July 19, 2018

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

This is the first update to the original CTS communication distributed on July 6th.

As previously communicated, all CTS healthcare partners will remain on the Grifols Zika clinical trial until at least the end of October 2018, which coincides with the end of the WNV season. Until conversion to a licensed Zika test, you must continue to distribute donor consent information and label all blood products as being tested with an investigational assay.

There is no current plan to implement pooled Zika under the existing Grifols clinical trial, as CTS is focusing our resources on being able to offer you a pooling option, once we convert to the licensed Zika test. The licensed Zika test will be more expensive than the current test price which is calculated on a cost recovery basis.

We do not have pricing information for either the pooled or individual donation (ID) licensed Zika test at this time. In part, the price will depend on how many CTS healthcare partners convert to a pooled testing strategy verses remaining on ID Zika. CTS will be distributing a Zika survey in the coming weeks to ask you this and other important questions. Thank you in advance for your prompt response.

Licensed pooled Zika testing should be less expensive than licensed ID Zika testing, but requires you to have a triggering strategy. We urge you to discuss with your professional colleagues and industry leaders what strategies are being considered.

CTS will enter your positive Zika samples into the AABB Biovigilance website with your assistance, as we do for your positive WNV samples. Your Zika triggering strategy needs to remain in place year round, and you are required to notify your neighboring blood collection centers and possibly the local Health Department.

Finally, there is no licensed Zika confirmatory test, but there is an IgM test for donor counseling. We will ask you in the Zika survey if you would like this test available for an addition fee. Of note, all Zika positive donors can donate again after 120 days.

Additional communications will be distributed as more information is available. CTS customer service is preparing a webinar for distribution in August, and will schedule group telephone conference calls after the webinar to provide you with an opportunity to ask questions. These group telephone conference calls will be similar to the calls CTS convened when we implemented 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), or O’Dina Hurlburt (ohurlburt@mycts.org).