



# Expansion Pharmacist, Pharmacy Intern, and Certified Pharmacy Technician Testing Authority During COVID-19

Updated 5/27/2020

*This guidance has been updated to reflect an [advisory opinion](#) released by the U.S. Department of Health and Human Services (HHS) issued on May 19, 2020.*

In order to address testing capacity during the COVID-19 outbreak, the State of Ohio Board of Pharmacy has adopted the following guidance on the authority of pharmacists, pharmacy interns, and certified pharmacy technicians to order and conduct FDA-authorized COVID-19 testing under certain conditions.

This guidance is being issued in accordance with a Board resolution adopted on May 5, 2020 and shall remain in effect until rescinded by the Board.

To access a list of FDA-authorized COVID-19 testing, visit: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>

A pharmacist, pharmacy intern, and certified pharmacy technician may administer FDA-authorized COVID-19 tests under the following conditions:

## Who Can Order Testing?

- On April 14, 2020, HHS issued an advisory opinion that licensed pharmacists are considered "qualified persons" under the PREP act. As the PREP act preempts any state or local legal requirements, pharmacists are authorized to order FDA-authorized COVID-19 testing. (For more information on the PREP act, visit: <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>)

## Who Can Perform Testing?

- Pharmacists, pharmacy interns, and certified pharmacy technicians may perform FDA-authorized COVID-19 tests.
- Certified pharmacy technicians and pharmacy interns must be under the direct supervision of a pharmacist (see *Supervision of Staff* section).

## Supervision of Staff

- Interns and certified pharmacy technicians must be under the direct supervision of a pharmacist. This means a pharmacist shall be physically present in the pharmacy, or in the area where the testing is occurring, to:
  - Answer questions of the pharmacy intern or certified pharmacy technician; and



- Be fully responsible for the practice of the pharmacy intern or certified pharmacy technician.
- The standard 2:1 pharmacy intern to pharmacist ratio, as required by rule 4729:2-1-01 of the Administrative Code, is hereby waived for the provision of COVID-19 testing. **NOTE:** There is no certified pharmacy technician supervision ratio in administrative rule. A pharmacist must use their professional judgement to determine the appropriate level of staff a they may appropriately supervise.

### **CLIA Certificate**

- All sites where a pharmacist, pharmacy intern, or certified pharmacy technician are performing FDA-authorized COVID-19 testing must have a CLIA certificate for the appropriate type of testing that will be performed. For more information on obtaining a CLIA certificate visit:
  - [The Ohio Department of Health - Laboratory Certification](#)
  - [Center for Medicare and Medicaid Services](#)

### **Reporting to a Local Health District**

- By [law](#), any terminal distributor or pharmacist shall be responsible for reporting any confirmed test results within 24-hours to the local health district in which the person resides (or the local health district wherein the person is being medically evaluated if the person's residence is unknown or not in Ohio).
- For pharmacies and other facilities that may choose to partner with a hospital or other healthcare facility to conduct testing, there must be policies in place to determine who is responsible for reporting test results in compliance with Ohio law.
- To find your local health district, please visit: <https://odh.ohio.gov/wps/portal/gov/odh/find-local-health-districts>

### **Patient Notification**

- All patients must be notified of their test results in a timely manner that maintains patient privacy in accordance with state and federal laws, rules, and regulations.

### **Training**

- **For sites licensed as terminal distributors of dangerous drugs:** The terminal distributor of dangerous drugs responsible for the administration of COVID-19 testing shall ensure all pharmacists, pharmacy interns, and certified pharmacy technicians conducting COVID-19 testing receive appropriate training to conduct testing in a safe and effective manner. This includes adherence to the manufacturer's instructions and the mandatory reporting of test results to a local health district. This provision applies to testing conducted at pharmacies as well as pharmacies that use employees to conduct testing off-site (for example, partnering with a hospital or third-party laboratory).
- **For sites that are not licensed as terminal distributors of dangerous drugs:** A pharmacist practicing at a site holding an appropriate CLIA certificate that is not currently licensed as a terminal distributor of dangerous drugs shall be responsible for ensuring that

the pharmacist and all pharmacy interns and certified pharmacy technicians under the direct supervision of the pharmacist conducting COVID-19 testing receive appropriate training to conduct testing in a safe and effective manner. This includes adherence to the manufacturer's instructions and the mandatory reporting of test results to the appropriate local health district.

### **Testing Guidance – UPDATED 5/8/2020**

- The Ohio Department of Health has established the following guidance for COVID-19 testing in Ohio (Revised on 5/8/2020): <https://coronavirus.ohio.gov/wps/portal/gov/covid-19/healthcare-providers-and-local-health-districts/for-healthcare-providers/updated-covid-19-testing-guidance>
- Licensees are expected to adhere to the Ohio Department of Health's [COVID-19 Testing Guidance](#) and any subsequent revisions or updates issued by ODH.

### **PPE and Infection Control**

- All COVID-19 testing must be conducted by staff wearing appropriate PPE, including face masks and gloves. Additionally, all testing areas must be regularly disinfected.

### **Billing and Reimbursement**

- As the Board has no jurisdiction over insurance companies, it cannot offer any guidance on reimbursement for COVID-19 testing administered by pharmacy personnel.