

**Dynamiker Pets Biotechnology (Tianjin) Co., Ltd.**

Canine Lyme Disease Antibody Test

Catalogue No: DNP-014

User Manual / 10 tests

**1. INTENDED USE**

The Canine Lyme Disease Antibody Test is a test cassette to diagnose the presence of *Borrelia burgdorferi* antibodies in dog's serum specimen.

Assay Time: 10-15 minutes

Specimen: Serum, plasma.

**2. PRINCIPLE**

The Canine Lyme Disease Antibody Test is based on sandwich lateral flow immunochromatographic assay. The test card has a testing window for the observation of assay running and result reading. The testing window has an invisible T (test) zone and a C (control) zone before testing. When the treated sample was applied into the sample well on the device, the liquid will laterally flow through the surface of the test strip and react with the pre-coated *Borrelia burgdorferi* recombinant antigens. If there are *Borrelia burgdorferi* antibodies in the specimen, a visible T line will appear. The C line should always appear after a sample is applied, which indicates a valid result. By this means, the device can accurately indicate the presence of *Borrelia burgdorferi* antibodies in the specimen.

**3. REAGENTS AND MATERIALS**

Components	Quantity
Test Cassette in Foil Bag	10 Tests
Desiccant in Foil Bag	10 Pcs
Disposable Dropper in Foil Bag	10 Pcs
Assay Buffer	10*1.0 mL
User Manual	1 Pc

**4. STORAGE AND STABILITY**

The kit can be stored at room temperature (4-30°C). The test kit is stable through

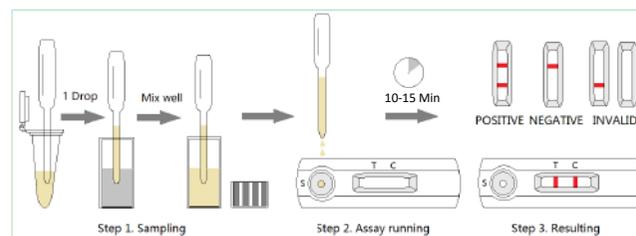
the expiration date marked on the package label. DO NOT FREEZE. Do not store the test kit in direct sunlight.

**5. SPECIMEN PREPARATION AND STORAGE**

- 5.1 Specimen should be obtained and treated as below. Serum or plasma: collect the whole blood for the patient dog, centrifuge it to get the plasma, or place the whole blood into a tube which contains anticoagulants to get serum.
- 5.2 All specimen should be tested immediately. If not for testing right now, they should be stored at 2-8°C.

**6. TEST PROCEDURE**

- 6.1 Allow all materials, including specimen and test device, recover to 15-25°C before testing.
- 6.2 Take out the test card from the foil bag and place it horizontally.
- 6.3 Collect 20µL of the prepared specimen into a vial of assay buffer and mix well. Then add 3 drops (approx. 120µL) of the diluted sample into the sample well labelled "S" of the test card.
- 6.4 Interpret the result in 10-15 minutes. Result after 10 minutes is considered as invalid.



**7. INTERPRETATION OF RESULTS**

- Positive (+): Presence of both "C" line and "T" line, no matter "T" line is clear or vague.
- Negative (-): Appearance of single "C" line. No red "T" line.
- Invalid: No red "C" line appears. No matter if "T" line appears.

**8. PRECAUTIONS**

- All reagents must be at room temperature before testing.
- Do not remove test cassette from its bag until immediately before use.
- Do not use the test beyond its expiration date.
- The components in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.
- All specimens are of potential infection. It must be strictly treated according to the rules and regulations by local states.

**9. LIMITATION**

The Canine Lyme Disease Antibody Test is for in vitro veterinary diagnosis use only. All result should be considered with other clinical information available with veterinarian. It is suggested to apply a further confirmative method such as RT-PCR or microscopy when positive result was observed.

**10. MANUFACTURER**

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**[SYMBOLS USED]**

Symbol	Description
	Use-by date
	Lot Number
	Manufacture Date
	Keep Away from Sunlight
	Temperature Limitation