

## [PRODUCT NAME]

Canine Ehrlichia Antibody Rapid Test Kit

## [PACKING SPECIFICATIONS]

1/5/10/25/50 test(s)/kit

## [INTENDED USE]

This product does not require any additional equipment and is used for qualitative detection for Ehrlichia canis (E. canis) antibody in canine whole blood/serum/plasma.

## [TEST PRINCIPLE]

This product adopts the principle of immunocolloidal gold technology and immunochromatography technology. When the sample contains E. canis antibodies, the antibody reacts with the colloidal gold labeled antigen on the conjugate pad to form a labeled antigen-antibody complex. The complex moves upward by capillary action and captured by the protein coated on test line (T), and a red band appeared. On the contrary, no red band appears in the test line (T). Regardless of whether there is E. canis antibody in the tested sample, The complex continues to chromatograph upward and a red band appears on the control line (C). The red band presented in the control line (C) is the standard for judging whether the chromatography process is normal, and it also serves as the internal control standard for the test pad.

## [MAIN COMPONENTS]

| Component                           | 1test/kit | 5tests/kit | 10tests/kit | 25tests/kit | 50tests/kit |
|-------------------------------------|-----------|------------|-------------|-------------|-------------|
| Test pad                            | 1         | 5          | 10          | 25          | 50          |
| Instruction manual                  | 1         | 1          | 1           | 1           | 1           |
| Sample extraction tube with diluent | 1         | 5          | 10          | 25          | 50          |
| Swab                                | 1         | 5          | 10          | 25          | 50          |
| Disposable lancet                   | 1         | 5          | 10          | 25          | 50          |
| Disposable plastic straw(optional)  | 1         | 5          | 10          | 25          | 50          |
| Medical waste bag (optional)        | 1         | 5          | 10          | 25          | 50          |

**Note: The components in kits from different batch numbers are not interchangeable.**

**Warning: If the diluent gets onto the skin or eyes, the user should wash it off immediately with clean water.**

## [STORAGE CONDITIONS AND VALIDITY PERIOD]

1. Storage conditions: The original packaging should be stored in a dry place at 2-30°C, protected from light, and do not freeze.

2. Validity period: 24 months.

3. The test pad should be used as soon as possible within 1 hour after unpacking the aluminum foil bag; it is recommended to use it as soon as possible when the surrounding temperature is higher than 30°C or in a high humidity condition.

## [SAMPLE REQUIREMENTS]

1. Sample type: Whole blood, serum, plasma.

## 2. Sample collection

2.1 Serum/plasma: Serum and plasma should be separated as soon as possible after whole blood collection to avoid hemolysis.

2.2 Whole blood: Use disposable lancet and swabs for collection.

2.2.1 Take off the safety cap of the disposable lancet.

2.2.2 Then prick the edge of the dog's ear with the disposable lancet.

2.2.3 When you see a full droplet of blood, take the swab and collect the sample.

2.2.4 At the end of collection, gently press on the dog's ear to stop the bleeding.

## 3. Sample storage

3.1 Whole blood should be tested immediately.

3.2 Serum/plasma: Stable at 2-8°C for no more than 1 month. Long-term storage requires freezing at -20°C~-70°C. Samples should be equilibrated back to room temperature before testing. In addition, frozen samples must be completely thawed and mixed well before use. Avoid repeated freezing and thawing.

## [TEST METHOD]

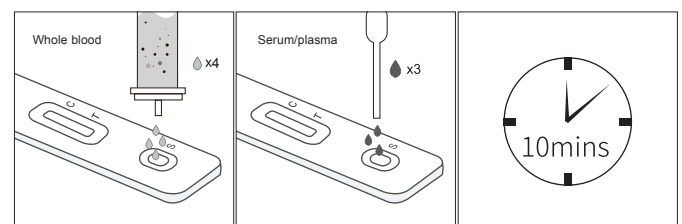
1. Unopened test pads should be allowed to equilibrate to room temperature before test.

2. Whole blood: Tear off the foil of the extraction tube, using the swab to collect blood, after the swab is red throughout and will no longer absorb any more blood, then place in the tube with diluent and rotate it several times against the inner wall of the tube to fully dissolve the canine whole blood in the sample diluent, mix thoroughly, then cap the extraction tube and set aside. Tear the aluminum foil bag along the incision, take out the test pad and place it flat on a clean table. Slowly add 4 drops vertically from the extraction tube into sampling hole (S) of the test pad and start timing.

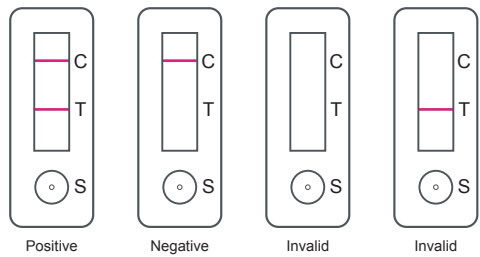
3. Serum/plasma: Tear the aluminum foil bag along the incision, take out the test pad and place it flat on a clean table. Using pipette to take serum/plasma (about 75 µL, if using the disposable plastic straw, add 3 drops of sample) into sampling hole (S) of the test pad and start timing. Refrigerated samples need to be restored to 15-25°C before testing.

4. Read the result in 10-30 minutes and the result is invalid after 30 minutes.

**Note: Please read the results within the specified time: Interpreting less than or exceeding time may lead to erroneous results.**



[INTERPRETATION OF TEST RESULTS]



**Positive Result:**  
A red bands appear in both the test line (T) and the control line(C). The results show that the sample contained *E. canis* antibodies.

**Negative Result:**  
A red band only appears in the control line (C). The results show that the sample does not contain *E. canis* antibodies.

**Invalid Result:**  
If there is no red band in the control line (C), the result is invalid. A re-test is recommended.

*Note: Even if the control line (C) or test line (T) is faint or not uniform, the test should be considered to have been performed properly, and the test result should be interpreted as above. Positive results should be interpreted by the veterinarian in conjunction with the clinical history and other available data.*

[LIMITATIONS]

- 1. This kit is for in vitro qualitative diagnosis only.
- 2. The test results of this kit are for clinical reference only. The clinical management should be comprehensively considered in conjunction with symptoms/signs, medical history, other laboratory tests, and treatment response.

[PRECAUTIONS]

- 1. For animal use only.
- 2. The product is for single-use, please use it within the validity period.
- 3. Please read the instruction manual carefully before use, required to be operated by professionally trained inspectors, and carry out the test operation in strict accordance with the procedure.
- 4. If the aluminum foil bag packaging is found to be damaged, please do not use it. After tearing open the aluminum foil bag and taking out the test pad, it should be used as soon as possible to prevent the test pad from getting damp.
- 5. Temperature has a great impact on test results.
- 6. Only the sample diluent in the kit can be used during testing. Do not use tap water, purified water, or distilled water.
- 7. All samples, waste liquids and wastes should be treated as infectious agents, and attention should be paid to the biological safety of operations. All used consumables, test pads and other wastes should be put into medical waste bags in accordance with relevant local regulations to be handled properly.

[VERSION AND UPDATE DATE]

Version: 2.0  
Updated date: 2024.05.09

[PRODUCTION DATE AND EXPIRATION DATE]

See label for production date and expiry date.

[LABEL INTRODUCE FOR USER]

| Abbreviation                                                                        | Explanation                      | Abbreviation                                                                        | Explanation              |
|-------------------------------------------------------------------------------------|----------------------------------|-------------------------------------------------------------------------------------|--------------------------|
|    | Do not use if package is damaged | <b>LOT</b>                                                                          | Batch code               |
|    | Contains sufficient for<n>tests  |  | Date of manufacture      |
|    | Manufacturer                     |  | Use-by date              |
|    | Keep away from sunlight          |  | Temperature limit: 2~30℃ |
| <b>REF</b>                                                                          | Catalogue number                 |  | Keep dry                 |
|    | Consult instructions for use     |  | Do not re-use            |
|  | Biological risks                 |                                                                                     |                          |



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