available evacuated collection tubes containing sodium citrate at 3.2% concentration.

MATERIALS AVAILABLE
Contact reagents.
Consultation instrumentation.

INSTRUMENTS
This reagent has been validated and qualified for use on the following instruments:
Coag-A-Mate® MXTX Thrombolyzer Compact XR
Coag-A-Mate® MXTX Thrombolyzer Rack Rotor
OPTION Plus MAX Thrombolyzer Compact X
OPTION Plus MAX Thrombolyzer Compact X
AMAX 200/400

Please refer to the instrument operator manual and/or method adaptations provided by Trinity Biotech for information regarding the following:
• Operation principles, instructions, precautions, and hazards.
• Manufacturer's specifications and performance characteristics.
• Installation and special requirements.
• Service and maintenance information.

Note: Reagent performance must be validated if reagent is applied to an instrument platform that is not mentioned in this package insert.

STORAGE AND STABILITY

Store TriniCLOT PT Excel S Reagent and Diluent in a cool, dry place. Expiration date printed on the vial indicates unrecrystallized limits of stability. The reagent is stable for four days in 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.

STANDARD COLLECTION AND PREPARATION

Collection: No fasting or special preparation of the patient is necessary. Plasma anticoagulated with 3.2% sodium citrate (0.109 M) has been recommended.¹⁻⁴ To ensure accurate results, a ratio of nine parts blood to one part anticoagulant should be used. The results of plasma samples that are hemolyzed, clotted, or lipemic should be disregarded.

Storage: Store at 2-4°C or 18-24°C capped, testing must be completed within 24 hours of sample collection. If plasma is frozen, it should be frozen rapidly (up or down) and thawed rapidly (37°C) to prevent degradation of fibrinogen.⁵

PROCEDURE

WARNINGS AND PRECAUTIONS
1. Do not pipet any of the materials by mouth. Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
2. Use disposable gloves and handle all blood specimens used in the test cautiously as though capable of transmitting infectious agents. Immediately discard gloves and any blood materials that are ingested or come in contact with open lacerations, lesions, or other breaks in the skin.
3. 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.
4. Treatment of blood products prior to disposal:
a. Autoclave for 60 minutes at 121°C.
b. Incubate disposable materials.
c. 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
1. Prepare a sufficient volume of reconstituted TriniCLOT PT Excel S 37°C (0.2 ml needed per test). Take care to ensure reconstitution is completed for longer than 60 minutes. Discard the reagent that has been held at 37°C for 60 minutes or longer.
2. On OPTION Plus instrument, do not hold the reagent at 37°C for longer than 60 hours and discard reagent that has been held at 37°C for 6 hours or longer.
3. Label a test tube for each sample (patient and control) to be tested.
4. Pipet 0.1 ml of sample or control into the test tube.
5. Incubate each sample and control at 37°C for 3 to 10 minutes.
6. Incubate each sample and control at 37°C for 3 to 10 minutes.
7. Record the time, in seconds, required for clot detection.

PROCEDURAL NOTES AND PRECAUTIONS
1. Use of clean glassware (or plasticware) is important. Container surface and surface area may affect activity. Containers are recommended for use in the test.
2. 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.

3. The use of control plasmas (TriniCHECK Level 1, 2 and 3 or TriniCHECK Control 1, 2 and 3 (assayed)) is recommended for monitoring coagulation (TriniCHECK Level 1, 2 and 3 or TriniCHECK Control 1, 2 and 3 (assayed)).

QUALITY CONTROL
Verify 1, 2 and 3 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.⁶

2. If control values are out of range, do not report patient results. Determine which one 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 Ratio = Patient PT / Normal PT X

International Normalized Ratio (INR): 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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

INTERPRETATION OF RESULTS

Although most manual or automated methods for clot detection may be used with TriniCLOT PT Excel S,

