ARIZONA DEPARTMENT OF HEALTH SERVICES

Recommendations for Long-term Care Facility Diagnostic Testing

Diagnostic tests check samples from the respiratory system, such as a swab from the inside of the nose, to see if someone is currently infected with SARS-CoV-2, the virus that causes COVID-19. Some tests are point-of-care (POC) tests, meaning results may be available at the testing site in less than an hour. Other tests must be sent to a laboratory to analyze, a process that may take days once received by the lab.

The Centers for Disease Control and Prevention (CDC) recommends diagnostic testing for:

- Individuals with signs or symptoms consistent with COVID-19.
- Asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 to control transmission.
- Asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings.
    - Certain settings, such as long-term care facilities, can experience rapid spread of SARS-CoV-2 due to vulnerable populations being in close quarters for extended periods of time.

The sections below provide recommendations on testing methods and procedures for long-term care facilities.

Type of Test Recommended

- A diagnostic test for SARS-CoV-2, including:
    - Polymerase Chain Reaction (PCR)
    - Antigen (Ag)-.
- Antibody (Ab)/serology tests are not diagnostic, so they are not recommended for screening for current infection.

Vaccination

- **"Fully vaccinated" refers to a person who is ≥2 weeks following receipt of the second dose in a 2-dose series, or ≥2 weeks following receipt of one dose of a single-dose vaccine.**
- **"Unvaccinated" refers to a person who does not fit the definition of "fully vaccinated," including people whose vaccination status is not known, for the purposes of this guidance.**

Recommended Test Frequency

Follow CMS guidance on facility testing requirements for residents and staff in CMS certified facilities.

- When prioritizing individuals to be tested, facilities should prioritize individuals with signs and symptoms of COVID-19 first, then perform testing triggered by an outbreak.

Table 1: Testing Summary

Testing Trigger	Staff	Residents
Symptomatic individual identified	Staff, *vaccinated and unvaccinated,* with signs and symptoms must be tested	Residents, *vaccinated and unvaccinated,* with signs and symptoms must be tested
Outbreak (Any new case arises in facility)	Test all staff, *vaccinated and unvaccinated,* that previously tested negative until no new cases are identified*	Test all residents, *vaccinated and unvaccinated,* that previously tested negative until no new casesare identified*
Routine testing	According to Table 2 below	Not recommended, unless the resident leaves the facility routinely.

*For outbreak testing, all staff and residents should be tested, *regardless of vaccination status,* and all staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result.

- Routine testing of unvaccinated staff should be based on the extent of the virus in the community. Fully vaccinated staff do not have to be routinely tested. Facilities should use the county positivity rate in the prior week published by CMS as the trigger for staff testing frequency.

Table 2: Routine Testing Intervals Vary by Community COVID-19 Activity Level

Community COVID-19 Activity	County Positivity Rate in the past week	Minimum Testing Frequency *of Unvaccinated Staff*[+]
Low	<5%	Once a month
Medium	5% - 10%	Once a week*
High	>10%	Twice a week*

[+]*Vaccinated staff do not need be routinely tested.*

***This frequency presumes availability of Point of Care testing on-site at the nursing home or where off-site testing turnaround time is <48 hours.**

Planning for Specimen Collection, Testing, and Data Management

- Establish a plan that outlines who is responsible for performing specimen collection from staff and residents, a process for specimen collection and transport (if needed), and who is responsible for conducting POC testing.
    - Consider what facility staff can collect specimens on themselves/from other staff or whether additional support is needed for specimen collection (i.e., specimen collection contractor). The facility's staff may need to be trained to collect specimens correctly. Training should include infection prevention and control requirements and correct personal protective equipment (PPE) use.
    - Determine whether staff can be tested at the facility or if they will be tested off-site.
        - Develop an informed consent process to ensure the facility can receive results.
        - Although CMS requires routine staff testing, facility policies and procedures should be referenced for staff refusing to be tested.

    - Determine how results will be shared with the facility, the Arizona Department of Health Services (ADHS), and the local health department.
    - Determine a process that captures which staff were tested or were unable to be tested.

Coordinating Reporting of Testing Results

- For off-site testing, laboratories that can quickly process large numbers of tests with rapid reporting of results (e.g., within 48 hours) should be selected for testing intended to inform facility infection prevention initiatives to prevent and limit transmission.
    - Ideally, one laboratory should be selected to process specimens from staff to facilitate data collection and analysis.
- Report positive and negative results of on-site COVID-19 testing (e.g., antigen testing) directly to ADHS pursuant to Executive Order 2021-07 . Results that are suspected or confirmed to be false-negative or false-positive still need to be reported.There are two main methods for reporting these results to ADHS:
    - The preferred method is to register your facility with this Google Form. Once registered, you will receive another link to enter reports into a separate Google Form. A guidance document on this process is available on the Lab Resources webpage.
    - The second option is to follow the flat file reporting requirements outlined on the Lab Resources webpage. If files are not submitted in the proper format, you will be required to resubmit the file in the appropriate format.
    - If your facility is reporting in the NHSN COVID-19 test module, ADHS needs to conduct data validation to make sure the reports coming from NHSN are meeting the Arizona reporting requirements for your facility.
        - Please make sure your facility is reporting all test results to both reporting methods (POC web entry and NHSN) paying special attention to the collection & result dates.
        - To meet the state requirements, reports from tests performed at your facility still need to be submitted through the POC web entry until you receive communication from ADHS indicating you passed the validation.
        - If you would like to discuss using NHSN's COVID-19 test module for reporting to ADHS, please contact reportingquestions@azdhs.gov.
- Ensure COVID-19 positive results and suspected outbreaks are reported to the local health department pursuant to Arizona Administrative Code R9-6-202.
    - Submit a report within 24 hours after a case or suspect case is diagnosed, treated, or detected or an occurrence is detected.
    - Submit a report within 24 hours after detecting an outbreak of Respiratory Disease in a Health Care Institution or Correctional Facility.
- The facility should maintain records of staff who have positive tests.
- Testing should be carried out in a way that protects confidentiality to the extent possible and is consistent with applicable laws and regulations.
- When employers become aware of cases, the Recordkeeping and Reporting Occupational Injuries and Illness standard (29 CFR 1904), requires certain employers to keep a record of serious work-related injuries and illnesses including work-related COVID-19.

Recommendations for Conducting Swabbing

General considerations

- Follow CDC's Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing
- The number of people present during specimen collection should be limited to only those essential for care and procedure support.
    - Visitors or other bystanders should not be present for specimen collection.
- Swabbing of multiple individuals should not be performed in the same room at the same time, unless appropriate separation between swabbing stations can be maintained.

Consider if self-collection is appropriate

- Some diagnostic tests use samples that are self-collected, such as saliva and nasal swabs.
- PPE use can be minimized through self-collection while staff remain at least 6 feet away from the individual being swabbed.
- Nasal Swabs: The individual must be able to correctly self-swab and place the swab in transport media or sterile transport device and seal.
    - If the individual needs assistance, assistance can be provided by placing the swab into transport media or a sterile transport device and sealing it for them.
- If bulk-packaged swabs are used for sample collection, care must be exercised to avoid contamination of any of the swabs in the bulk-packaged container.

Location of specimen collection for staff

- Ideally, specimen collection should be performed one individual at a time in a room with the door closed and no other individuals present. If individual rooms are not available, other options include:
    - Large spaces (e.g., gymnasiums) where sufficient space can be maintained between swabbing stations (e.g., greater than 6 feet apart).
    - An outdoor location, weather permitting, where other individuals will not come near the specimen collection activity.
- Considerations for multiple staff being swabbed in succession in a single room:
    - Consider the use of portable HEPA filters to increase air exchanges and to expedite removing infectious particles.
    - Minimize the amount of time the staff will spend in the room. Staff awaiting swabbing should not wait in the room where swabbing is being done. Those swabbed should have a face mask or cloth cover in place for source control throughout the process, only removing it during swabbing.
- Minimize the equipment kept in the specimen collection area. Consider having each person bring their own prefilled specimen bag containing a swab and labeled sterile viral transport media container into the testing area from the check-in area.

PPE for swabbing

- Staff in the room or specimen collection area should wear a well-fitting N95 or higher-level respirator (or well-fitting facemask if a respirator is not available) and eye protection. A single pair of gloves and a gown should also be worn for specimen collection or if contact with contaminated surfaces is anticipated.

    - If respirators are not readily available, they should be prioritized for other procedures at higher risk for producing infectious aerosols (e.g., intubation), instead of for collecting nasopharyngeal specimens.
- Extended use of respirators (or facemasks) and eye protection is permitted. However, care must be taken to avoid touching the necessary face and eye protection. If extended use equipment becomes damaged, soiled, or hard to breathe or see through, it should be replaced. Hand hygiene should be performed before and after manipulating PPE.
- Gloves should be changed and hand hygiene performed between each person being swabbed.
- Gowns should be changed when there is more than minimal contact with the person or their environment. The same gown may be worn for swabbing more than one person provided the staff collecting the test minimizes contact with the person being swabbed. Gowns should be changed if they become soiled.
- Consider having an observer who does not engage in specimen collection but monitors for breaches in PPE use throughout the specimen collection process.
- Staff who are handling specimens, but are not directly involved in collection (e.g., self-collection) and not working within 6 feet of the individual being tested, should follow Standard Precautions; gloves are recommended, as well as a well-fitting facemask for source control.

Cleaning and disinfection between individuals

- Surfaces within 6 feet of where specimen collection was performed should be cleaned and disinfected using an Environmental Protection Agency-registered disinfectant from List N if visibly soiled and at least hourly.
- Terminal cleaning and disinfection of all surfaces and equipment in the specimen collection area should take place at the end of each day. Resident rooms should be cleaned and disinfected in accordance with Implementing Environmental Infection Control in the Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic.
- Used testing cassettes and collection swabs should be disposed of in a biohazard container.

Considerations for Use of Antigen Testing in Long-term Care Facilities

When to consider confirmatory PCR after antigen test results

As the sensitivity of antigen tests is generally lower than PCR, FDA EUA recommends that negative POC antigen tests be considered presumptive. Clinical staff in long-term care facilities should consider when confirmatory PCR testing might be needed prior to making clinical decisions, cohorting residents, or excluding staff from work. When interpreting the results of antigen tests, test characteristics and probability of infection should be considered.

- Test sensitivity might vary between antigen testing platforms. Facilities should be aware of which platform is being used and the sensitivity of the test for the patient population to be tested.
- Factors that increase the probability of infection include the presence of symptoms in the person being tested, recent exposure to someone diagnosed with COVID-19, and whether testing is being conducted in a facility with an outbreak or within a

high-prevalence community. These factors inform the decision of whether confirmatory testing by PCR is indicated following an antigen test.

If a confirmatory PCR test is performed within 48 hours, individuals should be assumed infectious until the confirmatory test results are completed.

Example 1: If a symptomatic resident tests presumptive negative on an antigen test and a PCR is performed, the resident should remain on Standard, Contact, and Droplet precautions until the PCR test results.

- If PCR positive (false negative antigen result), then the resident should remain on transmission-based precautions until no longer infectious.
- If PCR negative (true negative antigen result), then the resident can be placed on appropriate transmission-based precautions based on symptoms.

Example 2: If an asymptomatic staff working in a long-term care facility tests antigen positive, they should be excluded from work until a negative PCR test is available.

- If PCR positive (true positive antigen result), then the staff should be excluded from work until no longer infectious.
- If PCR negative (false positive antigen result), then the staff can return to work.

CDC and ADHS **do not** recommend a test-based strategy to discontinue isolation.

Uses of antigen testing in long-term care facilities

- Testing of symptomatic residents and staff,
- Testing of asymptomatic residents and staff in facilities as part of an COVID-19 outbreak response, and
- Testing of asymptomatic unvaccinated staff in facilities without a COVID-19 outbreak as required by CMS recommendations.

Testing in other circumstances are likely to occur, such as testing asymptomatic residents and staff who were exposed to persons with COVID-19 outside of the facility (e.g., recent hospitalization or outpatient services) or through other screening activities. The principles described here can be used to guide the interpretation of antigen test results in those situations.

Antigen tests should not be utilized to determine the duration of transmission-based precautions nor when staff can return to work.

Considerations for when performing testing

- Before beginning testing, read and become familiar with the instrument manufacturer's instructions/package insert (abbreviated to IFU), and user manual if included.
    - Be familiar with the timing of the tests. Most antigen tests need to either sit for 15 minutes before being read or must be read within a specified window or they will not be valid. This information can be found in the package insert instructions.
- Quality control (QC) must also be performed before patient testing and should be based on the manufacturer's recommendations.
    - If issues are noted with the QC, or it does not pass, contact the instrument manufacturer technical support.
- Before testing, it is recommended to have all supplies on hand, including a timer, sharpie or other marker that can write on the testing kits to label samples, a spreadsheet or

similar form to document the results, and a biohazard disposal to discard used testing cassettes and collection swabs.
- If collecting samples before immediate testing, ensure samples are properly labeled with patient identifying information.

Considerations for interpreting antigen test results in long-term care facilities

Testing of symptomatic residents and staff

- If an antigen test is positive, no confirmatory test is necessary.
    - Residents should be placed in transmission-based precautions, and staff should be excluded from work.
    - If the resident or staff is the first positive test for SARS-CoV-2 within the facility (i.e., an index case), an outbreak response should be initiated immediately.*
    - Confirmatory testing may be considered in some situations, including if there are other unexpected positive results from testing performed on specimens collected from other persons that were run on the same day or if the person has a low likelihood of SARS-CoV-2 infection (e.g., non-respiratory systemic symptoms soon after SARS-CoV-2 vaccine administration in a staff or resident with no known exposures in a non-outbreak facility).
- If an antigen test is presumptive negative, perform PCR immediately (e.g., within 48 hours).
    - Symptomatic residents and staff should be kept in transmission-based precautions or excluded from work until PCR results return.
    - Clinical discretion should be utilized to determine if individuals who test negative on such platforms should be retested with PCR. Some antigen platforms have higher sensitivity when testing individuals within 5 days of symptom onset. In some instances, confirmatory testing may not be necessary if the individual has a low likelihood of SARS-CoV-2 infection (e.g., non-respiratory systemic symptoms soon after SARS-CoV-2 vaccine administration in staff or residents with no known exposures in a non-outbreak facility).
    - Facilities should test for both influenza and SARS-CoV-2 if influenza and SARS-CoV-2 are circulating in the community.
    - If antigen and confirmatory tests are negative and the individual resides or works in an outbreak facility, the confirmatory negative test does not affect implementation of appropriate precautions for facilities with an outbreak. Additionally, both residents and staff should be serially tested every 3–7 days until no new cases are identified for 14 days.
    - If antigen and confirmatory tests are negative and the person is a known contact, residents should remain in quarantine for 14 days from exposure and staff should follow risk assessment guidance. For additional guidance, refer to the ADHS 'Release from Isolation and Quarantine' guidance.
    - Symptomatic staff who test negative for SARS-CoV-2 should continue work exclusion and return to work per institutional policy.Note: if an individual has recovered from SARS-CoV-2 infection in the past 3 months and develops new symptoms suggestive of COVID-19, alternative diagnoses should be considered prior to retesting for SARS-CoV-2.

Testing of asymptomatic residents or staff in facilities as part of an outbreak response or those who are known close contacts of persons with COVID-19*

- If an antigen test is positive, perform PCR immediately (e.g., within 48 hours).
    - Residents should be placed in transmission-based precautions in a single room or, if single rooms are not available, remain in their current room pending results of confirmatory testing. They should not be transferred to a COVID-19 unit or placed in another shared room with new roommates. Staff should be excluded from work.
    - In situations where the probability of infection is high (e.g., facility with large outbreak, such as prevalence >20%, and the person resided with another infected person), the antigen positive test might not require confirmation and the individual should be treated as infectious.
- If the confirmatory test is positive, then the resident should be transferred to a COVID-19 unit. Staff should remain excluded from work until they are no longer infectious.
- If an antigen test is presumptive negative OR if the antigen test is positive but the confirmatory test (performed within 48 hours) is negative:
    - Residents should be placed in appropriate transmission-based precautions for facilities with an outbreak. Staff should be allowed to continue to work with continued symptom monitoring. The facility should continue repeat testing (antigen or PCR) every 3–7 days until no new cases are identified for a 14-day period.
    - If antigen and confirmatory tests are negative and the person is a known contact, residents should remain in quarantine for 14 days from exposure and staff should follow risk assessment guidance. For additional guidance, refer to the ADHS 'Release from Isolation and Quarantine' guidance.
- Note: asymptomatic individuals who have recovered from SARS-CoV-2 infection in the past 3 months and live or work in a long-term care facility performing facility-wide testing should not be tested for SARS-CoV-2.

Testing of asymptomatic staff in facilities without an outbreak per CMS recommendations

CMS recommends serial testing of all unvaccinated staff at an interval based on local incidence of COVID-19.

- If an antigen test is positive, perform confirmatory PCR test within 48 hours of the antigen test.Staff should be excluded from work until confirmatory test results are completed but outbreak response, including facility-wide testing, can be delayed until confirmatory test results are completed.
    - If the confirmatory test is positive, then exclude the staff from work until they are no longer infectious and initiate an outbreak response including facility-wide testing of all residents and staff.
    - If the confirmatory test is negative, the antigen test should be considered a false positive and staff should return to work.
- If an antigen test is presumptive negative, allow staff to continue to work. Staff should continue to monitor for symptoms, and repeat testing should continue per CMS recommendations.
- Note: Staff who have recovered from SARS-CoV-2 infection in the past 3 months and are asymptomatic should not be tested for SARS-CoV-2.

*A COVID-19 outbreak response in a long-term care facility is triggered when a resident or staff tests positive for SARS-CoV-2. An index infection in a resident should include SARS-CoV-2 infections that originated in the long-term care facility and should not include:

- Residents who were known to have COVID-19 on admission to the facility and were placed into transmission-based precautions.
- Residents who were placed into transmission-based precautions on admission and developed SARS-CoV-2 infection within the 14-day period after admission.

Table of Considerations for On-site vs. Off-site Testing

	As Needed Testing by Facility (On-site)	As Needed Testing by Laboratory (Off-site)	Routine Staff Testing by Facility (On-site)	Routine Staff Testing by Laboratory (Off-site)
Reason for Testing	Individuals are symptomatic or have exposure to SARS-CoV-2	Individuals are symptomatic or have exposure to SARS-CoV-2	Staff Screening	Staff Screening
Type of Test	Polymerase Chain Reaction (PCR) or Antigen	Polymerase Chain Reaction (PCR) or Antigen	Polymerase Chain Reaction (PCR) or Antigen	Polymerase Chain Reaction (PCR) or Antigen
Prerequisites	CLIA Certified Obtain point-of-care instrument and kits Get informed consent from staff to receive results	Contract with laboratory and/or specimen collection contractor Get informed consent from staff to receive results	CLIA Certified Obtain point-of-care instrument and kits Get informed consent from staff to receive results	Contract with laboratory and/or specimen collection contractor Get informed consent from staff to receive results
What staff will be tested?	Determine on a case-by-case basis (e.g., staff with close contact to a known or suspected case: <6 feet for at least 15 minutes)	Determine on a case-by-case basis (e.g., staff with close contact to a known or suspected case: <6 feet for at least 15 minutes)	All unvaccinated staff	All unvaccinated staff

Who is collecting specimens from staff?	Self-collection or collection by health professional	Self-collection or collection by health professional	Self-collection or collection by health professional	Self-collection or collection by health professional
PPE requirements for self-collection and maintaining at least 6 feet distance	Gloves and facemask	Gloves and facemask	Gloves and facemask	Gloves and facemask
PPE requirements for health professional performing specimen collection	Gloves, gown, facemask or respirator, and eye protection.	Gloves, gown, facemask or respirator, and eye protection.	Gloves, gown, facemask or respirator, and eye protection.	Gloves, gown, facemask or respirator, and eye protection.
Cleaning and disinfection between on-site specimen collections	Clean and disinfect surfaces within 6 feet of specimen collection using EPA List N if visibly soiled at least hourly.	Clean and disinfect surfaces within 6 feet of specimen collection using EPA List N if visibly soiled at least hourly.	Clean and disinfect surfaces within 6 feet of specimen collection using EPA List N if visibly soiled at least hourly.	Clean and disinfect surfaces within 6 feet of specimen collection using EPA List N if visibly soiled at least hourly.
Reporting Requirements	Report positive and negative results to ADHS. Report positive results and suspected outbreaks to local health department.	Report positive results and suspected outbreaks to local health department.	Report positive and negative results to ADHS. Report positive results and suspected outbreaks to local health department.	Report positive results and suspected outbreaks to local health department.

Resources

Abbott BinaxNOW COVID-19 Ag Card

- Please contact your local health department if you need additional BinaxNOW tests.
- Package Insert
- Training Materials

BD Veritor System for Rapid Detection of SARS-CoV-2

- Ordering Information
- Package Insert
- Webinar Slides

Quidel Sofia SARS Antigen FIA

- Ordering Information
- Package Insert
- Webinar Slides

HHS Webinar: Antigen Testing in Nursing Homes (September 3, 2020)

- Test manufacturers, BD (view slides) and Quidel (view slides) walk through steps associated with performing the BD Veritor and Quidel Sofia SARS-CoV-2 antigen tests.

ADHS

- Healthcare Providers, Facilities, and Partners
- Laboratory Resources
  - Reporting Guidance for Facilities using Point-of-Care Devices
- Long-term Care Facility COVID-19 Guidance
  -
- Release from Isolation and Quarantine Guidance
- CLIA Information for Point-of-Care Testing

CDC

- SARS-CoV-2 Antigen Testing in Long Term Care Facilities
- Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing
- Interim Guidance for Antigen Testing for SARS-CoV-2
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
- Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing
- Testing and Management Considerations for Nursing Home Residents with Acute Respiratory Illness Symptoms when SARS-CoV-2 and Influenza Viruses are Co-circulating

CMS

- CMS Guidance on Long Term Care Testing Requirements for Staff and Residents and Revised COVID-19 Focused Survey Tool (updated 4/27/2021)
- CLIA FAQs
- CLIA Updating Requirements for Reporting of SARS-CoV-2 Test Results (posted 8/26/2020)
- COVID-19 Nursing Home Data

FDA

- Emergency Use Authorizations for Antigen Diagnostic Tests for SARS-CoV-2
- FAQs on Testing for SARS-CoV-2