

Lyme Disease

(Borrelia burgdorferi & Borrelia mayonii)

DISEASE REPORTABLE WITHIN 24 HOURS OF DIAGNOSIS

Per NJAC 8:57, health care providers and administrators shall report by mail or by electronic reporting within 24 hours of diagnosis, confirmed cases of Lyme disease to the health officer of the jurisdiction where the ill or infected person lives, or if unknown, wherein the diagnosis is made. A directory of local health departments in New Jersey is available at <http://localhealth.nj.gov>.

If the health officer is unavailable, the health care provider or administrator shall make the report to the Department by telephone to 609-826-5964 between 8:00 A.M. and 5:00 P.M. on non-holiday weekdays or to 609-392-2020 during all other days and hours.



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THE DISEASE AND ITS EPIDEMIOLOGY

A. Etiologic Agent

In the United States, Lyme disease (LD) is a tick-borne disease caused primarily by infection with *Borrelia burgdorferi* (*B. burgdorferi*) bacteria. Another related species, *Borrelia mayonii* (*B. mayonii*), has also been shown to cause Lyme disease in the upper midwestern United States. The majority of patients with Lyme disease present with symptoms within 30 days of infection, often with a characteristic rash (*erythema migrans*); untreated infection can involve multiple organ systems.

B. Clinical Description

Untreated LD can produce a wide range of symptoms, depending on the stage of infection. Approximately 60-80% of persons will develop an erythema migrans (EM) rash, which can assist in diagnosis (https://www.cdc.gov/lyme/signs_symptoms/rashes.html), but depending on the location of the tick bite, it may be undetected. A small bump or redness at the site of a tick bite that occurs immediately and resembles a mosquito bite is common. This irritation generally goes away in 1-2 days and is not a sign of LD. Early signs and symptoms can last for several weeks in untreated patients. Within weeks to months following infection, patients may develop neurological or cardiac abnormalities. Weeks to years following infection (mean 6 months), patients may develop intermittent episodes of swelling and pain in large joints, leading to chronic arthritis; neurological manifestations (e.g., lymphocytic meningitis, cranial neuritis -particularly facial palsy (unilateral or bilateral); radiculoneuropathy, encephalomyelitis); or cardiovascular concerns (e.g., acute onset of high-grade (2nd-degree or 3rd-degree) atrioventricular conduction defects sometimes associated with myocarditis). Late-stage symptoms can persist for several years but tend to resolve spontaneously.

Early Signs and Symptoms (3 to 30 days after tick bite)

- Flu-like symptoms: fever, chills, headache, fatigue, muscle and joint aches, stiff neck, and swollen lymph nodes (lymphadenopathy)
- Erythema migrans (EM) rash:
 - Begins at the site of a tick bite after a delay of 3 to 30 days (average is about 7 days)
 - Expands gradually over several days reaching up to 12 inches or more (30 cm) across
 - May feel warm to the touch but is rarely itchy or painful
 - Sometimes clears as it enlarges, resulting in a target or “bull’s-eye” appearance
 - May appear on any area of the body

Later Signs and Symptoms (days to months after tick bite)

- Severe headaches and neck stiffness

- Additional EM rashes on other areas of the body (secondary lesions indicate that the infection has spread into the blood and resemble the primary lesion but tend to be smaller)
- Arthritis with severe joint pain and swelling, particularly the knees and other large joints.
- Facial palsy (loss of muscle tone or droop on one or both sides of the face)
- Intermittent pain in tendons, muscles, joints, and bones
- Heart palpitations or an irregular heartbeat (Lyme carditis)
- Episodes of dizziness or shortness of breath
- Inflammation of the brain and spinal cord (meningitis, encephalitis)
- Nerve pain
- Shooting pains, numbness, or tingling in the hands or feet
- Problems with short-term memory

Treatment

People treated with appropriate antibiotics in the early stages of Lyme disease usually recover rapidly and completely. Early diagnosis and proper antibiotic treatment of Lyme disease can help prevent late Lyme disease. Recommended antibiotics include doxycycline, amoxicillin, and cefuroxime. Treatment regimens vary based on the stage of illness and clinical presentation. CDC provides [treatment guidance](#) for healthcare providers, but an infectious disease specialist should be consulted regarding individual patient treatment decisions.

C. Reservoirs

The primary vector for LD in New Jersey is the blacklegged or deer tick, *Ixodes scapularis*.

Ticks become infected as larvae or nymphs when they feed on infected animals, especially the white-footed mouse, and they remain infected for life. Nymphal ticks pose the greatest threat of transmitting infectious organisms to animals and humans because they are small in size (< 2mm) and may go undetected. Nymphs are most abundant between May and July, and they are typically found in wooded areas, brush, and grassy areas near woodland edges. Toward the end of summer through fall, the nymphs mature to the adult stage. Although adult ticks remain capable of transmitting *B. burgdorferi* to humans, they are larger in size and easier to detect. As such, adult ticks are often removed before they can transmit LD. Deer are an important source of food for adult ticks, but do not transmit *B. burgdorferi*.



D. Modes of Transmission

LD is acquired from the bite of an infected tick. In most cases, the tick must be attached for 36 to 48 hours or more before the LD bacteria can be transmitted. Ticks can attach to any part of the human body but are often found in hard-to-see areas such as the groin, armpits, and scalp. As a result, cases of diagnosed LD frequently have no known history of a tick bite.

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LD acquired during pregnancy may lead to infection of the placenta and possible stillbirth; however, no negative effects on the fetus have been found when the mother receives appropriate antibiotic treatment. There are no reports of LD transmission from breast milk. LD could potentially be transmitted through blood transfusion, although there are no documented reports.

Dogs and cats can get LD, but there is no evidence that they spread the disease directly to their owners. However, pets can bring infected ticks into the home or yard.

E. Incubation Period

EM rashes typically develop 7 to 10 days after exposure (range: 3 to 30 days). However, early signs of illness may be unapparent, and the patient may present with later manifestations, which could be several months later.

F. Period of Communicability or Infectious Period

LD is not generally communicable from person to person, although there is a potential risk of transmission through blood transfusion and there are some case reports of LD in pregnancy.

G. Epidemiology

Lyme disease is the most common tick-borne illness in North America. Reports of LD have increased dramatically in the United States since 1975 when the disease was first recognized in Lyme, Connecticut. Each year, approximately 30,000 cases of LD are reported to CDC, but recent estimates using other methods suggest that approximately 476,000 people may get Lyme disease each year in the United States. While cases have been reported from nearly every state, cases are concentrated in the Northeast and upper Midwest with about 90% of LD cases reported from 16 high-incidence states: Connecticut, Delaware, Iowa, Maine, Maryland, Minnesota, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Vermont, Virginia, West Virginia, and Wisconsin. In 2019, New Jersey had an incidence of 40.8 confirmed and probable cases per 100,000 population.

In New Jersey, the highest risk for acquiring LD occurs in wooded rural or suburban environments. However, all parts of the state are considered endemic for LD, and human cases have been reported from all counties in New Jersey. Hunterdon, Warren, and Sussex counties had the highest LD incidence in 2019. Most cases in N.J. occur between May and October.

2 LABORATORY TESTING

Several forms of laboratory testing for LD are available, some of which have [not been adequately validated](#). *B. burgdorferi* bacteria only enter the bloodstream transiently, and direct detection methods such as culture or PCR are typically insensitive for most specimen sources (e.g., blood, spinal fluid). Due to this limitation, diagnostic testing for Lyme disease relies on indirect detection of infection by measuring a patient's antibody response to the spirochete. No single serologic test

for Lyme disease is sufficiently sensitive and specific on its own and instead testing has relied on a standard two-tiered testing (STTT) method. All US Food and Drug Administration (FDA) cleared tests were based on the STTT method until 2019, when the FDA cleared assays for use in a modified two-tiered testing (MTTT) method, as an alternative serologic approach for detection of Lyme disease. APHL has [guidance for laboratories and clinicians](#) on interpretation and reporting of LD serologic test results.

Existing tests for Lyme disease are sensitive and specific if performed as recommended at appropriate times post-infection or for manifestations of disseminated disease. False positive tests do occur, primarily in cases with a low prior probability of Lyme disease, such as for patients without likely exposure to infected blacklegged ticks. Similarly, false negative results may occur in patients who are tested too soon following infection, at which point the patient's serologic response has not developed and is therefore not yet detectable.

The STTT begins with an immunoassay (enzyme immune assay) detecting IgM or IgG antibodies to *B. burgdorferi*. If the immunoassay is negative, no further testing is necessary. If the total IgM/IgG immunoassay, or either one or both of the first tier IgM and IgG immunoassays are positive or equivocal, reflex testing by immunoblot is required. For samples collected from patients with symptoms lasting 30 days or less, both IgM and IgG specific anti-*B. burgdorferi* immunoblots should be performed and interpreted to guide clinical decisions. For samples collected over 30 days post symptom onset, only the anti-*B. burgdorferi* IgG immunoblot should be performed or interpreted. The immunoblot looks for antibodies against specific *B. burgdorferi* antigens. A Western Blot (WB) is a type of immunoblot that requires interpretation of bands. Used appropriately, this test is designed to be highly specific, meaning that it will usually be positive only if a person has been truly infected. If the WB is negative, it suggests that the first test was a false positive.

The MTTT method utilizes two immunoassays, based on multiple *B. burgdorferi* antigens, that have been cleared by FDA for this use. The MTTT begins with an immunoassay detecting antibodies to *B. burgdorferi*. Samples negative by this first tier test do not require further testing. If the total IgM/IgG immunoassay is positive or equivocal, reflex testing by a second immunoassay is required. The second immunoassay may be either total IgM/IgG or separated IgM and IgG.

FDA initially granted clearance to ZEUS Scientific and Gold Standard Diagnostics (GSD) for use of these assays when using MTTT. Additional manufacturers are expected to offer MTTT methods in the future.

While not often performed, *B. burgdorferi* and *B. mayonii* can be isolated in culture and detected through specific nucleic acid amplification test (NAAT) assay, e.g., PCR. While not generally useful in detecting *B. burgdorferi*, PCR testing can be effective to detect the bacteria in certain specimens, e.g., synovial fluid, and it is helpful to detect *B. mayonii*. *B. burgdorferi* group-specific antigens can also be detected using immunohistochemical assay on biopsy or autopsy tissues, which may be useful in diagnosing cases of Lyme disease-associated carditis deaths.

The NJDOH Public Health and Environmental Laboratories (PHEL) does not provide human testing for the detection of *B. burgdorferi* or *B. mayonii*.

3 CASE DEFINITION

The NJDOH Infectious & Zoonotic Disease Program follows the most current Lyme disease case definition as published on the CDC National Notifiable Disease Surveillance System (NNDSS) website.

Lyme Disease Case Definition: <https://www.cdc.gov/nndss/conditions/lyme-disease/>

Case definitions enable public health to classify and count cases consistently across reporting jurisdictions and should not be used by healthcare providers to determine how to meet an individual patient's health needs.

A. NEW! 2022 Case Definition

Owing to the focal nature of Lyme disease, the surveillance objective in high-incidence states - to sustainably monitor the burden and long-term trends in a population known to be at high risk of infection, is very different than in low incidence states, where the goal is to determine if Lyme disease is newly emerging or expanding into an area. High-incidence states are those that have had an average Lyme disease incidence of ≥ 10 confirmed cases/100,000 population for a period of three consecutive years. Prior to 2022, state-to-state variation in high-incidence state surveillance methodologies had defeated the purpose of standardized surveillance and made annual and geographic comparisons nearly impossible. The 2022 case definition further differentiates surveillance approaches for Lyme disease between high-incidence jurisdictions (including New Jersey) and low-incidence jurisdictions. High-incidence jurisdictions will report cases that meet laboratory evidence without need for health departments to gather corresponding clinical information. All cases meeting criteria will be reported as probable cases. The new case definition will allow for increased comparability among states that collectively represent approximately 95% of all reported cases in the United States. Preliminary analysis suggests that the average number of reported cases using a laboratory-based approach is likely to yield total case counts about 20% higher than what was reported to CDC on average during 2012-2018. The other changes to the 2022 case definition are an expansion of confirmatory laboratory evidence of infection to include immunohistochemistry, PCR, including *Borrelia mayonii*, and modified two-tier (MTTT) serologic testing; and to reclassify single-tier IgG immunoblots as presumptive, not confirmatory laboratory evidence.

B. Clinical Description

For the purposes of surveillance, clinical criteria will no longer be considered in New Jersey for classifying LD cases.

C. Laboratory Criteria

For the purposes of surveillance, laboratory evidence includes:

Confirmatory laboratory evidence:

- Isolation of *B. burgdorferi* sensu stricto or *B. mayonii* in culture
- Detection of *B. burgdorferi* sensu stricto or *B. mayonii* in a clinical specimen by a *B. burgdorferi* group-specific nucleic acid amplification test (NAAT) assay, including PCR
- Detection of *B. burgdorferi* group-specific antigens by immunohistochemical assay on biopsy or autopsy tissues
- Positive serologic tests¹ in a two-tier or equivalent format, including:
 - Standard two-tier test (STTT): a positive or equivocal first-tier screening assay, often an enzyme immunoassay [EIA] or immunofluorescence assay [IFA] for IgM, IgG or a combination of immunoglobulins, followed by a concordant positive IgM² or IgG³ immunoblot interpreted according to established criteria, **OR**
 - Modified two-tier test (MTTT): (positive or equivocal first-tier screen, followed by a different, sequential positive or equivocal EIA in lieu of an immunoblot as a second-tier test⁴)

Presumptive laboratory evidence:

- Positive IgG immunoblot⁵ without positive or equivocal first-tier screening assay interpreted according to established criteria

¹ Currently, there are no serologic tests available for *B. mayonii* infection, but cross-reactivity with *B. burgdorferi* testing may occur.

² IgM WB is considered positive when at least two of the following three bands are present: 24 kilodalton (kDa) outer surface protein C (OspC)*, 39 kDa basic membrane protein A (BmpA), and 41 kDa (Fla). Low incidence states should disregard IgM results for specimens collected >30 days after symptom onset. *Depending upon the assay, OspC could be indicated by a band of 21, 22, 23, 24 or 25 kDa.

³ IgG WB is considered positive when at least five of the following 10 bands are present: 18 kDa, 24 kDa (OspC)*, 28 kDa, 30 kDa, 39 kDa (BmpA), 41 kDa flagellin (Fla), 45 kDa, 58 kDa (not GroEL), 66 kDa, and 93 kDa. *Depending upon the assay, OspC could be indicated by a band of 21, 22, 23, 24 or 25 kDa

⁴ The MTTT algorithm should be performed using assays specifically cleared by the US Food and Drug Administration (FDA) for this purpose. (Mead et al, 2019)

⁵ While a single IgG WB is adequate for surveillance purposes, a two-tier test is still recommended for clinical diagnosis.

D. Case Classification

CONFIRMED – NO LONGER USED TO CLASSIFY CASES IN N.J.

PROBABLE

- A case that meets confirmatory laboratory evidence

POSSIBLE

- A case that meets presumptive laboratory evidence (single-tier IgG immunoblot)
- Clinician reported case of erythema migrans rash (EM) without laboratory evidence of infection

NOT A CASE

- A case not meeting laboratory evidence of infection and lacking a reported EM rash

Effective January 1, 2021, new cases should be created once in a calendar year.

4 PURPOSE OF SURVEILLANCE AND REPORTING

- Monitor burden and trends of Lyme disease over time and geographically in N.J.
- Provide information to clinicians that may assist with patient care
- Inform resident care-seeking and tick bite prevention programs and activities

5 CASE INVESTIGATION

A. Investigation

As a high-incidence state for Lyme disease, effective 2022 N.J. is implementing laboratory-only surveillance for routine cases. As such, LHDs do not need to investigate routine reports of Lyme disease. LHDs should enter laboratory test results (if not reported electronically into CDRSS) and clinician reported LD reports into CDRSS.

As the approach and priorities for Lyme disease surveillance evolve (e.g., to characterize severe or unusual presentations, to evaluate impact of a vaccine or other prevention measures), NJDOH may provide updated investigation guidance for LHDs.

Manual receipt of laboratory test results

If LHDs receive faxed/mailed laboratory reports that meet laboratory evidence, check if there is an existing case in CDRSS for the current calendar year.

- If YES, add the new report to the existing case, classify the case based on whether the laboratory evidence for that case is confirmatory (PROBABLE CASE) or presumptive (POSSIBLE CASE) and change report status to LHD CLOSED. If the report status is DHSS APPROVED or DHSS REVIEW, email CDSVectorTeam@doh.nj.gov and ask for the case to be reopened so the laboratory report can be entered.
- If NO, create a new case, classify the case based on whether the laboratory evidence is confirmatory (PROBABLE CASE) or presumptive (POSSIBLE CASE) and change report status to LHD CLOSED.

Electronic laboratory reports

Electronic laboratory reports should append to existing cases created in the same calendar year as the date of specimen collection. These cases are automatically assigned a case status/report status as PROBABLE/DHSS REVIEW. NJDOH reviews and classifies these cases.

Clinician-reported Erythema Migrans Rash

If a clinician reports a case of EM rash to a LHD and there is an existing case without acceptable laboratory evidence for that calendar year (any case status other than PROBABLE), enter the EM rash and any other symptoms in the signs/symptoms section based on the clinician report and close the case as POSSIBLE/LHD CLOSED; otherwise create a new case, enter the EM rash in the signs/symptoms section, and close the case as POSSIBLE/LHD CLOSED.

6 CONTROLLING FURTHER SPREAD

B. Isolation and Quarantine Requirements / Protection of Contacts of a Case

There are no isolation or quarantine restrictions.

C. Managing Special Situations

Removing a Tick

Ticks should be removed as soon as they are found on the skin. Fine-tipped tweezers should be used to firmly grasp the tick very close to the skin. Using a steady motion, the tick's body should be pulled away from the skin. Efforts should be made to not twist or jerk the tick - this can cause the mouth-parts to break off and remain in the skin. If this happens, the mouth-parts should be

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removed with tweezers. If they can't be removed, it isn't cause for concern. Once the mouthparts are removed from the rest of the tick, it can no longer transmit the LD bacteria. After the tick is removed, the bite area should be cleaned with rubbing alcohol, an iodine scrub, or soap and water.

Dispose of a live tick by submersing it in alcohol, placing it in a sealed bag/container, wrapping it tightly in tape, or flushing it down the toilet. Never crush a tick with fingers.

Petroleum jelly, a hot match, nail polish, or other products should not be used to remove a tick. An area of redness occurring within several hours of a tick bite represents a hypersensitivity reaction and does not represent an EM. The date of tick attachment should be documented so if symptoms develop, this information can be relayed to a healthcare provider.

Tick Testing and Identification:

Tick testing of individual ticks is not useful because:

- If the test shows that the tick contained disease-causing organisms, that does not necessarily mean that the person has been infected.
- If someone has been infected, s/he will probably develop symptoms before results of tick testing are available. Treatment should not be delayed while waiting for tick testing results.
- Negative results can lead to false assurance. For example, the person concerned may have been unknowingly bitten by a different tick that was infected.

Tick identification (not testing) may be of value when discussing tick bite exposures with a healthcare provider. County mosquito control agencies or agricultural extension offices may offer tick identification services. The TickEncounter Resource Center also has tick identification resources online: http://www.tickencounter.org/tick_identification.

D. Preventive Measures

Preventing ticks in the yard: Prevention of LD involves keeping wildlife (especially deer and rodents) out of the backyard and making it less attractive to ticks.

- Clear tall grasses and brush around homes and at the edge of lawns.
- Place a 3-ft wide barrier of wood chips or gravel between lawns and wooded areas and around patios and play equipment. This will restrict tick migration into recreational areas.
- Mow the lawn frequently and keep leaves raked.
- Stack wood neatly and in a dry area (discourages rodents that ticks feed on).
- Keep playground equipment, decks, and patios away from yard edges and trees and place them in a sunny location, if possible.

- Remove any old furniture, mattresses, or trash from the yard that may give ticks a place to hide.
- When using acaricides (tick pesticides) around the home, always follow the label instructions and never use near streams or other bodies of water.

Preventing ticks on pets: Although dogs and cats can get LD, there is no evidence that they spread the disease directly to their owners. However, pets can bring infected ticks into the home or yard. For these reasons, it's important to use a tick preventive product for dogs.

Preventing tick bites on people: The best preventive measure is to avoid tick-infested areas. In areas where contact with ticks may occur, individuals should be advised to do the following:

- Wear long-sleeved shirts and long, light-colored pants tucked into socks or boots.
- Stay on trails when walking or hiking and avoid high grass.
- Use repellent that contains 20 percent or more DEET, picaridin, or IR3535 on exposed skin for protection that lasts several hours. Always follow product instructions. Parents should apply this product to their children, avoiding hands, eyes, and mouth.
- Use products that contain permethrin on clothing. Treat clothing and gear, such as boots, pants, socks and tents with products containing 0.5% permethrin. It remains protective through several washings.
- Bathe or shower as soon as possible after coming indoors (preferably within 2 hours) to wash off and more easily find ticks that are crawling on you.
- Conduct a full-body tick check using a hand-held or full-length mirror to view all parts of your body upon return from tick-infested areas. Parents should check their children for ticks under the arms, in and around the ears, inside the belly button, behind the knees, between the legs, around the waist, and especially in their hair.
- Examine gear and pets. Ticks can ride into the home on clothing and pets, then attach to a person later, so carefully examine pets, coats, and day packs.
- Tumble dry clothes in a dryer on high heat for 10 minutes to kill ticks on dry clothing after you come indoors.

Tick Bite Prophylaxis: In areas that are highly endemic for Lyme disease, including New Jersey, a single prophylactic dose of doxycycline (200 mg for adults or 4.4 mg/kg for children of any age weighing less than 45 kg) may be used to reduce the risk of acquiring Lyme disease after the bite of a high risk tick bite. Benefits of prophylaxis may outweigh risks when all of the following circumstances are present:

- Doxycycline is not contraindicated
- The attached tick can be identified as an adult or nymphal *I. scapularis* tick

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- The estimated time of attachment is ≥ 36 h based on the degree of engorgement of the tick with blood or likely time of exposure to the tick
- Prophylaxis can be started within 72 h of tick removal
- LD is common in the county or state where the patient lives or has recently traveled, (i.e., CT, DE, MA, MD, ME, MN, NH, NJ, NY, PA, RI, VA, VT, WI).

Additional information is available at <https://www.cdc.gov/ticks/tickbornediseases/tick-bites-prevention.html>

E. Immunization & Preventive Treatments

A vaccine for Lyme disease is not currently available. The only vaccine previously marketed in the United States, LYMERix[®], was discontinued by the manufacturer in 2002, citing insufficient consumer demand. Due to waning immunity, persons who received the LD vaccine before 2002 are probably no longer protected against LD.

Clinical trials of new vaccines for Lyme disease are currently underway as is a human monoclonal antibody designed to be used as pre-exposure prophylaxis (PrEP) for Lyme disease. More information: <https://www.cdc.gov/lyme/prev/vaccine.html>

Additional Information

NJDOH: <http://www.nj.gov/health/cd/topics/lyme.shtml>

CDC: <https://www.cdc.gov/lyme/>

References

Centers for Disease Control and Prevention. National Notifiable Diseases Surveillance System (NNDSS), Case Definitions: <https://ndc.services.cdc.gov/case-definitions/lyme-disease-2022/>

Centers for Disease Control and Prevention. Lyme Disease: <https://www.cdc.gov/lyme/>.

Nadelman, R.B., Nowakowski, J., Durland, F., et al. *Prophylaxis with Single-Dose Doxycycline for the Prevention of Lyme Disease after an Ixodes scapularis Tick Bite*. N Engl J Med 345:79-84.

New Jersey State Health Assessment Data. Complete Health Indicator Report of Lyme Disease: https://www-doh.state.nj.us/doh-shad/indicator/complete_profile/LymeDisease.html