November 1, 2018

FDA Releases Zika Virus (ZIKV) Guidance and Grifols ZIKV Assay Licensed

This is the sixth update to the previous CTS communications distributed on July 6th, July 20th and August 7th, September 21st and October 12th.

On Monday, November 26th CTS will begin transitioning all 6 labs from the current clinical trial to a licensed Zika test. This transition will take the entire week, as we recently learned that each Grifols Panther testing instrument will need to be brought offline to have the operating system reinstalled and then revalidated. Each Grifols Panther will be offline for approximately 6-8 hours, and given the number of testing instruments at each CTS lab, the entire process is expected to take a full week.

We are taking all possible precautions to avoid any delay to reporting your test results on time. If there is a delay during this transition, you will be notified through the normal channels.

Beginning Monday, December 3rd all test results reported by CTS will be tested using the licensed Zika reagents. Therefore, CTS recommends that you modify your SOPs and other systems so that beginning on Monday, December 3rd or anytime thereafter, you STOP:

1. Distributing Zika donor consent information, and
2. Labelling your blood products as tested for Zika under a clinical IND.

CTS will continue to test all blood donation samples individually and your Zika test fee will remain the same through December 31, 2018.

In order to take advantage of the lower pooled Zika test fees beginning January 1, 2019, your institution should be developing a Zika individual donation trigger strategy.

A Zika triggering strategy may involve modifying your electronic order file to be able to differentiate between pooled and individual donation testing. Alternatively, you will be able to order Zika testing through the CTS website beginning January 1, 2019.

As previously communicated, we are updating the CTS website to be available early in January 2019. The website will have an updated appearance and will be more user-friendly. All the basic functions of the current website will be available but will be easier to use and all selective tests will be available to order on individual samples. A website training guide will be distributed in November 2018.

**Impact to the Clients:**
- CTS will convert from a Zika clinical trial to a licensed test the week of November 26, 2018.
• Beginning Monday, December 3rd all test results reported by CTS will be tested using the licensed Zika reagents.
• CTS will be scheduling validations for Zika triggering to individual testing during the month of December for FTP users.
• A revised and improved version of the CTS website will be available early in 2019.

Client Action Items
• Stop distributing Zika donor consent information as well as labeling blood products on or after December 3, 2018.
• Develop and be prepared to implement a selective triggering strategy for Zika effective January, 1, 2019.
• Watch for the revised website training guide.
• Notify appropriate staff of the Zika 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).