ZOOLAB Lyme Ab Rapid Test Kit

+Introduction

Lyme disease is caused by a spirochete, Borrelia burgdorferi which is transmitted to dogs through the bite of a tick. Once in the blood stream, the Lyme disease organism is carried to many parts of the body and is likely to localize in joints or kidneys. Affected dogs have been described as if they were walking on eggshells. Often these pets have high fevers. Dogs may also begin limping. This painful lameness often appears suddenly and may shift from one leg to another .

The Lyme Ab Rapid Test Kit uses chromatographic immunoassay for the qualitative detection of Lyme disease antibody in blood. Sample to be tested is loaded to the sample pad, and then capillary flow along on the test strip. The detection antigen which is coupled with colloidal gold as conjugate will mix with the sample fluid. Where Lyme disease antibody is present, a complex is formed by Lyme disease antibody and colloidal gold labelled antigen. The labelled antigen–antibody complex is then bound by 'capture-antibody' that recognizes the complex, and which is immobilized as T line on the test strip. A positive result therefore generates a visible wine-red line of antigen–antibody complex. A wine-red C line will appear to confirm the test is operated correctly.

+Components

1	Test Device	10
2	Dropper	10
3	Dilution Buffer	1
4	Instruction	1

+Notice

1) Use for in-vitro diagnostic purposes only.
2) Use within 10 minutes after opening the pouch because the test kit is very sensitive to moisture and its effect may diminish. DO NOT use the test device if its foil pouch is broken.
3) Be careful of not touching the result window.
4) Every specimen should be used with different droppers.
5) For testing, the buffer included should be used.
6) Do not use specimen showing hemolysis or being contaminated with microbes, which may cause false positive or false negative result.
7) Deal with specimen carefully. They can deliver unknown virus or infectious bacteria.
8) Use disposable gloves when you suspect the infection caused by specimen. And wash your hands later.
9) Make sure the used test device is treated properly according to the local biosafety 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 marked on the package label.

+Collection and Preparation of Sample

1.The test should be performed using serum, plasma, or whole blood (anticoagulated). Please follow the below method for sample collection and preparation.
2.If the test kit and samples are refrigerated, they should be brought to room temperature (15~30 °C) prior to use.
3.Collection:
1) Whole blood and plasma should be collected with a disposable syringe and added to a tube containing anticoagulant (Heparin, EDTA or Citrate).
2) Serum: Blood should be collected with a disposable syringe and added to a serum collection tube (no anticoagulant), leave to settle for 30 minutes for blood coagulant and then centrifuge to get serum supernatant.
4.Sample storage:
1) Whole blood should be tested immediately or within 4 hours at room temperature. It must be stored at 2~8 o C for 24 hours. * Note: Blood samples should not be frozen prior to testing. Severely hemolyzed blood samples may affect the result.
2) Serum and plasma can be stored at 2~8 °C (35.6~46.4 °F) for up to 2weeks. For longer storage, they can be stored frozen at -20 °C (-4 °F) or below for up to 1 year.

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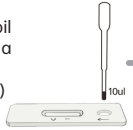
+Test Procedure

1) Whole blood, plasma or serum is collected for testing.

2) Take out the test device from the foil pouch and put on a flat surface. Using a dropper as a pipette, obtain the specimen and dispense 10ul (black line) of the fluid into the specimen well marked "S" on the device.



3) Add 3 drops of dilution buffer into sample well marked "S" on the device. During this period, wine-red fluid flow over the membrane inside the window can be observed. If no flow is observed, gently press the position between sample well and window to help the fluid flow.

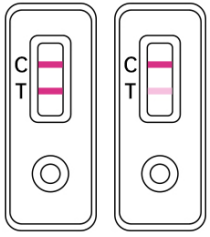
4) Place the device on a flat surface upward and wait for 5~10 minutes.

5) Read the result of color change in T line and C line within 10 minutes. Color change after 10 minutes is not valid result.

+Interpretation of the Result

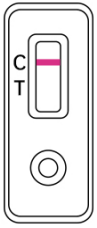
1) Positive result

Wine-red color line appeared on both T and C line. Indicate specimen contains Lyme disease antibody.



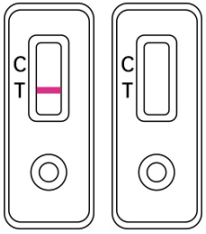
2) Negative result

No color appeared on T line, wine-red color appeared on C Line. Indicate Lyme disease antibody concentration is out of test's limit, further clinical approach may be considered.



3) Invalid result

No color appears on C Line. Indicate something wrong with the test kit or operation. The result shall not be considered as valid.



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