

* Anigen Rapid CHW Ag Test Kit 2.0

■ Principles

The Anigen Rapid CHW Ag Test Kit 2.0 is a chromatographic immunoassay for the qualitative detection of Canine *Dirofilaria immitis* antigen in canine serum, plasma, or whole blood.

The Anigen Rapid CHW Ag Test Kit 2.0 has a letter of “T” and “C” as test line and control line on the surface of the device. Both the test line and the control line in the result window are not visible before applying any samples. The control line is used for procedural control. The control line should always appear if the test procedure is performed properly and the test reagents of the control line are working. A purple color at the test line will be visible in the result window if there are heartworm antigens in the specimen.

The specially selected Canine *Dirofilaria immitis* antibodies are used in the test band as both capture and detector materials. These enable the Anigen Rapid CHW Ag Test Kit 2.0 to identify Canine *Dirofilaria immitis* antigen in canine serum, plasma, or whole blood with a high degree of accuracy.

■ Materials provided (10 tests/kit)

- 1) Ten (10) Anigen Rapid CHW Ag test devices
- 2) Ten (10) disposable droppers for specimen
- 3) Ten (10) Anticoagulant tube
- 4) One (1) Instruction for use

■ Precautions

- 1) For veterinary diagnostic use only.
- 2) For best results, strict adherence to these instructions is required.
- 3) All specimens should be handled as being potentially infectious.
- 4) Do not open or remove test kit from their individually sealed pouches until immediately before their use.
- 5) Do not use the test kit if the pouch is damaged or the seal is broken.
- 6) Do not reuse test kit.
- 7) All reagents must be at room temperature (15~30 °C) before running the assay.
- 8) Do not use reagents beyond the stated expiration date marked on the label.
- 9) Do not mix components from different lot numbers. The components in this kit have been quality control tested as standard batch unit.

■ Storage and stability

- 1) The kit can be stored at room temperature or refrigerated (2~30 °C). **DO NOT FREEZE.**
- 2) Do not store the test kit in direct sunlight.
- 3) The test kit is stable through the expiration date marked on the package label.

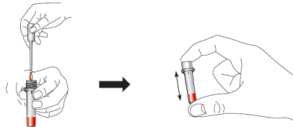
■ Specimen collection and preparation

- 1) The test can be performed with serum, plasma, or whole blood (with anticoagulant such as EDTA). Please follow the below method for Specimen collection and Preparation.
- 2) If the test kit and specimens are stored refrigerated, they should be brought to room temperature prior to use.

[Whole blood]

- (1) Blood should be collected with a disposable syringe and added to a tube containing anticoagulant (Heparin, EDTA, or Citrate). For the user's convenience, Anigen CHW Ag Test Kit 2.0 provides Anticoagulant tubes containing 20ul of EDTA. Please follow the directions below.

- A. Put the collected blood sample into the EDTA tube.
- B. Close the cap on the EDTA tube and invert the tube five times to mix the blood and the EDTA.



- (2) Collected blood should be tested immediately or within 4 hours at room temperature. If blood specimens are not immediately tested, they should be refrigerated at 2~8 °C and used within 24 hours.
- (3) **Severely hemolyzed blood samples may affect the result.**

[Plasma]

- (1) Blood should be collected with a disposable syringe and added to a tube containing anticoagulant (Heparin, EDTA, or Citrate), and then separate plasma by centrifugation.
- (2) Plasma should be stored at 2~8 °C for up to 2 weeks, for longer storage (1 year) freeze at below -20 °C.

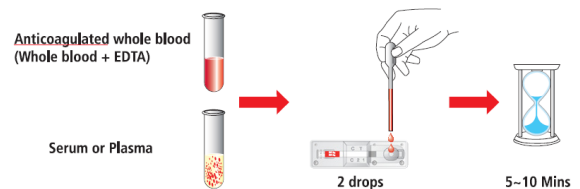
[Serum]

- (1) Blood should be collected with a disposable syringe and added to a serum collection tube (no anticoagulant).
- (2) Collected blood should be left at room temperature for 30 minutes to coagulate, and then separate serum by centrifugation.
- (3) Serum should be stored at 2~8 °C for up to 2 weeks, for longer storage (1 year) freeze at or below -20 °C.

■ Procedure of the test

- 1) Remove the test device from the foil pouch, and place it on a flat and dry surface.
- 2) Draw up the specimen using the disposable dropper.
- 3) Add two (2) drops (approximately 80ul) of canine serum, plasma or whole blood into the sample hole. **If the migration has not appeared after 1 minute, add one more drop into the sample well.**
- 4) As the test begins to work, you will see a purple color move across the result window in the center of the test device.
- 5) Interpret test results at **5 ~ 10 minutes**. Do not decide after 20 minutes.

[Figure for test Procedure]



■ Interpretation of the test

A colored band “C” will appear in the left section of the result window to show that the test is working properly. This band is the control band. The right section of the result window indicates the test results.

1) Negative result

The presence of only one band “C” within the result window indicates a negative result.



2) Positive result

The presence of two colored bands (“T” and “C”) within the result window, no matter which band appears first indicates a positive result.



3) Invalid result

If the control purple colored band (“C”) is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



■ Limitations of the test

Although the Anigen Rapid CHW Ag Test Kit 2.0 is very accurate in detecting Canine *Dirofilaria immitis* antigen, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the veterinarian after all clinical and laboratory findings have been evaluated.

In a study conducted in the US, the kit showed a specificity of 100% (54/54) and a sensitivity of 96.4% (53/55). In samples with “2 or more female worms” recovered at necropsy, the sensitivity was 100% (41/41). In a separate multicentric field trial study conducted in the US, the sensitivity (15/15) and specificity (5/5) were found to be 100%.