Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000
Governor Asa Hutchinson
Nathaniel Smith, MD, MPH, Secretary of Health

April 16, 2020

Directive Regarding the Use of Nucleic Acid Amplification Test for the Diagnosis of SARS-CoV-2 Infections in Physician Offices, Urgent Care Settings and Pharmacies

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.

Nucleic acid amplification tests (NAATs) are molecular assays that detect a pathogen's (virus, bacteria, fungus, parasite) genetic material in a clinical sample (respiratory, body fluid, tissue, or excreta.) from a patient. Food and Drug Administration (FDA)-authorized NAAT tests for detection of SARS-CoV-2 meet the FDA Emergency Use Authorization (EUA) statutory standard. Based on currently available data, NAATs for the detection of SARS-CoV-2 are believed to be highly accurate (i.e. high sensitivity and specificity), meaning that a positive or a negative result from a NAAT is likely to be true. The FDA has given EUA for several molecular diagnostic platforms used for the diagnosis of SARS-CoV-2: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.

Such tests can be carried out in a patient care setting that is qualified to perform the test as a result of operating under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver or Certificate of Compliance. The term "point of care (POC)" may include settings such as hospitals, physician offices, urgent care settings, outreach clinics, pharmacies, and temporary patient care settings that have appropriately trained personnel to perform the test. It does not apply to home specimen collection or at home testing.

The Arkansas Department of Health (ADH) recognizes the importance of having diagnostic NAATs for the detection of SARS-CoV-2 at POC settings such as those listed above during the current public health emergency. In the interest of patient safety, the ADH requires that all POC NAAT devices and assays used outside of CLIA approved laboratories have written approval from the Arkansas Secretary of Health. In addition, ADH requires that all results (positive, negative, or indeterminate) from NAATs used in POC settings must be reported to the ADH electronically as soon as they are available.

Providers with questions can call the ADH COVID-19 Physicians' Call Line at 1-844-930-3023.