Arkansas Department of Health

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Governor Asa Hutchinson
Nathaniel Smith, MD, MPH, Secretary of Health

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Directive Regarding Prohibition of the Use of Non-FDA Approved Serologic Tests for the Diagnosis of SARS-CoV-2 Infections

The Secretary of Health, in consultation with the Governor, has sole authority over all instances of quarantine, isolation, and restrictions on commerce and travel throughout Arkansas, as necessary and appropriate to control disease in the state of Arkansas, as authorized by Ark. Code Ann. §20-7-109—110 and the Arkansas State Board of Health Rules Pertaining to Reportable Disease (2019). Based on available scientific evidence, it is necessary and appropriate to take further action to ensure that COVID-19 remains controlled and that residents and visitors in Arkansas remain safe.

The antibody response to infection occurs over days to weeks following SARS-CoV-2 infection. The robustness of antibody response depends on multiple factors (i.e. age, nutritional status, severity of disease, medications or infections that suppress the immune system). In some cases of confirmed SARS-CoV-2 infection (RT-PCR test positive) weak, late, or even absent antibody responses have been reported. Antibody detection through SARS-CoV-2 serologic tests may cross-react with other pathogens, including other human coronaviruses, yielding false-positive results. There have been discussions regarding whether detecting SARS-CoV-2 antibodies could predict whether an individual was immune to reinfection by the virus. To date, there is no evidence supporting this.

Licensing of serologic tests for the detection of infectious agents is regulated by the Food and Drug Administration (FDA) and requires vigorous testing to document efficacy of the test in question. This testing usually requires clinical trials involving large numbers of subjects taking many months or years to complete. Multiple serologic assays have now been approved by the FDA under an Emergency Use Authorization (EUA). The FDA is reviewing the EUA process for serologic tests to ensure that accuracy of test results is not compromised. For a complete list of FDA EUA approved tests click below:

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd

The Arkansas Department of Health (ADH) has learned that some manufacturers of serologic tests for the detection of SARS-CoV-2 antibodies are falsely claiming that their serological tests are FDA approved/authorized, or that they can diagnose COVID-19. **The ADH prohibits the use of SARS-CoV-2 serologic tests that have not been FDA approved through the EUA process or that have not received written approval by the Secretary of Health. Further, the ADH prohibits the use of all serologic assays, including rapid point of care devices, outside of CLIA-certified laboratories or settings.**