ONE STEP Leishmania Antibody Test

For veterinary diagnostic use only

Anigen Rapid Leishmania Ab Test Kit

Principles

The **Anigen Rapid Leishmania Ab Test Kit** is a chromatographic immunoassay for the qualitative detection of *Leishmania infantum* antibodies in canine whole blood, plasma, or serum.

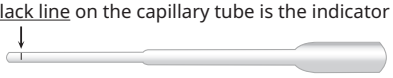
The **Anigen Rapid Leishmania Ab Test Kit** has two letters which are test ("T") line and control ("C") line on the surface of the device. The test line and control line in the result window are not visible before applying any samples. The control line is a reference line which indicates the test is performing properly. It has to appear every time when the test has performed. If the *Leishmania infantum* antibody is present in the sample, a purple test line would appear in the result window.

The highly selective Leishmania antigens are used as capture and detector materials. These are capable of detecting Leishmania antibodies in canine sample with high accuracy.

Materials provided

Reagent	10 Tests/Kit
Anigen Rapid Leishmania Ab Test device	10
Assay diluent bottle	1
Disposable capillary tube	10
Anticoagulant tube	10
Instructions for use	1

♣ A black line on the capillary tube is the indicator line for 10 µl.



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 foil pouch.
3) Do not reuse the test components.
4) Apply the sample and assay diluent 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, reaction 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 direct sunlight.
3) The test kit is stable within the expiration date marked on the package label.

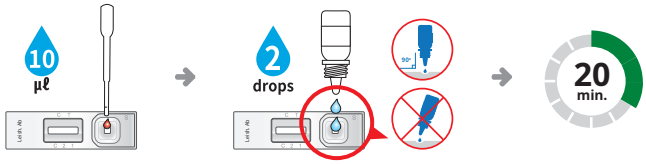
Sample Collection and Preparation

1) Canine whole blood, serum, or plasma should be used with this test.
   [Whole blood] Collect the whole blood into the anticoagulant tube (Max.vol. 1.5 ml) provided. It is recommended to immediately use the anticoagulated whole blood. If samples are not tested immediately, they can be stored at room temperature for up to four hours from the sample collection, or up to 24 hours if stored at 2~8 ℃ (35.6~46.4 ℉).
   [Serum] Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate), leave it to settle for 30 minutes for blood coagulation, and then centrifuge to get the serum supernatant.
   [Plasma] Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) and then centrifuge to get the plasma.
2) The collected plasma and serum can be stored at 2~8 ℃ (35.6~46.4 ℉) for up to 2 weeks. For longer storage, they can be stored frozen at -20 ℃ (-4 ℉) or below for up to 1 year. Frozen samples should be brought to room temperature (15~30 °C) prior to use.
3) Samples containing precipitate may yield inconsistent test results. Such samples must be clarified prior to assaying.
4) The use of hemolytic or bacterially contaminated samples should be avoided. An erroneous result may occur.

Procedure of the test

1) All reagents and samples must be at room temperature (15~30 °C) before use.
2) Remove the test device from the foil pouch, and place it on a flat and dry surface.
3) Using the disposable capillary tube, **10 µl of the sample** into the sample hole (S), and then **add 2 drops of the assay diluent.**
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 assay diluent to the sample hole (S).
5) Interpret test results at **20 minutes**. Do not interpret after 30 minutes.

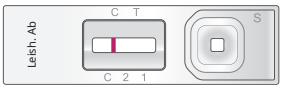
[Test procedure]



Interpretation of the test

1) Negative result

One Control ("C") line appears in the result window.



2) Positive result

Test ("T") line and Control ("C") line within the result window indicate the presence of *Leishmania infantum* antibodies.

3) Invalid Result

If the Control ("C") line does not appear, the result might be considered invalid. The samples should be retested.

Limitations of the test

1) Although the Anigen Rapid Leishmania Ab Test Kit is very accurate in detecting canine Leishmania antibodies, a low incidence of false results can be occurred. Other clinically 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 Inc. and its distributors cannot be held responsible for the consequences of misuse or misinterpretation of the results given by the test.

Doc. No.: I2104-12E
Issued date: Aug. 12, 2022

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