Alabama Department of Public Health (ADPH)
Alabama Emergency Response Technology (ALERT)
Health Alert Network (HAN)
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Alternative Testing Methods for SARS-CoV2 (COVID-19)

The Alabama Department of Public Health (ADPH) has received numerous inquiries of late regarding the validity of some newly marketed diagnostic tests for COVID-19, in particular, serological tests, to detect the presence of antibodies to the COVID-19 virus. As a whole, these tests, although approved by the Federal Drug Administration (FDA) for distribution by commercial manufacturers, or development and use by laboratories, are not reviewed or validated by the FDA, nor do they have Emergency Use Authorization (EUA) before being made available for use.

On March 25, 2020, the FDA issued additional guidance for COVID-19 diagnostic tests, re-emphasizing that although it did not "intend to object" to the development, distribution or use of serology tests for COVID-19, it requires those test reports to provide "information along the lines of the following":

- This test has not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

See Section IV.D of the FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019 at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency and the FDA's Frequently Asked Questions for Diagnostic Testing at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2. A list of commercial manufacturers and laboratories that have notified the FDA that they have validated and are offering serology tests as set forth in the FDA's policy appears on the FDA's website.

Based on these facts, ADPH does not recommend the use of serological tests whose validation has not been reviewed by the FDA. ADPH is receiving reports of increasing numbers of false positive serological test results on asymptomatic people who are then being sent to already overwhelmed emergency rooms for treatment. Patients who are "presumptive positive" based on "testing methods not approved for confirmation" tests, including serological testing, should be retested using nasopharyngeal swabs.

The patient testing criteria set forth in ADPH's HAN Message for March 23, 2020 (URGENT UPDATE: Changes to Testing Criteria to Focus Testing on Patients Most at Risk) remains in effect. Persons with no symptoms should not be tested. Testing is also not recommended for persons with mild symptoms. Please direct patients to stay home, practice home care, and call if symptoms worsen; do not direct them to the emergency room.