Reference

1. Green RA, Thomas JS. Hemostatic disorders: coagulopathies and thrombosis. In: Ettinger SJ, Feldman EC, eds. *Textbook of Veterinary Internal Medicine*. 4th ed. Philadelphia, PA: WB Saunders; 1995:1946–1963.

Suggested reading

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Gralnick HR, Kessler CM, Palmer R. The prothrombin time: variables affecting results. In: Triplett DA, ed. *Standardization of Coagulation Assays: An Overview*. Skokie, IL: College of American Pathologists; 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(9): 1455–1460.

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IDEXX **Coag Dx***
Prothrombin Time (PT)

Package insert

06-12895-03

Intended Use

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

This test is for veterinary diagnostic use only.

Summary and explanation

The PT, a test of the extrinsic and common coagulation pathways, can be performed using fresh whole blood at the patient's side. Since no sample processing is required, PT results are obtained in less than 2 minutes.

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 analyzer utilizes a mechanical endpoint clotting mechanism in which clot formation occurs within the disposable PT cartridge. Following whole blood sample introduction, the analyzer precisely measures 15 µL of blood and automatically moves it into the test channel within the 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 endpoint has been achieved when the movement decreases below a predetermined rate. The PT whole blood clotting time is reported in whole seconds.

Reagents

Each box of PT test cartridges contains the following:

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

The PT test cartridge is a self-contained disposable test chamber preloaded with a dried preparation of thromboplastin, 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 (36˚F–46˚F/2°C–8°C), the foil-pouched PT cartridges are stable until the marked expiration date. Room temperature storage (59˚F–86˚F/15°C–30°C) is optional for unopened, pouched cartridges. PT cartridges should not be exposed to temperatures in excess of 98.6˚F/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 (IV) 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.[1] 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: Samples must not be collected until the analyzer indicates "Add Sample" and "Press Start."

Syringe sample, from indwelling line

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.

Using a tuberculin (1 mL) or 3 mL syringe, collect a minimum of 0.2 mL of blood from a previously flushed access port. Do not allow bubbles to form in the syringe.

Syringe sample, from a venipuncture

1. Prepare the venipuncture site by cleansing with alcohol and allowing to air-dry completely.
2. Obtain a minimum of 0.2 mL of blood.

Operating instructions

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

Material provided

- PT test cartridges

Material required (not provided)

- Coagulation analyzer
- Plastic syringes
- 23-gauge needle or larger (for syringe sampling)

Note: 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 5 minutes before a "START...TIMED OUT" message displays. If this occurs, a new test cartridge must be placed in the analyzer.
3. Obtain the blood sample. (See the Sample Collection section for more information.)
4. Immediately dispense one drop of blood into the center sample well of the test cartridge; fill from the bottom of the well up. This may be done either with or without a needle. 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 into the outer sample well.
5. 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.
6. 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.

Sample 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 PT is affected by poor technique, including blood collection and the transfer of blood to the sample well. The accuracy of the test is largely dependent upon the quality of the blood sample, which may be affected by the following:

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

Performance characteristics

Reference intervals

Whole blood samples were obtained from normal healthy animals and tested with the PT test. Reference intervals were developed as follows:

Species	Canine	Feline	Equine
Reference interval (seconds)	11–14	13–22	15–18

Limitations

Whole blood 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.