July 6, 2018

**FDA Releases Pooled Zika Guidance and Grifols Zika Assay Licensed**

On July 6, 2018 the FDA released an industry guidance document for transitioning from individual to pooled Zika testing. Additionally, on July 5th Grifols received licensure for their NAT Zika test for both individual and pooled donations.

All CTS clients are tested using the Grifols Procleix Zika virus assay currently being used under an investigational new drug (IND) application. Please continue to distribute the Grifols clinical trial consent forms until further notice. CTS’s current plan is to remain on the clinical trial protocol until October of 2018, but we are evaluating converting from individual to pooled Zika testing under the IND.

Your assistance is needed to convert from individual to pooled Zika as you would need to be prepared to implement the FDA recommended triggering strategy, should your facility or a neighboring blood collection facility detect a positive Zika donation. The FDA proposed Zika triggering strategy is similar to but not exactly the same as West Nile Virus triggering strategy currently used by the blood community.

Please review the FDA guidance document: [Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components](#) to determine the specific impact to your facility.

CTS will distribute further communications as more information is available. Additionally, CTS customer service will schedule group telephone conference calls in the coming weeks to provide you with an opportunity to ask questions and receive additional information. These telephone conference calls will be similar to the calls CTS convened when we implementing Zika testing in the fall of 2016.

**Questions and Additional Information:**
Please email your questions or requests for additional information to Lindsey Houghton ([lhoughton@mycts.org](mailto:lhoughton@mycts.org)), or O’Dina Hurlburt ([ohurlburt@mycts.org](mailto:ohurlburt@mycts.org)).