ONE STEP *Dirofilaria immitis* Antigen and *Ehrlichia canis, Leishmania infantum, Anaplasma phagocytophilum/platys* Antibody Test

For veterinary diagnostic use only

Anigen Rapid CaniV-4(Leish) Test Kit

Principles

The Anigen Rapid CaniV-4(Leish) Test Kit is a chromatographic immunoassay for the qualitative detection of *Dirofilaria immitis* antigen, *Ehrlichia canis* antibody, *Leishmania infantum* antibody and *Anaplasma phagocytophilum/ Anaplasma platys* antibody in canine serum, plasma or whole blood.
The Anigen Rapid CaniV-4(Leish) Test Kit has two letters which are test line ("T") and control line ("C") on the surface of device. Test line and control line in the result window are not visible before applying any samples. The control line is a reference line which indicates the test is performing properly. The control line has to appear every time when the test has performed. If the target antigens and/or antibodies are present in sample, a purple test line would appear in the result window.
The highly selective recombinant antigen or antibody is used as a capture or detector in the assay. These are capable of detecting *Dirofilaria immitis* antigen(HW Ag), *Ehrlichia canis* antibody(E.canis Ab), *Leishmania infantum* antibody(Leishmania Ab) and *Anaplasma phagocytophilum/Anaplasma platys* antibody(Anaplasma Ab) in canine sample with high accuracy.

Materials provided

Reagent	5 Tests/Kit	10 Tests/Kit
Anigen Rapid CaniV-4(Leish) Test Devices	5	10
Assay diluent bottles	1	1
Anticoagulant tubes	5	10
Disposable capillary tubes (20 μℓ)	5	10
Instructions for use	1	1

♣ A black line on the capillary tube is the indicator line for 20 μℓ.

Materials required, but not provided

1) Timer, Micropipette

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 foil pouch.
3) Do not reuse the test components.
4) Apply the sample using dropper or capillary tube 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 afterwards.
10) Decontaminate and dispose of all samples, used kits and potentially contaminated materials safely in accordance with national and local regulations.

Storage and Stability

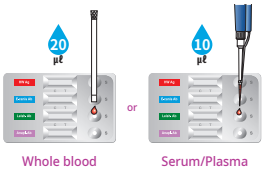
1) Store the test kit at 2~30°C. **DO NOT FREEZE.**
2) Do not store the test kit in the direct sunlight.
3) The test kit is stable within the expiration date that marked on the package label.

Collection and Preparation of Sample

1) Whole blood, serum, or plasma should be for this test.
[Whole blood] Collect the whole blood into the anticoagulant tube (Max. vol. 1.5ml) provided. If anticoagulated whole blood is not immediately tested, they should be refrigerated at 2~8°C and used within 24 hours.
[Serum] Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate), leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get supernatant.
[Plasma] Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) and then centrifuge blood to get plasma.
2) Serum samples should be stored at 2~8°C. For longer storage, freeze the samples at -20°C or below. Avoid repeated freezing and thawing.
3) Samples containing precipitate may yield inconsistent test results. They must be clarified prior to assaying.
4) Hemolyzed or contaminated samples may give erroneous results.

Procedure of the Test

1) All reagents and samples must be at room temperature (15~30°C) before running assay.
2) Remove the test device from the foil pouch, and place it on a flat and dry surface.
3) Using a disposable capillary tube, add 20 μℓ of whole blood into each sample hole. Or, add 10 μℓ of serum/ plasma into each sample hole using a micropipette.

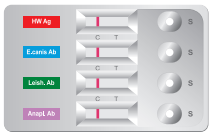


4) Dispense 3 drops of assay diluent into each sample hole.
5) Start the timer. The sample will flow across the result window. If it does not appear after 1 minute, add one more drop of assay diluent to the sample hole.

6) Interpret test results at **15 minutes**. Do not read after 25 minutes.

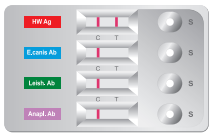
Interpretation of the Result

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

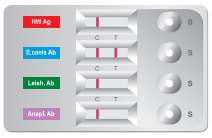


2) Positive result
Test line ("T") and control line ("C") within the result window indicate the presence of target antigens and/or antibodies.
* NOTE: Test strip of Anaplasma Ab can't differentiate between *A.phagocytophilum and A.platys*: a positive result indicates presence of antibodies to *A. phagocytophilum* and/or *A. platys*

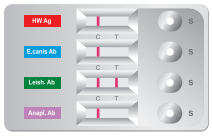
CHW Ag Positive



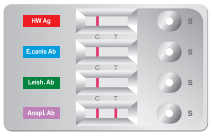
E.canis Ab Positive



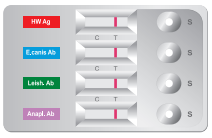
Leishmania Ab Positive

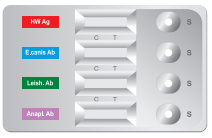


Anaplasma Ab Positive



3) Invalid Result
If the control line ("C") does not appear, the result might be considered invalid. The sample should be retested.





Limitations of the Test

1) Although the Anigen Rapid CaniV-4(Leish) Test kit is very accurate for detecting *Dirofilaria immitis* antigen, *Ehrlichia canis* antibody, *Leishmania infantum* antibody and *Anaplasma phagocytophilum/Anaplasma platys* antibody, a low incidence of false results can be occurred. Other clinical and/ or laboratory tests might be required if questionable results are obtained. As other diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should be diagnosed 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 Samsung1ro 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