

**NM Board of Pharmacy
Pharmacist Ordering and Administering COVID-19 Testing**

On April 8, 2020, the United States Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health (OASH) issued [Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act](#). As the authority having jurisdiction under the Public Readiness and Emergency Preparedness Act (PREP Act), the OASH-issued guidance authorizes licensed pharmacists to order and administer [Food and Drug Administration \(FDA\) Authorized COVID-19 tests](#) to their patients.

During the declared federal public-health emergency due to COVID-19, unless otherwise amended:

In accordance with the HHS Guidance, pharmacists may administer FDA-authorized tests that can be performed in a patient care setting operating under a CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver.

As defined by CLIA, waived tests are categorized as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.” The FDA determines which tests meet these criteria when it reviews manufacturer’s applications for test system waiver.

Where the FDA authorizes tests for use at the point-of-care (POC) under an Emergency Use Authorization (EUA), such tests are deemed CLIA waived tests. These COVID-19 tests are listed on the [FDA’s EUA webpage](#):

Date EUA Issued	Manufacturer	Diagnostic (Letter of Authorization)	Technology	Authorized Setting(s) ¹	Authorization Documents ²	Other Documents/
05/08/2020	Quidel Corporation	Sofia 2 SARS Antigen FIA	Antigen	H, M, W	HCP, Patients, IFU	None
03/27/2020	Abbott Diagnostics Scarborough, Inc.	ID NOW COVID-19	Molecular	H, M, W	HCP, Patients, IFU	Letter Granting EUA Amendment(s) (April 21, 2020)

W Patient care settings operating under 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. The document includes a link to the [Form CMS-116](#). Send your completed application to the address below. Additionally, check with your [State Agency](#) (listed below) for any other state-specific requirements.

NEW MEXICO

Health Facility Licensing & Certification Bureau Bank of the West Building
5301 Central Avenue NW, Suite 400
Albuquerque, NM 87108 (505) 222-8646 FAX: (505) 841-5834
Email: CLIA.DHI@state.nm.us
Webster: <http://dhi.health.state.nm.us/index.php>

[Register your screening and testing location](#) with the NM Department of Health (DOH). Contact the DOH prior to beginning testing, and follow these [instructions to report test results](#).

Pharmacist Administering and Ordering COVID-19 Testing:

Pharmacies and pharmacists must follow screening and testing recommendations, and comply with DOH test result reporting requirements. COVID-19 diagnostic testing is to be consistent with current [DOH criteria](#) and [CDC priority testing recommendations](#), which are based on testing capacity.

Pharmacists who engage in testing are to follow current CDC and FDA COVID-19 testing related guidelines, including:

- [CDC Information for Healthcare Professionals about COVID-19](#)
- [Evaluating and testing persons for COVID-19](#)
- [Infection Control Guidance for Healthcare Professionals about COVID-19](#)

Test Administration: Pharmacists, and pharmacist interns under the direct supervision of a pharmacist, may administer a POC COVID-19 test that has an EUA.

Test Ordering: A pharmacist may order a moderate or high-complexity COVID-19 test that has an EUA for subsequent laboratory analysis. Prior to collection of patient specimens (e.g. venous blood for serology testing), the pharmacy must identify and coordinate with an authorized laboratory to conduct the testing. No CLIA Certificate of Compliance or Waiver is required for specimen collection.

Policies and Procedures: The Pharmacist-In-Charge is responsible for implementing and maintaining proper policies, procedures, training and engineering [controls](#).

Policies and procedures must include:

1. COVID-19 testing related activities, including: infection prevention and control practices (standard and transmission-based precautions), availability and proper use of [personal protective equipment](#) (PPE), screening, [specimen collection and handling](#), test result evaluation and reporting, patient notification, and follow up and referrals for evaluation for positive COVID-19 diagnostic or serologic IgM test results. All notifications, including referrals, will be timely and in accordance with state and federal laws and regulations. Pharmacists will strictly follow the manufacturer's test kit product insert instructions, and provide patient information fact sheets.
2. Training: each person must complete proper training prior to engaging in COVID-19 testing related activities. Training will include policies and procedures, an assessment of proper PPE use, and specimen collection and handling. Staff who use respirators must be familiar with proper use and follow a complete respiratory protection program that complies with OSHA Respiratory Protection standard (29 CFR 1910.134). Staff training will include [appropriate donning and doffing of PPE](#). Training must be documented in accordance with CLIA requirements.
3. Infection prevention and control practices:
 - a. Specimen collection and testing must be conducted **outside the physical area of the pharmacy** (e.g. parking lot for mass testing, separate dedicated closed-door exam room for limited serology specimen collection). The pharmacy drive through may not be utilized for testing.
 - b. Environmental security measures will be in place to prevent the spread or transmission of the Coronavirus by a potentially infected individual presenting to the testing site.
 - c. Proper PPE must be available, and used appropriately (face shield or goggles, respirator or facemask, gloves, gowns). Cloth face coverings are not PPE.
 - d. Proper hand (glove) hygiene/disinfection, including before and after patient testing.
 - e. Testing areas must be disinfected routinely, including following potential contamination.
 - f. Pharmacies should utilize [self-collection options](#) as appropriate.
 - g. Specimens or potentially COVID-19 contaminated items may not be taken into the restricted pharmacy area.
4. Notification to the test kit manufacturer and FDA (via email at CDRH-EUA-Reporting@fda.hhs.gov) of any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test kit.
5. As applicable, follow DOH procedures, and manufacturer's instructions to collect, store, and ship specimens appropriately, including during afterhours or on weekends/holidays.
6. Pharmacies and pharmacists will 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.
7. Required documentation will be available for Board inspection.

Pharmacies and pharmacists are reminded of the following:

It is the Board's long-standing position that pharmacists may administer CLIA waived tests. Ordering moderate or high-complexity COVID-19 tests that have an EUA is a specific allowance during the declared federal public-health emergency, pursuant to the HHS OASH guidance under the PREP Act.

The FDA reported [possible accuracy concerns with Abbott ID Now Point-Of-Care test](#). Pharmacies and pharmacists are to stay informed of current test information or issues for any tests used.

The FDA has issued alerts regarding fraudulent COVID-19 test kits. The sale of fraudulent COVID-19 products is a threat to the public health. Consumers and health care professionals can help by reporting suspected fraud to the FDA's [Health Fraud Program](#) or the [Office of Criminal Investigations](#). You can also email FDA-COVID-19-Fraudulent-Products@fda.hhs.gov.

Issued: 5/11/2020, updated 5/20/2020 (DOH reporting instructions, FDA report of possible accuracy concerns with POC test)

Resources:

NM Human Services Department Centennial Care 2.0: [Special COVID-19 LOD #8 – COVID-19 Testing and Treatment Services and Codes](#)

CMS [Medicare Pharmacies and Other Suppliers May Temporarily Enroll as Independent Clinical Diagnostic Laboratories to Help Address COVID-19 Testing](#)

[CDC Clinical Questions about COVID-19: Questions and Answers](#)

[CDC Fact Sheet for Healthcare Providers Emergency Use of SARS-CoV-2 Antibody Tests During the COVID-19 Pandemic](#)

[CDC Guidance – Proposed Use of Point-of-Care \(POC\) Testing Platforms for SARS-CoV-2 \(COVID-19\)](#)

[FDA FAQs on Diagnostic Testing for SARS-CoV-2](#)

FDA Industry Hotline: Coronavirus COVID-19 Diagnostic Tests and Shortages

- For Industry Questions: COVID-19 Diagnostic Tests, and COVID-19 device shortages, including all Personal Protective Equipment for masks and respirators
- Contact our toll-free line 24 hours a day: 1-888-INFO-FDA[®], choose option *
- Or Email: Shortages: deviceshortages@fda.hhs.gov Diagnostic Tests: COVID19DX@FDA.HHS.GOV