

+Introduction

Leptospirosis is a bacterial disease of dogs and other mammals that primarily affects the liver or kidneys. The bacteria (*Leptospira*) that cause leptospirosis, commonly called leptospire, thrive in water and they have a helical or spiral shape with a characteristic hook on one or both ends. There are many species and serovars (strains) of *Leptospira*, some of which cause disease in dogs. Leptospirosis in cats is very rare and is not associated with clinical disease.

The **Leptospira Ab Rapid Test Kit** uses chromatographic immunoassay for the qualitative detection of leptospira 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 leptospira antibody is present, a complex is formed by leptospira 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) DO NOT use the test device if it is expired or its foil pouch is broken. Make sure use the device within 1 hour after open the pouch.
- 2) The kit is suggested to be stored at ambient, if it is store in cold environment, do not open the foiled pouch before the test device back to ambient temperature to avoid condensation.

- 3) DO NOT touch the membrane from sample well and observation window.
- 4) To get accurate result, make sure to collect fresh sample without contamination. If sample contains too much blood lipid, centrifuge the sample, then take the serum without lipid contamination.
- 5) Store serum sample at 4°C when test take place in 48 hours, store at -20°C for long time preservation.
- 6) Whole blood sample without anticoagulant should be tested as soon as possible, if partially coagulated, please separate serum for test. Whole blood sample with anticoagulant should be tested within 24 hours, do not freeze it in case of hemolysis which will interfere the test.
- 7) 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

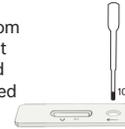
1. The test should be performed using serum, plasma, or whole blood (anticoagulated). Please follow the below method for sample collection and preparation.
2. If the test kit and samples are refrigerated, they should be brought to room temperature (15~30 °C) prior to use.
3. **Collection:**
 - 1) **Whole 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 °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 2 weeks. For longer storage, they can be stored frozen at -20 °C (-4 °F) or below for up to 1 year.

+Test Procedure

1) Collection of 0.5-1mL whole blood separated plasma or serum (3000 RPM/heart separated for 3-5 minutes, or 4°C overnight natural precipitation), or use whole blood with anticoagulant as a test sample. Whole blood without anticoagulants can also be used, but must be tested immediately.



2) Take out the test device from the foil pouch and put on a flat surface. Transfer 10 ul of blood sample into sample well marked "S" on the device by dropper.



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.



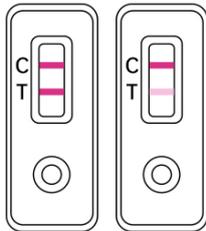
5) Read the result of color change in T line and C line within 10 minutes. Color change after 10 minutes is not valid result.



+Interpretation of the Result

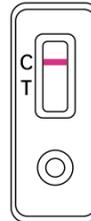
1) Positive result

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



2) Negative result

No color appeared on T line, wine-red color appeared on C Line. Indicate leptospira 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.

