QuickVet®
Diagnostic System

Package insert for
QuickVet® PT/aPTT Coag Combo Test™
Version: January 4, 2017

Introduction

The QuickVet® PT/aPTT Coag Combo test cartridge is a quantitative coagulation test intended for in vitro testing of the Prothrombin Time (PT) and the Activated Partial Thromboplastin Time (aPTT) in companion animals using citrate stabilized whole blood for detection of systemic bleeding.

This test is intended for veterinary use only and should not be used for human diagnostics.

This test is approved for canine and feline use only!

This package insert provides you with the necessary information to use the QuickVet® PT/aPTT Coag Combo test cartridge with the QuickVet® Analyzer. Please refer to the QuickVet® Analyzer Operator's Guide for more comprehensive information. If you have any further questions you are welcome to contact customer support. Contact information for your particular country can be found at www.quickvet.net.

The QuickVet® cartridge

Each QuickVet® test cartridge is clearly labeled with the test type and individually packaged in a sealed pouch with a desiccant bag. A one-time-use disposable pipette is also supplied with each cartridge.

When using QuickVet® test cartridges remember the following:

- The cartridge must be stored at 2 °C to 8 °C/36 °F to 46 °F.
- The cartridge is stable until the expiration date stamped on the pouch.
- The cartridge must not be exposed to direct sunlight and temperatures higher than 30 °C/86 °F.
- After opening the pouch the cartridge must be used within 60 minutes.
- Each QuickVet® cartridge can only be used once.
- The QuickVet® cartridge can only be used with the QuickVet® Analyzer.

Test characteristics

A Citrate PT/aPTT Combo test takes less than 15 minutes per form. The actual time depends on the blood sample and test environment. At room temperature it takes about 90 seconds for the instrument to warm up the test cartridge to 37 °C/99 °F. Lower and higher temperatures may change the warm up time. Test results obtained under normal operating conditions have a CV (Coefficient of Variation) of 7 % or better. All clotting times are reported in seconds.

	Canine	Feline
PT	14-19	15-21
aPTT	75-105	90-130

Limitations

Caution The accuracy of QuickVet® Analyzer test results is largely dependent on the quality of the blood specimen which is in turn dependent on the blood sample collection, the proper volume of blood /citrate, the proper mixing of the citrated blood, and the proper introduction of the blood sample into the cartridge well. Please observe all precautions cited in this manual and use good blood sampling technique at all times.

Caution The veterinarian is always the final arbiter of test result interpretation and impact on diagnosis. Therefore it is highly recommended that QuickVet® test results should be scrutinized in the light of a specific patient's condition and medical history, as well as current or potential therapy. Any test result exhibiting inconsistency with a patient's status should be repeated and/or supplemented with additional diagnostic tests.

Caution Blood samples with a hematocrit of less than 15 % or greater than 65 % are not recommended for use with the QuickVet® Analyzer. Blood samples outside this range may result in an instrument error or faulty test result.

Precautions before blood sample collection

- The accuracy of the QuickVet® Analyzer coagulation tests is strongly dependent on the quality of the blood sample. The way the blood is collected and handled can greatly affect the blood sample quality.
- Contamination from thromboplastin, alcohol and intravenous solutions will interfere with the coagulation assay. Hemolysis and foaming of the blood sample are the potential sources of erroneous test results.
- When collecting the blood sample it is important that the excitement of the patient is minimized. Excitement will increase the amount of blood cells in the blood. This can 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.
- Sedatives and analgesics can also influence blood coagulation.

Collecting the blood sample

- To avoid mechanical hemolysis the syringe should have a 21 gauge needle or larger.
- Clear the vein puncture site with alcohol and allow it to air dry completely.

- Collect the blood in a test tube containing 3.2 % sodium citrate. The QuickVet® PT/aPTT Coag Combo has been validated with Greiner Vacuette and BD Vacutainer citrate tubes. Tubes from other vendors might result in inferior test performance.

- Approximately 60 µL of sample is required for one test.

- It is very important to collect the right amount of blood in the test tube. The correct amount of blood is indicated on the test tube. If there is no indication, contact the manufacturer for information.

- Gently invert the blood filled citrate tube 8-10 times to enhance the mixing of the blood sample and the citrate in the tube.

Handling of blood sample

- Blood samples should be collected about 5 minutes before testing to stabilize the mixture of blood and the citrate.

- If possible incubate the blood sample using a blood rocker. Alternatively, tip the tube slowly 10 times every 10 minutes.

- If testing is delayed keep the blood sample at room temperature.

- If the blood sample is placed on a blood rocker or tipped slowly 10 times every 10 minutes, it may be tested up to two hours after it has been collected without affecting the test result.

General rules

Do not use blood samples with visible clot ting or debris accumulation.

Do not use blood that shows signs of agglutination.

Do not use the blood if the red blood cells sediment unusually fast.

Do not use blood that has been cooled or frozen.

Do not use blood that is over-filled or under-filled in the citrate tube.

Do not use EDTA stabilized blood.

Do not use the last 5 mm of blood in the test tube.

Do not use blood with a hematocrit of less than 15 % or greater than 65 % .

Operating precautions

Do not use QuickVet® cartridges that are damaged, past their expiration date, or have been improperly stored.

Caution Used test cartridges, pipettes and collection tubes are considered potentially infectious. Dispose of them properly in accordance to policies and regulations in practice at the place of operation.

Caution All biohazard safety guidelines pertaining to the handling and disposal of animal blood samples should be strictly adhered to when collecting and handling blood samples and when operating the QuickVet® Analyzer.

Operating instructions

Before per forming any tests, please refer to the QuickVet® Analyzer Operator's Guide for detailed operating instructions.

Important Before performing any tests make sure that the instrument has been installed according to the instructions in the QuickVet® Analyzer Operator's Guide and software upgrade to the appropriate version for this test. The version number is DDMMYYYY_hhmm. The version date stamp must be 02072010_1344 or later.

Important Make sure that the blood sample has been collected according to the guidelines in this package insert.

Materials provided

- QuickVet® Citrate PT/aPTT Combo test cartridges.
- One-time-use disposable pipettes.

Material required but not provided

- QuickVet® Analyzer
- QuickVet® Operator's Guide
- Syringes (21 gauge needle)
- Sample tubes containing 3.2 % sodium citrate.

Test procedure

Step 1 Let the cartridge reach room temperature (15 °C to 30 °C/59 °F to 86 °F).

Step 2 Touch the Analyze button button in QuickVet® Analyzer's main menu.

Step 3 When the *Please insert new cartridge* is shown on the screen, insert a new QuickVet® test cartridge in the cartridge slot.

Step 4 Use the on-screen keyboard to enter the 9-digit cartridge code. The cartridge code can be found on the cartridge pouch label.

Step 5 Chose either Dog button or Cat button as appropriate by touching on of the two buttons.

Step 6 Touch the Confirm button button to acknowledge that the blood sample has been obtained in a citrate test tube (blue top).

Step 7 Touch the Patient ID button or Sample ID button button to enter patient ID and/or sample ID.

Step 8 Start the test by touching the Next button button in QuickVet® Analyzer's main menu. To abort the test touch the Cancel button button.

Step 9 Gently tip the test tube 10 times to obtain a uniform mixture of blood cells and plasma. When the message *Add blood*

and wait is displayed on the screen add a droplet of blood to the sample well using the supplied pipette. Make sure to fill the whole sample well with blood. Approximately 60 µL of blood is required. Avoid bubbles.

Step 10 A test usually takes a few minutes. When the test is finished the test result is displayed on the screen. If a printer is connected to the instrument the test result can be printed by touching the Print button button.

Step 11 Return to the main menu by touching the Done button button and remove the used test cartridge and dispose of it properly.

QuickVet® Analyzer and QuickVet® cartridges are manufactured by

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