Wisconsin Department of Health Services
Division of Public Health
P-01886 (01/2025)

Communicable Disease Case Reporting and Investigation Protocol
Babesiosis

I. IDENTIFICATION AND DEFINITION OF CASES

A. **Clinical Description:** Babesiosis is a parasitic disease caused by intraerythrocytic protozoa of the genus *Babesia* (*B. microti* most commonly in the U.S.). *Babesia* are transmitted in nature through the bites of infected ticks, primarily *Ixodes scapularis* (blacklegged tick), but can also be acquired through contaminated blood components from asymptomatic parasitemic donors or, more rarely, through the placenta. *Babesia* infection can range from subclinical to life threatening. Clinical manifestations, if any, can include nonspecific influenza-like signs and symptoms and hemolytic anemia. Splenomegaly, hepatomegaly, or jaundice may be evident. In addition to anemia, other laboratory findings may include thrombocytopenia, proteinuria, hemoglobinuria, and elevated levels of liver enzymes, blood urea nitrogen, and creatinine. Risk factors for severe babesiosis include asplenia, advanced age, and other causes of impaired immune function (for example, human immunodeficiency virus (HIV), malignancy, corticosteroid therapy). Severe cases can be associated with marked thrombocytopenia, disseminated intravascular coagulation, hemodynamic instability, acute respiratory distress, myocardial infarction, renal failure, hepatic compromise, altered mental status, and death.

B. **Clinical Criteria:**
- **Objective:** Fever as reported by patient or healthcare provider, anemia, or thrombocytopenia.
- **Subjective:** Chills, sweats, headache, myalgia, or arthralgia.

C. **Laboratory Criteria:**

1. **Confirmatory Laboratory Evidence:**
- Identification of intraerythrocytic *Babesia* organisms by light microscopy in a Giemsa, Wright, or Wright-Giemsa–stained blood smear; **or**
- Detection of *Babesia* spp. DNA in a whole blood specimen through nucleic acid testing such as polymerase chain reaction (PCR) assay, nucleic acid amplification test (NAAT), or genomic sequencing that amplifies a specific target, in a sample taken within 60 days of illness onset; **or**
- Serological evidence of a four-fold change in IgG-specific antibody titer to *B. microti* antigen by indirect immunofluorescence assay (IFA) in paired serum samples (one taken within two weeks of illness onset and a second taken two to ten weeks after acute specimen collection) [1].

2. **Presumptive Laboratory Evidence[2]:**
- Serologic evidence of an elevated IgG or total antibody reactive to *B. microti* antigen by IFA at a titer ≥1:256 in a sample taken within 60 days of illness onset.

3. **Supportive Laboratory Evidence[2]:**
- Serologic evidence of an elevated IgG or total antibody reactive to *B. divergens* antigen by IFA at a titer ≥1:256 in a sample taken within 60 days of illness onset; **or**
- Serologic evidence of an elevated IgG or total antibody reactive to *B. duncani*/WA1 antigen by IFA at a titer ≥1:512 in a sample taken within 60 days of illness onset.

[1]A four-fold change in titer is equivalent to a change of two dilutions (for example, 1:64 to 1:256). A four-fold rise in titer should not be excluded as confirmatory laboratory criteria if the acute and convalescent specimens are collected within two weeks of one another.

[2]IgM test results are not used as laboratory evidence for case classification. Positive IgG results with a titer <1:256 (or <1:512 *B. duncani*) in a single specimen do not meet laboratory evidence for case classification. Positive IgG titer <1:256, however, may be used as one of paired serum sample to demonstrate four-fold or greater change in IgG-specific antibody titer.

D. **Wisconsin Surveillance Case Definition:**
   1. **Confirmed:** A case that meets confirmatory laboratory evidence and at least one of the objective or subjective clinical criteria.
   2. **Probable**: A case that meets presumptive laboratory evidence and meets at least one of the objective clinical criteria (subjective criteria alone are not sufficient).
   3. **Suspect**:
      a. A case that meets supportive laboratory evidence and at least one of the objective clinical criteria (subjective criteria alone are not sufficient); **or**
      b. A case that meets confirmatory, presumptive, or supportive laboratory evidence, but has insufficient clinical information available for case classification (for example, only a laboratory report was provided and clinical criteria information is unavailable).

E. **Criteria to Distinguish a New Case:** A new case is one that has not been previously enumerated within the same calendar year (January through December).
Note: Using calendar year allows case counting which more closely corresponds with the seasonality of babesiosis than using a number of months between case reports.

II. REPORTING

A. **Wisconsin Disease Surveillance Category II – Methods for Reporting:** This disease shall be reported to the patient's local or Tribal health officer or to the local or Tribal health officer's designee within 72 hours of recognition of a case or suspected case, per Wisconsin 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.

B. **Responsibility for Reporting**: According to Wisconsin Administrative Code § DHS 145.04(1), persons licensed under Wisconsin State chapter 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.

C. **Clinical Criteria for Reporting:** Not applicable.

D. **Laboratory Criteria for Reporting:** All results that meet confirmatory, presumptive, or supportive laboratory evidence.

III. CASE INVESTIGATION

A. **Responsibility for case investigation**: It is the responsibility of the local or Tribal health department (LTHD) to investigate or arrange for investigation of suspected or confirmed cases as soon as 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.

B. **Required Documentation:**
   1. Complete the WEDSS disease incident investigation report, including appropriate, disease-specific tabs. Upon completion of investigation, set WEDSS disease incident process status to "Sent to State."
   2. For confirmed and probable cases, complete the travel history, history of blood transfusion and organ transplantation, known tick bite, outdoor activities, and occupation questions on the babesiosis "Risk" tab in WEDSS, and complete the history of blood or organ donation and treatment questions on the babesiosis "Intervention" tab in WEDSS.

C. **Additional Investigation Responsibilities:** Transfusion-associated babesiosis infections are an ongoing risk. In 2019, the FDA issued guidance to blood collection agencies recommending the screening of donated products for *Babesia* spp. in areas where tickborne transmission was known to occur, which includes Wisconsin. In 2020, universal blood screening of all blood donations made in Wisconsin was initiated using an FDA-approved nucleic acid test. In Wisconsin, blood collection agencies report these parasitemic donors (identified through blood screening) to public health agencies via fax and WEDSS web-reports.

- **Parasitemic donors identified by blood collection agencies:** LTHDs should attempt to contact parasitemic donors reported to public health by blood collection agencies to ensure the client was notified of their result, to inquire if they have experienced any signs or symptoms of babesiosis in either the 60 days before their donation or since their donation, to answer any questions, and to encourage them to contact a healthcare provider to discuss treatment and re-testing if they develop any clinically compatible signs or symptoms. Generally, asymptomatic parasitemic donors do not need to be re-tested or treated, but clients with questions or concerns should be advised to contact a healthcare provider.
- **Donors identified by routine public health surveillance:** While most donors are initially reported to public health by the blood collection agency, LTHDs should also ask clients with a reported babesiosis case if they have donated or been a recipient of blood, blood products, or an organ in the year before illness onset. Findings should be documented in the appropriate data entry fields in WEDSS on the "Risk" and "Intervention" tabs. Please notify the Wisconsin Division of Public Health, Vectorborne Diseases Program by phone (608-267-9003) if any client has donated or received blood, blood products, or an organ in the 60 days before illness onset. Please note, LTHDs do not need to notify the Vectorborne Diseases Program if the initial babesiosis report was made to public health by the blood collection agency due to donor screening, or if the client has donated or received blood, blood products, or an organ more than 60 days before illness onset.

IV. PUBLIC HEALTH INTERVENTIONS AND PREVENTION MEASURES

A. In accordance with Wisconsin Administrative. Code § DHS 145.05, local or Tribal 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. Because *Babesia* spp. can be acquired by blood transfusion or organ transplantation, ascertain whether patient recently received or donated blood or blood products or recently received or donated an organ.

C. Patient education as needed to minimize future risk of exposure to infected ticks.

V. CONTACTS FOR CONSULTATION

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

B. Bureau of Communicable Diseases, Communicable Diseases Epidemiology Section: 608-267-9003

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

VI. RELATED REFERENCES

A. Heymann DL, ed. Babesiosis. In: *Control of Communicable Diseases Manual*. 21st ed. Washington, DC: American Public Health Association, 2022: 58-61.

B. Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. Babesiosis. In: *Red Book*: *2021-2024 Report of the Committee on Infectious Diseases*. 32nd ed. Itasca, IL: American Academy of Pediatrics, 2021: 217-219.

C. Centers for Disease Control and Prevention website: https://www.cdc.gov/babesiosis/about/

Appendix 1: Additional Guidance for National Reporting of Positive Blood Donors

This appendix provides guidance for case finalization and reporting of cases in people whose donated blood products are found to be positive for *Babesia* infection through screening tests.

The clinical criteria outlined above in the Wisconsin Surveillance Case Definition does not support inclusion of **asymptomatic** parasitemic donors in routine disease counts. Asymptomatic parasitemic donors should be classified as Not a Case; however, if reported donors are found to have clinically compatible illness within 60 days of the reactive blood donation, the laboratory screening test performed by the blood collection agency is sufficient laboratory evidence for classification and reporting. It should be noted that the current approved assay for blood product screening does not offer species-specific results, as the assay does not differentiate beyond the genus level. The following scenarios may be helpful in determining when the Wisconsin Department of Health Services will report infected blood donors as cases for national surveillance purposes.

Examples:
• Blood Donor A: A blood donor who tests positive for *Babesia* on a standard donor screening assay but never develops a compatible illness or for whom an investigation is not performed.

• Blood Donor B: A blood donor who tests positive for *Babesia* on a standard donor screening assay and during investigation, self-reports a fever that occurred within 60 days of the donation.

• Blood Donor C: A blood donor who tests positive for *Babesia* on a standard donor screening assay and seeks additional testing or advice from the healthcare system; during clinic visit, donor reports headache and chills that occurred within 60 days of donation.

• Blood Donor D: A blood donor who tests positive for *Babesia* on a standard donor screening assay and seeks additional testing or advice from the healthcare system; reports fever and aches that occurred three months prior to donation.

• Blood Donor E: A traceback investigation from a transfusion-associated case of babesiosis implicates a donor, and a reserved donor sample is positive for babesiosis; the donor jurisdiction attempts an investigation but cannot reach the donor for additional information.

	Meets Laboratory Evidence Criteria	**Meets Clinical Evidence Criteria**	**Case Status**
Donor A	Yes	No	Not a Case
Donor B	Yes	Yes (objective criteria met)	Confirmed
Donor C	Yes	Yes (subjective criteria met)	Confirmed
Donor D	No (sample >60 days from onset)	Yes (objective criteria met)	Not a Case
Donor E	Yes	Unknown	Not a Case