

VetScan VSpro PT/aPTT Combination Test Cartridge

For Veterinary Use Only

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INTENDED USE

The VetScan VSpro PT/aPTT Combination test cartridge is used in conjunction with the VetScan VSpro Analyzer for in-vitro point-of-care coagulation testing. They are intended for use in performing rapid quantitative determination of PT (prothrombin time) and aPTT (activated partial thromboplastin time) simultaneously from 1-2 drops of citrated canine or feline whole blood.

SUMMARY AND EXPLANATIONS OF TEST

The VetScan VSpro and the VetScan VSpro PT/aPTT Combination Test Cartridge comprise an in-vitro diagnostic system that can provide immediate blood coagulation information to veterinarians at their clinics to aid in diagnosing systemic coagulation disorders in their patients.

Blood clotting events can be categorized into three inter-related pathways: the intrinsic and the extrinsic pathways, both leading to the common coagulation pathway and the formation of a fibrin clot. PT is a measure of the extrinsic and common pathways while aPTT measures the intrinsic and common pathways.

The VetScan VSpro Analyzer uses citrated whole blood for the determination of PT/aPTT. A minimum of 60 µL (equivalent to one drop) of blood sample is required for performing a combined PT/aPTT test. The PT and aPTT

results are obtained in less than 10 minutes. Since citrated whole blood is used, the testing can be performed within two hours after sample collection without affecting test results.

PRINCIPLE OF OPERATION

The insertion of a new PT/aPTT Combination Test Cartridge into the VetScan VSpro Analyzer cartridge slot will trigger the warming up of the cartridge to 37 °C (98.6 °F). After the introduction of an adequate volume of citrated whole blood sample into the sample well of the cartridge, the blood travels automatically towards the two circular PT and aPTT optical detection windows. The window nearest the sample well is the PT detection window. Each detection cartridge is preloaded with dried reagents specific for the PT and aPTT test. The mixing of samples and reagents is automatic and results in the blood clot formation.

The clot detection mechanism consists of a system of LED lights and optical detectors aligned with the two detection windows in the test cartridge. The speed at which the sample travels in the respective detection window is measured. As clot formation begins, the sample flow decreases. The clot end point is determined when the VetScan VSpro detects that the sample flow rate is below a predetermined value. Both PT and aPTT clotting times are reported in units of seconds.

CARTRIDGE STORAGE AND HANDLING

Each test cartridge is preloaded with dry reagent beads specific for the PT and aPTT tests. All blood clot formations occur within the cartridge. No other reagents are required. *Each test cartridge can only be used once.*

Each cartridge is individually packaged in a sealed pouch with a desiccant bag to keep moisture out. One disposable transfer pipette is provided for each test in the box.

The test cartridge must be stored at 2-8 °C (39-46 °F), and must not be exposed to direct sunlight.

The test cartridge is stable until the expiration date which is printed on the pouch label. *Do not use the cartridge after the expiration date.*

A torn or otherwise damaged pouch may allow moisture to reach the test cartridge and adversely affect reagent performance. *Do not use a test cartridge from a damaged pouch.*

Open the pouch just prior to use. *Once the pouch has been opened, the test cartridge must be used within 10 minutes.*

The VetScan VSpro test cartridge can only be used with the VetScan VSpro Analyzer.

VETSCAN VSpro ANALYZER

Refer to the VetScan VSpro Operator's Manual for complete information on using the VetScan VSpro analyzer.

BLOOD SAMPLE COLLECTION AND PREPARATION

Precautions

The method in which blood is collected and handled will affect the quality of the blood sample, which in turn affects the performance of the VetScan VSpro's ability to generate accurate results.

Contamination from thromboplastin, alcohol and intravenous solutions will interfere with the coagulation assay. Hemolysis and foaming of the blood sample are other potential causes of erroneous test results.

When collecting the blood sample it is important that the excitement of the patient is minimized. Excitement can potentially cause splenic contraction and release of blood cells. Excitement can also increase platelet count and/or aggregation, levels of Von Willebrand factors, fibrinogen and factors V and VIII, which have significant influence on the coagulation cascade. Note that sedatives and analgesics also can influence blood coagulation. To avoid mechanical hemolysis, the syringe used for blood collection should have an appropriate size needle. The needle should be removed prior to placing blood in the blue top tube.

Blood Sample Collection

Clean the venipuncture site with alcohol and allow to air dry completely. Collect the blood using an evacuated blue top tube containing sodium citrate (3.2%). The blood is drawn into the tube until the flow stops. Alternatively the blood can be collected by filling the tube by the natural blood flow or by drawing the sample into a regular syringe, removing the needle from the syringe and the cap from the tube, and gently dispensing the blood into the tube immediately after obtaining the sample. It is very important to collect the right amount of blood in the tube. The correct amount of blood is usually indicated on the test tube label. If there is no indication, fill the test tube to the top of the label. Gently invert the blood filled citrate tube 8-10 times to enhance the mixing of the blood sample and the citrate in the tube.

Blood samples should be collected about 5 minutes before testing to stabilize the mixture of blood and the citrate. If possible place the blood sample on a blood rocker. Alternatively, invert the tube slowly 10 times every 10 minutes. If testing is delayed keep the blood sample at room temperature. Blood may be tested up to two hours after it has been collected without affecting the test result.

Important

- Do not use blood from a citrate tube that is over-filled or under-filled.
- Do not use blood samples with visible clotting or debris accumulation.
- Do not use blood that shows signs of agglutination.
- Do not use blood if the red blood cells settle unusually fast.
- Do not use blood that has been cooled or frozen.
- Do not use Lithium Heparin or EDTA stabilized blood.
- Do not use the last 5 mm of blood in the bottom of the test tube

OPERATION INSTRUCTIONS

Before performing any tests, please refer to the VetScan VSpro Operator's Manual for detailed operating instructions.

Material provided

- VetScan VSpro PT/aPTT Combination Test Cartridge.
- One-time-use disposable pipettes.

Test procedure

- Step 1: Touch the “Analyze” button in the Home menu screen.
- Step 2: Insert a new test cartridge when the message “Please insert new cartridge” is displayed on the screen.
- Step 3: Enter the cartridge code located on the pouch label.
- Step 4: Select the appropriate species by touching “Cat” or “Dog” and select “Done” to continue.
- Step 5: Confirm that the sample has been obtained in a citrate test tube (blue top).
- Step 6: Enter Patient ID and Patient Name and start the test by touching the “Next” button.
- Step 7: When the message “Add sample and wait” is displayed on the screen, add the blood sample to the sample well on the test cartridge using the supplied pipette. Make sure to fill the whole sample well with blood (~60 µL). Avoid bubbles. The measurement will start automatically once the blood is detected by the analyzer. Do not refill if an inadequate sample volume has been added to the well. Repeat the measurement with a new test cartridge.
- Step 8: When the measurement is finished the test result is displayed on the screen. If a printer is connected, the test result can be printed out by pressing the “Print” button.
- Step 9: Return to the Home screen by touching the “Done” button and remove the used test cartridge when the message “Please remove cartridge” is displayed on the screen.

Note: Each step in the testing procedure can be cancelled by pressing the “Cancel” button.

Limitations

The accuracy of the VetScan VSpro Coagulation Analyzer test results are dependent on the quality of the blood sample. The quality of the blood sample is dependent upon the blood sample collection, the proper blood to citrate ratio, the proper mixing of the citrated blood and the proper introduction of the sample into the sample well. Please observe all precautions cited in the VetScan VSpro Operator's manual and good blood sample collection techniques at all times.

As with any laboratory test result, signs, symptoms and any other procedures should be considered before making a final diagnosis. Any test result exhibiting inconsistency with a patient's status should be repeated and/or supplemented with additional testing.

Blood samples with a hematocrit of less than 15% or greater than 65% are not recommended for use with the VetScan VSpro and may cause an error message to be generated.

TEST CHARACTERISTICS

The time it takes to perform a measurement with the VetScan VSpro depends on factors such as type of test and test environment. At room temperature it takes about 90 seconds for the instrument to warm up the test cartridge to 37°C (98.6°F). Lower and higher temperatures may change the warm up time. A PT test takes 1-3 minutes whereas an aPTT test takes 5-8 minutes (warm-up times not included). Test results obtained under normal operating conditions have a CV (Coefficient of Variation) of 7% or less. All clot times are reported in seconds. The test dynamic ranges for PT and aPTT measurements are 11-35 seconds and 30-200 seconds, respectively. Clot times outside of these dynamic ranges are reported as clot time >35 for PT and >200 for aPTT.

Canine and Feline Reference Range (seconds)	Test/Species	Canine	Feline
	PT	14-19	15-21
	aPTT	75-105	86-137

REFERENCES

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