Arkansas Department of Health

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Governor Asa Hutchinson
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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.

As a response to shortages of laboratory-based molecular testing capacity and reagents for the diagnosis of SARS-CoV-2, multiple manufacturers have developed or are in the process of developing rapid and easy-to-use methods to facilitate testing outside of laboratory settings. These kits are based either on detection of proteins from the COVID-19 virus in respiratory samples (e.g. sputum, throat swab) or detection of human antibodies in blood or serum generated in response to infection. The latter are called “serologic tests”. These can help healthcare professionals identify individuals who have been infected with SARS-CoV-2.

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. In the majority of SARS-CoV-2 infected persons an antibody response develops only in the second week following onset of symptoms. The significance of this is that an antibody-based diagnosis of SARS-CoV-2 infection will often only be possible in the recovery phase. Thus, opportunities for clinical intervention or interruption of transmission have already passed. The serologic tests cannot, for the most part, be used to determine when an infected individual is no longer shedding the virus. Antibody detection through SARS-CoV-2 serologic tests may cross-react with other pathogens, including other human coronaviruses, yielding false-positive results. Lastly, 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. Only after such studies have been conducted and the results evaluated and found favorable by FDA, will a diagnostic test be licensed for use in the United States. To date, only a single antibody detection serologic assay has been approved by the FDA (Cellex, qSARS-CoV-2 IgG/IgM Rapid Test). That assay was subject to limited testing (128 patients) and was approved under an Emergency Use Authorization (EUA).

Over 70 manufacturers have indicated plans to sell antibody detection tests. None, other than the Cellex test, is FDA approved/authorized.

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.