

One-Step Leishmania Antibody Test

Rapide - Leishmania Ab Test Kit

■ Principles

The **Rapide - Leishmania Ab Test Kit** is a chromatographic immunoassay for the qualitative detection of *Leishmania infantum* antibodies in canine whole blood, serum, or plasma. The **Rapide - Leishmania Ab Test Kit** has the letter “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 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 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 **Rapide - Leishmania Ab Test Kit** to identify *Leishmania infantum* antibodies in canine whole blood, serum, or plasma with a very high degree of accuracy.

■ Materials provided (10 tests/kit)

- 1) Ten (10) **Rapide - Leishmania Ab Tests**.
 - 2) One (1) Bottle containing 4 ml of whole blood diluent.
 - 3) One (1) Bottle containing 4 ml of developing buffer.
 - 4) Ten (10) test tubes for whole blood dilution.
 - 5) One (1) Paper rack.
 - 6) Ten (10) Disposable capillary tubes for specimens.
 - 7) Ten (10) Disposable droppers for whole blood dispensing.
 - 8) One (1) Instruction for use.
- ♣ A dark color score line on the capillary tube is the indicator line for 10 μ l.



■ Precautions

- 1) For veterinary diagnostic use only.
- 2) For the best results, strict adherence to the instructions is required.
- 3) All specimens should be handled as being potentially infectious.
- 4) Do not open or remove test kits from their individually sealed pouches until immediately before use.
- 5) Do not use the test kit if the pouch is damaged or the seal is broken.
- 6) Do not reuse test kits.
- 7) All reagents must be at room temperature (15 $^{\circ}$ C~30 $^{\circ}$ C) 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 or refrigerated (2 $^{\circ}$ C~30 $^{\circ}$ C). The test 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

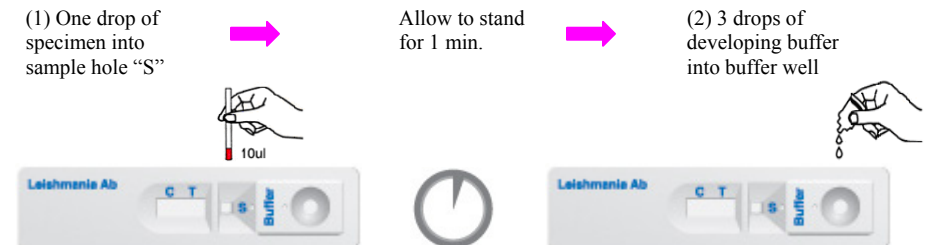
- 1) The test should be performed using serum, plasma, or whole blood.
- 2) [Whole blood]: Collect an anticoagulated blood sample in EDTA, heparin or citrate using standard clinical laboratory procedures. Anticoagulated whole blood samples should be tested within 24 hours of drawing. If delays are expected between sampling and testing, the sample should be stored either on ice or refrigerated (2~7 $^{\circ}$ C), 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 $^{\circ}$ C) for up to 72hours; for longer storage, freeze at or below -20 $^{\circ}$ C 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 $^{\circ}$ C) for up to 72 hours; for longer storage, freeze at or below -20 $^{\circ}$ C in vials with air-tight seals.

Note: Refrigerated and frozen samples should be brought to room temperature prior to use. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

■ Test Procedure

[Serum & Plasma specimen]

- 1) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
- 2) Add 10ul of serum, or plasma to the sample hole marked “S” on the test device with a capillary tube and wait for 1 minute, then add 3 drops of the developing buffer into the buffer well.



- 3) As the test begins to work, you will see a purple color move across the result window in the center of the test device. Interpret test results at 20 minutes. Do not interpret after 30 minutes.

[Whole-blood]

- 1) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
- 2) Dispense 3 drops of the whole-blood diluent into the test tube for the whole-blood dilution. Add 1 drop (30ul) of the whole-blood sample with a disposable dropper; mix and allow to stand for 1 minute.
- 3) Add 10ul of the mixed sample into the sample hole marked "S" on the test device with a capillary tube and wait for 1 minute.
- 4) Dispense 3 drops of the developing buffer into the buffer well.

(1) 3 drops of the whole-blood diluent



Allow to stand for 1 min.



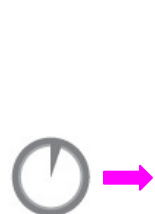
(2) 1 drop of the whole-blood into the test tube



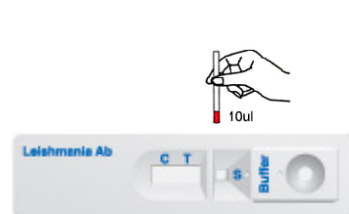
(4) 3 drops of developing buffer into buffer well



Mix & allow to stand for 1 min.



(3) 1 drop of the mixed sample into sample hole "S"



- 2) **Positive:** The presence of two color bands ("T" band and "C" band) within the result window, no matter which band appears first, indicates a positive result.



- 3) **Invalid:** 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.



■ Performance

In a study using 123 samples, **Rapide** - Leishmania Ab Test kit was compared to Immunofluorescent Antibody Test (IFA), a reference standard technique in laboratory diagnostics; the sensitivity was 95.6% and specificity was 98%.

■ Limitations of the test

Although the **Rapide** - 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.

■ 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 line ("C"). The right section of the result window indicates the test result. This band is the Test line ("T").

- 1) **Negative:** The presence of only one purple color band "C" within the result window indicates a negative result.



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