OFFICE OF THE DIRECTOR
Kate Brown, Governor

Oregon Health Authority

500 Summer St NE E20
Salem OR 97301
Voice: 503-947-2340
Fax: 503-947-2341

October 8, 2020

Provisional Guidance for Point-of-care Antigen Testing for COVID-19 in Long-term Care Facilities

Background

On July 14, 2020, the Centers for Medicare and Medicaid (CMS) announced an initiative to distribute point-of-care (POC) antigen COVID-19 testing devices and tests to all nursing facilities (NFs) in the United States. Oregon facilities have begun receiving devices and tests. NFs will receive one of two antigen testing devices listed below.

- Quidel Sofia 2 SARS Antigen FIA, and
- BD Veritor System for Rapid Detection of SARS-CoV-2

On Sept. 2, 2020, the U.S. Department of Health and Human Services (HHS) announced it will distribute Abbott BinaxNOW COVID-19 Ag Card POC antigen tests to additional long-term care facilities (LTCFs).* The following facilities are scheduled to start receiving the Abbott BinaxNOW COVID-19 Ag Card testing supplies in late September:

- Nursing facilities located in "red" or "yellow" positivity counties (CMS standards)
- Assisted living facilities (ALFs), and
- Residential care facilities (RCFs)

These card tests do not require a device to process the sample. All three tests require a Clinical Laboratory Improvement Amendments (CLIA) waiver.

Purpose

The Oregon Health Authority allows the use of POC antigen testing in LTCFs. This document will provide guidance on using POC antigen testing for COVID-19 in LTCFs. This guidance is considered provisional; it will be updated as evidence-based information about COVID-19 test performance emerges from the Centers for Disease Control and Prevention (CDC), CMS, HHS or similar entities that oversee or direct standards for long-term care settings.

*Nursing facilities, residential care and assisted living facilities are collectively referred to as long-term care facilities.

Clinical considerations

Point-of-care (POC) antigen testing for COVID-19 will play an important role in Oregon's testing strategy. These tests provide extremely rapid results. However, they are less accurate than molecular testing, such as polymerase chain reaction (PCR) or nucleic acid amplification testing (NAAT). **POC antigen tests have not been studied for use in patients without symptoms; thus, we do not know how well they will perform in this population**.

Nationally, the issue of false positive antigen test results has received considerable media attention. In other states, a false positive antigen test has been defined as a positive antigen test followed by a negative molecular (e.g., PCR) test. In Oregon, all positive antigen tests are considered cases of COVID-19 regardless of follow-up testing results. Both molecular (e.g., PCR) and antigen tests for COVID-19 carry a significant risk of false negative results. For this reason, Oregon does not allow one negative COVID-19 test to overrule a previously positive COVID-19 test. Mathematically, the probability of false positive test results increases in patients without symptoms or exposure risk.

How should long-term care facilities use point-of-care antigen testing?

The most accurate test available should be used in long-term care facility (LTCF) residents and staff with symptoms consistent with COVID-19. However, testing turnaround time (TAT) and how quickly facilities can obtain results are important factors.

- **If a facility has access to molecular testing (e.g., PCR or NAAT) for COVID-19 with rapid turnaround time*,** use POC antigen testing to:
  - Test asymptomatic residents and staff in facilities without an outbreak of COVID-19, such as ongoing testing required by Oregon's Long-Term Care Facility Testing Plan or CMS Long-Term Care Facility Testing Requirements for Staff and Residents
  - Test symptomatic residents and/or staff, with PCR follow-up if antigen is negative.
- **If a facility does not have access to molecular testing (e.g., PCR or NAAT) for COVID-19 or rapid test turnaround time,** use POC antigen testing to:
  - Test symptomatic residents and staff, and
  - Test asymptomatic residents and staff in facilities with an outbreak of COVID-19

Each facility should:

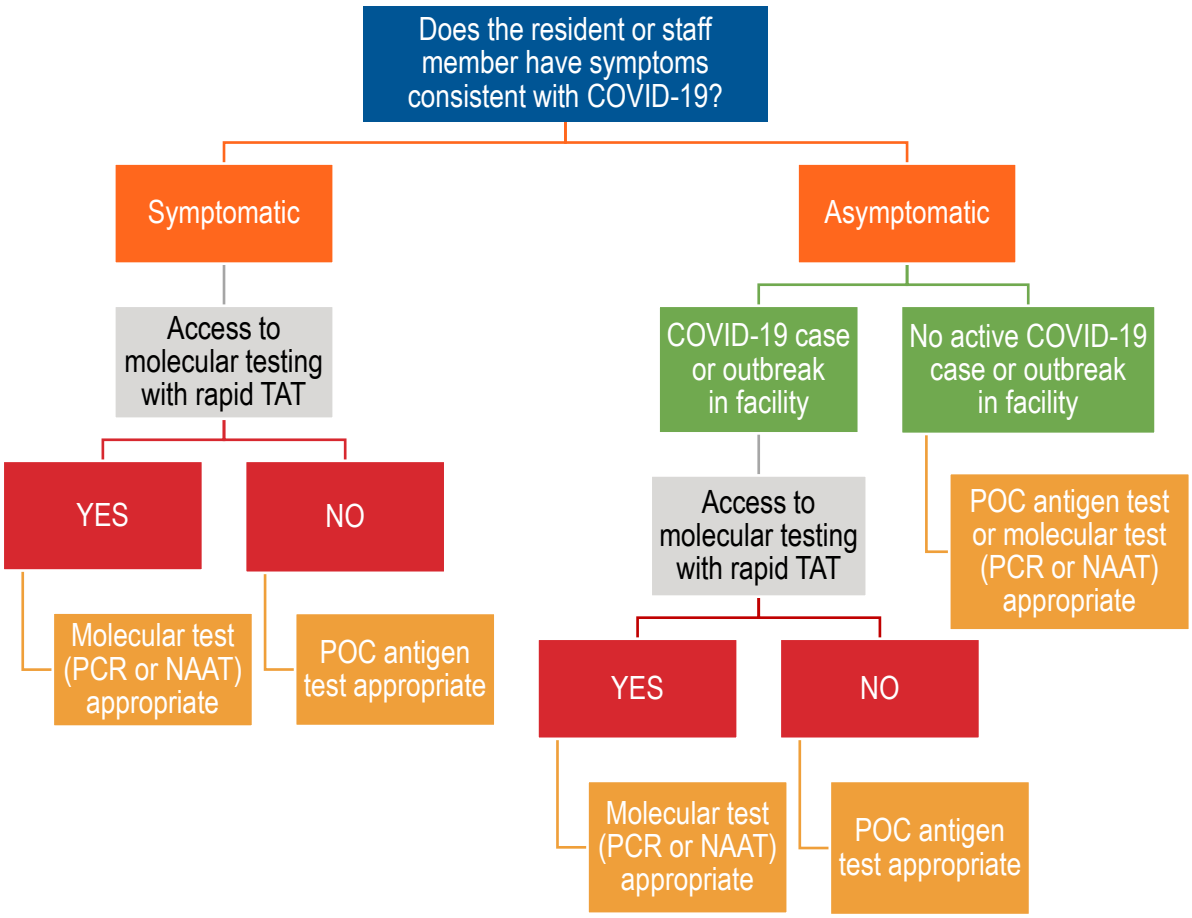
- Evaluate their access to accurate molecular testing (e.g., PCR or NAAT) for COVID-19
- Have an agreement with a testing vendor for PCR or NAAT testing, and

*Rapid turnaround time should be considered up to 48 hours between the time the lab receives the specimen and the result is available.

- Frequently ask about turnaround times for COVID-19 testing results

These important pieces of information will determine how to use POC antigen testing capacity.

Figure 1. Use of point-of-care antigen testing in long-term care facilities



How should facilities interpret point-of-care antigen test results?

Both molecular (e.g., PCR or NAAT) and POC antigen tests for COVID-19 are unlikely to produce false positive results. Oregon considers any person with a positive molecular or POC antigen test for COVID-19 a confirmed case of COVID-19, regardless of symptoms. This differs from CDC guidance that requires confirmatory molecular testing for positive POC antigen tests in patients without symptoms.

Because of national reports of false positive POC antigen test results, LTCF residents without symptoms of COVID-19 who test positive by POC antigen testing must have a follow up molecular test (e.g., PCR or NAAT) within 48 hours to inform cohorting of residents and staff. These LTCF residents should be isolated but should not be moved to dedicated COVID-19 facilities or units or cohorted in a shared room with a confirmed case of COVID-19 unless the follow-up molecular test is also positive. These LTCF residents should complete the recommended isolation period using the time-based strategy if the follow-up molecular test is negative.

Both molecular and POC antigen tests may produce false negative results. A negative test result does not rule out the possibility that a person has COVID-19. For this reason, it is important to maintain an appropriate level of suspicion in residents or staff with symptoms consistent with COVID-19, even with a negative test result.

Point-of-care antigen test result	Interpretation	Actions
Positive	Patient has COVID-19.	Isolate/exclude from work. If index case, initiate outbreak response. If asymptomatic, isolate but do not move to a COVID-dedicated facility or unit, or to a shared room with a confirmed case of COVID-19 unless molecular testing (e.g., PCR or NAAT) is also positive.
Negative	Patient may or may not have COVID-19.	Maintain a high level of suspicion of negative test result in patients with symptoms consistent with COVID-19 and retest with a molecular test (e.g., PCR or NAAT). Isolate/exclude from work until molecular results return. Consider testing for additional respiratory viruses (e.g., influenza).

Is follow-up testing necessary?

Persons with a **positive** POC antigen test do not need follow-up testing unless they are an asymptomatic LTCF resident in which case follow-up molecular (e.g., PCR or NAAT) testing is required to inform cohorting. Even if a follow-up molecular test (e.g., PCR or NAAT) is negative, the person is considered a case of COVID-19. The person should be isolated according to recommendations from public health.

Persons with a **negative** POC antigen test should receive follow-up testing with a molecular test (e.g., PCR or NAAT) if the person has symptoms consistent with COVID-19.

Reporting requirements for POC antigen testing

Reporting to OHA

The Coronavirus Aid, Relief, and Economic Security (CARES) Act mandates reporting of test results to state or local public health departments. Oregon Administrative Rule 333-018-0016 requires that laboratories must report all COVID test results (negative, positive, indeterminate and inconclusive).

To satisfy both federal and state reporting requirements, facilities should report COVID results from their POCs to OHA via the OHA COVID Reporting Portal. Once submitted, OHA routes COVID test result data both to CDC and to local health departments.

More information on how to report testing results to OHA can be found at https://healthoregon.org/howtoreport. Other reporting options may be available. Please visit https://healthoregon.org/elr or contact ELR.Project@dhsoha.state.or.us for details about other methods of reporting or other questions.

Reporting to DHS

Per Oregon Administrative Rule 411-060-0050, facilities must also report all positive test results to Safety, Oversight & Quality's (SOQ's) licensing units. Current guidance and details about reporting suspected or confirmed cases to SOQ is available here; it is subject to updates. To report, please email NF.Licensing@dhsoha.state.or.us and CBC.Team@dhsoha.state.or.us.

NHSN reporting

All nursing facilities must report to the COVID-19 LTCF module within the National Healthcare Safety Network (NHSN) per CMS reporting requirements. The module includes questions about the availability and use of POC antigen testing within the facility. Please visit https://www.cdc.gov/nhsn/ltc/covid19/index.html for details around the specific testing questions and frequency of reporting to NHSN.

Infection control considerations

LTCF staff performing testing on FDA-authorized antigen diagnostic tests must receive training developed by the platform manufacturer to ensure proper use of the instrument. Information about available training materials is available in CMS Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/Nursing Homes.

Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver

HHS will distribute POC antigen tests to nursing facilities authorized for use under a CLIA Certificate of Waiver. Some ALFs/RCFs and NFs have purchased devices on their own. Facilities are responsible for the following:

- Obtaining and maintaining a CLIA Certificate of Waiver
- Ensuring accurate demographic information is uploaded into the federal database by following guidelines in the "Reporting requirements for POC antigen testing" section below
- Following the manufacturer's instructions for the waived tests, and
- Notifying the Oregon State Public Health Laboratory's Laboratory Compliance Section of any changes in ownership, name, address or laboratory director within 30 days or to add more complex tests.

Guidelines for submitting CLIA Application for Certification (CMS 116) to perform COVID-19 testing

1. **Complete the CMS 116 form.** Here are two ways to complete a CLIA application for COVID-19:

    - Completely fill out a blank CMS 116 form, or
    - Call the Laboratory Compliance Section (503-693-4125) for a pre-populated CMS 116 form. Strike out incorrect information and substitute correct information alongside it.

Following is the pertinent information on the CMS 116 form that CMS CLIA and HHS require for tracking COVID-19 testing activity:

Section I. General information

- Check box "Other Changes (Specify)"; write in COVID-19 NH.
- Verify the current Tax Identification Number.
- Update email address.
- Update name of director and credentials.

Section II. Type of certificate requested

- Check "Certificate of Waiver."

Section VI. Waived testing

- List all test systems you are performing, i.e., glucose (test), and name of glucometer (manufacturer name).

- Include the test: Quidel Sofia 2 SARS-CoV-2 Antigen assay, Becton Dickinson Veritor SARS-CoV-2 Antigen assay or Abbott BinaxNOW COVID-19 Ag Card.
- **Must** provide estimated total annual test volume.

Section X. Director affiliation with other laboratories

- Laboratory director **must** sign and date the bottom of page 5.

2. **Submit completed CMS 116 form with updated information and addition of test(s)** to The Laboratory Compliance Section, which is the CMS CLIA state agency : Phone: 503-693-4125; fax: 503-693-5602; email: LC.info@state.or.us.

3. **The Oregon State Public Health Laboratory (OSPHL) will enter the CMS 116 form immediately into the federal database**. You will receive a letter of confirmation of the test system in use at your facility and the effective date you can begin testing patients.

   Note: There must be an Emergency Use Authorization (EUA) and package insert for the test system the facility will use. HHS will allocate either a Quidel Sofia SARS-CoV-2 antigen assay, Becton Dickinson Veritor or Abbott BinaxNOW COVID-19 Ag Card. The laboratory **must** adhere to both the EUA and package insert (PI).

   Based on the COVID-19 test system you receive from HHS, you must include an Emergency Use Authorization letter and package insert in your established laboratory manual.

Resources

Resources for the three test systems include the following:

BD Veritor — Review the following manufacturer website for long-term care facilities. Bookmark and save these links for future reference:

- https://www.bdveritor.com/long-term-care-facilities/training/
  - Resources provided on this webpage.
- https://www.bdveritor.com/long-term-care-facilities/educational-resources/
  - This link gives access to the Emergency Use Authorization (EUA) letter, fact sheet for health care providers and patients, notice of laboratory data reporting, and more.

Quidel Sofia SARS Antigen test system — Review website, bookmark and save for future reference:

- https://www.quidel.com/immunoassays/rapid-sars-tests/sofia-sars-antigen-fia
  - Resources provided on this webpage.
- https://www.quidel.com/node/5004
  - Includes information for setup and calibrate, run quality control, run patient specimens.

- Watch videos and training certificate.

Abbott BinaxNOW COVID-19 Ag Card — Review website, bookmark and save the following link for future reference:

- https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html

Set-up and training

- https://www.globalpointofcare.abbott/en/product-details/navica-binaxnow-covid-19-us.html
  - Resources provided on this include product documents, package inserts and training video.
- https://www.fda.gov/media/141567/download
  - FDA issued EUA letter

You must document the following information as required evidence of following the EUA and PI:

Maintain all records associated with both documents until otherwise notified by FDA as well as to comply with state and federal retention requirements.*

- Temperature storage of test kit, optimal temperature for the instrument performance must be documented on a temperature log
- Lot # and expiration dates of reagent kits; Quality Control material must be documented
- Quality Control reaction results must be documented — Internal and External in the frequency stated in the package inserts.
- Documentation of collection of specimens must be included and monitored to be processed and tested within the time frame specified in the package insert.
- See templates of log sheets for documentation in the Ready, Set, Test booklet.*

Although there are no CLIA regulations specifying the qualifications of testing personnel, it is prudent for the laboratory director (LD) to:

- Specify in a written policy the testing personnel responsibilities, and
- Sign off on all training records and competency assessments of each testing personnel.

  Note: All test systems websites — BD Veritor, Quidel Sofia and Abbott — offer certificates for training records to be included with all other site-specific training records.

Additional requirements for long-term care facilities to be compliant with state and federal regulations are:

*See Ready, Set, Test booklet for templates and reference material.

- Laboratory director must ensure prior to testing patients' specimens that the testing complies to the Oregon Revised Statute (ORS) 438.430(1) Examination, specimens; reports and results. Except as otherwise provided in ORS 438.010 to 438.510, a clinical laboratory shall examine specimens only at the request of a physician, dentist or other person authorized by law to use the findings of laboratory examinations.
- Report SARS-CoV-2 test results in standardized formal and frequency specified by HHS secretary. See Ready, Set, Test booklet for templates and reference material.

  Note: Failure to report SARS-CoV-2 test results will result in a condition level violation of the CLIA regulation and may result in the imposition of a civil money penalty (CMP) as required under §§ 493.1804 and 493.1834.

  Note: Facilities can contact the Laboratory Compliance Section at 503-693-4126 for assistance in completing the CMS 116 application.

Reference materials

The following reference materials are available:

- Laboratory Guidelines
  https://www.oregon.gov/oha/PH/LABORATORYSERVICES/CLINICALLABORATORYREGULATION/Documents/CLIA-COVID19.pdf
- CLIA Brochure Laboratory Director Responsibilities
  https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/brochure7.pdf
- CLIA Brochure: What Do I need to Do to Assess Personnel Competency?
  https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf
- Retention requirement
  https://www.oregon.gov/oha/PH/LABORATORYSERVICES/CLINICALLABORATORYREGULATION/Documents/retent.pdf
- QSO-20-37-CLIA, NH
  https://www.cms.gov/files/document/qso-20-37-clianh.pdf

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