



Patient Tool Kit

Do you suspect that you or a loved one is suffering from Lyme disease? If so, these steps will empower you to advocate for a proper diagnosis and treatment options.

Introduction: Lyme disease is caused by a spiral shaped bacteria (*Borrelia burgdorferi*) and is transmitted by certain species of black-legged ticks that can be as small as the size of a poppy seed. In addition to Lyme, ticks harbor many other infections that can be transmitted to humans, including Babesia, Tularemia, Anaplasma, Mycoplasma, Ehrlichia, Rocky Mountain Spotted Fever, *Borrelia miyamotoi*, Bartonella, Bourbon Virus, Heartland Virus, and Powassan disease among others. Lyme and tick-borne diseases are prevalent across the entire United States. Less than 1/2 of patients with Lyme disease recall a tick bite or any rash. Although the bulls-eye red rash is considered a classic sign and warrants an immediate clinical diagnosis, it is not the most common dermatologic manifestation of early Lyme infection and atypical forms of this rash are actually far more common. For many patients, symptoms are far less clear and may be mistaken for other conditions such as the flu, Amyotrophic lateral sclerosis (ALS), Multiple sclerosis (MS), Chronic Fatigue Syndrome (also known as myalgic encephalomyelitis), Fibromyalgia, Alzheimer's, Parkinson's, Lupus, or autism.

Step 1: Determine whether you have symptoms of Lyme disease.

Infection with the Lyme disease bacteria alone can lead to early symptoms such as severe headaches, debilitating fatigue, joint pain, and skin rashes, while long-term symptoms can expand to include the central nervous system, the gastrointestinal system, eyes, the heart, as well as any other organ. Symptoms of Lyme disease vary for each individual patient, and also vary in intensity over the course of the disease. This [questionnaire](#) will help you determine the likelihood that you have Lyme disease, and provide information to share with your medical care provider. If your provider is not receptive to exploring Lyme testing, consider finding a different provider or a Lyme specialist.

Step 2: Finding a specialist.

The average patient sees 5 doctors over nearly 2 years before being diagnosed. It is critical for patients to advocate for proper care and in many cases, patients must [find a specialist](#) who is well trained in the complexities of Lyme disease. We encourage all doctors to obtain training through [International Lyme and Associated Diseases Society \(ILADS\)](#), noting that grants are typically available for first time conference attendees.

Step 3: Lyme disease and co-infection testing.

Based upon currently available tests, it is difficult to determine who has the disease, the effectiveness of a course of treatment, and the end point of treatment. Laboratories have varying levels of sensitivity, specificity and cost. Due to testing unreliability, most Lyme specialists advise patients to skip the initial Lyme disease ELISA screen (sometimes known as an EIA or IFA assay), and instead start with the Western Blot using a CLIA approved lab:

[IGeneX](#) IgM and IgG Western Blot – generally regarded as more sensitive because IGeneX tests for more strains and reports more bands on a Western blot. Insurance and/or Medicare may provide reimbursement.

[Stony Brook University](#) IgM and IgG Western Blot – typically covered by insurance. This is considered to be a more sensitive test if the ordering medical care provider checks the box to also include CDC non-specific bands on the Western Blot.

[MDL](#) - typically covered by insurance; testing for divergent strains available

[Labcorp/Quest](#) - IgM and IgG Western Blot – typically covered by insurance but limited testing for divergent strains and only reports a limited number of Western Blot bands, which may lead to decreased sensitivity and more false negative results.

Don't forget other possible tick-borne infections that can have considerable overlapping symptoms with Lyme disease. For Bartonella testing, we recommend [Galaxy Diagnostics](#); for Babesia, we recommend using [IGeneX](#).

Step 4: Interpreting Lyme disease tests and recognizing the test limitations.

Unfortunately, two-tier testing paradigm for Lyme disease recommended by the Centers for Disease Control (CDC) misses approximately 1/2 of actual cases pursuant to numerous peer-reviewed studies. Maryland and Virginia have enacted laws requiring laboratories or doctors to explicitly inform patients that even if you test negative for Lyme disease, you may still have the infection. Otherwise stated, you cannot rule out Lyme disease with existing laboratory tests. Due to the limits of serological testing, a clinical diagnosis is often necessary.

If initial testing does not show evidence of exposure to Lyme disease, you may (1) opt to consider more sensitive interpretive criteria, discussed below; (2) use more sensitive Lyme disease testing that may or may not be covered by insurance; (3) consider an antibiotic trial to gauge response; and/or (4) consider the possibility of co-infections.

More sensitive test interpretation criteria. Western Blot test results will include both IgG and IgM assays. Carefully consider Lyme-specific bands (those bands that represent serological evidence of exposure to *Borrelia burgdorferi*). Many Lyme specialists believe that a single Lyme-specific band, along with clinical presentation, is sufficient to diagnose Lyme disease. Likewise, in [China](#), a single (do you want to keep China reference?) positive IgG band coupled with a single IgM band is considered to be a positive test result. The following bands are generally considered to be “significant” or Lyme-specific: 18 (most sources), 22-25, 28, 30, 31, 34, 35, 37, 39, 58 (some sources), 66 (some sources), 83 and 93.

Step 5: Treatment options.

There is a deep division within the medical community as to how patients should be treated if they do not respond to a standard course of antibiotics lasting several weeks. There are two evidence-based standards of care: ILADS and Infectious Diseases Society of America (IDSA). If a patient relapses or is not well after completion of IDSA recommended treatment, the ILADS approach offers a patient centered approach that considers clinical presentation, response to treatment, duration of infection before diagnosis, the potential need for further treatment due to persistent infection, and the need to potentially treat tick-borne co-infections as well.

While the [CDC estimates](#) that up to 20% of patients will suffer persistent symptoms after standard Lyme treatment, in a [study](#) by researchers at Johns Hopkins University, the treatment failure rate for early Lyme disease was estimated to be as high as 36%. According to another recent Johns Hopkins [study](#), over 63% of patients treated for Lyme disease continued to suffer symptoms that could be debilitating. In recent [studies](#) conducted by the CDC, doctors reported using a longer duration than recommended by the IDSA up to 61% of the time, suggesting that the IDSA's approach is simply not effective for many patients. Moreover, there is a growing body of credible [research](#) demonstrating persistent Lyme infection after antibiotic treatment.

[ILADS](#), [Dr. Richard Horowitz](#) and [Dr. Joseph Burrascano](#) have published treatment protocols which may be utilized by physicians.