STATE OF CALIFORNIA—HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF SOCIAL SERVICES
744 P Street • Sacramento, CA 95814 • *www.cdss.ca.gov*

KIM JOHNSON
DIRECTOR

GAVIN NEWSOM
GOVERNOR

March 30, 2022 PIN 22-10-ASC

TO: ADULT AND SENIOR CARE PROGRAM LICENSEES

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

SUBJECT: **USE OF AT-HOME, OVER-THE-COUNTER (OTC) CORONAVIRUS DISEASE 2019 (COVID-19) ANTIGEN TESTING KITS**

Provider Information Notice (PIN) Summary

PIN 22-10-ASC provides guidance for Adult and Senior Care (ASC) facilities about the use of at-home OTC COVID-19 antigen testing kits and reminds licensees of the free Clinical Laboratory Improvement Amendments of 1988 (CLIA) waiver and free antigen tests available through the California Department of Public Health (CDPH) Antigen Testing Program.

Please post/keep this PIN in the facility where persons in care can easily access it and distribute the PIN Summary for Persons in Care (located at the end of this PIN) to persons in care and, if applicable, their representatives.

NEW! All COVID-19 ASC PINs are organized by topic on a new page that can be accessed from the COVID-19 Landing Page, under the ASC Program PIN banner. This page is titled ASC COVID-19 PINs Organized by Topic. PINs are also organized by number and available directly under both the ASC Program PIN banner and the ASC PINs page.

According to the Centers for Disease Control and Prevention (CDC) and other major health organizations, an extensive testing network is essential to success in stopping the spread of COVID-19. The recent emergence of the Omicron variant further emphasizes the importance of vaccinations, boosters, and prevention efforts, including testing, needed to continue protecting against COVID-19.

This PIN notifies all Community Care Licensing Division (CCLD) ASC licensees that the use of **self-administered** Food and Drug Administration (FDA) authorized OTC COVID-19 antigen tests by visitors, staff, and persons in care is acceptable for all CCLD testing requirements, as specified.

Important! **Providers must keep in mind the following:**

- FDA-authorized OTC COVID-19 antigen tests ***must*** be used without deviation from the manufacturer's instructions for use.
- When FDA-authorized OTC COVID-19 antigen tests are both **self-administered *and* self-read** on-site, their use generally does not require a CLIA waiver (please see Addendum A: *OTC COVID-19 Antigen Tests and CLIA Applicability* for more information).
- Any OTC COVID-19 antigen test that is both **administered *and* read** onsite at an ASC facility by anyone other than the individual being tested is strictly prohibited.
- Any onsite **self-administration *and* self-reading** of OTC COVID-19 antigen tests among facility staff, visitors, and persons in care ***must*** be observed in real time by an authorized ASC facility staff member or by an authorized telehealth proctor.

The results from FDA-authorized OTC COVID-19 antigen tests may be used by ASC facilities to adhere to CDC, CDPH, California Department of Developmental Services (CDDS), California Department of Social Services (CDSS), California Department of Industrial Relations (Cal/OSHA), and local health department guidance or health orders during the COVID-19 pandemic.

ASC facilities may continue to participate in the CDPH BinaxNOW™ Antigen Testing Program. See Addendum A for additional information about the benefits of this Program.

If there are differing requirements between the most current CDC, CDPH, CDDS, CDSS, Cal/OSHA, and local health department guidance or health orders, **licensees should follow the strictest requirements.** However, there may be times where a licensee will need to contact their Regional Office for assistance in reconciling these differences, especially if the strictest requirements appear to be in conflict with the best interest of persons in care.

OTC COVID-19 Antigen Tests to Meet ASC Facility Employer Testing Requirements

When ASC facility staff use an FDA-authorized OTC COVID-19 antigen test, the test must be self-administered and self-read by that ASC facility staff member and observed in real time by another authorized ASC facility staff member or by an authorized telehealth proctor. The observation may be done in person at the facility or via live streaming platforms such as Zoom or Skype. For additional information,

see Cal/OSHA's COVID-19 Emergency Temporary Standards FAQ updated on January 27, 2022.

Persons in Care Use of OTC COVID-19 Antigen Tests

When a person in care uses an FDA-authorized OTC COVID-19 antigen test, the test must be self-administered and self-read by that person in care and observed in real time by an authorized ASC facility staff member.

Visitor Use of OTC COVID-19 Antigen Tests

When a visitor uses an FDA-authorized OTC COVID-19 antigen test, the test must be self-administered and self-read by that visitor and observed in real time by an authorized ASC facility staff member. For additional information, see the CDPH Public Health Order FAQ updated on February 11, 2022, visitors' self-administration and self-reading of FDA-authorized OTC COVID-19 antigen tests.

OTC COVID-19 Antigen Test Recordkeeping and Reporting

Recordkeeping

- For persons in care, facilities must document how positive or negative test results will be tracked and methods for communication of facility results to the local health jurisdiction and to the local Community Care Licensing Regional Office. For more information, please see PIN 20-23-ASC, page 2, section titled "Testing for COVID-19 in Residential Facilities."

- For staff who are exempt from vaccination requirements or who have not yet received their booster dose, facilities must maintain records of the workers' COVID-19 testing results. For more information, please see PIN 21-53-ASC, page 6, section titled "Recordkeeping of Worker Vaccination and Exemption Status."

- For visitors, records of vaccination verification and/or documentation of a negative COVID-19 test must be kept on file at the facility and made available, upon request, to CDSS and/or to the local health jurisdiction for purposes of case investigation. For more information please see PIN 22-07-ASC, page 6, subsection titled "Proof of Vaccination and Recordkeeping."

Licensees who conduct diagnostic screening testing at the facility should have a plan in place for tracking test results, conducting workplace contact tracing, and reporting results to local public health jurisdictions. For more information, please see PIN 21-32.1 ASC page 5, and PIN 21-33-ASC page 4.

Reporting

Individuals should report their test results using their test manufacturer's instructions. Please see CDPH Guidance for use of Over-the-counter tests for Local Health Jurisdictions section titled "Individual reporting of self-test results" for more details.

Where to Find a List of FDA-Authorized OTC COVID-19 Antigen Tests

OTC COVID-19 antigen tests must be authorized for home use by the FDA to be considered valid for ASC licensees. A list of current FDA-authorized OTC COVID-19 antigen tests is constantly being updated and is available on this FDA website. Tests authorized for OTC home use have the word "Home" indicated in the "Authorized Setting(s)" column of the webpage.

In addition, to assist in the expansion of this critical testing network in a fair and equitable manner the Centers for Medicare & Medicaid Services (CMS) have alerted the public that starting January 15, 2022, most people can go online, or to a pharmacy or store to purchase an at-home OTC COVID-19 antigen test authorized by the FDA, either free of charge or through reimbursement by their health insurance provider.

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

Adult and Senior Care Regional Offices

ADDENDUM A: OTC COVID-19 Antigen Tests and CLIA Waiver Applicability

A "CLIA waiver," or CLIA Certificate of Waiver, is a certificate issued by the Centers for Medicare & Medicaid Services (CMS) that allows a facility to carry out onsite administering and reading of certain tests, such as the Abbott BinaxNOW™ COVID-19 Ag Card tests described in PIN 21-16-ASC, that have been "waived" by the Food and Drug Administration (FDA). In general, a CLIA waiver is not required for an FDA-authorized OTC COVID-19 antigen test, as long as the test is **self-administered** in strict compliance with the manufacturer's instructions for use.

However, if the FDA-authorized OTC COVID-19 antigen test is either administered by someone other than the individual being tested (e.g., other ASC facility staff, or any other individual), or the results are read (interpreted) and reported by someone other than the individual, then a CLIA waiver is required which explicitly allows the use of the OTC COVID-19 antigen test. This is because the FDA-authorized OTC COVID-19 antigen test is not being self-administered and, therefore, becomes a waived test which means:

- The facility where it is done must have a CLIA Certificate of Waiver, a state registration, and a lab director qualified under Business and Professions Code 1209(a)(2).
- The test must be administered by a person qualified under Business and Professions Code 1206.5(a).
- The test must be ordered by a healthcare provider authorized to order clinical testing.
- The results must be reported through the State's CalREDIE reporting system as required in Title 17 section 2505 of the California Code Of Regulations

If an individual administers and reads their own FDA-authorized OTC test and then shows their test result to someone else (e.g., ASC facility staff) as proof of their result, CMS does not consider this to be "interpretation" or "reporting". This is because the individual has administered and interpreted their own test in accordance with the manufacturer's instructions for use for that particular test. In this case, a CLIA waiver is not required.

An ASC staff member who provides assistance to an individual while that individual self-administers an FDA-authorized OTC COVID-19 antigen test is not, by virtue of that assistance, subject to CLIA as long as the test is administered by the individual being tested in strict accordance with the manufacturer's instructions for use for that particular test.

Additional information about OTC COVID-19 tests and CLIA applicability is found in the CMS Frequently Asked Question (FAQ) OTC and CLIA Applicability document.

As a reminder, all ASC licensees may still enroll in the Department of Public Health (CDPH) BinaxNOW™ Antigen Testing Program for Coronavirus Disease 2019 (COVID-19), as described in PIN 21-30-ASC. Enrollment in this program offers many benefits including:

- Free ongoing supplies of Abbott BinaxNOW™ tests for professional use (not OTC) which provide accurate results in approximately 15 minutes
- A free CLIA waiver, which is required for this professional grade test kit
- Free training to ASC facility staff members on how to easily test each other, residents, and visitors before entry
- A free and user-friendly platform called Primary to meet the program's reporting requirements.

Note: The BinaxNOW™ test kits used in the CDPH BinaxNOW™ Antigen Testing Program for COVID-19 are professional tests that require a CLIA waiver and are not authorized to be self-administered.

Facilities may directly apply to CDPH's BinaxNOW™ Antigen Testing Program through its application webpage.

Important! When filling out your Antigen Testing Application Form, please select "Department of Social Services (DSS) facility" under the "Type of Organization" dropdown menu. Then, select the appropriate facility type from the "DSS Facility Type" dropdown menu.

For questions or more information about enrolling in CDPH's BinaxNOW™ Antigen Testing Program, please contact the CDPH at RCFEbinax@cdph.ca.gov.

PIN Summary for Persons in Care

A Companion Guide for Provider Information Notice (PIN) 22-10-ASC Adult and Senior Care (ASC) facilities use of at-home over-the-counter (OTC) Coronavirus Disease 2019 (COVID-19) antigen testing kits.

According to the Centers for Disease Control and Prevention (CDC) and other major health organizations, an extensive testing network is essential to success in stopping the spread of COVID-19. The recent emergence of the Omicron variant further emphasizes the importance of vaccinations, boosters, and prevention efforts, including testing, needed to continue protecting against COVID-19.

This PIN notifies all Community Care Licensing Division (CCLD) licensed ASC facilities that the use of **self-administered** Food and Drug Administration (FDA) authorized OTC COVID-19 antigen tests by visitors, staff, and persons in care is acceptable for all CCLD testing requirements.

Important! FDA-authorized OTC COVID-19 antigen tests ***must*** be used without deviation from the manufacturer's instructions for use. The self-administration and self-reading of the test ***must*** be observed by ASC facility staff in person or via live streaming platforms such as Zoom or Skype. Any OTC COVID-19 antigen test that is both **administered *and* read** onsite at an ASC facility by anyone other than the individual being tested is strictly prohibited, unless it is administered by a medical professional or authorized staff at an ASC facility that has received a Clinical Laboratory Improvement Amendments of 1988 (CLIA) Certificate of Waiver from the Centers for Medicare & Medicaid Services (CMS).

Where to Find a List of FDA-Authorized OTC COVID-19 Antigen Tests

Only OTC COVID-19 antigen tests that have been authorized for home use by the FDA may be considered valid by ASC licensees. A list of current FDA-authorized COVID-19 tests is constantly being updated and is available on the FDA website. Tests authorized for OTC home use have the word "Home" indicated in the "Authorized Setting(s)" column of the webpage.

To assist in the expansion of this critical testing network in a fair and equitable manner, CMS has alerted the public that starting January 15, 2022, most people can go online, or to a pharmacy or store to purchase an at-home OTC COVID-19 antigen test authorized by the FDA, either free of charge or through reimbursement by their health insurance provider.

Your care providers, the licensee of your facility, and your local Long-Term Care Ombudsman (call 1-800-510-2020) are available to answer your questions.