

## COVID-19 TESTING

### UPDATED APRIL 13, 2020

COVID-19 is a threat to the well-being of our residents and employees. While there is a sense of urgency to quickly obtain samples and expedite testing results, there are some considerations and challenges for community leaders:

- Having residents leave the building for testing is problematic in that it can potentially expose residents to additional sources of COVID-19.
- “Drive thru” testing can be time consuming and is less than ideal.
- Having third-parties enter the community to conduct testing can introduce another potential source of COVID-19.
- If testing within the community, a decision would need to be made regarding where sample collection would take place.
- Regardless of which approaches are adopted, HIPAA regulations are still in effect.

The following information is intended as assistance for all senior living communities that are contemplating and/or performing testing in their community.

### BACKGROUND

- In February 2020, the test kit [“Centers for Disease Control and Prevention \(CDC\) 2019-Novel Coronavirus \(2019-nCoV\) Real-Time Reverse Transcriptase \(RT\)-PCR Diagnostic Panel”](#) was developed by CDC to test for SARS-CoV-2. This test is a Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel that can provide results in four to six hours.
- In the U.S., these test kits are intended for use only in [CLIA-certified laboratories](#). (CLIA certification can be verified through the [CDC registry](#).)
- The tests are still too new to meet the lengthy approval process typically used for a new test. However, at the request of CDC, on February 4, 2020, the [U.S. Food & Drug Administration \(FDA\) issued Emergency Use Authorization \(EUA\)](#) of these tests.
- Given the urgent demand for testing, on February 28, 2020, the American Society for Microbiology (ASM) submitted a [letter to FDA](#) voicing concerns about the impact of Emergency Use Authorization (EUA) regulations on the use of diagnostic tests by clinical laboratories during the COVID-19 outbreak.
- As reported in the [Washington Post on February 29, 2020](#), the FDA responded the next day and took steps to expand testing for SARS-CoV-2, allowing clinical laboratories to begin using their local laboratory developed tests (LDTs) before FDA clearance.

- The FDA publishes a list of [In Vitro Diagnostics EAUs](#) that shows the test manufacturer, the date the EAU was issued, and related information. This list is being updated almost daily as additional laboratory providers receive authorization to test.
- There are new tests expected to reach the market within the next week that can detect the presence of SARS-CoV-2 within five minutes and rule out the pathogen in under 15 minutes (e.g., [Abbott Laboratories ID NOW COVID-19 tests](#)). Like other tests currently available, these tests will still need to be sent to a lab for processing.
- There is also a serological test (e.g., [Cellex qSARS-CoV-2 IgG/IgM Rapid Test](#)), which can be used to detect antibodies in blood. The ability to identify people who have already been exposed or recovered from COVID-19 and have immunity could help with identification of workers. The first of these tests received Emergency Use Authorization from FDA on April 1, 2020. However, availability remains limited.

## WHO SHOULD BE TESTED?

According to [CDC guidance](#) as of publication, not everyone needs to be tested for COVID-19. However, this guidance is based in part on the limitation of available testing capacity and is subject to change. There are advantages to broader testing, such as reducing anxiety among senior living residents that could be attributed to selected testing.

The following information is excerpted from CDC guidance as of March 24, 2020. This information might help in making decisions about seeking care or testing.

- Most people have [mild illness](#) and are able to [recover at home](#).
- There is no treatment specifically approved for this virus.

CDC has [guidance](#) for who should be tested, but **decisions about testing are at the discretion of state and local health departments and/or individual clinicians**. (See [Evaluating and Testing persons for Coronavirus Disease 2019 \(COVID-19\)](#)).

- Clinicians should work with their state and local health departments to coordinate testing through public health laboratories, or work with clinical or commercial laboratories.
- Clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Most patients with confirmed COVID-19 have developed fever (subjective or confirmed) and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing).
- Other considerations that may guide testing are epidemiologic factors such as the occurrence of local community transmission of COVID-19 infections in a jurisdiction.
- **Clinicians are strongly encouraged to test for other causes of respiratory illness.**

Anecdotally, one laboratory reported a coinfection rate of 76% for patients 65 and older who tested positive for COVID-19, with some patients having up to five coinfections. This is significant as both the COVID-19 virus and the coinfection(s) must be treated at the same time. These coinfections may lead to secondary infections, which are the main causes of bacterial pneumonia and which are treatable.

## **PRIORITIES FOR TESTING**

### **PRIORITY 1**

Ensure optimal care options for all hospitalized patients, lessen the risk of nosocomial infections, and maintain the integrity of the healthcare system. (e.g., hospitalized patients, symptomatic healthcare workers)

### **PRIORITY 2**

Ensure that those who are at highest risk of complication of infection are rapidly identified and appropriately triaged. (e.g., patients in long-term care facilities with symptoms, patients 65 years of age and older with symptoms, patients with underlying conditions with symptoms, and first responders with symptoms)

### **PRIORITY 3**

As resources allow, test individuals in the surrounding community of rapidly increasing hospital cases to decrease community spread and ensure health of essential workers. (e.g., critical infrastructure workers with symptoms, individuals who do not meet any of the above categories with symptoms, health care workers and first responders, individuals with mild symptoms in communities experiencing high COVID-19 hospitalizations)

**NON-PRIORITY:** Individuals without symptoms

## **HOW TO GET TESTED**

The first step is to secure an order from a doctor, nurse practitioner, or a physician's assistant that testing is necessary. The ordering provider will need a National Provider Identification (NPI) and ICD-10.

- The primary care physician may already be affiliated with a laboratory that has received Emergency Use Authorization to provide COVID-19 tests (as part of a Respiratory Pathogen Panel).
- If the physician is not registered with a laboratory that offers COVID-19 testing, or if lag times are such that additional lab options are warranted, refer the physician to the [FDA's list of laboratories authorized to provide COVID-19 testing](#).
- Use this link to [find a qualified lab or to verify lab qualifications](#).

## [Additional Background: Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge](#)

On March 30, 2020, CMS issued a temporary waiver of several requirements related to COVID-19, including testing. The following points were excerpted from the section titled “Further Promote Telehealth in Medicare:”

- “CMS is expanding access to telehealth services for people with Medicare. This means they can receive care where they are: at home or in a nursing or assisted living facility. If they have COVID-19, they can remain in isolation and prevent spread the virus. If they aren’t infected, they can get care without risking exposure to others who may be ill.”
- “CMS will now pay for more than 80 additional services when furnished via telehealth. These include emergency department visits, initial nursing facility and discharge visits, and home visits, which must be provided by a clinician that is allowed to provide telehealth.”
- “If a physician determines that a Medicare beneficiary should not leave home because of a medical contraindication or due to suspected or confirmed COVID-19, and the beneficiary needs skilled services, he or she will be considered homebound and qualify for the Medicare Home Health Benefit. As a result, the beneficiary can receive services at home.”
- “Virtual Check-In services, or brief check-ins between a patient and their doctor by audio or video device, could previously only be offered to patients that had an established relationship with their doctor. Now, doctors can provide these services to both new and established patients.”

### **COLLECTION OF SAMPLES**

Each laboratory will have a specified sample collection protocol. However, the person taking the specimen must be trained in obtaining a nasal specimen, and their skills must be validated. The person collecting the specimen must have proper PPE including respirator, goggles or face mask, gloves, and gown.

Some communities already collect nasopharyngeal samples that are used for testing for influenza, other respiratory pathogens, and SARS-CoV-2. Individuals who have had their skills validated by a person trained in the procedure are qualified to collect samples.

For communities that do not already have staff qualified to collect samples, options are to train staff or delegate sample collection to a qualified third party.

The [video at this link](#) provide instruction on the nasopharyngeal swab procedure used to collect samples. [Here’s a second video.](#) The collection procedure is also described in the section below. Individuals who are being trained to collect samples must also have proper PPE.

Consider whether it would be preferable to collect samples in a resident's room or another area within the community.

From the section above on "How to get tested," following are additional excerpts from the [CMS Guidance](#) related to testing and sample collection:

- "The new CMS guidelines allow healthcare systems, hospitals, and communities to set up testing and screening sites exclusively for the purpose of identifying COVID-19 positive patients in a safe environment."
- "The guidance describes circumstances in which hospital emergency departments can test and screen patients for COVID-19 at drive-through and off-campus test sites."
- **"Medicare Specific:** Medicare will pay laboratory technicians to travel to a beneficiary's home to collect a specimen for COVID-19 testing, eliminating the need for the beneficiary to travel to a healthcare facility for a test and risk exposure to themselves or others. Under certain circumstances, hospitals and other entities will also temporarily be able to perform tests for COVID-19 on people at home and in other community-based settings."

## LABORATORY COLLECTION PROCESS

1. If a resident is exhibiting symptoms of COVID-19, immediately isolate and call their PCP or telehealth provider to obtain an order for testing. The order can be provided verbally to a nurse or sent via fax. Be prepared to ask the provider for:
  - The provider's NPI number
  - ICD-10 code(s)
  - Type of test: Upper Respiratory Panel with COVID-19 (the CDC recommends that a full respiratory panel be complete to rule out other viruses and/or upper respiratory bacterial infections).
2. Obtain a lab specimen bag and a nasopharyngeal collection tube. Document the needed information for the person being tested on the sample container, including name, date of birth, and collection date on the tube.
3. Put on PPE and enter the room where sample collection will take place. Explain the sample collection procedure to the person being tested.
4. Swab Collection:
  - Gently insert the swab into a nostril and insert as far up into the nostril as the person will tolerate. If there is visible drainage, a drainage sample will suffice.
  - Gently swab the nostril in a circular motion about 5 times. PCR does not require a large amount of the specimen like culture technique.
  - Slowly remove the swab and place the swab in the tube. Bend back tube of swab back and forth until it breaks at the top of the tube.
  - Use caution and avoid touching the top of the swab to prevent contamination.
  - Tightly cap the tube and place it in a lab specimen bag.

5. Fill out the required requisition sheet that is to be sent with the specimen. It is important to have this completely and appropriately filled out, otherwise this will delay results. A face sheet and copy of the person's insurance cards can be accompanied with the requisition form.
6. Place in the appropriate shipping bag and arrange for pick-up.
7. Dispose of PPE according to the community's procedures.

## **REPORTING**

Report positive findings to your local health department using the attached form, [Human Infection with 2019 Novel Coronavirus – Person Under Investigation \(PUI\) and Case Report Form](#).

Information includes:

- Demographic, clinical, and epidemiologic characteristics
- Exposure and contact history
- Course of clinical illness and care received

## **DISCLAIMER**

Argentum, its executive staff and consultants, have attempted to provide the best possible information as a service to the association's membership in a situation that is very quickly evolving and about which so much is unknown. Therefore, Argentum can provide no assurances nor even make any representations about the reliability or accuracy of this information. Each senior living company and each community must make decisions that each regards as in the best interests of the health and safety of residents and staff. Argentum specifically disclaims responsibility or liability for the information it is providing from any legal, regulatory, medical, or compliance point of view.

The following information has been compiled to assist with decision making on issues related to testing for COVID-19.