

test is largely dependent upon the quality of the blood specimen, which may be affected by:

- Foaming of the sample
- Hemolysis of the sample
- Clotted or partially clotted blood

Performance Characteristics

Reference ranges

Citrated whole blood samples were obtained from normal healthy animals and tested with the Citrate PT assay. Reference ranges were developed as follows:

Species	Canine	Feline	Equine
Reference Range (sec)	11–17	15–22	15–20

Limitations

Whole blood Citrate PT test results under 7 seconds or over 100 seconds are not reported. Instead, either an “Out of range - Lo” or “Out of range - Hi” message is displayed.

References

Green RA, Thomas JS. Hemostatic Disorders: Coagulopathies and Thrombosis. In Ettinger SJ, Feldman EC: *Textbook of Veterinary Internal Medicine*, 4th ed. Philadelphia, Pa: WB Saunders; 1995:1946–1963.

Suggested Readings

Evatt BL, Brogan D, Triplett DA, et al. Effect of thromboplastin and analyzer on the prothrombin time test. *Clin Lab Haematol.* 1981;3:331–342.

Gralnick HR, Kessler CM, Palmer R. The Prothrombin Time: Variables Affecting Results. In: Triplett DA, ed. “Standardization of Coagulation Assays: An Overview,” College of American Pathologists, Skokie, Il: 1982.

Tseng LW, Hughes D, Giger U. Evaluation of point-of-care coagulation analyzer for measurement of prothrombin time, activated partial thromboplastin time, and activated clotting time in dogs. *Am J Vet Res.* 2001;62:1455–1460.

06-12908-01

IDEXX Coag Dx™

Citrate Prothrombin Time (PT)

Package Insert

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Intended Use

The Citrate PT is a unitized coagulation test intended for in vitro use in performing a quantitative, one-stage prothrombin time. The Citrate PT test is performed using citrated canine, feline or equine whole blood. This test is to be used in the Coag Dx™ Analyzer and is also compatible with the SCA2000™ Coagulation Analyzer.

This test is for veterinary use only and not for human diagnostic use.

Summary and Explanation

The Citrate PT, a test of the extrinsic and common coagulation pathways, can be performed using citrated whole blood at the patient’s side. Since little specimen processing is required, PT results are obtained in less than two minutes. In addition, because the test is performed using a citrated whole blood sample, testing can be performed for up to two hours after sample collection without affecting test results.

Patient-side testing is especially valuable during procedures and therapeutic interventions, for hemostasis assessment before or after blood transfusions, and for diagnosis of anticoagulant rodenticide toxicity.

Traditionally, the events leading to the formation of a fibrin clot have been simplified in coagulation theory into two coagulation pathways: the intrinsic and extrinsic, both leading to the common pathway and the formation of a stable fibrin clot. The PT is a measure of the extrinsic and common coagulation pathways.

Principle of Operation

The coagulation analyzer utilizes a mechanical endpoint clotting mechanism in which clot formation occurs within the disposable Citrate PT cartridge. Following citrated whole blood sample introduction, the analyzer precisely measures 15 microliters of blood and automatically moves it into the test channel

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within the Citrate PT cartridge. The remainder of the blood sample, not needed for testing, is automatically drawn into the waste channel of the cartridge. Sample/reagent mixing and test initiation are also performed automatically, requiring no operator interaction. After mixing with the reagent, the sample is moved back and forth within the test channel and observed for clot formation.

The clot detection mechanism consists of a series of LED optical detectors aligned with the test channel of the cartridge. The speed at which the blood sample moves between the detectors is measured. As clot formation begins, blood flow is impeded and the movement slows. The analyzer recognizes that the clot end point has been achieved when the movement decreases below a predetermined rate. The Citrate PT whole blood clotting time is reported in whole seconds.

Reagents

Each box of Citrate PT test cartridges contains:

- 10 pouches, each containing one Citrate PT test cartridge and one desiccant

The Citrate PT test cartridge is a self-contained disposable test chamber preloaded with a dried preparation of thromboplastin, calcium salts, stabilizers and buffers. Each cartridge is individually packaged in a pouch. Cartridge pouches are stamped with a lot-specific expiration date.

Caution: All used test cartridges should be considered as potentially infectious, handled with care and disposed of properly.

Storage and Stability

When refrigerated (2°–8°C), the foil-pouched Citrate PT cartridges are stable until the marked expiration date. Room temperature storage (15°–30°C) is optional for unopened, pouched cartridges. Citrate PT cartridges should not be exposed to temperatures in excess of 37°C.

Note: Room temperature redating is to a maximum of 4 weeks, but must never exceed the marked expiration date. Redating is necessary if stored at room temperature.

Mark the outer box with the new expiration date when cartridges are stored at room temperature.

Sample Collection

Blood samples to be used for coagulation testing must be collected in the following manner to prevent contamination with tissue thromboplastin, or indwelling intravenous (I.V.) solutions that interfere with the coagulation assays. Poorly collected blood samples with visible clotting or debris accumulation must be discarded and a fresh sample collected.

Patient excitement should be minimized as this can increase platelet count, platelet aggregation, and the levels of von Willebrand Factor (vWF), fibrinogen, and Factors V and VIII. Prolonged venous stasis and excessive probing for the vessel should be avoided. Use of the cephalic or saphenous veins are advised as bleeding is easier to control from these sites (Green, et al, 1995). If a syringe is used, it should have a 23-gauge needle or larger. Use of excessive force when expelling the blood specimen through the needle may cause hemolysis.

Note: It is recommended that coagulation testing be performed within two hours of sample collection if stored at room temperature.

Note: Blood samples for testing should be collected at least 5 minutes prior to testing to allow for adequate mixing of the sodium citrate with the sample.

Citrated sample, from a direct venipuncture

1. Prepare the venipuncture site by cleansing with alcohol and allowing to air-dry completely.
2. Collect blood sample directly into an evacuated test tube containing sodium citrate (3.2%) and allow blood to be drawn into tube until the flow stops.
3. Mix gently.

Syringe sample, from indwelling line or venipuncture

Note: The amount of blood required to adequately flush the line until it is free of contaminants is dependent on the amount of solution contained within the line. Greater volumes will be required to clear longer lines.

1. Collect sufficient sample to fill the blood collection tube.

2. Attach a needle to the syringe. Carefully puncture the stopper of an evacuated test tube containing sodium citrate (3.2%) and allow blood to be drawn into the tube until the flow stops.
3. Mix gently. Discard the syringe with the needle.

Operating Instructions

Before performing any assay, refer to the IDEXX Coag Dx™ Analyzer Operator's Guide for detailed operating instructions.

Material provided

- Citrate PT test cartridges
- 11 single-use disposable pipettes

Material required (not provided)

- Coagulation analyzer
- Evacuated tube containing sodium citrate (3.2%)
- Blood collection needle

Note: Citrate PT test cartridges must be at room temperature prior to use. Once removed from the refrigerator, this may take up to 60 minutes. For best results, the pouch should be opened immediately prior to testing.

Test procedure

Refer to the IDEXX Coag Dx™ Analyzer Operator's Guide if any fault message should appear during this procedure.

1. Insert a test cartridge into the cartridge opening of the analyzer. The cartridge must be inserted with the blood reservoir facing up. The analyzer will automatically identify the test cartridge and display the test type.
2. During the warming stage, observe the display for fault messages.

The analyzer emits an audible tone when it is ready and alternately displays the "Add Sample" and "Press Start" messages. The analyzer remains in the "Ready" mode for five minutes before a "START... timeout" message displays. If this occurs, a new test cartridge must be placed in the analyzer.

3. Citrated samples should be collected prior to start of test. (See the Sample Collection section for more information.)
4. Before testing, invert the test tube at least four times to ensure complete mixing of sample.
5. Remove the stopper. Then, using a syringe or a pipette, transfer one drop of citrated blood into the sample well of the test cartridge; fill from the bottom of the well up. A sufficient quantity of blood must be added directly to the center sample well to fill it flush to the top. Should a large drop of blood extend above the center sample well, push it over into the outer sample well.
6. Press the **Start** key. A single beep signals the start of the test. The analyzer automatically mixes the sample with the reagent and detects clot.
7. The analyzer emits a single beep when the test is complete.

The test result, in seconds for whole blood, remains on the screen until the test cartridge is removed from the analyzer and for 120 seconds following its removal.

Operating Precautions

Do NOT use cartridges that are past their marked expiration date, or that have been improperly stored.

Do NOT force a cartridge into the analyzer. If resistance to insertion is encountered, gently remove the cartridge and examine the cartridge slot. Remove any obstruction before attempting further use of the analyzer.

Specimen collection and handling for all coagulation testing requires careful adherence to guidelines. As with all diagnostic tests, test results should be scrutinized in light of a specific patient's condition and anticoagulant therapy. Any results exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional test data.

The Citrate PT is affected by poor technique including blood collection and the transfer of blood to the sample well. The accuracy of the