Leishmania Canis Antibody Rapid Test

Intended Use

Leishmania Canis Antibody Rapid Test is a lateral flow immunoassay for the qualitative detection of leishmania canis antibodies in canine serum, plasma or whole blood samples. It is an auxiliary method for detecting leishmania canis infection, which is only used for in vitro diagnosis of canine.

Principle

The Leishmania Canis Antibody Rapid Test uses highly specific antibody-antigen reactions and immunochromatographic techniques to detect Leishmania canis antibodies in specimens. The test device has a testing window which has test line region(T) and control line region(C). Before testing, no colored line in the testing window. During the test, if the specimen, which is added to the specimen well (S) on the test device, contains leishmania canis antibodies, the antibodies will react with the leishmania antigen immobilized in the gold labeled pad to form a complex. The complex will move upwards and react with the anti-dog IgG antibodies pre-coated in the test line region(T), a clear colored line will appear in the test line region(T) , indicating a positive result. If the specimen does not contain the leishmania canis antibody, a colored line will not appear in the test line region(T), indicating a negative result. As a procedural control, a colored line will always appear in the control line region(C) indicating that proper volume of specimen has been added and the membrane has been wicking through.

Storage and Stability

The test device is sealed and stored away from light at room temperature or refrigerated (4-30℃). DO NOT FREEZE.

The test kit should be used before the expiration date marked on the package label.

Precautions

- The test kit is for canine use only. Do not use for other animals.
- Humidity and temperature can influence the results.
- Make sure that the foil pouch containing the test is not damaged before opening it for use. Perform the test immediately after removing the test device from the foil pouch.
- Do not reuse test components.
- Do not use after the expiry date.
- Do not mix components from different lot numbers and be sure to use the reagents supplied with this kit. Because the components in this kit have been quality control tested as standard batch unit.
- All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterwards.
- Decontaminate and dispose of all samples, used kits and potentially contami-nated materials safely in accordance with national and local regulations.

Additional Special Equipment

Materials Provided

• Test devices • Droppers • Buffer • Package insert

Materials Required But Not Provided

• Timer

Direction For Use

1. Collect specimens

Serum or plasma: fresh dog blood should be collected and centrifuged to obtain serum, or dog blood should be placed in a tube containing anticoagulant for static placement or centrifuged to obtain plasma. Do not leave the specimens at room temperature for prolonged periods.

If serum or plasma specimens need to be preserved, they may be stored at 2-8℃ for 24h. For more than 24h storage, specimens should be kept below -20℃. Restore sample to room temperature before use.

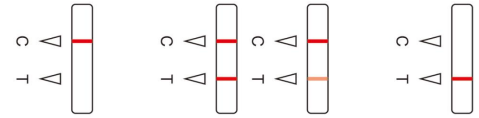
2. Test procedure

Remove the test device from the sealed aluminum foil bag, and place it on a clean, flat table.

Use a disposable dropper, add 1 drop (approximately 10ul) of the serum, plasma, or whole blood specimen to the specimen well (S) on the test device, and then add 3 drops (approximately 90ul) of diluent to the specimen well (S) on the test device.

Read the result in 10 minutes. The result is invalid after 20 minutes.

Interpretation of Results



Negative Positive Invalid

Positive (+): Two colored lines appear. One line should always appear in the control line region(C), and another one apparent colored line should appear in the test line region(T).

Note: The intensity of the color in the test line regions(T) may vary depending on the concentration of leishmania canis antibody present in the specimen. Therefore, any shade of color in the test line region(T) should be considered positive.

Negative (-): Only one colored line appears in the control line region (C), and no colored line appears in the test line region (T).

Invalid: No colored line appears in the control line region (C), indicating that the test result is ineffective. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. In this case, read the package insert carefully and test again with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Limitations

Although the Leishmania Canis Antibody Rapid Test is very accurate in detecting leishmania canis antibody, a low incidence of false results may 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.

Symbols

IVD	Medical in vitro diagnosis		Storage temperature limits (4-30°C)
	Manufacturer		Tests per set
LOT	Batch code		Do not reuse
	Follow the instructions for use	EC REP	European Authorised Representative
	Expiry date	REF	Catalogue number
	Keep away from sunlight		Keep dry