ONE STEP Canine Heartworm Antigen Test

For veterinary diagnostic use only

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 the letter "T" and "C" as the test line and control line on the surface of the device. Both the test line and control line in the result window are not visible before applying any samples. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working. A purple test line will be visible in the result window if there are enough heartworm antigens in the sample.
The highly selective antibodies to Canine *Dirofilaria immitis* antigens are used as each capture and detector in the assay. These are capable of detecting Canine *Dirofilaria immitis* antigen in sample with high accuracy.

Materials provided

Materials	2 Tests/Kit	5 Tests/Kit	10 Tests/Kit
Anigen Rapid CHW Ag 2.0 Test device	2	5	10
Disposable dropper	2	5	10
Anticoagulant tube	2	5	10
Instructions for use	1	1	1

Materials required, but not provided

1) Timer

Precautions

1) The test Kit is for canine use only. Do not use for other animals.
2) The test device is sensitive to humidity as well as heat. Perform the test immediately after removing the test device from the aluminum foil pouch.
3) Do not reuse test components.
4) Apply the sample vertically.
5) Do not touch the membrane in the result window of test device.
6) Do not use the test kit beyond the stated expiration date marked on the package label.
7) Do not use the test kit if the pouch is damaged or the seal is broken.
8) Do not mix components from different lot numbers because the components in this kit have been quality control tested as standard batch unit.
9) All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterward.
10) Decontaminate and dispose of all samples, used kits and potentially contaminated materials safely in accordance with national and local regulations.
11) Strictly follow the test procedures to minimize false or invalid test results due to improper administration of the product usage or doses.

Storage and Stability

1) Store the test kit at 2~30 °C. **DO NOT FREEZE.**
2) Do not store the test kit in the direct sunlight.
3) The test kit is stable within the expiration date that marked on the package label.

Collection and Preparation of Sample

1. The test should be performed using serum, plasma, or whole blood (anticoagulated). Please follow the below method for sample collection and preparation.
2. If the test kit and samples are refrigerated, they should be brought to room temperature (15~30 °C) prior to use.

[Whole blood]

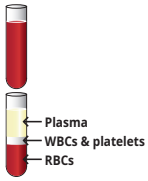
1) Blood should be collected with a disposable syringe and added to a tube containing anticoagulant (Heparin, EDTA or Citrate).
For the user's convenience, Anigen Rapid CHW Ag Test Kit 2.0 provides anticoagulant tubes (Max. vol. 1.5 ml). Please follow the directions below.

A. Put the collected blood sample into the anticoagulant tube.
B. Close the cap on the anticoagulant 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. It must be stored at 2~8 °C for 24 hours.
* Note: Blood samples should not be frozen prior to testing.
3) Severely hemolyzed blood samples may affect the result.

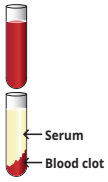
[Plasma]

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) The collected plasma can be stored at 2~8 °C (35.6~46.4 °F) for up to 2 weeks. For longer storage, they can be stored frozen at -20 °C (-4 °F) or below for up to 1 year.



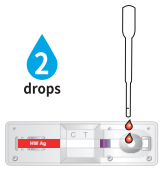
[Serum]

1) Blood should be collected with a disposable syringe and added to a serum collection tube (no anticoagulant), leave to settle for 30 minutes for blood coagulant and then centrifuge to get serum supernatant.
2) The collected serum can be stored at 2~8 °C (35.6~46.4 °F) for up to 2 weeks. For longer storage, they can be stored frozen at -20 °C (-4 °F) or below for up to 1 year.



Procedure of the Test

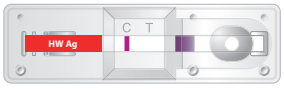
1) All reagents and samples must be at room temperature (15~30°C) for 15~30 minutes prior to use.
2) Remove the test device from the aluminum foil pouch, and place it on a flat and dry surface.
3) Using the disposable dropper, add **2 drops (approximately 80 µl) of sample** into the sample hole.



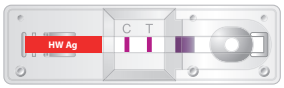
4) Start the timer. The sample will flow across the result window. If it does not appear after 1 minute, add one more drop of mixed sample to the sample hole.
5) Interpret test results at **5~10 minutes**. Do not read after 20 minutes.

Interpretation of the Result

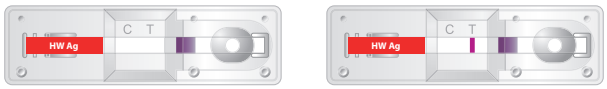
1) Negative result
Only Control ("C") line appears in the result window.



2) Positive result
The Test ("T") line and Control ("C") line within result window indicate the presence of Canine *Dirofilaria immitis* antigen.



3) Invalid Result
If the Control ("C") line does not appear, the result might be considered invalid. The sample should be re-tested.



Limitations of the Test

1) Although the Anigen Rapid CHW Ag Test kit 2.0 is very accurate in detecting Canine heartworm 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.
2) The reading window may show a light pink background coloration; this will not affect the accuracy of the results.
3) BioNote and its distributors cannot be held responsible for the consequences of misuse or misinterpretation of the results given by the test.

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Manufactured by BIONOTE
BioNote, Inc.
22, Samsung 1-ro 4-gil, Hwaseong-si, Gyeonggi-do 18449, Republic of Korea
TEL: 82-31-211-0516 I FAX : 82-31-8003-0618 I www.bionote.co.kr