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Provisional Guidance for BinaxNOW Point-of-care Antigen Testing

Background

On September 28, 2020, the White House announced an initiative to distribute Abbott Laboratories BinaxNOW point-of-care (POC) antigen COVID-19 tests nationwide through the end of the year.

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

Purpose

This document provides guidance on using BinaxNOW point-of-care antigen COVID-19 tests in the general population. **Specific guidance regarding the use of POC antigen testing in long-term care facilities is available here**. This guidance is considered provisional; it will be updated as evidence-based information about test performance emerges.

Clinical considerations

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 other nucleic acid amplification testing (NAAT). **POC antigen tests have not been studied for use in children or patients without symptoms; thus, we do not know how well they will perform in this population**.

How should BinaxNOW point-of-care antigen testing be used?

The most accurate test available should be used in severely ill persons with symptoms consistent with COVID-19. BinaxNOW POC antigen tests are most appropriately used in outpatient, urgent care or emergency department settings. BinaxNOW POC antigen tests may be used in patients with symptoms consistent with COVID-19, close contacts of COVID-19 cases, or in outbreak investigations. They may also be used in long-term care facilities; **specific guidance regarding the use of POC antigen testing in long-term care facilities is available here**. BinaxNOW POC antigen tests are not recommended for general screening in asymptomatic persons without epidemiologic risk factors, such as

exposure to a known or presumptive case of COVID-19 due to concerns regarding test accuracy for asymptomatic persons.

OHA does not recommend using the NAVICA app associated with the BinaxNOW POC antigen test. A negative result by POC antigen testing does not guarantee that a person is not infected with or incubating COVID-19. The NAVICA app may provide individuals with a false sense of security that they do not have COVID-19.

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

Both molecular (e.g., PCR or other NAAT) and POC antigen tests for COVID-19 are unlikely to produce false positive results. OHA 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.

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 persons 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.
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. Providers may consider retesting with a molecular test (e.g., PCR or NAAT) and testing for additional respiratory viruses (e.g., influenza) if clinically appropriate. Isolate/exclude from work until 24 hours following fever resolution without the use of antipyretics and symptom improvement.

Is follow-up testing necessary?

A person with a **positive** POC antigen test does not need follow-up testing. 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.

Providers may consider retesting for COVID-19 with a molecular test (e.g., PCR or NAAT) and testing for additional respiratory viruses (e.g., influenza) in persons with a **negative** POC antigen test and symptoms consistent with COVID-19. The decision to repeat COVID-19 testing should include respiratory virus circulation, available resources, and whether the test would alter or inform medical decision-making.

Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver

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: 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 Laboratory Compliance Section, CMS CLIA State Agency, 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. The laboratory **must** adhere to both the EUA and package insert (PI).

Resources

- https://alere.wistia.com/medias/0wacsomvlr

Set-up and training

- Resources provided on the below link include product documents, package inserts and training video:
  - https://ensur.invmed.com/ensur/contentAction.aspx?key=ensur.542951.S2R4E4A3.20200910.10292.4344263FDA issued EUA letter:
  - https://www.fda.gov/media/141567/download

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; this will also 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.

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

- Lot # and expiration dates of reagent kits; Quality Control material must be documented.
- Quality Control reaction results, Internal and External, must be documented 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 recommended that the laboratory director (LD):

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

  Note: Abbott offers five training videos to providing a detailed step-by-step guide to the test process. The training modules should be completed in their entirety before performing tests on individuals. Completion of the training videos should be documented as signed and dated by the testing personnel as evidence of training. Competency is the ability of personnel to apply their skill, knowledge and experience to perform their laboratory duties correctly and is approved by the laboratory director.

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

- 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 format 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

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-19 test results (negative, positive, indeterminate and inconclusive).

To satisfy both federal and state reporting requirements, facilities should report COVID-19 results from their POCs to OHA via the OHA COVID-19 Reporting Portal. Once submitted, OHA routes COVID-19 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.

Infection control considerations

Providers that will be performing testing on FDA-authorized antigen diagnostic tests should receive training developed by platform manufacturer to ensure proper use of instrument.

Providers that are collecting specimens or are within 6 feet of patients suspected to have COVID-19, should practice appropriate infection control and use recommended personal

protective equipment. Providers that are using instruments to process clinical specimens, but are not directly involved in specimen collection, should follow standard precautions as detailed in CDC's Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019.

Document accessibility: For individuals with disabilities or individuals who speak a language other than English, OHA can provide information in alternate formats such as translations, large print, or braille. Contact the Health Information Center at 1-971-673-2411, 711 TTY or COVID19.LanguageAccess@dhsoha.state.or.us