

Under 21 CFR 606.122(h), FDA states “the circular of information must include the names and results of all tests performed when necessary for safe and effective use.” As new testing requirements are implemented or new information becomes available, the October 2017 Circular must be updated to accurately reflect the changes.

### **Babesia Testing Language Update**

In the May 2019 FDA guidance, Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis, FDA recommends implementation of testing where applicable, within 12 months following the guidance issuance date.

In the May 2019 Guidance, FDA states:

- ~~1. When testing is performed, you must update your circular of information (21 CFR 606.122(h)). We recommend the following statement:~~

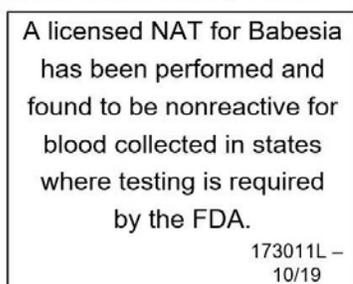
~~**A licensed NAT for Babesia has been performed and found to be nonreactive.**~~

2. If a blood system distributes components from both tested and untested donations, we recommend the following statement:

**A licensed NAT for Babesia has been performed and found to be nonreactive for blood collected in states where testing is required by FDA.**

Note: FDA has clarified that statement #2 applies for blood establishments with a “mixed inventory” that includes both tested and untested units.

Example Babesia Sticker (173011L – 10/19)



### **ZIKV Testing Language Update**

In FDA’s July 2018 Guidance, Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components, FDA states:

- **You must update your circular of information to include the non-reactive test result using an FDA-licensed test for ZIKV (21 CFR 606.122(h)).**

The following language, developed by the AABB Task Force and accepted by FDA in 2017, is similar to that used for other licensed NAT tests that are required. This language should be added to the *Circular* until it can be incorporated in a future version:

- **A licensed nucleic acid test (NAT) for Zika Virus RNA has been performed and found to be nonreactive**

COI Zika sticker  
173011K-01/18

