SARS-CoV-2 Testing Considerations

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Conversation Series

For more information: www.cdc.gov/COVID19
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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

Before symptom onset
- Detection unlikely

After symptom onset
- PCR - Likely positive
- PCR - Likely negative

Antibody detection

Symptom onset
- Nasopharyngeal swab PCR
- Bronchoalveolar lavage/sputum PCR
- Virus isolation from respiratory tract
- Stool PCR
- IgM antibody
- IgG antibody

### Understanding SARS-CoV-2 tests

<table>
<thead>
<tr>
<th></th>
<th>Molecular</th>
<th>Antigen</th>
<th>Serology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test type</strong></td>
<td>Viral</td>
<td>Viral</td>
<td>Antibody</td>
</tr>
<tr>
<td><strong>Diagnostic test</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>Measure</strong></td>
<td>Current Infection with SARS-CoV-2</td>
<td>Current Infection with SARS-CoV-2</td>
<td>Past exposure to SARS-CoV-2</td>
</tr>
</tbody>
</table>
| **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 day 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 facility-wide viral testing

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

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

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

- **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.

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 nursing home-onset 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

- 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 facility-wide testing, an estimated 1.3 additional cases were identified.

[Graph showing 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]

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6932e5-H.pdf
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

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**

[Diagram and flowchart from CDC website](https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html)
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

https://www.youtube.com/watch?v=8oCRqLY1kJw
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

Testing Guidelines for Nursing Homes

Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents and Healthcare Workers

Summary of Changes:

Revisions were made on July 17, 2020, to reflect the following:

- Updated "Testing to determine resolution of infection" to add information about people immunocompromised.

Revisions were made on July 1, 2020, to reflect the following:

- Focus on testing recommendations for nursing home residents only.
  - Create separate guidance for testing healthcare personnel (HCP), which is available in Testing Healthcare Personnel for SARS-CoV-2.

Note: This document is intended to provide guidance on the appropriate use of testing among nursing home residents and does not dictate the determination of payment decisions or insurance coverage except as may be otherwise referenced (or prescribed) by another entity or federal or state agency.

Testing conducted at nursing homes should be implemented in addition to recommended

COVID-19 Resources for Nursing Homes

Infection Control Guidance
SARS-CoV-2 Testing Guidance
Assessment tools
Training resources

Nursing Homes and Long-Term Care Facilities

Infection Control Guidance
- Infection Control for Nursing Homes
- Public Health Response in Nursing Homes
- Infection Control in Memory Care Units
- Infection Control FAQs

SARS-CoV-2 Testing Guidance
- Testing Nursing Home Residents
- Testing Healthcare Personnel
- Facility-wide Testing in Nursing Homes
- Testing FAQs

Infection Control Assessment Tool
Nursing Home COVID-19 Infection Control Assessment and Response (ICAR) Tool
Tool to help nursing homes and assisted living facilities develop a comprehensive COVID-19 response plan.

Training Resources

Applying COVID-19 Infection Control Strategies in Nursing Homes
Case-based scenarios are used to discuss how to apply infection prevention and control guidance for nursing homes and other long-term care facilities preparing for and responding to COVID-19.

Nursing Home Infection Prevention Training Course (CDC TRAIN)
CDC TRAIN course, a free service from the Public Health Foundation

Videos for Training Front Line Long-Term Care Staff
Mini Webinar training series for front-line staff to help protect residents from COVID-19
- Keep COVID-19 Out
