# Anigen Rapid Leishmania Ab Test Kit

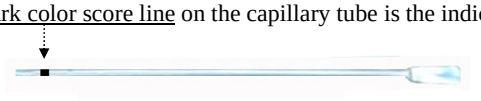
## ■ Principles

**The Anigen Rapid Leishmania Ab Test Kit** is a chromatographic immunoassay for the qualitative detection of Leishmania infantum antibodies in canine whole blood, serum, or plasma. The Anigen Rapid Leishmania Ab Test Kit has a letter of "T" and "C" as 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 sample. The control line is used for procedural control, and should always appear if the test procedure is performed correctly and the test reagents are working. A purple test line will be visible in the result window if Leishmania antibodies are present in the specimen. The specially selected Leishmania antigens are used in the test band as both capture and detector materials. These enable the Anigen Rapid Leishmania Ab Test Kit to identify Leishmania infantum antibodies in canine whole blood, serum, or plasma with avery high degree of accuracy.

## ■ Materials provided (10 Tests/Kit)

1) Ten (10) Anigen Rapid LeishmaniaAb Tests.
2) One (1) Bottle containing 4 ml of Assay diluents.
3) Ten (10) Anticoagulant bottles.
4) Ten (10) Disposable capillary tubes for specimens.
5) One (1) Instruction for use.

♣ A dark color score line on the capillary tube is the indicator line for 10㎕.



## ■ 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 before running the assay.
8) Do not use reagents beyond the stated expiration date marked on the label.
9) The components in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.

## ■ Storage and Stability

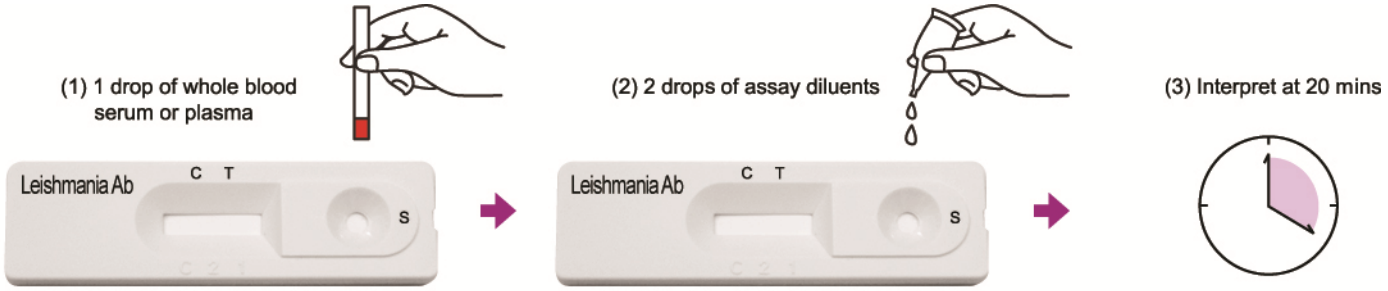
The kit can be stored at room temperature (2~30℃) or refrigerated. The kit is stable through the expiration date marked on the package label. **DO NOT FREEZE**. Do not store the test kit in direct sunlight.

## ■ Specimen Collection and Preparation

1) The test should be performed using serum, plasma, or whole blood.
2) [Whole blood]
Collect an anticoagulated blood sample in EDTA, heparin for citrate using standard clinical laboratory procedures. Anticoagulated whole blood samples should be tested within 24 hours of drawing. If delays are expected samples should be stored either on ice or refrigerated (2~7℃), but should not be frozen. If anticoagulated whole blood samples cannot be tested within this period of time, separate plasma by centrifugation and store as described in the next section.
3) [Plasma]
Collect an anticoagulated blood sample using standard clinical laboratory procedures. Separate plasma by centrifugation. Plasma samples may be stored refrigerated (2~7℃) for up to 72hours; for longer storage, freeze at or below -20℃ in vials with air-tight seals.
4) [Serum]
Collect and prepare serum samples using standard clinical laboratory procedures. Serum samples may be stored refrigerated (2~7℃) for up to 72 hours, for longer storage freeze at or below -20℃ in vials with air-tight seals.

## ■ Test Procedure

1) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
2) Add 10 ㎕ of whole blood, serum, or plasma to the sample hole marked "S" on the test device with a capillary tube and then add 2drops(approsimately 80 ㎕) with bottle containing assay diluents.
3) For the test result, you will see the purple band in the result window of the kit. Interpret test results at 20 minutes. **Do not interpret after 30 minutes.**



## ■ Interpretation of the test

A color band 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. If another color band appears in the right section of the result window, it is the test band.

**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 color bands (“T” and “C”) within the result window, no matter which band appears first indicates a positive result.


**3) Invalid Result**

If the purple color 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 Leishmania Ab Test kit is very accurate for detecting Canine Leishmania Antibodies, a low incidence of false results can occur. Other clinical 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

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