

QuickVet® Analyzer Diagnostic System

Package insert for:
QuickVet® Citrate PT/aPTT Combo™ test cartridge
Version 2010-06-30

INTRODUCTION

The QuickVet® Citrate PT/aPTT 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 not for human diagnostic use.

This test is approved for canine and feline use only!

This package insert provides you with the necessary information you need to use the QuickVet® Citrate PT/aPTT 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 2-8 °C (36-46 °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 10 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 perform. 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 (98.6 °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.

Test/Species	Canine	Feline
PT	14-19	15-21
aPTT	75-105	94-125

LIMITATIONS

WARNING: 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.

WARNING: 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.

WARNING: 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.

COLLECTION OF BLOOD SAMPLE

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 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 BLOOD SAMPLE

- To avoid mechanical haemolysis the syringe should have a 21 gauge needle or larger.
- The vein puncture site is first cleaned with alcohol and allowed to air dry completely.
- Blood is collected using a test tube containing sodium citrate (3.2% or 3.8%). 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 clotting 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.
- **WARNING:** 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.
- **WARNING:** 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 performing any tests, please refer to the QuickVet® Analyzer Operator's Guide for detailed operating instructions.

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 sodium citrate (3.2% or 3.8%).

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.

Test procedure

- Step 1:** Let the cartridge reach room temperature (15 °C (59 °F) - 30 °C (86 °F)).
- Step 2:** Touch the "Analyze"- 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 7-digit cartridge code. The cartridge code can be found on the cartridge pouch label.
- Step 5:** Chose either Dog or Cat as appropriate by touching on of the two buttons
- Step 6:** Touch the "Confirm"- button to acknowledge that the blood sample has been obtained in a citrate test tube (blue top).
- Step 7:** Confirm species (Canine or feline) by touching the appropriate button.
- Step 8:** Touch the "Patient ID"- button and enter patient ID.
- Step 9:** Touch the "Sample ID"- button and enter sample ID.
- Step 10:** Start the test by touching the "Next"- button in QuickVet® Analyzer's main menu. To abort the test touch the "Cancel"- button.
- Step 11:** 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 12:** 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.
- Step 13:** Return to the main menu by touching the "Done"- button and remove the used test cartridge and dispose of it properly.

The QuickVet® Analyzer and QuickVet® test cartridges are manufactured by:

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