January 21, 2020

Licensed Babesia Testing Effective 4/20/20

In response to the FDA guidance document for Babesia, CTS will implement the licensed Grifols Babesia test for samples received on April 20, 2020 at the Charlotte, Dallas, Phoenix, St. Louis and Tampa laboratories.

For those clients not routinely collecting blood in states requiring Babesia testing or whose products are not pathogen reduced, we suggest you review the FDA guidance document as you may still be affected. Centers in this category must at least revise their donor history questionnaire.

A two year deferral period is required before you can re-enter a donor that previously tested positive for Babesia. If you have donors who meet this two year deferral criteria, you can either collect from this donor again sending the three sample tubes as usual. The fourth tube collected for Babesia should be sent separately with the revised CTS-00173 requesting Babesia. If clients wish to request just Babesia, send the one tube with the revised CTS-00173 Form to request the test in Special Testing.

Finally, the licensed Grifols Procleix Babesia Assay package insert is now available. CTS will continue to monitor this issue and will distribute additional communications as necessary. The new CTS Assay List, Platform History List and Babesia Interpretation sheet will be available on the website upon implementation.

Impact to the Clients:

- CTS will implement licensed Babesia testing on April 20, 2020.
- Clients will be able to submit samples for Babesia testing for donors that were previously positive for Babesia.

Client Action Items

- Review the guidance document attached to this communication.
- Review the link to the revised CTS0173 Form included in this communication.
- Review the link to the licensed Babesia package insert included in this communication. Notify your Customer service manager if you anticipate the need to begin selectively testing for Babesia.
- Notify appropriate staff of the Babesia updates.
Questions and Additional Information:
Please email your questions or requests for additional information to Lindsey Houghton (lhoughton@mycts.org), or O’Dina Hurlburt (ohurlburt@mycts.org).