

The Pharmacist's Role in COVID-19 Testing

In a previously released statement, the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health released guidance under the Public Readiness and Emergency Preparedness Act (PREP) authorizing pharmacists to order and administer COVID-19 tests that had been authorized by the U.S. Food and Drug Administration (FDA). Additionally, under this guidance, pharmacists ordering and administering COVID-19 tests will qualify as “covered persons” under the PREP act, providing them liability immunity for any loss related to the administration of use of a FDA-authorized COVID-19 test.

Prior to offering any Point of Care (POC) test in a community pharmacy, including a COVID-19 test, the pharmacy must obtain a CLIA waiver. Before you perform a test on a patient, verify that the test is deemed to be authorized in a CLIA-waived setting by checking the list of test kits manufacturers with an FDA emergency use authorization. When the FDA authorizes a POC test under an EUA, the test may be used in a CLIA waived pharmacy if the pharmacy has a CLIA waiver and the EUA designates the test is authorized for use in a “patient care setting” with a CLIA certificate of waiver.

COVID-19 Testing Checklist:

1. Obtain required training for COVID-19 testing. CE program can be accessed by going to:
<https://www.lecturepanda.com/v2/register/ag1zfnJ4Y2V0cmFja2VychMLEgZDRV VzZXIYglCA8sSI9AkM/ag1zfnJ4Y2V0cmFja2VycicLEgZDRV VzZXIYglCA8sSI9AkMCxIHTGVjdHVyZRIgIDvh43CCgw/new>
2. Determine if the test you wish to offer is authorized by the FDA in a CLIA waived setting. To access a list of the available test to be used in a CLIA waived pharmacy go to <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>. Tests with a designation of “W” under “Authorized Settings” are considered appropriate for use in a CLIA waived setting.
3. If you already have a CLIA waiver, update your CLIA waiver to include the COVID-19 test you will be offering. You will need to contact the Kentucky CLIA Program Office to notify them you are adding COVID-19 testing to your CLIA waiver. They will need to know the specific test you will be offering. Phone 502-564-7963 ext 3322
4. If you do not have a CLIA waiver, apply for the CLIA waiver. For instructions and information on how to obtain a CLIA waiver go to:
<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf>.

Kentucky contact information and website:

KENTUCKY CLIA PROGRAM Office of Inspector General Division of
Healthcare
275 East Main Street, 5E-A Frankfort, KY 40621-0001
(502) 564-7963 Ext 3322
FAX: (502) 564-6546
Email: KYCLIALabinquiries@ky.gov

5. Develop policies and procedures and provide appropriate training to staff on the ordering, administering, documentation, quality assurance and use or appropriate PPE when testing for COVID-19.
6. Ensure the ordering and administering of COVID-19 tests are performed according to testing priorities set forth by the Kentucky Department for Public Health.

To read the Order authorizing pharmacies to order and administer COVID-19 testing with or without a prescription or medical order, click here:

<https://pharmacy.ky.gov/Documents/2020.4.24%20-%20Secretary%20Order%20-%20Board%20of%20Pharmacy.pdf>

To additional information go to the FDA FAQs on diagnostic Testing for SARS-CoV-2 at:

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>.

NCPA has developed additional information on COVID-19 testing, best practices and billing. To access these resources go to: <https://ncpa.org/covid-info-community-pharmacy>.