



Interim Guidance on Antigen Testing for COVID-19 in Long-Term Care

This interim guidance addresses the use of COVID-19 antigen testing in long-term care (LTC) facilities and is aligned with guidance released by the Centers for Disease Control and Prevention (CDC).^{1,2} The U.S. Food and Drug Administration (FDA) has granted emergency use authorization to antigen point-of-care (POC) testing systems to detect the presence of SARS-CoV-2 viral protein.

- Lab-based RT-PCR tests, which detect the genetic material (RNA) of the virus, are considered the “gold standard” for diagnostic accuracy and are preferred. In contrast, COVID-19 POC tests, including antigen tests, are less sensitive but have the advantage of providing results in 15 minutes and at lower cost.
- If an LTC facility cannot access RT-PCR testing with less than a 48 hour turn-around time, then antigen testing should be considered for diagnostic purposes and to meet repeat screening testing requirements from the Centers for Medicare and Medicaid Services (CMS).³

A Clinical Laboratory Improvement Amendment (CLIA) Waiver Is Required for POC Testing

According to CMS Rules³, in order to conduct POC antigen testing, a facility must first obtain a CLIA Certificate of Waiver. COVID-19 POC antigen test systems are authorized for use in patient care settings that operate under a CLIA Certificate of Waiver. Facilities can find information on how to obtain a CLIA waiver at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf>.

If an LTC facility already has a CLIA waiver, they will need to submit a CLIA Certificate Type Change form to indicate that COVID-19 POC testing will be conducted. More information can be found at the IDPH CLIA program website located at <http://www.dph.illinois.gov/topics-services/health-care-regulation/CLIA>.

¹ CDC, Interim Guidance for Rapid Antigen Testing for SARS-CoV-2. Available at:

<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

² CDC, Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes. Available at:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html>

³ CMS, Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements and Revised COVID-19 Focused Survey Tool (QSO-20-38-NH). Available at: <https://www.cms.gov/files/document/qso-20-38-nh.pdf>

Under CLIA rules, staff who perform POC tests must be appropriately trained to perform the test and must use appropriate personal protective equipment when handling samples. Facility administrators and testing personnel new to CLIA-waived testing will find it useful to complete CDC's online training module (continuing education available) at <https://www.cdc.gov/labtraining/training-courses/ready-set-test.html>.

Considerations for COVID-19 POC Antigen Testing and Interpreting Results

Results from COVID-19 POC antigen testing should be interpreted based upon the test sensitivity and specificity, whether the individual being tested has symptoms, and level of transmission in the community and the facility. **A confirmatory RT-PCR test may be needed in certain situations as described below and in the CDC algorithm on interpreting results that is attached to this memo.**⁴

- **Antigen testing for persons with symptoms (diagnostic, not screening).** The intended use of currently available antigen POC testing equipment is for evaluating persons with symptoms suggestive of COVID-19. The test should be performed within the first five to seven days of symptom onset. A person with a positive test is classified as a probable case.⁵ Therefore, **positive test results should lead to immediate infection control measures, such as placing the individual in isolation and considering facility-wide testing.**

If a resident or a staff member has symptoms of COVID-19 and an antigen test is negative, a confirmatory RT-PCR test must be performed within 48 hours. The individual should be in isolation pending the result of the confirmatory RT-PCR test.

- **Antigen testing for asymptomatic persons (outbreak response or staff screening).** Serial testing of asymptomatic individuals is used either for staff and residents, as part of an outbreak response, or for routine staff screening to detect unsuspected COVID-19 infection.

There are only limited data to guide the use of rapid antigen tests to screen asymptomatic persons to detect COVID-19 infection. Based on the CDC algorithm:

- A **negative antigen test** does not need a confirmatory RT-PCR test.
- In an outbreak, a **positive antigen test** does not need a confirmatory RT-PCR test, and appropriate infection control measures should be taken.
- For routine staff screening a **positive antigen test**, especially in counties with low positivity rates, should be confirmed by RT-PCR test within 48 hours. The individuals should be placed in isolation pending the results of the confirmatory test. If the RT-PCR is negative, and the person remains asymptomatic, the person can return to work.

⁴ CDC, Considerations for interpreting antigen test results in nursing homes. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf>

⁵ Council of State and Territorial Epidemiologists (CSTE), Interim-20-ID-02, August 7, 2020

LTC Facilities Must Report Testing to Public Health Authorities

Added reporting requirement for point-of-care testing. LTC facilities that perform POC testing must report each individual positive and negative test result, per federal requirements.^{6,7} A system for nursing homes to report patient-level COVID-19 antigen POC results to the CDC's National Healthcare Safety Network (NHSN) is currently under development. Until that system is in place, nursing homes and other LTC facilities must report to IDPH according to the instructions below.

- Register in IDPH's reporting system with the facility's CLIA certificate number at: <https://redcap.link/dph.illinois.gov.pocovid19registration>.
- You will need your CLIA number, ordering provider, facility name, address, phone number, the type of testing platform & the point of contact email and phone number.
- Once the facility's registration has been processed, the individual who submitted the registration will receive an email with a link to begin reporting. This link is unique to the facility and can be shared with facility staff who will be reporting results.
- Each positive and negative test result must be reported to IDPH system within 24 hours.
- If you have questions, please email: dph.elrresp@illinois.gov

Requirements that apply to both POC and lab-based testing.

- Regardless of the testing method employed, facilities must report aggregate test results via the weekly online IDPH "Look Forward" survey.
- Regardless of the testing method employed, facilities must report each positive test result to their certified local health department and follow their guidance.

Contact. Questions regarding COVID-19 testing can be directed to DPH.LTCtesting@illinois.gov.

Links to Manufacturer's Antigen POC Training

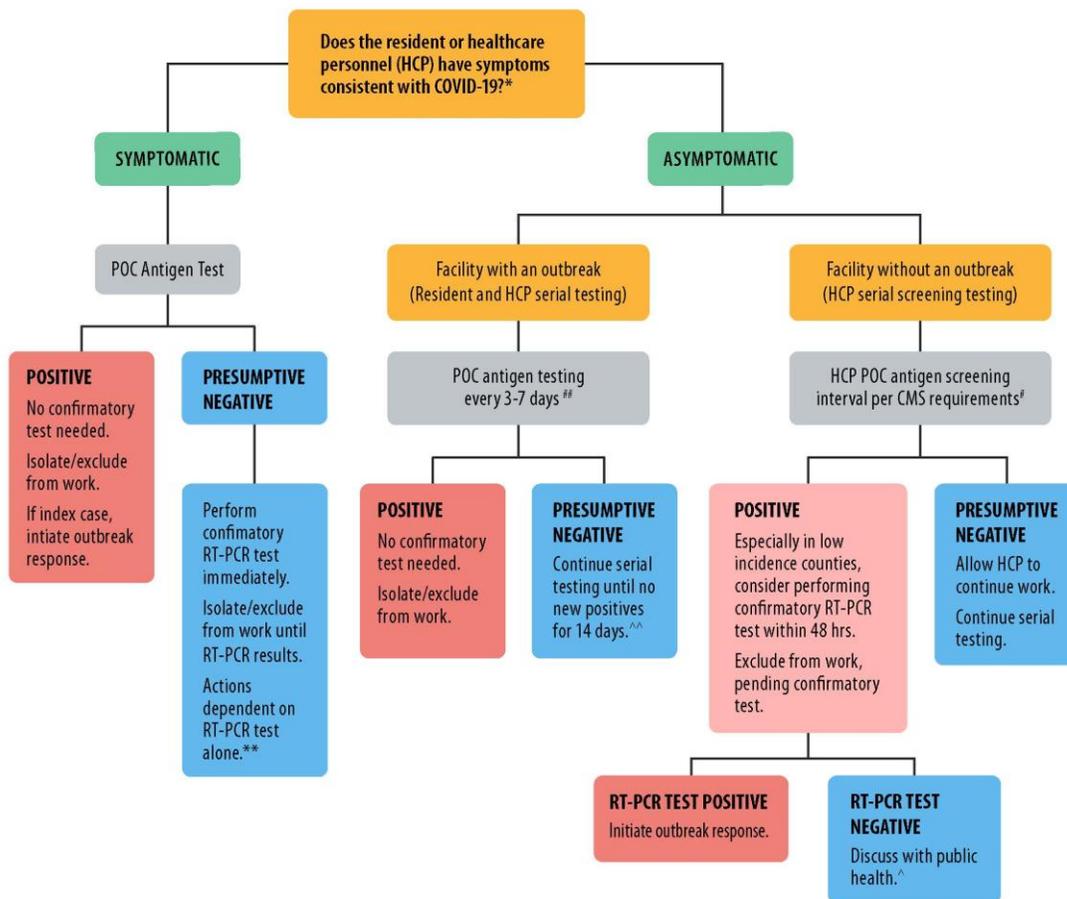
1. Quidel Sofia 2: <https://togetheragain.quidel.com/>
2. BD Veritor: [YouTube BD Veritor System Set-up and Use](#) and <https://www.bdveritor.com/>
3. Abbott BinaxNOW: <https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html>

⁶ COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115.

<https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>

⁷ CMS, Interim Final Rule (IFC), CMS-3401-IFC, Updating Requirements for Reporting of SARS-CoV-2 Test Results by Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (QSO-20-37-CLIA,NH). Available at: <https://www.cms.gov/files/document/qso-20-37-clianh.pdf>

CONSIDERATIONS FOR INTERPRETING ANTIGEN TEST RESULTS IN NURSING HOMES



This algorithm should be used as a guide, but clinical decisions may deviate from this guide if indicated. Contextual factors including community incidence, characteristics of different antigen testing platforms, as well as availability and turnaround times of RT-PCR, further inform interpretation of antigen test results.

RT-PCR: reverse-transcriptase polymerase chain reaction

POC: point-of-care

HCP: healthcare personnel

Index case: a newly identified case of SARS-CoV-2 infection in a resident or HCP in a nursing home facility with no known infections of SARS-CoV-2 infection in the previous 14-day period.

COVID-19 outbreak response in a nursing home is triggered when one nursing home-onset SARS-CoV-2 infection in a resident or one HCP SARS-CoV-2 infection.

* Asymptomatic individuals who have recovered from SARS-CoV-2 infection in the past 3 months and live or work in a nursing home performing facility-wide testing do not need to be retested. 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.

** Some antigen platforms have higher sensitivity when testing individuals within 5 days of symptom onset. Clinical discretion should be utilized to determine if retesting by RT-PCR is warranted.

[CMS recommendations](#) for testing asymptomatic HCP in facilities without a case
[CDC guidance on testing residents of nursing homes](#). [CDC guidance on testing HCP](#)

^ In discussion with the local health department, community incidence and time between antigen test and RT-PCR test can be utilized to interpret discordant results and determine when HCP can return to work.

^^ If an antigen test is presumptive negative in a facility with an outbreak, residents should be placed in transmission-based precautions or HCP should be allowed to continue working while monitoring for symptoms.



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