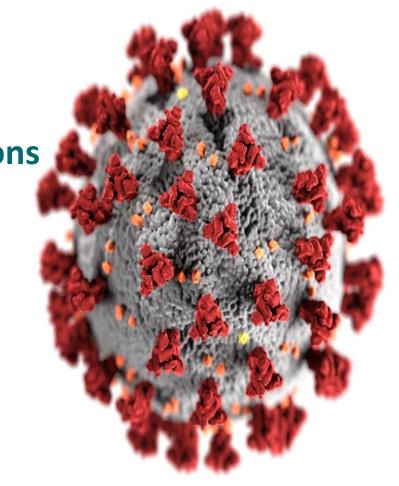
SARS-CoV-2 Testing Considerations

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Conversation Series



For more information: www.cdc.gov/COVID19

Financial Disclosures

No disclosures to report.



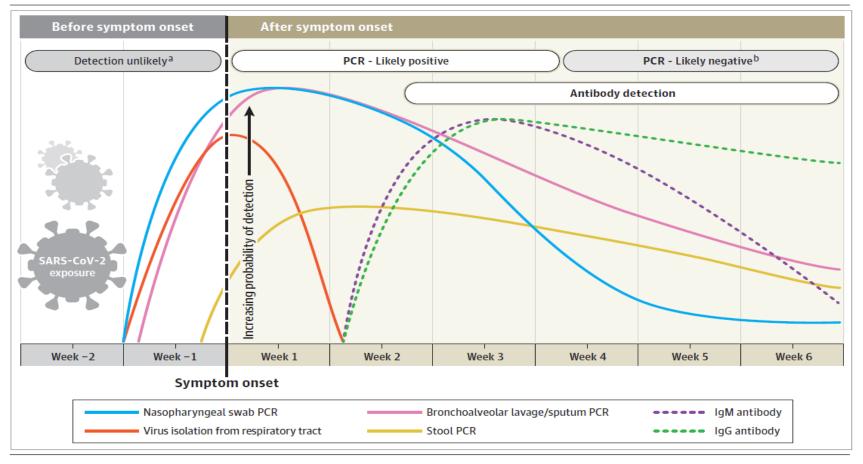
Learning topics

- Describe the different SARS-CoV-2 testing options and considerations for their use
- Apply the SARS-CoV-2 testing guidance for nursing home residents and healthcare personnel (HCP)
- Discuss factors that impact the interpretation of test results



COVID-19 infection timeline and testing

Figure. Estimated Variation Over Time in Diagnostic Tests for Detection of SARS-CoV-2 Infection Relative to Symptom Onset





Understanding SARS-CoV-2 tests

	Molecular	Antigen	Serology
Test type	Viral	Viral	Antibody
Diagnostic test	Yes	Yes	No
Measure	Current Infection with SARS-CoV-2	Current Infection with SARS-CoV-2	Past exposure to SARS-CoV-2
Testing window	Days 1-28 after symptom onset, optimal days 3-12	Days 1-28 after symptom onset, optimal days 3-12	IgA/IgM: From day 5 after symptom onset, optimal 14- 21 IgG: From day 14 after symptom onset up to 6 weeks

- Only viral diagnostic tests can be used to determine presence of active COVID-19 infection
- Serology, or "antibody" testing is used to determine previous infection
 - Residents and staff with positive serology should still be included in facilitywide viral testing

Chau CH et al. Pharmacotherapy 2020 Jul 8;10.1002/phar.2439. doi: 10.1002/phar.2439 https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html



SARS-CoV-2 viral testing: Molecular vs. antigen

Table 2. Summary of Some Differences between RT-PCR Tests and Antigen Tests

	RT-PCR Tests	Antigen Tests
Intended Use	Detect current infection	Detect current infection
Analyte Detected	Viral RNA	Viral Antigens
Specimen Type(s)	Nasal Swab, Sputum, Saliva	Nasal Swab
Sensitivity	High	Moderate
Specificity	High	High
Test Complexity	Varies	Relatively easy to use
Authorized for Use at the Point-of- Care	Most devices are not, some devices are	Yes
Turnaround Time	Ranges from 15 minutes to >2 days	Approximately 15 minutes
Cost/Test	Moderate	Low

☐ Clinical sensitivity:

Accuracy of detecting positive patients with infection – lower sensitivity leads to higher false negative results

Clinical specificity:

Accuracy of detecting negative patients without infection – lower specificity leads to higher false positive results



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

Testing strategies

Diagnostic testing

- Intended to diagnose current infection and identify outbreaks
- Performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2

Screening

- Intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2.
- Performed to identify persons who may be contagious so that measures can be taken to prevent further transmission



Current recommendations for testing in nursing homes

Diagnostic testing:

- Test any symptomatic residents and HCP immediately
- Testing practices should aim for rapid turnaround times (e.g., less than 24 hours) in order to facilitate effective interventions

Outbreak testing:

Triggered by a new SARS-CoV-2 infection in any HCP or any <u>nursing home-onset</u> SARS-CoV-2 infection in a resident

Non-outbreak testing:

- Baseline testing: Test all residents and staff once as part of reopening
- Serial staff screening: test asymptomatic staff at frequency determined by county positivity (monthly, weekly, twice weekly)



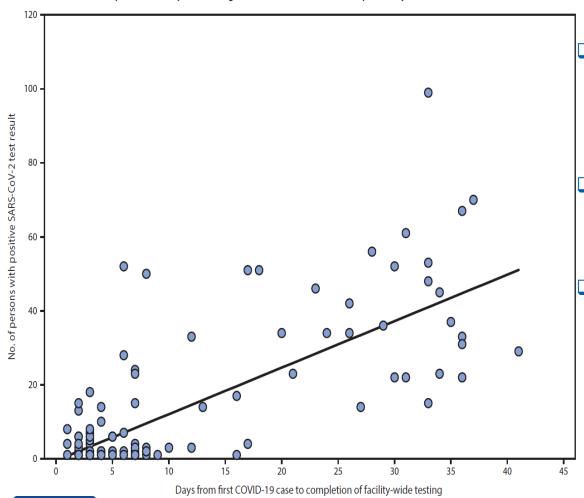
Outbreak testing in response to a new SARS-CoV-2 case

- Expand diagnostic testing for all residents and HCP
 - Initiate facility-wide testing as soon the first SARS-CoV-2 case is confirmed
- Perform repeat testing of all previously negative residents and HCP
 - Optimal outbreak testing occurs every 3 days during the first 14 days from the initial case identification; followed by testing every 7 days
 - Continue serial testing until no new positive cases are identified for a period of 14 days from the most recent positive result.
 - If testing capacity is limited, prioritize testing for residents with known exposure to a case, residents and HCP on affected units, and residents who leave and return to the facility



Timing of facility-wide testing associated with new cases

FIGURE. Association between total number of persons with positive SARS-CoV-2 test results after facility-wide testing and number of days from first case identification until completion of facility-wide testing* — five state and local health department jurisdictions,† United States, March–June 2020



- 93 nursing homes working with 5 health departments performed targeted COVID-19 testing in response to a case
- Median time was 7 days from first case to facility-wide testing (range: 1-41)
- □ For each additional day before completion of initial facilitywide testing, an estimated 1.3 additional cases were identified



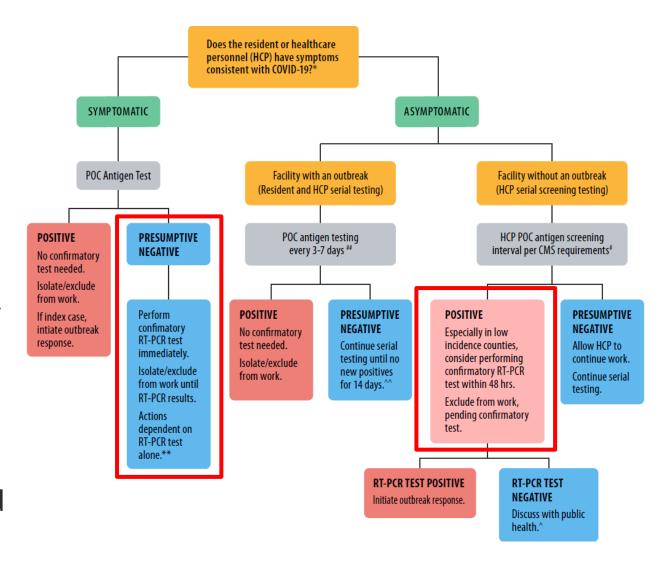
Considerations when implementing testing in nursing homes

- Managing residents and HCP clinically recovered from COVID-19
 - If within 3 months of symptom onset of their most recent illness, no need to quarantine or retest for SARS-CoV-2 during outbreak response or staff screening
 - If testing positive for SARS-CoV-2 more than 3 months from recovery, should be considered infectious and placed in isolation or work exclusion
 - Retesting within first 3 months may be warranted for new symptoms consistent with COVID-19 if alternative etiologies for the illness cannot be identified
- Unclear benefit to regular screening tests for asymptomatic residents outside of outbreak response
 - Could result in false-positive results and lead to unnecessary testing
 - Consideration could be given to testing asymptomatic residents who
 frequently leave the facility of medical treatment, especially in communities
 with moderate to substantial SARS-CoV-2 transmission

https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Testing-in-Nursing-Homes
https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Patients-with-Persistent-or-Recurrent-Positive-Tests

Considerations for use of SARS-CoV-2 POC antigen tests

- Testing scenarios:
 - Symptomatic individuals
 - Asymptomatic individuals in facilities with an outbreak
 - Asymptomatic staff in facilities without an outbreak
- Identifies when POC antigen results should be confirmed by RT-PCR





Factors that can impact interpretation of test results

- Quality of the specimen collection
 - Inadequate sampling or specimen mishandling
 - Running tests on specimens collected outside of the recommended time period recommended by manufacturer's instructions for use
- Proper use of the testing platform
 - Trained personnel, proficient in sample handling with dedicated time
 - Space designated for running POC tests should be free of clutter, with regular surface cleaning/disinfection to prevent sample contamination
 - Quality controls should be used according to manufacturer's instructions for use (e.g., new operators, new lots of test kits/reagents)
- Clinical presentation at the time of the test (e.g., symptoms)
- Prevalence of COVID-19 infections in the center and community



Responding to POC antigen results

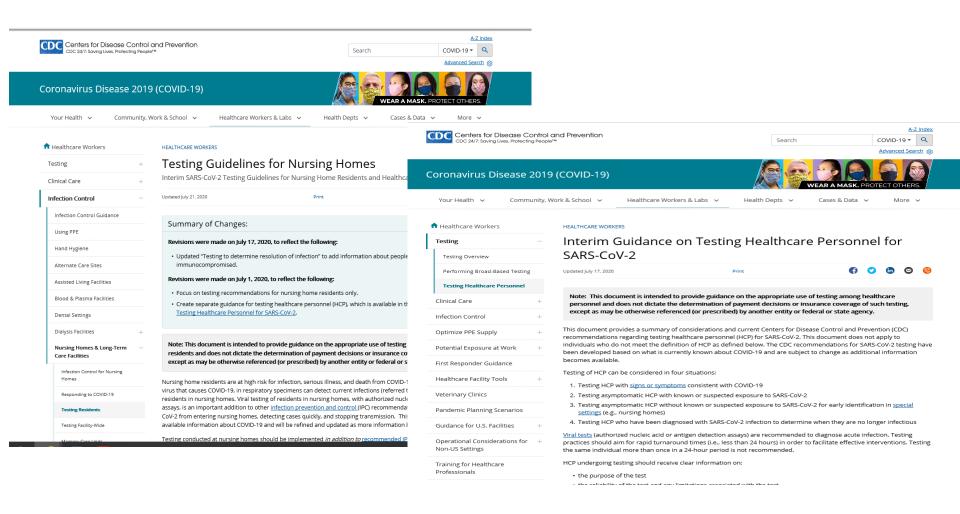
- While awaiting confirmatory test results for potential false-negative or false-positive antigen test results, maintain IPC measures (e.g., HCP work exclusion, resident placement in Transmission-Based Precautions)
 - Select a confirmatory test with high sensitivity (e.g., RT-PCR)
 - Perform confirmatory test within 2 days of initial result
 - Additional testing of asymptomatic residents or other close contacts can be delayed until results of confirmatory testing are available, unless additional symptomatic individuals are identified
 - Only move residents with confirmed infection to a dedicated COVID-19 unit
- Confirmatory RT-PCR testing after a positive antigen test result is not recommended when the person being tested is symptomatic or had recent exposure to a SARS-CoV-2 case (e.g. during an outbreak)



Limitations to SARS-CoV-2 testing

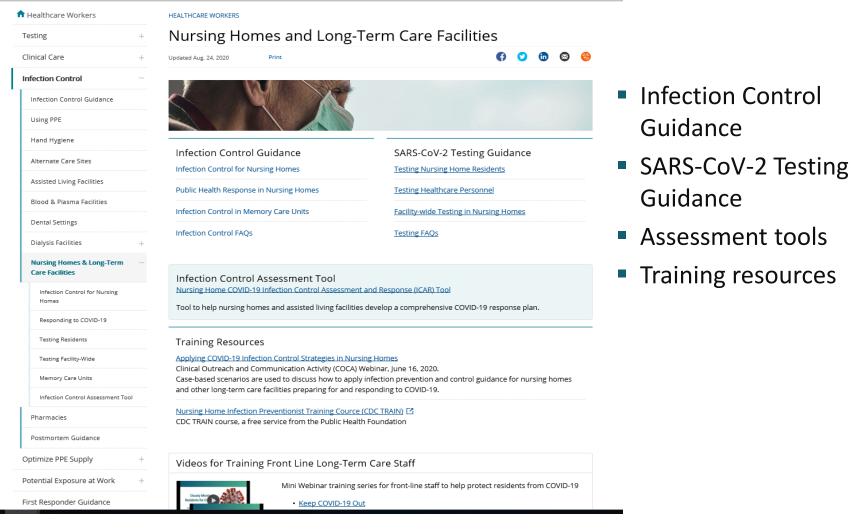
- A single negative test may not rule out COVID-19 infection in asymptomatic individuals
 - A person can be incubating SARS-CoV-2 for up to 14 days before manifesting clinical illness or having detectable virus
 - Testing immediately before or after admission cannot be used to remove a resident from 14-day quarantine
- Clinicians must consider the likelihood of COVID-19 infection as part of interpreting test results
 - A negative test in someone with exposure and symptoms consistent with COVID-19 infection should be verified
 - A positive test in an asymptomatic person, in a community with low prevalence of COVID-19 infection should be verified
- Testing alone cannot prevent the spread of SARS-CoV-2
 - Facilities must remain committed to all infection prevention strategies to protect residents and staff

CDC Testing Guidance and FAQs



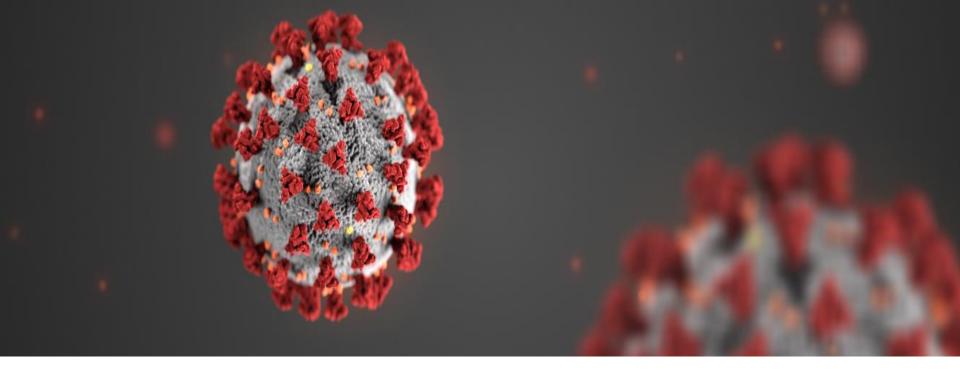
https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html
https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-healthcare-personnel.html
https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Testing-in-Nursing-Homes

COVID-19 Resources for Nursing Homes





https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-home-long-term-care.html



For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.cdc.gov

Thank you!

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

