Which COVID-19 Tests are Pharmacists Allowed to Order and Administer?
For the duration of the relevant federal emergency declaration, pharmacists may order and administer tests that have been CLIA-waived or approved by the FDA.[1] A test for which an Emergency Use Authorization ("EUA") has been issued by the FDA is CLIA-waived and may be ordered and administered by pharmacists.

Such tests may be ordered and administered only in a patient care setting operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

How Do Pharmacists Know Which Tests are CLIA-waived for Point-of-Care Testing?
To identify CLIA-waived point-of-care tests:

1. Access the FDA's EUA website (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization).
2. Scroll down to find "In Vitro Diagnostics EUAs."
3. Tests that are indicated with a "W" under the "Authorized Setting(s)" section of the list are CLIA-waived point-of-care tests.

Which pharmacists are allowed to order and administer CLIA-waived COVID-19 tests at the pharmacy?
Pharmacists practicing in a pharmacy that operates under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation are allowed to order and administer CLIA-waived COVID-19 tests.

How Can My Pharmacy Obtain a CLIA Certificate of Waiver?
To obtain a CLIA Certificate of Waiver, please see the Centers for Medicare and Medicaid Services (CMS) document "How to Obtain a CLIA Certificate of Waiver," which details the process and includes FAQs (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/HowObtainCertificateofWaiver.pdf).

Is a CLIA Certificate of Waiver Required to Collect Samples?
No. If the pharmacy is only collecting specimen samples to be sent to a laboratory that will perform the test, then the pharmacy is not required to obtain a CLIA Certificate of Waiver. However, pharmacists should ensure that they have received adequate training before collecting samples or overseeing a patient's self-collection, in order to ensure valid and accurate results, and should ensure that the laboratory to which they are submitting samples for testing is properly certified.

Who Should Pharmacists Test?
COVID-19 diagnostic testing should be prescribed or ordered consistent with current CDC guidelines, which are based on testing capacity. CDC guidelines be found here: "Evaluating and testing persons for COVID-19" (https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html).

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[1] The federal government has issued a variety of emergency declarations related to the COVID-19 pandemic. The declaration authorizing EUAs for COVID-19 tests is the Secretary of Health and Human Services' February 4, 2020 declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the PREP Act, 21 U.S.C. § 360bbb-3(b)(1). EUAs issued under that declaration will be in effect for the duration of that declaration, unless the authorization is terminated or revoked sooner.

When Must Patients be Notified of Test Results?
All patients must be notified of their test results in a timely manner that maintains patient privacy in accordance with state and federal laws and regulations. Some patients may have further questions as to what the result of the test means. Patient should consult with their physician or other qualified healthcare provider regarding such questions.

Is Training Required in Order to Collect and Perform Tests?
Pharmacies must ensure that pharmacists collecting specimen samples and performing COVID-19 tests receive the training necessary to conduct the activity in a safe and effective manner. This requires adhering to the testing device manufacturer's instructions. Completion of training must be documented. For additional information, refer to the "General Guidelines" section on CDC's website.

Is Reimbursement Available for Pharmacies Collecting Specimen Samples and/or Performing COVID-19 Testing?
The Board cannot offer guidance on reimbursement. Please consult with relevant insurance carriers or administrators.

Must I Report the Results of Point of Care Testing?
Yes. As required by Governor Abbott's executive order, every public or private entity utilizing an approved or EUA test for COVID-19 shall submit to DSHS, as well as the entity's local health department, **daily** reports of all positive, negative, and indeterminate test results from both serology and diagnostic tests. This includes any point-of-care testing performed in pharmacies. More information can be found at the DSHS website (https://dshs.texas.gov/coronavirus/lab-reporting.aspx).

You must ensure that your facility is reporting all point-of-care testing results. If you have questions about submitting lab results to DSHS, contact IDI@dshs.texas.gov for more information on how to report.

Must Pharmacies Maintain Records of Tests Provided?
Yes, pharmacies must maintain documentation of COVID-19 testing, including test results, patient notification, and follow up and referrals for evaluation for positive diagnostic or serologic IgM COVID-19 test results. Documentation must be available for Board inspection.

Are There Guidelines Regarding Waste Disposal?
The Texas Commission on Environmental Quality (TCEQ) says that until further notice, it will exercise enforcement discretion for pharmacies that provide COVID-19 testing and treat COVID-19 waste on-site using an approved treatment method. Such pharmacies must maintain records as prescribed under 30 Texas Administrative Code (TAC) Sections 326.39(b) and 326.41(b). Additionally, once the medical waste is treated, it may be managed as routine municipal solid waste in accordance with 30 TAC Sections 326.39(c) and 326.41(c).

TCEQ will also, until further notice, exercise enforcement discretion with regard the following requirements for pharmacies that provide COVID-19 testing: (1) Medical Waste Transporter registration and fee requirements (found in 30 TAC Sections 326.53 and 326.87); and (2) Medical Waste Mobile Treatment Unit registration and fee requirements (found in 30 TAC Section 326.55 and 326.87).

NOTICE TO PATIENTS TESTED FOR COVID-19

If you have any questions about the results or accuracy of your COVID-19 test, or about what you should do in light of your results (especially for treatment or to protect yourself and those around you), we encourage you to consult with your doctor or other qualified healthcare provider.