HIGHLIGHTS OF THE *MAY 2019 BABESIA GUIDANCE* RECOMMENDATIONS

1. Update your donor history questionnaire (DHQ) and accompanying materials as necessary to incorporate the recommendations of the guidance. (V.A.1)
   - Example DHQ v2.0 Revised Q38 *Babesia* - for states that are not required to test
   - Example DHQ v2.0 Revised to REMOVE Q38 *Babesia* - for states where testing or pathogen reduction technology (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
2. 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." (V.A.3)
3. As an alternative to testing, the guidance allows for use of 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. (V.A.2)
4. When testing or PRT is performed, you may discontinue asking donors questions about a history of babesiosis. (V.A.3.b)
5. The guidance recognizes that some centers may opt to retain the revised Q38 when also testing for *Babesia* (and with PRT). For example, operations may be simplified with the use of one version of the DHQ (retaining the question) for centers collecting in multiple states where requirements differ for testing. If the revised donor screening question is used, the guidance states: *"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. (V.A.3.b)
6. 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*?" (V.A.4.a)
7. When a donor:
   - reports a history of a positive test for *Babesia,* or
   - was previously deferred for a positive test for *Babesia*, or
   - tests reactive for *Babesia* (refer to donor notification V.A.3.a and donor counseling V.A.5)

   you must defer the donor for at least 2 years from the date of the most recent positive test result. Return eligibility and reentry criteria apply. (V.A.3.c and V.A.4.c)
8. Product Management, Retrieval, Quarantine and Notification of Consignees – The guidance provides detailed options for product management. In Section **V.B.2, FDA provides an important clarification for all products that are tested, including PRT products, "**You must not ship or use a donation that is reactive for *Babesia*, unless an exception for shipment or use is applicable (21 CFR 610.40(h) and 21 CFR 630.30(b)(1))." (V.B.2)
9. The guidance requires an update your Circular of Information and provides the language for the update. Refer to the AABB Circular of Information webpage for the details necessary to update your *Circular*. (V.D)
10. The guidance addresses Product Disposition and Labeling and provides appropriate language for relabeling where applicable. (V.C)

11. FDA addressed implementation: “FDA intends to begin requiring compliance with the underlying regulatory requirements regarding relevant transfusion-transmitted infection screening, testing, and product management 12 months after the guidance issuance date.” Annual and/or prior approval supplement reporting requirements of §601.12 apply. (VI.A, B and C)