October 12, 2018

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

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

During the week of November 26, all six CTS labs will transition from the current Zika clinical trial to a licensed Zika test. The exact date of your CTS lab’s conversion will be communicated to you as soon as it is known.

Once conversion to the licensed Zika test takes place at your CTS lab, you no longer need to: (1.) distribute Zika donor consent information or (2.) label 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.

Zika licensed fees for pooled and individual donation testing were sent to you on October, 1st or 2nd and these fees will take effect on January 1, 2019.

In order to take advantage of the lower pooled Zika test fees, your institution needs to develop a Zika pooled to individual donation trigger strategy.

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

Any modification to your CTS test request process will likely require a communication validation. The CTS Information Technology Department will be available in the month of December 2018 to perform communication validation with your institution’s IT Department. Please contact CTS Customer Service to schedule a communication validation appointment.

All ZIKA NAT reactive donations will reflex to IgM with an additional reflex to PRNT if the IgM is positive:

Zika IgM Rapid Test
- ChemBio DPP Zika IgM Assay System
- Results: Negative, Presumptive Positive, Not Tested (QNS, unacceptable sample, etc.)
- Turn-around time: Approximately 1 week from sample submission

Zika Plaque Reduction Neutralization (PRNT)
- In-house developed assay
- Results: Negative, Positive, Not Tested (QNS, unacceptable sample, etc.)
- Turn-around time: Approximately 2 weeks after Zika IgM Rapid Test

**Impact to the Clients:**

- CTS will convert from a Zika clinical trial to a licensed test the week of November 26, 2018.
- CTS will be scheduling validations for Zika pooling during the month of December for FTP and CTS website users
- Zika fees will be held at the current through December 31, 2018.
- All ZIKA NAT reactive donations will reflex to IgM with an additional reflex to PRNT if the IgM is positive.

**Client Action Items**

- Decide if your facility will implement a selective triggering strategy for Zika or remain on individual Zika testing.
- If so, contact your customer service manager to schedule validations for Zika pooling during the month of December.
- Notify appropriate staff of the Zika updates.

**Questions and Additional Information:**
Please email your questions or requests for additional information to Claudia Barnett 314-658-2060 cbarnett@mycts.org.