

qLabs® Vet PT Test Strips

REF QSV-3 Contains: 12 test strips



REF QV-2 qLabs® Vet
REF QV-3 Plus qLabs® Vet

For Veterinarian Professional Use Only

INTENDED USE

The qLabs® Vet PT Test Strips is designed to provide quantitative determination of Prothrombin Time (PT) on fresh venous blood and citrated whole blood of canine and feline patients.

The qLabs® Vet PT test is performed on the qLabs® Vet (QV-2, QV-3 Plus) instrument. When combined with Activated Partial Thromboplastin Time (APTT) test, it assists in the diagnosis and evaluation of excessive bleeding, hereditary bleeding disorders, disseminated intravascular coagulopathy (DIC), rodenticide poisoning, hepatic disease and monitoring therapy and progression of disease states.

NOTES:

- The qLabs® Vet PT Test Strips is intended ONLY for in vitro veterinary diagnostic use.
- It is suitable for professional use only.

INTRODUCTION

Blood coagulation or clotting is the process by which the blood changes from a liquid to form solid masses, or clots. It typically results in hemostasis, the cessation of blood loss from a damaged vessel, followed by repair. Disorders of coagulation are disease states which can result in bleeding or obstructive clotting. Analysis of the blood coagulation can assist in measuring the integrity of the coagulation system and diagnosing disorders that can seriously affect the health of the patient.

Blood clotting in the body is initiated through two pathways: the extrinsic and the intrinsic pathway. The extrinsic pathway is activated by external trauma that causes blood to escape from the vascular system. It involves factor VII and is quicker than the intrinsic pathway. The intrinsic pathway is activated by trauma inside the vascular system, and is activated by platelets, exposed endothelium, chemicals or collagen. Both pathways meet and finish the pathway of clot production in what is known as the common pathway which involves factors I (fibrinogen), II (prothrombin), V and X.

Prothrombin Time (PT) is a laboratory test commonly used to measure the integrity of the extrinsic pathway as well as factors common to both pathways. Specifically, the PT evaluates the activities of factors VII, V and X, prothrombin and fibrinogen.

The qLabs® Vet PT test is designed and validated for determining Prothrombin Time on fresh venous blood and citrated whole blood of canine and feline patients.

TEST PRINCIPLE

qLabs® PT Vet test strips are used together with the qLabs® Vet (QV-2, QV-3 Plus). The meter automatically detects the insertion of a PT test strip and heats the strip up to a preset operating temperature. After a drop of blood is applied to the strip, the capillary channels carry the blood to the reaction zones, where the blood mixes with the pre-printed reagents and starts to coagulate. Each strip contains two reaction zones: one for PT testing, another for QC testing. Each reaction zone contains one pair of metallic electrodes, to which a constant voltage is applied by the meter. As the coagulation of the blood proceeds, the current monitored across the two electrodes changes. The meter detects the change of the current in the reaction zone and identifies a clot endpoint for each of the two reaction zones. Based on analyses of the test data, the resultant clot endpoints for PT and QC testing are converted to a PT value and a QC value, respectively.

REAGENTS

Each test strip contains a dual standardized amount of reagents on the test zones: recombinant thromboplastin, heparin neutralizing reagent, and stabilizers on the PT test zone, and thrombin, stabilizers and buffers on the QC test zone. An individual test strip is packaged in a pouch with one desiccant bag.

PRECAUTIONS & WARNINGS

- For in vitro veterinary diagnostic use only. Do not take internally.
- Follow proper infection control guidelines when handling all blood specimens and related items.
- Use fresh non anti-coagulated whole blood or citrated whole blood. Do not use plasma.
- Never add more blood to a test strip after the test has begun.
- Do not move the meter during a test.
- Do not use test strip that exceeds the marked expiration date or that has been stored improperly.

The health status of the patient may affect the test. Please take this into consideration before making a therapeutic judgment based on the test results. Failure to do so may cause serious consequences. The health status of the patient may affect the test. Please take this into consideration before making a therapeutic judgment based on the test results. Failure to do so may have serious consequences.

STORAGE & HANDLING

Strips can be stored at room temperature until the marked expiration date. Refrigerated storage at 2-8°C is optional. Strip should not be exposed to temperature that exceeds 32°C. Do not freeze.

Store strips in their original foil pouch until ready to use.

If refrigerated, allow the sealed pouch to come to room temperature for 5 minutes before opening it for testing.

Use the test strip within 10 minutes after opening the foil pouch.

SAMPLE PREPARATION

1. Testing fresh venous whole blood samples

Gather the necessary materials:

- qLabs® Vet
- qLabs® Vet PT Test Strips
- 21-gauge needle or larger with 1.0 mL syringe
- Sterile alcohol
- Disposable glove
- Puncture-resistant container for medical sharps
- Sterile band aid
- Bio-hazardous container

2. Testing citrated whole blood samples

Gather the necessary materials:

- qLabs® Vet
- qLabs® Vet PT Test Strips
- qLabs® Re-Calcification Reagent
- 100 µL pipette and pipette tips
- Disposable glove
- Sterile alcohol

- Disposable venous blood lancet
- 1.8 or 2.7 mL 3.2% (w/v) sodium citrate venous collection tube
- Bio-hazardous container

TEST PROCEDURE

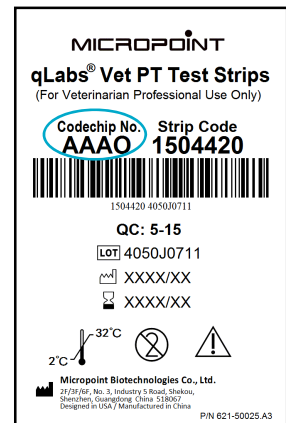
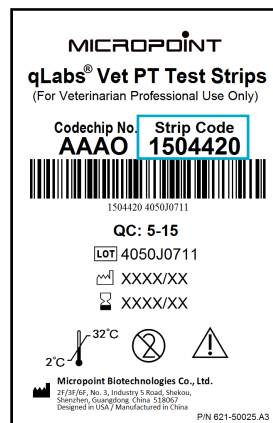
⚠ When the meter is powered on, refer to the User's Manual of qLabs® Vet to enter the Test Mode which prompts you to insert a test strip.

- Insert a test strip into the test strip guide on the meter. Remove a fresh test strip from its foil pouch. Insert the strip into the test strip guide so that the electrode end goes in first. On the light purple end of the strip you should be able to read the word "PT" appearing from left to right.
- Input the Strip Code / strip Codechip number.
 - For QV-2 meter, input the Strip Code information. The Strip Code can be inputted through manually input or by scanning the barcode labelled on the pouch. Then check the Strip Code to see if it is the same as the code on the pouch, correct once the code is wrong
 - For QV-3 Plus meter, input the Codechip number of the test strip. The Codechip number is inputted manually, or by scanning the barcode labeled on the pouch with the QV-3 model. Insert the Codechip of the strip into the chip slot. The qLabs® Vet will automatically confirm the entered Codechip number. If not correct, meter will display an error, and user needs to re-test by inputting the correct strip Codechip number or inserting the correct strip Codechip to continue the test.

⚠ Always match the Strip Code or Codechip number on the display with these on the strip pouch. Failure to do so may yield inaccurate results.

Strip Code

Codechip number



3. Wait for the meter to warm up. The meter will warm up automatically for the test. When it is ready to perform a test, the meter will beep and prompt user to apply a blood sample. The sample must be added within 600 seconds

4. Collect whole blood samples and run test.

4.1 Collect fresh venous whole blood samples.

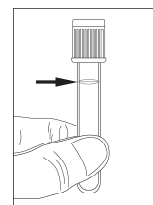
- Clean the venipuncture site with alcohol and allow it to air-dry completely.
- Collect >0.1 mL of venous blood into 1.0mL syringe.
- Remove the needle from the syringe.
- Add one drop of blood to the sample port of the strip which initiates the test.

⚠ Do not exceed 30 seconds from venipuncture to adding blood sample.

4.2 Prepare citrated whole blood samples and run test.

- Clean the venipuncture site with alcohol and allow it to air-dry completely.
- Collect venous blood to a 1.8 or 2.7 mL 3.2% (w/v) sodium citrate tube and mix well.

Important! Make sure that the blood level reaches to the correct filling line of the tube. Under- or over-filling of blood in the tube can cause inaccurate volume ratio of blood-to-citrate which leads to inaccurate results. After collection, mix the sample thoroughly by repeated inversion of the tube. Allow the sample tube to sit at room temperature for at least 1 minute before proceed to re-calcification step. After collection, the citrated sample should be tested within 2 hours when stored at room temperature or within 4 hours when at 2-8°C.



4.2.3 Obtain one tube of the qLabs® Re-calcification Reagent kit from the packing box.

4.2.4 Notice that the reagent liquid is usually spread in a multi-dot manner inside the tube due to transportation conditions.

4.2.5 Tap the bottom of the tube against a lab bench to collect all the reagent liquid into bottom of the tube.

4.2.6 Taking off the screw cap then place the reagent tube on the laboratory table.

4.2.7 Obtain one test strip and insert it into the Electrometer.

4.2.8 Start heating the meter by following the instructions in the Electrometer User's Manual.

4.2.9 While waiting for the heat-up to complete, use a 100 µL volume pipette to pick up 100 µL of citrate blood sample and pierce through the heat-sealed foil lid with the pipette tip. Then transfer the sample into the tube and mix the mixture well by pipetting for 6-8 times.

4.2.10 When prompted by the meter, add 10 to 15µL of the sample mixture on the test strip to start the sample test.

Important! Accuracy of the qLabs® test results is strongly dependent on quality of the samples which can be compromised by improper blood collection, inaccurate volume ratio of blood-to-citrate and incomplete mixing for re-calcification treatment. Precautions cited in the User's Manual should be

- observed at all times to ensure good venous sampling process and citrated sample preparation.
- Record the results when the test is completed.
 - Dispose of the used syringes to sharps bio-hazardous container
 - Dispose of the used strips and other contaminated items according to the local biohazard procedures.

REFERENCE INTERVALS

The reference intervals of PT for normal and healthy canine and feline by the qLabs® test are as follows:

Species	PT
Canine	12 – 17 s
Feline	13 – 20 s

NOTES: The reference intervals cited in this datasheet are established in line with those by the Quickve® PT/aPTT combination test.

LIMITATIONS

- The qLabs® system is designed to use fresh venous whole blood and citrated whole blood. Plasma should not be used.
- The drop of blood added to strips must be >10 µL.
- Hematocrit ranges between 20% and 70% will not affect test results.
- In vitro studies show no significant effect in blood samples containing up to 10 mg/dL of bilirubin, 100 mg/dL of hemoglobin.
- The qLabs® Vet PT Test Strips are validated to perform at temperatures in the range 10 to 35°C, and 10 to 90% RH (relative humidity). This includes a 10 minute out of pouch exposure of the strips at these conditions.
- As with all diagnostic tests, qLabs® Vet PT 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 or repeated with other testing methods.










ADDITIONAL INFORMATION

If you have any questions regarding the use of this product, please call your local representative/distributor, or our customer service at +86 755 86296766

PERFORMANCE CHARACTERISTICS

Category	Performance Specification
Species	Canine, Feline
Sample type	Non-anticoagulated venous whole blood or citrated whole blood
Sample volume	10 ~ 20µL
HCT	20% – 70%
Time to results	90 s
Reportable range	5 – 75 s
Reference Intervals	Canine PT: 12 – 17 s Feline PT: 13 – 20 s
Precision	CV ≤ 5%
Operating temperature	10°C – 35°C
Operating humidity	10% – 90% RH
Shelf life	12 months

SYMBOLS EXPLANATION

Symbols	Explanation
	Name and Address of Manufacturer
	Temperature limitation
	Lot number
	Date of Manufacture
	Expiry Date
	Do not reuse
	Catalogue number
	Contains sufficient for n tests
	Caution! Read Carefully.

MICROPOINT

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