

## **COVID -19 TESTING**

Pharmacists may now be involved in certain types of COVID-19 testing, see link below.

The FDA recently clarified that, when it grants an Emergency Use Authorization (EUA) for a point-of-care test, the test is deemed to be CLIA-waived.

Pharmacists may now take part in COVID-19 testing that involves the use of point-of-care tests that have an Emergency Use Authorization approved by the FDA. As of April 16, 2020, none of the serology tests approved by the FDA are considered to be point-of-care tests.

A list of COVID-19 tests that have obtained EUAs from the FDA is available at: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

Pharmacies are reminded that in order to do any CLIA-waived testing they also must have a CLIA Certificate of Waiver. That has been a long-standing requirement. Information about obtaining the Certificate of Waiver can be found on the ADPH Web site: <https://www.alabamapublichealth.gov/providerstandards/clia.html>

Testing must be conducted in compliance with CDC recommendations.

<https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html>

<https://www.cdc.gov/coronavirus/2019-ncov/downloads/priority-testing-patients.pdf>

Only pharmacists, and pharmacist interns under the immediate supervision of a pharmacist, can perform the allowed tests. Self-administered swabbing by patient is optimal to reduce opportunity for exposure.

Pharmacy technicians can only be involved in completing required paperwork, including the required reporting.

Before they can perform tests, pharmacists and pharmacist interns must have appropriate training.

Pharmacies must also provide staff with appropriate personal protective equipment.

Testing must be conducted outside the physical area of the pharmacy (i.e. parking lot, separate closed door exam room, etc.)

The Alabama Department of Public Health (ADPH) has an information page for Healthcare Providers on reporting requirements.

<https://www.alabamapublichealth.gov/covid19/healthcare.html>

Pharmacists conducting COVID-19 tests are subject to the reporting requirements specified on that Web page.

Additional resources:

ADPH COVID-19 information and resources: <http://www.alabamapublichealth.gov/infectiousdiseases/2019-coronavirus.html>

CDC healthcare professionals information: <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html>