



Communicable Disease Case Reporting and Investigation Protocol **LYME DISEASE**

I. IDENTIFICATION AND DEFINITION OF CASES

A. Clinical Description:

A multi-systemic disease caused by a spirochete *Borrelia burgdorferi* (or, more rarely, by a new emerging species *Borrelia mayonii*) transmitted through the bite of infected *Ixodes scapularis* (commonly known as the deer tick or blacklegged tick) in Wisconsin. Within 3–30 days of the tick bite, 70%–80% of infected individuals exhibit a distinctive rash called erythema migrans (EM) that expands in size over a period of days or weeks (see description below in Clinical Criteria). A hallmark of EM is its gradual expansion over several days. The expansion of the EM rash helps to differentiate from an allergic reaction at the site of the bite; unlike the EM rash, an allergic reaction does not expand and disappears within a few days. However, about 25% of patients do not develop EM rash, or the lesion is unnoticed by the patient or health care provider. EM is often accompanied by malaise, fatigue, headache, fever, chills, and swollen lymph nodes. After several weeks to months, untreated patients may develop facial palsy; severe headaches; neck stiffness; migratory pain in joints, tendons, muscles, or bones; neurologic abnormalities; or cardiac disturbances. After several months to years, approximately 60% of untreated patients may develop intermittent bouts of arthritis including pain and swelling in large joints, about 15% may develop neurological symptoms, and 5% may have cardiac manifestations.

B. Clinical Criteria:

Confirmatory clinical criteria:

Erythema migrans (EM): For the purposes of surveillance, EM is defined as a skin lesion that typically begins as a red, gray, or brown (depending on skin tone) macule or papule and expands over a period of days to weeks to form a large round lesion, often with partial central clearing creating a “bull’s-eye” appearance. To meet the case definition, a single primary lesion must reach greater than or equal to 5 cm in size across its largest diameter. Secondary lesions may also occur. Annular (ring-like) erythematous (red) lesions occurring within several hours of a tick bite represent hypersensitivity reactions and do not qualify as EM. For most patients, the expanding EM lesion is accompanied by other acute symptoms, particularly fatigue, fever, headache, mildly stiff neck, arthralgia, or myalgia. These symptoms are typically intermittent. **The diagnosis of EM must be made by a health care provider.**

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, OR
- Detection of *B. burgdorferi* sensu stricto or *B. mayonii* in a clinical specimen by a *B. burgdorferi* group-specific NAAT assay, OR
- Detection of *B. burgdorferi* group-specific antigens by immunohistochemical assay on biopsy or autopsy tissues, OR
- 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, interpreted according to established criteria⁴, without positive or equivocal first-tier screening assay

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 kDa (OspC)*, 39 kDa (BmpA), and 41 kDa (Fla). *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 (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.

Note: The categorical labels used here to stratify laboratory evidence are intended to support the standardization of case classifications for public health surveillance. The categorical labels should not be used to interpret the utility or validity of any laboratory test methodology.

D. Wisconsin Surveillance Case Definition:

The surveillance case definition is adapted from the revised 2021 Council of State and Territorial Epidemiologists (CSTE) Lyme disease national surveillance case definition and became effective on January 1, 2022. The Wisconsin surveillance case definition was developed to accommodate standardized national reporting of Lyme disease cases and to meet statewide surveillance needs. The surveillance case definition is not intended to be used to make a clinical diagnosis.

Wisconsin is considered a high incidence state for Lyme disease by the Centers for Disease Control and Prevention, therefore only Lyme disease cases meeting the probable case classification criteria will be reported to the National Notifiable Disease Surveillance System (NNDSS) and be enumerated in national surveillance data. For the purposes of state surveillance, cases meeting the confirmed and probable case classification criteria will be enumerated.

- **Confirmed:** Provider diagnosed EM rash greater than or equal to 5 cm in size across its largest diameter.
- **Probable:** Laboratory evidence of infection that meets the confirmatory laboratory criteria listed in Section B above.
- **Suspect:** Laboratory evidence of infection that meets the probable laboratory criteria listed in Section B above.
- **Not A Case:** Any case report that does not meet the confirmed, probable, or suspect category.

II. REPORTING

- **Wisconsin Disease Surveillance Category II – Methods for Reporting:** This disease shall be reported to the patient's local health officer or to the local health officer's designee within 72 hours of recognition of a case or suspected case, per Wis. Admin. Code § DHS 145.04 (3) (b). Report electronically through the Wisconsin Electronic Disease Surveillance System (WEDSS), or mail or fax a completed Acute and Communicable Disease Case Report ([F-44151](#)) to the address on the form.
- **Responsibility for Reporting:** According to Wis. Admin. Code § [DHS 145.04\(1\)](#), persons licensed under Wis. Stat. ch. [441](#) or [448](#), laboratories, health care facilities, teachers, principals, or nurses serving a school or day care center, and any person who knows or suspects that a person has a communicable disease identified in [Appendix A](#).
- **Clinical Criteria for Reporting:**

Required reporting:

Erythema migrans (EM) in a Wisconsin resident that has been diagnosed by a physician or other health care provider and is greater than or equal to 5 cm in diameter. Report date of illness onset and patient demographic information including address, birth date, gender, race, and ethnicity.

- **Laboratory Criteria for Reporting:** Laboratories must continue to report all Lyme disease positive test results.

III. CASE INVESTIGATION

- A. **Responsibility for case investigation:** It is the responsibility of the LHD (local health department) to investigate or arrange for investigation of suspected or confirmed cases as soon as is reasonably possible. A case investigation may include information collected by phone, in person, in writing, or through review of medical records or communicable disease report forms, as necessary and appropriate.

Additional positive labs received for a patient within the same calendar year as a previous “Lyme Laboratory Report” are unlikely to be evidence of a new infection.

Lyme laboratory reports:

As of 2022, LHDs are *not* expected to review incoming electronic laboratory reports or call providers for clinical signs and symptoms when a positive laboratory report is received. Lyme laboratory results that are received electronically will be auto-imported into WEDSS as a “Lyme Laboratory Report” and will be set to the appropriate Resolution Status and finalized. Paper copies of the laboratory reports received at the LHD should be entered at the LHD as a “Lyme Laboratory Report”, set to the appropriate Resolution Status, and mark the Process Status as “Sent to State”.

EM reports:

As of 2022, LHDs are expected to review incoming reports of EM rash and call providers to obtain required WEDSS data elements for accurate case classification (i.e., demographic information, presence of provider-diagnosed EM rash, and onset date). Optional disease investigation to complete Risk and Intervention tabs may be completed according to local needs and priorities.

B. Required Documentation:

1. For “Lyme Laboratory Report” disease incidents
 - a. “Lyme Laboratory Reports” will be automatically imported from staging.
 - b. LHDs do NOT need to do any follow-up with the “Lyme Laboratory Report” records, but may choose to conduct follow-up to collect clinical and exposure information, and to provide patient education.
 - i. If local follow-up identifies an unreported provider-diagnosed EM rash, a new “Lyme Disease, Erythema Migrans (EM) Rash” disease incident should be created to report the EM rash separately.
 - c. Do not attach or merge “Lyme Disease, Erythema Migrans (EM) Rash” reports to “Lyme Laboratory Reports”.
2. For “Lyme Disease Erythema Migrans (EM) Rash” disease incidents
 - a. Complete the required data fields in the WEDSS disease incident investigation report (i.e., demographic information, presence of provider-diagnosed EM rash, and onset date). If additional information is obtained or reported, completion of the appropriate data fields in the WEDSS disease incident investigation report is strongly encouraged.
 - b. Upon completion of investigation, set WEDSS disease incident Process Status to “Sent to State”.

IV. PUBLIC HEALTH INTERVENTIONS AND PREVENTION MEASURES

- A. In accordance with Wis. Admin. Code § [DHS 145.05](#), local public health agencies should follow the methods of control recommended in the current editions of *Control of Communicable Diseases Manual*, edited by David L. Heymann, published by the American Public Health Association, and the American Academy of Pediatrics’ *Red Book: Report of the Committee on Infectious Diseases*, unless otherwise specified by the state epidemiologist.
- B. LHDs should train their local providers to report all cases of EM rash meeting surveillance criteria and encourage their local providers to report via WEDSS instead of submitting cases by paper copy.

C. Patient education as needed to minimize future tick exposure.

V. CONTACTS FOR CONSULTATION

A. Local health departments and tribal health agencies: <https://www.dhs.wisconsin.gov/lh-depts/index.htm>

B. BCD, Communicable Diseases Epidemiology Section, Vectorborne Epidemiologists: 608-267-9003

C. Wisconsin State Laboratory of Hygiene: 1-800-862-1013

D. Tick Identification: The public can send in ticks or pictures electronically for identification at no charge through the [Midwest Center of Excellence for Vectorborne Disease](#).

VI. RELATED REFERENCES

A. Heymann DL, ed. Lyme Disease. In: *Control of Communicable Diseases Manual*. 20th ed. Washington, DC: American Public Health Association, 2015: 363-367.

B. Pickering LK, ed. Lyme Disease. In: *Red Book: 2015 Report of the Committee on Infectious Diseases*. 31st ed. Elk Grove Village, IL: American Academy of Pediatrics, 2018-2021: 515-523.

C. Centers for Disease Control and Prevention website: <http://www.cdc.gov/lyme/index.html>

D. Tick Identification: <http://mcevbd.wisc.edu/ticks>