

## **Alabama Department of Public Health Advises Health Care Providers in Use of COVID-19 Tests not Approved by the United States Food and Drug Administration**

The Alabama Department of Public Health (ADPH) supports health care workers' efforts to care for Alabama citizens during this COVID-19 health crisis. As this public health emergency evolves, there is need for increased availability of SARS CoV-2 diagnostic testing. In response to this demand, the United States Food and Drug Administration (FDA) released policies to authorize emergency use of *in vitro* diagnostics to increase testing capacity and development to promote widespread testing for COVID-19. As a result, the availability of commercial testing devices proliferated, many with false claims by distributors. ADPH therefore advises health care providers to choose COVID-19 testing systems that are FDA approved when making decisions regarding their patients.

Tests not approved by the FDA can produce false results and lead to unintended consequences for the patient and broader community. A false negative result from a non-approved kit may lead someone who has COVID-19 to think they are not infected and cannot spread the illness. Patients need accurate information about their health, and health care providers and officials need accurate information to provide appropriate medical care and make public health decisions.

Currently, the most accurate FDA-approved testing available is polymerase chain reaction (PCR) assays. PCR tests can detect small amounts of the virus collected in samples from the patient's nose or throat. Public health, commercial, and some clinical laboratories use PCR technology to diagnose COVID-19 infections. Many of these tests have FDA approval through emergency use authorization (EUA).

Serology testing is gaining momentum in the marketplace as collection of blood samples is easy and many platforms are point of care with results in minutes. Serological tests detect if an individual's body is developing antibodies against COVID-19. While these tests can be used to track disease, they are not reliable as recommended for diagnostics and is even stated on most package inserts. At this time, there are only three serological tests that are EUA approved (<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>).

If your facility is considering a serology-based test that is not EUA approved by FDA, understand that:

- Currently no Centers for Disease Control and Prevention guidance exists as to how to interpret or take public health action in response to a positive or negative COVID-19 serology result.
- These tests have not had performance reviews by FDA.
- Negative serology results do not rule out COVID-19 in a patient.
- Serological testing should not be the sole basis to diagnose or exclude infection, or to inform infection status.
- The immune response to SARS-CoV-2 infection is poorly understood at this time.
- Cross reactivity is likely. Positive results could reflect past or present infection with non-SARS-CoV-2 strains.
- False negative results could occur when the immune response is too low to be detected.
- If serology-based test results are submitted to ADPH, they will not be included in the COVID-19 counts at this time due to lack of guidance regarding interpretation.

ADPH fully supports health care providers on the front lines of this pandemic and trust they will use this advisory to make informed decisions regarding their patient's health. It is important to be aware of distributors' false claims. Thank you for your commitment and dedication in service for the citizens of Alabama. If you have questions regarding this information, contact Burnestine Taylor, M.D., at [burnestine.taylor@adph.state.al.us](mailto:burnestine.taylor@adph.state.al.us).