STATE OF CALIFORNIA—HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF SOCIAL SERVICES
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March 15, 2021 PIN 21-16-ASC

TO: ALL ADULT AND SENIOR CARE PROGRAM LICENSEES

Original signed by Kevin Gaines
FROM: KEVIN GAINES
Deputy Director
Community Care Licensing Division

SUBJECT: **GUIDANCE ON THE USE OF ANTIGEN TESTS, INCLUDING THE BINAXNOW™ POINT-OF-CARE (POC) CORONAVIRUS DISEASE 2019 (COVID-19) AG CARD TEST KIT**

Provider Information Notice (PIN) Summary

PIN 21-16-ASC provides guidance to licensees about antigen tests in general, and specifically, about the Abbott BinaxNOW™ COVID-19 Ag Card test kit.

Please post this PIN in any facility that uses the BinaxNOW™ POC COVID-19 antigen tests in a place where persons in care can easily access it and distribute the following sections of this PIN to persons in care and, if applicable, their representative:

1) Addendum A: Precautions and Limitations
2) Fact Sheet for Persons in Care

According to the Centers for Disease Control and Prevention (CDC), there are two (2) types of tests available for COVID-19:

1. Viral tests provide information on current infection.
2. Antibody tests may inform of past infection.

PIN 20-23-ASC identifies the COVID-19: polymerase chain reaction (PCR), which is a type of viral test, as the test that should be used for testing persons in care and staff in Adult and Senior Care facilities. This PIN updates the information in PIN 20-23-

ASC by including the viral antigen test as an alternative for facilities.

This PIN does not alter prior Community Care Licensing Division (CCLD) PIN guidance, including but not limited to PIN 20-23-ASC and PIN 20-38-ASC, regarding when a person in care or staff should be tested, with the following important notes:

- Antigen testing may be used to test symptomatic and asymptomatic individuals, as well as for screening testing purposes. However, every time an antigen test is performed, it is important that the licensee be aware of the accuracy limitations of antigen testing (please see Addendum A).

- The CDC has clarified that: 1) antigen testing is not as accurate as PCR testing; 2) confirmatory PCR testing may need to be performed within 48 hours of antigen testing; and 3) the evaluation of antigen test results depends on different testing scenarios (e.g., symptomatic, asymptomatic and known exposure, asymptomatic and no known exposure).

    - When an individual is symptomatic, a positive antigen test (e.g., BinaxNOW™ COVID-19 Ag Card) result is considered valid and does not need confirmatory PCR testing to verify this result.

    - When an individual is symptomatic and the antigen test returns a negative result, the licensee should perform a confirmatory PCR test within 48 hours.

    - When an individual is asymptomatic, a positive antigen test result should be verified by a confirmatory PCR test within 48 hours, regardless of known exposure to COVID-19.

    - Staff who have known exposure to a person confirmed to have COVID-19 and who receive a negative antigen test result may, at the facility's discretion, continue to work as long as there is continued symptom monitoring and ongoing testing (antigen or PCR) is being performed every 3-7 days.

For additional information, including other testing scenarios, it is recommended that licensees refer to the CDC Interim Guidance for Antigen Testing for COVID-19. The CDC updates the information on their website, so licensees should visit this CDC website regularly.

The California Department of Public Health (CDPH) has also provided Guidance on the Use of Antigen Tests for Diagnosis of Acute COVID-19 which includes scenarios in which antigen tests may reasonably be used for outbreak investigations and for asymptomatic testing (e.g., routine screening or pre-admission testing in congregate settings where there are no confirmed cases of COVID-19).

Because there are many different types of COVID-19 tests, and each facility has different supplies as well as resources in their community, each facility may determine how and when to use their tests.

FACILITIES RECEIVING BINAXNOW™ COVID-19 AG CARD TEST KITS

BinaxNOW™ COVID-19 Ag Card tests have received U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA). According to the terms of the EUA, only those facilities with a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation, may use the BinaxNOW™ COVID-19 Ag Card tests.

Note: A forthcoming PIN will be issued by CCLD explaining how facilities which do not have a CLIA certificate may begin receiving these tests.

The Centers for Medicare and Medicaid Services (CMS), the federal agency responsible for inspecting CLIA facilities, has issued a public statement regarding using antigen testing on asymptomatic individuals. Specifically, CMS has stated they will not cite facilities with a CLIA Certificate of Waiver when COVID-19 antigen tests are performed on asymptomatic individuals, as described in the Food and Drug Administration's FAQ.

BINAXNOW™ COVID-19 AG CARD TEST KIT DESCRIPTION

The BinaxNOW™ COVID-19 Ag Card test is a POC antigen test used for detecting active infections and relies on the use of a cotton nasal swab. The test provides results in about 15 minutes with no additional instruments required. Each book-shaped test card is about the size of a credit card and contains a test strip.

Each test kit contains the following:

- 40 test cards
- one 10-milliliter bottle of testing solution (reagent)
- 40 sterile nasal swabs (one can be used as a negative control swab)
- one positive control swab (containing a non-infectious dried COVID-19 antigen)
- one product insert including information about precautions and limitations, and
- one test procedure card
- 40 COVID-19 fact sheets (for patients)
- one COVID-19 fact sheet (for healthcare professionals)

Important! Required but not included in the test kit is a clock, timer, or stopwatch.

BINAXNOW™ COVID-19 AG CARD TRAINING REQUIREMENTS

Abbott is providing the training for this test which includes six modules. The Abbott BinaxNOW™ and NAVICA™ App Set-Up and Training website provides links to these modules, information related to this training, answers to frequently asked questions, and

support contact information. Abbott BinaxNOW™ training webinar registrations are also available.

Abbott states on page 1 of their Product Insert found in the "Helpful Documents" section of their training website that the test is "intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests". Lateral flow tests are relatively simple tests designed to detect the presence of a substance in a liquid sample.

All questions regarding training requirements should be directed to the Abbott Technical Services Team at

- 1-800-257-9525 between 8 a.m. and 8 p.m. EST Monday-Friday, or
- email ts.scr@abbott.com.

It is recommended that all facilities document their training.

ANTIGEN TEST RESULT REPORTING REQUIREMENTS

Facilities conducting antigen tests under a state registration and CLIA Certificate of Waiver are subject to regulations that require laboratories to report data for all testing completed, for each individual tested. Per Title 17 section 2505 of the California Code of Regulations (please see also the Additional Resources section), any entity performing COVID-19 testing is required to report both positive and non-positive results within 8 hours to the local public health department where the individual resides.

The California Reportable Disease Information Exchange (CalREDIE) Manual Lab Reporting Module (MLRM) is the statewide reporting system that can be used to meet these reporting requirements. Information about the steps to take to report via the CalREDIE MLRM system can be found on the CalREDIE HELP webpage in the Manual Reporting Section in the CalREDIE Manual Lab Reporting Module (PDF).

Important! According to CDPH's CalREDIE Manual Lab Reporting Module instructions, facilities in San Diego and Los Angeles Counties should not use this system. Instead, facilities in these counties should contact their local health department for instructions on how to report.

Questions can be directed to CalREDIE

- phone 1-866-866-1428, or
- fax 1-916-636-6218, or
- email CalREDIEHelp@cdph.ca.gov.

Note: CDPH is working on a software solution to better facilitate test result reporting. A forthcoming PIN will be issued providing additional information on this software solution once details are available.

ADDITIONAL RESOURCES

The resources below provide additional information regarding antigen tests and infection prevention and control practices:

- California COVID-19 website: Get tested webpage
- CDC: Recommended infection prevention and control (IPC) practices when caring for a patient with suspected or confirmed COVID-19 infection
- CDPH: All Facilities Letter 20-53.3 - Reporting Test Results (for facilities conducting tests under a CLIA Certificate of Waiver)
- CDPH: COVID-19 Quarantine Guidance

All providers should continue to follow all applicable Community Care Licensing Division PINs, guidance or instructions from health care providers, the Centers for Disease Control and Prevention (CDC), California Department of Public Health (CDPH), and local health departments.

If you have any questions, please contact your local licensing office:

Adult and Senior Care Regional Offices

ADDENDUM A: PRECAUTIONS AND LIMITATIONS OF BINAXNOW™ POINT-OF-CARE (POC) CORONAVIRUS DISEASE 2019 (COVID-19) ANTIGEN TESTS

1. This test is only authorized for the detection of the COVID-19 antigen, not for any other viruses or pathogens.

2. The test is not as accurate as a PCR test and, therefore, negative results in situations where there is a high probability of infection (e.g., COVID-19 symptoms present) may need to be followed-up with a confirmatory PCR test.

3. Proper sample collection, storage and transport are essential for correct results.

4. Do not use kit past the expiration date.

5. Leave test card in its foil pouch until just before use. Do not use if the pouch is damaged or open.

6. Do not mix components from different kit lots.

7. Do not reuse the used test card.

8. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.

9. All components of this kit should be discarded as biohazard waste according to Federal, State and local regulatory requirements.

10. Wear appropriate personal protective equipment during testing for suspected positive COVID-19 persons in care per the CDC's recommendation (gloves, face shield, N-95 mask or surgical mask if N-95 not available, and gown) when running each test and handling patient specimens. Practice proper hand hygiene – handwashing or using hand sanitizer before and after changing gloves when handling all specimens.

11. Swabs in the kit are approved for use with BinaxNOW™ COVID-19 Ag Card. ***Important!*** **Do not use other swabs.**

12. Follow manufacturer's directions for false negative results.

For a complete list of all precautions and limitations please refer to:

- The Abbott BinaxNOW™ COVID-19 Ag CARD informational sheet

Persons in Care Fact Sheet

A Companion Guide for Provider Information Notice (PIN) 21-16-ASC, Guidance on the Use of Antigen Tests including the BinaxNOW™ Point-Of-Care (POC) Coronavirus Disease 2019 (COVID-19) Ag Card Test Kit

The Community Care Licensing Division (CCLD) has prepared this Persons in Care Fact Sheet as a companion to PIN 21-16-ASC to inform you of guidance that CCLD provided to your facility concerning your care.

According to the Centers for Disease Control and Prevention (CDC), there are two (2) types of tests available for COVID-19:

1. Viral tests provide information on current infection.
2. Antibody tests may inform of past infection.

PIN 20-23-ASC identifies the COVID-19: polymerase chain reaction (PCR), which is a type of viral test, as the test that should be used for testing persons in care and staff in Adult and Senior Care facilities. This PIN updates the information in PIN 20-23-ASC by including the viral antigen test as an alternative for facilities.

This PIN does not alter prior PINs' guidance, including but not limited to PIN 20-23-ASC and PIN 20-38-ASC, on when a person in care or staff should be tested, with the following notes:

- Antigen testing may be used to test symptomatic individuals, asymptomatic individuals, and for screening testing purposes. However, every time an antigen test is performed, it is important that the licensee be aware of the accuracy limitations of antigen testing.

- The CDC has clarified that: 1) the performance of antigen testing is not as reliable as PCR testing; 2) confirmatory PCR testing may need to be performed within 48 hours of antigen testing; and 3) the evaluation of antigen tests results depends on different testing scenarios (e.g., symptomatic, asymptomatic and known exposure, asymptomatic and no known exposure).

    - When a person in care is symptomatic, a positive antigen test (e.g., BinaxNOW™ COVID-19 Ag Card) result is considered valid and does not need confirmatory PCR testing to verify this result.

    - In the interest of the safety of all persons in care, when an individual is symptomatic and the antigen test returns a negative result, the licensee should perform a confirmatory PCR test within 48 hours.

    - When a person in care is asymptomatic, a positive antigen test result should be verified by a confirmatory PCR test within 48 hours, regardless of known exposure to COVID-19.

The BinaxNOW™ COVID-19 Ag Card Test Kits

The BinaxNOW™ COVID-19 Ag Card test kits are manufactured by Abbott and have received U.S. Food and Drug Administration Emergency Use Authorization. These tests are intended for testing those individuals suspected of having COVID-19 within the first 7 days of symptom onset. However, the CDC and California Department of Public Health have recognized the value of using these tests for screening purposes.

BinaxNOW™ COVID-19 Ag Card Test Kit Description

The BinaxNOW™ COVID-19 Ag Card test is a test used for detecting active infections. The test can be done on site and it relies on the use of a cotton nasal swab. The test provides results in about 15 minutes with no additional instruments required. Each book-shaped test card is about the size of a credit card and contains a test strip.

Training and Test Reporting Requirements

The manufacturer (Abbott) is providing training for the BinaxNOW™ COVID-19 Ag Card test kit through readily available resources provided to facilities receiving these kits. Any entity performing COVID-19 testing is required to report both positive and non-positive results within 8 hours to the local public health department where the individual resides.

If you have questions, please contact your care provider, the licensee of your facility, or *the Ombudsman* (call 1-800-510-2020), all of whom are available to answer your questions.