# Canine Lyme Antibody Lateral Flow Test Kit

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## Background

Canine Lyme disease is a common vector-borne disease caused by the spirochete *Borrelia burgdorferi* which is transmitted to mammalian hosts by infected Ixodes ticks [1]. Immature Ixodes ticks become infected while feeding on wild rodents, and then pass along the infection to other animals after reaching the adult stage [2]. Ticks do not pass on the infection to an attached host until 24 to 48 hours after the initial attachment, providing a window of opportunity for the tick to be removed without infection [2].

Lyme disease is the most common tick-borne infection among people in North America and Europe [3]. In the United States, Lyme disease is predominantly found in the Northeast (13.3%) and Midwest regions (4.4%) [4]. The highest prevalence in Europe was found to be in central Europe. The geographic distribution has expanded because of bird migration, suburban sprawl and climate changes [5].

Identifying Lyme disease in canines can also provide insight into the risk to humans of Lyme disease [2]. Although canines themselves cannot transmit the disease to humans except via tick, an animal contracting Lyme disease suggests an elevated risk of Lyme infection [2].

## Symptoms and Risk Factors

Clinical signs of Lyme disease in dogs include fever, lethargy, loss of appetite, and joint disorders [6]. However, most infected canines remain clinically healthy after infection [2]. Other symptoms that may occur include vomiting and diarrhea [2].

Adequate tick avoidance measures are critical to the prevention of Lyme infection in canines [7]. Tick avoidance measures can include sprays, collars, and other forms of repellants [7]. Canines that are regularly exposed to ticks are at a higher risk of contracting Lyme disease than canines that are not regularly exposed.

## Diagnostics

Diagnosis of Lyme disease in dogs is based on clinical signs, the area where the dog lives and a high titer of Borrelia burgdorferi-specific antibodies [1].

The most commonly used point of care tests for Lyme borreliosis are the SNAP4Dx Plus (IDEXX Laboratories, Westbrook, Maine) and the VetScan Canine Lyme Rapid assay (Abaxis North America, Union City, California). Current guidelines do not recommend confirmatory testing, although the USDA recognizes the Indirect Fluorescent Antibody (IFA) test as the gold standard confirmatory test [5]. The SNAP4Dx Plus test has a 95.5% sensitivity and 98% specificity [8]. The VetScan test has a 100% sensitivity and 98% specificity [9].

## Lateral Flow Test Methodology

Biotech Laboratories U.S.A. LLC offers a lateral flow test kit, which provides rapid on-site results intended for use in diagnostics.

This test is a lateral-flow format nitrocellulose membrane-based test intended for the detection of antibodies to canine *Borrelia burgdorferi*. The sample (canine serum, plasma, or anticoagulated whole blood) is added to the sample well of the test device. The sample reconstitutes conjugates that have been dried in the test device. The sample and the reconstituted conjugates then migrate along the test strip. Two to three drops of chase buffer are added to force reagent flow up the strip.

The test results can be observed visually by the user. The presence of a test and control line are interpreted as a positive result, the presence of only a control line is interpreted as a negative result, and any test without a control line is inconclusive.

## Sensitivity and Specificity

A study was performed using tests produced by Biotech Laboratories R&D on January 4, 2017. Positive samples were from artificially infected animals participating in vaccine and antibiotic efficacy studies. Negative samples were from SPF dogs obtained from Liberty Research, Waverly, NY. All samples were concurrently tested on SNAP4Dx (IDEXX Laboratories, Westbrook, Maine) devices. Results are found in Table 1. Sensitivity and specificity were determined using IDEXX results with a 2x2 analysis table.

*Table 1: 2x2 Sensitivity and Specificity*

|  | IDEXX Pos | IDEXX Neg |
|---|---|---|
| **Biotech Pos** | 92 | 1 |
| **Biotech Neg** | 1 | 201 |
| Sensitivity | 98.9% (95% CI: 94.2, 100) | |
| Specificity | 99.5% (95% CI: 97.3, 100) | |

Based on the analysis, the sensitivity of the test kit is 98.9% and the specificity is 99.5%.

**Citations:**

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[3] Bowman, Dwight, et al, Prevalence and geographic distribution of Dirofilaria immitis, Borrelia burgdorferi, Ehrlichia canis, and Anaplasma phagocytophilum in dogs in the United States. Veterinary Parasitology, 160 (2009) 138-148.

[4] Little SE, Beall MJ, Bowman DD, Chandrashekar R, Stamaris J (2014) Canine infection with Dirofilaria immitis, Borrelia burgdorferi, Anaplasma spp., and Ehrlichia spp. in the United States, 2010–2012. Parasit Vectors 7: 1756–3305.

[5] Littman M, Gerber B, Goldstein R, Labato M, Lappin M, Moore G. ACVIM consensus update on Lyme borreliosis in dogs and cats. J Vet Intern Med. 2018;32:887–903.

[6] Magnarelli LA, Flavell RA, Padula SJ, Anderson JF, Fikrig E. 1997. Serologic diagnosis of canine and equine borreliosis: use of recombinant antigens in enzyme-linked immunosorbent assays. J. Clin. Microbiol. 35: 169– 173.

[7] R. K. Straubinger, "Overview of Lyme Borreliosis," Merck Veterinary Manual, 2019. [Online].

[8] IDEXX white paper 09-2098401-00.

[9] Abaxis white paper 888-6003 Rev. B.