

Evaluating Donors for Risk of *Babesia* Infection

Information on this page is based on the May 2019 FDA Guidance:

[Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry](#)

In addition to this document, AABB has:

- Updated the [Babesiosis webpage](#) – this content is available for public review.
- Posted for AABB members: [AABB Exclusive Member Offering: Babesia Toolkit](#)

FDA's current recommendations state:

You must update your donor history questionnaire (DHQ), including full-length and abbreviated DHQs, and accompanying materials as necessary to incorporate the recommendations of the guidance. You must also update your standard operating procedures to reflect any such changes ([21 CFR 606.100\(b\)](#)).

To revise your DHQ refer to these examples:

- [EXAMPLE DHQ v2.0 Revised Q38 Babesia](#) – for states that are not required to test
- [EXAMPLE DHQ 2.0 Revised to REMOVE Q38 Babesia](#) – for states where testing or PRT is required (the decision to renumber subsequent questions is based on your blood establishment computer system and other considerations, but is not necessarily a requirement of implementation)
- [EXAMPLE DHQ v2.0 Revised Q38 Screening Flowchart Babesia](#) – for states that are not required to test

How do I know when to test for Babesia?

FDA recommends year-round regional nucleic acid testing (NAT) for blood “when collected in Connecticut, Delaware, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Wisconsin and Washington, D.C.” (refer to section V.A.3)

Can I use Pathogen Reduction Technology (PRT) in place of testing?

As an alternative to testing, the guidance allows for use of pathogen reduction technology (PRT) for platelets and plasma using an FDA-approved pathogen reduction device. The guidance also permits implementation of additional PRT technologies as they are approved. (refer to section V.A.2)

When can I remove the Babesia Question?

When testing or pathogen reduction is performed, you may discontinue asking donors questions about a history of babesiosis. (refer to section V.A.3.b)

What must I do when I collect in a state NOT required to test or use PRT?

In states that are NOT required to implement a licensed NAT test for *Babesia* or use PRT, FDA recommends addressing transfusion-transmitted *Babesia* risk by revising the current question regarding a history of Babesiosis, to ask, “Have you ever had a positive test result for *Babesia*?” This includes tests obtained from either a medical diagnosis or a reactive donor screening test. (refer to section V.A.4)

Can I test AND ask the revised Babesia question?

If you choose to ask a donor question about *Babesia* you should follow the recommendations in section V.A.4” of the guidance. There is no option to disregard the donor’s response, regardless of testing. (refer to section V.A.3.b)

What must I do when a donor tests reactive for Babesia?

“You must defer donors with a reactive NAT result for *Babesia* for at least 2 years from the date of the reactive donation. You must make reasonable attempts to notify any donor whose blood tests reactive for *Babesia* of their deferral and of their test results, within 8 weeks after determining that the donor is deferred (21 CFR 630.40). Deferred donors must be counseled about the possible medical significance of the results (21 CFR 630.40(b)).” (refer to section V.A.3.a)

What must I do when a donor reports a history of a positive test result for *Babesia*?

You must indefinitely defer the donor or defer for at least 2 years from the date of the most recent positive test result for *Babesia*. (refer to sections V.A.3.c and V.A.4.b)

Can I requalify a donor who was previously deferred?

- **In states where testing or pathogen reduction is performed:**
Donors who were previously deferred for a history of babesiosis based on their responses on the donor history questionnaire may be eligible to donate provided they have not had a positive test result for *Babesia* in the last 2 years obtained from either a medical diagnosis or a positive donor screening test result and they meet all other donor eligibility criteria ([§CFR 630.35\(b\)](#)). (refer to section V.A.3.c)
- **In states that do not test donations for *Babesia* or pathogen reduce blood:**
Donors who were previously deferred for a history of babesiosis or deferred for a history of a positive test result for *Babesia* may be eligible to donate under [§CFR 630.35\(b\)](#) provided the following conditions are met:
 - On the day of donation, the donor has not had a positive test result for *Babesia* in the last 2 years and they meet all other eligibility criteria.
 - The donation must be tested for *Babesia* by a licensed NAT and found to be nonreactive at the time of blood collection ([§CFR 610.40\(a\)\(3\)\(ii\)\(A\)](#)). The results of diagnostic testing cannot be used to requalify a deferred donor with a reactive screening test by a licensed NAT. (refer to section V.A.4.c)