April 29, 2020

Dear Colleagues,

The Tennessee Department of Health (TDH) is providing this update on serology (antibody) testing for SARS-CoV-2, the virus which causes COVID-19.

There is high interest in the availability of antibody testing for COVID-19. However, it is important to understand the limitations around the options currently available. **An antibody test cannot definitively diagnose or rule out COVID-19 infection; and therefore is not recommended as the only test to diagnose acute infection.**

Serologic testing relies on the detection of antibodies to SARS-CoV-2. Depending on the type of serologic test selected, the assay may detect IgM antibodies (seen early after infection), IgG antibodies (seen later after infection), or both. It is not yet clear if antibodies to SARS-CoV-2 are virus-neutralizing or what their presence means for protection from reinfection.

To improve access to testing during the ongoing pandemic, the Food and Drug Administration (FDA) developed policies aimed to accelerate development of SARS-CoV-2 antibody tests by allowing private companies to market the serology tests without FDA approval. The companies or labs cannot claim that the FDA authorized the tests and must include disclaimers noting that such tests might falsely conclude whether a person had a prior infection. While many serologic assays are in development and in use, only eight have emergency authorization use by the FDA. More recently, the FDA said it will start evaluating COVID-19 antibody tests amid concerns about their accuracy.

Currently available serologic tests may lack sufficient accuracy and reliability for making decisions or recommendations to change individual or population-level behaviors. At this time, serologic testing should not be used to make decisions about individuals, e.g. to diagnose current infection or to establish proof of immunity.

As more data emerge on serologic tests, periodic review of this issue, including performance of the tests and interpretation of results, will be necessary. Recommendations may change based on new data.

Additional information from FDA on this topic is available here: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#serology

Please ensure that any testing offered in your facility meets all applicable regulatory requirements.

Visit our webpage for the most up to date information on case counts, information, and resources, including our triage and assessment guidelines, which have recently been updated to reflect additional symptoms to consider, based on recent CDC guidance.

Thank you for all that you do in keeping Tennesseans safe and healthy.

Tennessee Department of Health