July 10, 2019

**FDA Guidance for Industry for Babesia**

On May 9, 2019 the Food and Drug Administration issued a “Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis.” guidance document with a maximum 12 month implementation timeline. Per the FDA guidance document recommendations, CTS is developing a specific implementation plan for mandatory *Babesia* testing well before the May 8, 2020 deadline.

Once available, the CTS *Babesia* implementation plan will be communicated to all CTS clients that collect blood donations located within the stipulated 14 state area: Connecticut, Delaware, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Wisconsin as well as Washington, D.C.

CTS will perform licensed *Babesia* testing on the Grifols NAT platform in pools of 16, with breakout to individual donation testing for positive pools. The cost to perform *Babesia* testing is also not known at this time, and will be communicated when available.

CTS will provide additional updates as more information is available.

**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).