

## +Introduction

**Ehrlichiosis** develops after a dog has become infected with Ehrlichia canis bacteria, which are primarily transmitted to dogs through the bites of ticks. Dogs will appear perfectly normal for one to three weeks after being bitten by a tick carrying E. canis bacteria. If the dog is unable to fight off the infection during this time, he will enter what is known as the acute phase of infection. During this time, the bacteria are actively reproducing within a certain type of white blood cell and are spreading throughout the body.

**The Ehrlichia Ab Rapid Test Kit** uses chromatographic immunoassay for the qualitative detection of Ehrlichia 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 Ehrlichia antibody is present, a complex is formed by Ehrlichia 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

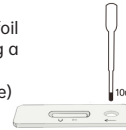
1. The test should be performed using serum, plasma, or whole blood (anticoagulated). Please follow the below method for sample collection and preparation.
2. If the test kit and samples are refrigerated, they should be brought to room temperature (15~30 °C) prior to use.
- 3. Collection:**
  - 1) **Whole 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 °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) 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.



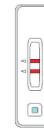
3) Add 3 drops of dilution buffer into sample well marked "S" on the device. During this period, wine-red fluid flow over the membrane inside the window can be observed. If no flow is observed, gently press the position between sample well and window to help the fluid flow.



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



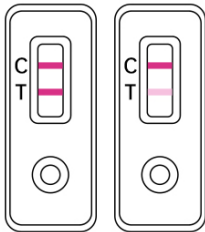
5) Read the result of color change in T line and C line within 10 minutes. Color change after 10 minutes is not valid result.



## +Interpretation of the Result

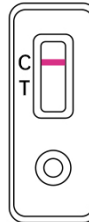
### 1) Positive result

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



### 2) Negative result

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

