August 7, 2018

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

This is the third update to the previous CTS communications distributed on July 6th and July 20th.

In working with Grifols on the availability of ZIKV test reagents, CTS projects that you should be prepared to convert from a ZIKV clinical trial test to a licensed test as early as October 29, 2018, but not before. Once the exact conversion date of your CTS testing lab is known, it will be communicated to you.

In preparation for conversion to a licensed ZIKV test – but not before – you will need to stop distributing the ZIKV consent information to all your donors and remove the tested for ZIKV under an IND labeling from all blood products. Blood products tested for ZIKV using a licensed test do not need to be labeled. However, under 21 CFR 606.122(h), the circular of information you must include the non-reactive test result using a FDA-licensed test for ZIKV (21 CFR 606.122(h)).

An informational webinar has been scheduled on August 15, 2018 at 11:00am PDT to review the FDA guidance on ZIKV. Details on how to join the webinar can be found below. We strongly recommend that someone from your organization attend. If you cannot attend or need additional information, please contact your CTS Customer Service Manager.

Finally, CTS needs your facility to complete a brief survey confirming your ZIKV testing strategy before August 10, 2018. The SurveyMonkey details are listed below.

Client Action Items

- Respond to the ZIKV survey by August 10, 2018.
- Attend live webinar on at August 15 at 1100 PDT, 1200 MDT 1300 CDT, 1400 EDT.
- Notify appropriate staff

ZIKV Survey

Click on the link below to start the survey and thank you in advance for your participation.

https://www.surveymonkey.com/r/JLB2C25

FDA Guidance ZIKV Testing Strategy Webinar

August 15, 2018

1100 PDT, 1200 MDT, 1300 CDT and 1400 EDT

Signup for the Webinar at:

https://register.gotowebinar.com/register/4183172644839054083
Note: After registering for the ZIKV Webinar you will receive a confirmation email containing information about how to join the Webinar.

**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).