24-ID-02

Committee: Infectious Disease

Title: Update to Public Health Reporting and National Notification for Babesiosis

☒Check this box if this position statement is an update to an existing standardized surveillance case definition and include the most recent position statement number here: 10-ID-27.

Synopsis:
The standardized surveillance position statement for babesiosis is updated with the proposed changes:

- Overall changes
  - Updates fever language to match other vectorborne disease case classification criteria
  - Moves from weekly to annual reporting tables for NNDSS
  - Adds an appendix to provide guidance on tracking positive blood donor reports
- Case ascertainment
  - Eliminates disease-specific guidance for initial reporting
- Case definition for case classification
  - Laboratory evidence:
    - Adds timeframes for serologic and molecular testing – specimens must be collected within 60 days of illness onset in order to count as confirmatory or presumptive laboratory evidence for case classification
    - Moves single IgG titers for *B. duncani* and *B. divergens* from presumptive to supportive laboratory evidence
    - Updates confirmatory laboratory evidence for *B. microti* to include a fourfold change in titer between specimens collected 2 to 10 weeks apart
    - Removes animal inoculation and IgG immunoblot from laboratory evidence
  - Removes epi-linkages for purposes of classifying cases
  - Adds guidance for when to enumerate a repeat report as a new case

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I. Statement of the Problem

Babesiosis is a parasitic disease caused by intraerythrocytic protozoa of the *Babesia* genus (*Babesia microti* and other species). *Babesia* parasites are transmitted in nature through the bites of infected ticks but can also be acquired through contaminated blood components from asymptomatic parasitemic donors or, more rarely, transplacentally (1). Nationally, most cases in the United States (U.S.) still occur in states in the Northeast and upper Midwest, but incidence in other parts of the country has also increased as populations of the primary vectors, *Ixodes* spp. ticks, have expanded into new areas. Additionally, since the addition of babesiosis to the Nationally Notifiable Condition List in 2011, the Food and Drug Administration (FDA) has recommended routine screening of blood donors in jurisdictions with evidence of vectorborne transmission of babesiosis, which has reduced cases of transfusion-associated babesiosis (2).

A revision to the babesiosis case definition, as established in CSTE position statement 10-ID-27, is being proposed to 1) update laboratory criteria for reporting and case classification to reflect current testing practices; 2) update reporting and case classification criteria for transfusion-associated cases to reflect the decrease in transfusion-associated cases resulting from the implementation of blood donor screening in endemic areas; and 3) add specific timeframes for specimen collection for convalescent testing and in relation to the onset of symptoms to align with other tickborne disease position statements

II. Background and Justification

In the U.S., most cases of babesiosis are caused by *Babesia microti*, transmitted through the bite of the *Ixodes scapularis* (blacklegged) tick. In the northeastern and upper midwestern U.S., *B. microti* circulates between ticks and animal reservoir hosts, (3) a cycle shared by the etiologic agents of Lyme disease (*Borrelia burgdorferi*) and anaplasmosis (*Anaplasma phagocytophilum*). Very rarely, U.S. cases caused by other *Babesia* species have been described, such as *B. duncani* (transmitted by *Dermacentor albipictus*) and *B. divergens* (possibly transmitted by *I. dentatus*) (4-7). Babesiosis typically presents with nonspecific symptoms (e.g., fever, chills, sweats, headache, myalgia, malaise, and fatigue) within one month of a tick bite. Additionally, laboratory anomalies such as hemolytic anemia, thrombocytopenia, and elevated levels of liver enzymes are often noted (1, 8).

Cases of babesiosis increased significantly between 2011 and 2019, with some northeastern states experiencing several fold increases in incidence rates (9). The disease is increasingly identified in non-endemic areas as tick populations expand, following a similar pattern to Lyme disease (7, 8) although at a slower pace for babesiosis (10). This pattern of disease emergence following vector expansion is well described (11, 12) and would seem to predict continued expansion in the future (13, 14). Babesiosis cases are also likely underreported, as non-specific symptoms and a relatively high proportion of asymptomatic infections can make diagnosis difficult (7).

Due in part to the ability of people to maintain low levels of parasitemia while asymptomatic, transfusion-transmitted babesiosis have been the most frequently reported parasitic disease associated with transfusions in the U.S. (15, 16). In 2019, FDA issued guidance (17) directing blood donor screening for *Babesia* spp. where vectorborne transmission was known to occur (14 states and the District of Columbia). Blood collection agencies in those jurisdictions initiated screening in 2020 using the FDA-approved nucleic acid test that detects multiple *Babesia* spp. (*B. microti*, *B. duncani*, *B. divergens*, and *B. venatorum*). Although the number of reported transfusion-associated cases of babesiosis decreased after the implementation of donor screening (2, 18), transfusion-associated babesiosis is not restricted to regions where tickborne babesiosis is endemic. Because of donor travel and the importation of blood products, blood-borne transmission in the U.S. has been reported outside of babesia-endemic regions (19), underscoring the importance of having thorough and complete nationwide surveillance to monitor trends.

Updates to the laboratory criteria are necessary. Some of the tests included as laboratory evidence in the current case classification (10-ID-27), such as IgG immunoblots and animal inoculation, are not recommended for routine diagnosis, and other diagnostic tools, like a four-fold change in in IgG-specific antibody titer by indirect immunofluorescence assay (IFA) in paired serum samples, are not included. Timeframes have been proposed for specimen collection in relation to symptom onset as well as for acute and convalescent specimens. Additionally,

single positive IgG serologic results for *B. duncani* and *B. divergens* have been moved to supportive laboratory criteria, reflecting the current limitations of serologic diagnostics for species other than *B. microti* (1, 6, 7, 20, 21).

Finally, this position statement proposes babesiosis case counts be included in NNDSS annual tables rather than weekly tables. Collecting sufficient information to accurately classify cases takes significant time, which can delay the notification of reliable case data to CDC. Initial case notifications may be deleted after subsequent case review, meaning weekly numbers are not useful to assess trends and are inconsistent with final annual data. Recent position statements for other vectorborne conditions (e.g., Lyme disease, anaplasmosis, ehrlichiosis, spotted fever rickettsiosis) have also made this change, and this update would align babesiosis with other common tickborne diseases.

III. Statement of the Desired Action(s) to be Taken

CSTE recommends the following actions:

1. Implement a standardized surveillance case definition for **babesiosis**.

    A. Utilize recommended reporting* sources for case ascertainment for **babesiosis**. Surveillance for **babesiosis** should use the recommended sources of data to the extent of coverage presented in Section V.

    B. Utilize standardized criteria for case ascertainment for **babesiosis** presented in Section VI and Table VI in Technical Supplement.

    C. Utilize standardized criteria for case classification for **babesiosis** presented in Section VII and Table VII in Technical Supplement.

2. Utilize standardized criteria for case ascertainment and classification (based on Sections VI and VII and Technical Supplement) for **babesiosis** and **update** babesiosis on the *Nationally Notifiable Condition List* using the following notification** timeframe:
    - ☐ Immediately notifiable, extremely urgent (within 4 hours)
    - ☐ Immediately notifiable, urgent (within 24 hours)
    - ☒ Routinely notifiable
    - ☐ No longer notifiable

3. CSTE recommends that all States and Territories enact laws (statute or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction. Jurisdictions (e.g., States and Territories) conducting surveillance (according to these methods) should submit case notifications to CDC.

4. CSTE recommends that all jurisdictions (e.g., States, Localities, or Territories) with legal authority should conduct public health surveillance and use the case classifications included in this standardized surveillance position statement.

5. Expectations for Message Mapping Guide (MMG) development for a newly notifiable condition: the National Notifiable Diseases Surveillance System (NNDSS) is transitioning to HL7-based messages for case notifications; the specifications for these messages are presented in MMGs. When CSTE recommends a new condition be made nationally notifiable, CDC must obtain Office of Management and Budget Paperwork Reduction Act (OMB PRA) approval prior to accepting case notifications for the new condition. Under anticipated timelines, notification using the Generic V2 MMG would support transmission of the basic demographic and epidemiologic information common to all cases and could begin with the new MMWR year following the CSTE annual conference. Input from CDC programs and CSTE would prioritize development of a disease-specific MMG for the new condition among other conditions waiting for MMGs.

6. CDC should publish data on **babesiosis** as appropriate (see Section IX). CSTE recommends the following case statuses be included in the CDC Print Criteria:
   - ☒Confirmed
   - ☒Probable
   - ☐Suspect
   - ☐Unknown

** Reporting: process of a healthcare provider, laboratory, or other entity submitting a report (case information) of a condition under public health surveillance to local, state, or territorial public health.*
***Notification: process of a local or state public health authority submitting a report (case information) of a condition on the* Nationally Notifiable Conditions List *to CDC.*

IV. Goals of Surveillance

This updated babesiosis case definition will help jurisdictions gather useful clinical and laboratory data to better describe the changing epidemiology of babesiosis and will continue to place an emphasis on excluding disease reports that do not reflect current babesiosis infections. Although the disease is well-established in some areas of the U.S., it is considered an emerging disease in others, and accurate public health surveillance data can be used to describe changes in distribution. Surveillance data will continue to provide information on the temporal, geographic, and demographic occurrence of babesiosis to inform prevention and control activities.

V. Recommended Data Sources and Methods for Surveillance

Surveillance for babesiosis should use the following recommended sources of data and/or methodologies and the extent of coverage listed in Table V.

Laboratory reporting will continue to be the most common source of data. An unpublished provisional review of recent data from several endemic states found that reports initiated by laboratories are far more common than other types of reports (e.g., healthcare provider reports) and serve as the starting point for most case investigations. Electronically generated (or paper, when applicable) reports of positive tests should be reported, and laboratories should report all tests meeting the criteria listed in Section VI subsection A to public health authorities.

Additionally, healthcare providers, blood banks, organ procurement agencies (OPOs), and facilities who diagnose or become aware of babesiosis cases should report them to public health authorities. Other data sources (e.g., hospital discharge data, diagnosis codes, or death certificates) may be used as supplementary case finding methods.

Table V. Recommended Sources of Data, Surveillance Methods, and Extent of Coverage for Ascertainment of Cases of Babesiosis.

Source of Data/Methodology for Case Ascertainment	Coverage	
	Population-Wide	Sentinel Sites
Clinician reporting	X	
Laboratory reporting	X	
Reporting by other entities, specify: • Hospitals • Blood banks • Organ procurement agencies (OPOs)	X	
Death certificates	X	
Hospital discharge or outpatient records	X	
Data from electronic medical records	X	
Telephone or online survey		
School-based survey		
Other, specify: N/A		

VI. Criteria for Case Ascertainment

Case ascertainment is the process through which public health identifies potential cases of a disease or condition using data reported or provided to public health by healthcare, laboratories, and other reporting entities. This public health reporting is triggered by the case ascertainment criteria (a single criterion or a combination of criteria) included in this position statement, and each initial report sent to public health should include common data elements and disease-specific data elements. Case ascertainment criteria are not intended to be used for clinical diagnosis purposes.

A. Narrative: A description of suggested criteria for case ascertainment of a specific condition and recommended reporting procedures.

Babesiosis surveillance should be routine, ongoing, and reported to public health authorities using standard case reporting timeframes. Report to public health authorities any infection or illness meeting the following criteria:

A1. Clinical Criteria for Reporting

N/A

A2. Laboratory Criteria for Reporting

- 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,
  OR
- Serologic evidence of elevated IgG or total antibody to *B. microti* by indirect fluorescent antibody (IFA) with a titer ≥1:256,
  OR
- Serologic evidence of elevated IgG or total antibody to *B. divergens* by indirect fluorescent antibody (IFA) with a titer ≥1:256,
  OR
- Serologic evidence of elevated IgG or total antibody to *B. duncani* by indirect fluorescent antibody (IFA) with a titer ≥1:512

A3. Epidemiologic Linkage Criteria for Reporting

- A person whose donated blood product or organ was linked to a transfusion- or transplant-associated case of babesiosis.

A4. Vital Records Criteria for Reporting

- A person whose death certificate lists babesiosis as an underlying cause of death or a significant condition contributing to death.

A5. Healthcare Record Criteria for Reporting

- A person whose healthcare record contains a diagnosis of babesiosis.

B. Disease-Specific Data Elements to be Included in the Initial Report

Disease-specific data elements should be included in addition to the common data elements that are to be reported for all initial individual case reports (see CSTE Position Statement 09-SI-01 “Common Core Data Elements for Case Reporting and Laboratory Result Reporting” https://cdn.ymaws.com/www.cste.org/resource/resmgr/PS/09-SI-01.pdf). Public health authorities do not expect that an initial report will contain all the information necessary for case investigation and case classification.

No additional disease-specific data elements are needed for initial individual case reports of babesiosis.

VII. Case Definition for Case Classification

This case definition for case classification is intended solely for public health surveillance purposes and does not recommend criteria for clinical diagnosis purposes. Once a public health agency has ascertained data on potential cases of a disease or condition from reporting entities, the public health agency assigns case statuses based on the case classifications included within this position statement.

A. Narrative: A description of criteria to determine how public health should classify a case of babesiosis.

Clinically, babesiosis can range from asymptomatic to life-threatening. Clinical manifestations, if any, typically appear 1 – 4 weeks after a tick bite and 1 – 9 weeks after blood transfusion. Common symptoms include fever, chills, sweats, headache, myalgia, malaise, and fatigue, and laboratory anomalies like anemia, thrombocytopenia, and elevated liver enzymes may be present. Risk factors for severe babesiosis include asplenia, advanced age, and other causes of immunosuppression.

Some people maintain a low-level parasitemia for an extended period while remaining asymptomatic or developing only mild symptoms. These infections may be detected via blood donor screening, and patients may or may not follow up with their healthcare provider for additional testing and evaluation. Asymptomatic blood donors should not be classified as cases of babesiosis for national surveillance purposes. If a positive blood donor is reported to a jurisdiction, and the person is found to be symptomatic within 60 days of the reactive blood donation, molecular testing conducted by the blood collection agency is sufficient confirmatory laboratory evidence for case classification.

A1. Clinical Criteria

- Objective: fever as reported by patient or healthcare provider, anemia, or thrombocytopenia
- Subjective: chills, sweats, headache, myalgia, or arthralgia

A2. Laboratory Criteria*

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[1] 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)[2]

Presumptive Laboratory Evidence:

- 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

Supportive Laboratory Evidence:

- Serologic evidence** of an elevated IgG*** or total antibody reactive to *B. divergens* antigen by IFA at a titer ≥1:256;
  OR
- Serologic evidence** of an elevated IgG*** or total antibody reactive to *B. duncani* antigen by IFA at a titer ≥1:512

[1] A four-fold change in titer is equivalent to a change of two dilutions (e.g., 1:64 to 1:256).
[2] 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.
** 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.*
*** Antibodies can be indicative of active or previously resolved infections, so it is recommended that laboratory results be evaluated in conjunction with information on symptoms and exposure whenever possible. If symptom information is available, specimens meeting supportive laboratory criteria should be collected within 60 days of illness onset.*
**** While a single IgG serologic test is adequate for surveillance purposes, molecular testing or blood smear are recommended for clinical diagnosis, especially in cases where species other than B. microti are suspected.*

A3. Epidemiologic Linkage Criteria
N/A

A4. Case Classifications

Confirmed:
- Meets confirmatory laboratory evidence criteria **AND** at least one of the objective or subjective clinical criteria.

Probable:
- Meets presumptive laboratory evidence **AND** meets at least one of the objective clinical criteria.

Suspect:
- Meets supportive laboratory evidence.

B. Criteria to Distinguish a New Case of babesiosis from Reports or Notifications which Should Not be Enumerated as a New Case for Surveillance.
A new case is one that has not been previously enumerated within the same calendar year (January through December)*.

** Using calendar year allows case counting which more closely corresponds with the seasonality of babesiosis than using a number of months between case reports.*

VIII. Period of Surveillance
Surveillance should be ongoing.

IX. Data Sharing/Release and Print Criteria
CSTE recommends the following case statuses* be included in the 'case' count released outside of the public health agency:

☒Confirmed
☒Probable
☐Suspect
☐Unknown
**Which case statuses are included in case counts constitute the "print criteria."*

Jurisdictions (e.g., States and Territories) conducting surveillance under this case definition can voluntarily submit de-identified case information to CDC, if requested and in a mutually agreed upon format.

Production of national data summaries and national data re-release for non-NNCs:
- Prior to release of national data summaries CDC should follow the CDC/ATSDR Policy on Releasing & Sharing Data, issued on April 16, 2003 and referenced in 11-SI-01 and custodians of such data should consult the CDC-CSTE Intergovernmental Data Release Guidelines Working Group report (www.cste2.org/webpdfs/drgwgreport.pdf) which contains data release guidelines and procedures for CDC programs re-releasing state, local, or territorial-provided data.
- CDC programs have a responsibility, in collaboration with states, localities, and territories, to ensure that CDC program-specific data re-release procedures meet the needs of those responsible for protecting data in the states and territories.

Additional Guidance:
- Notification to CDC of probable and confirmed cases of babesiosis is recommended.
- Finalized data should be published in the annual NNDSS tables. Summaries and analyses of reported cases of babesiosis are compiled and published periodically dependent upon accumulation of data and changes in disease activity and regional incidence.
- CDC may re-release finalized data on an ad hoc basis for research of public health activities in accordance with the Data Release Guidelines for NNDSS.

X. Revision History

Position Statement ID	Section of Document	Revision Description
24-ID-02	Section VI, A2	Added specific titer cutoffs for reporting.
24-ID-02	Section VII, A1	Changed 'fever' to 'fever as reported by patient or healthcare provider'
24-ID-02	Section VII, A2	• Removed animal inoculation and IgG immunoblot from laboratory evidence for case classification. • Added a fourfold change in titer for *B. microti* (within a specified window of time) to confirmatory laboratory evidence. • Added language to specify that specimens for serologic and molecular testing be collected within 60 days of illness onset. • Moved serologic evidence of elevated titers for *B. duncani* and *B. divergens* to supportive laboratory evidence.
24-ID-02	Section VII, A3	Removed epidemiologic linkage criteria for case classification.
24-ID-02	Section VII, A5	Updated suspect case classification.
24-ID-02	Section VII, B	Established criteria for identifying new cases for surveillance purposes.
24-ID-02	Section IX	Updated NNDSS print criteria to publish data on an annual instead of weekly basis.
NA	10-ID-27	Created a standardized case definition for babesiosis.

XI. References

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Technical Supplement

Table VI. Table of criteria to determine whether a case should be reported to public health authorities.

Criterion	Babesiosis
Clinical Criteria for Reporting	
N/A	
Laboratory Criteria for Reporting	
Identification of intraerythrocytic *Babesia* organisms by light microscopy in a Giemsa, Wright, or Wright-Giemsa–stained blood smear	S
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	S
Serologic evidence of elevated IgG or total antibody to *B. microti* by indirect fluorescent antibody (IFA) with a titer ≥1:256	S
Serologic evidence of elevated IgG or total antibody to *B. divergens* by indirect fluorescent antibody (IFA) with a titer ≥1:256	S
Serologic evidence of elevated IgG or total antibody to *B. duncani* by indirect fluorescent antibody (IFA) with a titer ≥1:512	S
Epidemiologic Linkage Criteria for Reporting	
A person whose donated blood product or organ was linked to a transfusion- or transplant-associated case of babesiosis	S
Vital Record Criteria for Reporting	
A person whose death certificate lists babesiosis as an underlying cause of death or a significant condition contributing to death	S
Healthcare Record Criteria for Reporting	
A person whose healthcare record contains a diagnosis of babesiosis	S

Notes:
S = This criterion alone is SUFFICIENT to report a case.

[*continued*]

Table VII.A. Classification Table: Criteria for defining a case of Babesiosis.

Criterion	Confirmed		Probable	Suspect
Clinical Evidence				
Objective Clinical Evidence				
Fever as reported by patient or healthcare provider	O	O	O	
Anemia	O	O	O	
Thrombocytopenia	O	O	O	
Subjective Clinical Evidence				
Chills	O	O		
Sweats	O	O		
Headache	O	O		
Myalgia	O	O		
Arthralgia	O	O		
Laboratory Evidence				
Identification of intraerythrocytic *Babesia* organisms by light microscopy in a Giemsa, Wright, or Wright-Giemsa–stained blood smear	O			
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		N		
Serological evidence of a four-fold change**Error! Bookmark not defined.** in IgG-specific antibody titer to *B. microti* antigen by indirect immunofluorescence assay (IFA) in paired serum samples (one taken in the first two weeks after illness onset and a second taken two to ten weeks after acute specimen collection)**Error! Bookmark not defined.**	O			
Serologic evidence[3] of an elevated IgG[4] or total antibody reactive to *B. microti* antigen by IFA at a titer ≥1:256			N	
Serologic evidence[3] of an elevated IgG[4] or total antibody reactive to *B. divergens* antigen by IFA at a titer ≥1:256				O
Serologic evidence[3] of an elevated IgG[4] or total antibody reactive to *B. duncani* antigen by IFA at a titer ≥1:512				O
Sample taken within 60 days of illness onset		N	N	
Epidemiologic Linkage Evidence				
N/A				

Notes: N = All "N" criteria in the same column are NECESSARY to classify a case.
O = At least one of these "O" (ONE OR MORE) criteria in each category (categories=clinical evidence, laboratory evidence, and epidemiologic evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to classify a case.

[1] A four-fold change in titer is equivalent to a change of two dilutions (e.g., 1:64 to 1:256).

[2] 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.

[3] Antibodies can be indicative of active or previously resolved infections, so it is recommended that laboratory results be evaluated in conjunction with information on symptoms and exposure whenever possible. If symptom information is available, specimens meeting supportive laboratory criteria should be collected within 60 days of illness onset.

[4] While a single IgG serologic test is adequate for surveillance purposes, molecular testing or blood smear are recommended for clinical diagnosis, especially in cases where species other than *B. microti* are suspected.

Table VII.B. Classification Table: Criteria to distinguish a new case of babesiosis from reports or notifications which should not be enumerated as a new case for surveillance.

Criterion	Confirmed	Probable	Suspect
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)*.	S	S	S

Notes: S = This criterion alone is SUFFICIENT to enumerate as a new case.
* Using calendar year allows case counting which more closely corresponds with the seasonality of babesiosis than using a number of months between case reports.

Appendix 1: Operational Guidance for Tracking and Reporting Positive Blood Donor Reports

This appendix provides guidance for jurisdictions interested in tracking reports of people whose donated blood products are found to be positive for *Babesia* infection through screening tests. Additional guidance may continue to be added or updated.

Due to the ongoing risk of transfusion-associated babesiosis infections, in 2019, the FDA issued guidance to blood collection agencies recommending the screening of donated products for *Babesia* spp. in areas where vectorborne transmission was known to occur. In 2020, blood screening was initiated using an FDA-approved nucleic acid test. In jurisdictions where babesiosis is a reportable condition, blood collection agencies should report these parasitemic donors (identified through blood screening) to public health authorities. State, local, and territorial health departments may choose to track these reports for surveillance purposes.

As described in the criteria for case ascertainment (section VI), the inclusion of asymptomatic, parasitemic donors in routine disease counts by local, state, and territorial public health departments is not supported by the case definition; 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 national 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 to report infected blood donors as cases to CDC.

- Blood Donor A: A blood donor who tests positive for *Babesia* on a standard screening 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 screening 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 screening and seeks additional testing/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 screening and seeks additional testing/advice from the healthcare system; reports fever and aches that occurred 3 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*	Include With Official Case Counts
Donor A	Yes	No	Not a Case	N/A
Donor B	Yes	Yes (objective)	Confirmed	Yes
Donor C	Yes	Yes (subjective)	Confirmed	Yes
Donor D	No (sample >60 days from onset)	Yes (objective)	Not a Case	N/A
Donor E	Yes	Unknown	Not a Case	N/A

**Case status here refers to the case status according to the classifications included in section VII of this position statement for formal notification and reporting to CDC. Some jurisdictions may choose to classify patients like Donor A or Donor E (positive lab report without investigation) as 'suspect' for internal tracking purposes.*