Hospital Operations Toolkit for COVID-19 Patient Care Policies/Processes: Testing

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Testing is critical to accurately diagnose COVID-19 and guide patient care. Accurate testing informs hospital resources, public health actions, and the need for additional medical support. Hospitals using proper testing protocol can target treatment and prevent further transmission within a community. The U.S. Food and Drug Administration continues to authorize additional tests to diagnose COVID-19 or detect antibodies from previous SARS-CoV-2 infections. Clinicians should understand the various types of tests available, when they should be used, and how to interpret results. Individual test performance varies bases on sensitivity (i.e., the ability of the test to correctly identify those who are infected), specificity (i.e., the ability of the test to correctly identify those who are not infected), the optimal time in the course of the infection to conduct testing, disease prevalence in the community, and proper sample collection methods.

COVID-19 Testing Purposes and Types

There are three fundamental purposes of testing: diagnostic, screening, and surveillance. Diagnostic testing identifies current infection in individuals exhibiting symptoms consistent with COVID-19 or in asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2. Testing in hospitals is most likely for diagnostic purposes. Screening tests identify infection in unvaccinated, asymptomatic individuals without known or suspected exposure to SARS-CoV-2. Screening is most common in congregate, school, and workplace settings to detect cases and quickly implement mitigation measures such as isolation and quarantine. Surveillance testing (e.g., wastewater surveillance programs) is used to monitor disease prevalence at the population level rather than to detect infection in individuals.

The two types of tests most often used by hospitals to detect current infection are molecular and antigen.

 Molecular tests (i.e., nucleic acid amplification tests) such as reverse transcription polymerase chain reaction (RT-PCR) detect very small amounts of SARS-CoV-2 RNA in a nasal, nasopharyngeal, oropharyngeal, sputum, or saliva specimen. Most molecular tests are processed in laboratories and may take up to three days or longer for results, depending on testing capacity and complexity. Some self-administered (i.e., home tests) and point of care molecular tests are available that can provide results as quickly as 15 minutes. • Antigen tests detect fragments of viral surface proteins in nasal and nasopharyngeal specimens. Most antigen tests are used at the point of care or self-administered. These lower complexity tests can usually provide results in 15-30 minutes.

Factors such as the time from exposure when the specimen is collected, the prevalence of disease in the community, and the quality of specimen collection can affect results. Both molecular and antigen tests have high specificity and false positives are unlikely. Individual test sensitivity varies. Laboratory-based molecular tests are the most sensitive and can be used to confirm the results of lower-sensitivity point of care or self-administered molecular tests and antigen tests, particularly when an individual tests negative but other factors (e.g., clinical observation, known exposure to SARS-CoV-2) indicate otherwise.

A third type of test detects SARS-CoV-2 antibodies produced in response to a prior infection. Antibody (serological) tests should not be used to diagnose or exclude SARS-CoV-2 infection.

Resources Related to COVID-19 Testing Purposes and Types

- American Society of Health-System Pharmacists: <u>COVID-19 Diagnostic Testing Chart</u>
- ASPR TRACIE: Essential Information for Use of Point-of-Care Tests for COVID-19 Diagnosis
- Association of Public Health Laboratories: <u>About COVID-19 Testing</u>
- Center for Infectious Disease Research and Policy: <u>Smart Testing for COVID-19 Virus and</u> <u>Antibodies</u>
- Centers for Disease Control and Prevention:
 - o Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing
 - o Interim Guidance for Antigen Testing for SARS-CoV-2
 - o Interim Guidelines for Collecting and Handling Clinical Specimens for COVID-19 Testing
 - o Interim Guidelines for COVID-19 Antibody Testing
 - o <u>Nucleic Acid Amplification Tests (NAATs)</u>
 - o <u>Overview of Testing for SARS-CoV-2 (COVID-19)</u>
- County of Los Angeles Public Health: <u>COVID-19 Testing</u>
- Infectious Diseases Society of America:
 - o <u>Guidelines on the Diagnosis of COVID-19: Antigen Testing</u>
 - o <u>Guidelines on the Diagnosis of COVID-19: Molecular Diagnostic Testing</u>
 - o <u>Guidelines on the Diagnosis of COVID-19: Serologic Testing</u>
- PATH: <u>COVID-19 Diagnostics Dashboards</u>
- U.S. Food and Drug Administration:
 - o <u>A Closer Look at COVID-19 Diagnostic Testing</u>
 - o <u>Coronavirus Disease 2019 Testing Basics</u>
 - o FAQs on Testing for SARS-CoV-2
 - o In Vitro Diagnostics EUAs Antigen Diagnostic Tests for SARS-CoV-2
 - o In Vitro Diagnostics EUAs Molecular Diagnostic Tests for SARS-CoV-2

Testing Considerations

Hospitals conducting SARS-CoV-2 testing should coordinate with their state, local, territorial, and tribal health departments and have the following in place:

- A test prioritization strategy with indicators to determine which tests are appropriate for the setting and testing objectives (e.g., pre-procedure testing, emergency and other departmental testing, admission/transfer testing).
- Specimen collection and handling protocols for each test type.
- Training on individual tests and their appropriate use.

Understanding viral circulation and transmission dynamics within the community supports accurate evaluation of test results to inform patient care. Hospitals should:

- Have a standardized test result notification process for patients. Clinicians should be prepared to answer patient questions and provide handouts or other educational material.
- Use standard communication scripts to reinforce the importance of isolation, identify potential contacts, or discuss medical support services for those who test positive. Clinicians should also inform patients of the possibility of false negatives relevant to the situation and provide information on any needed next steps.
- Be aware of testing limitations for at-risk populations, especially pediatric and pregnant patients.

FDA has authorized multiplex assay tests that simultaneously detect SARS-CoV-2 and other respiratory viruses such as influenza A and B and respiratory syncytial virus. These tests:

- Are useful in differentiating among co-circulating viruses that cause similar symptoms.
- Aid in conservation of testing supplies and laboratory workforce surge.

Hospital workplace testing programs should be accompanied by clear policies that:

- Establish where and under what circumstances testing should occur and what types of tests will be used.
- Include notification protocols for relaying results.
- Address inconclusive test results.
- Establish return to work policies.

As viral mutations occur, genetic variations affect the integrity of molecular, antigenic, and serological testing. Hospitals and clinicians should:

- Understand the effects of emerging variants on SARS-CoV-2 testing capabilities and results.
- Monitor which variants are circulating in their community.
- Maintain awareness of affected tests and consider tests using a variety of genetic targets that are less likely to be affected by viral changes.

T R A C I E

- Consider symptomology, epidemiological factors, and patient history in cases where viral mutations could cause false negative test results.
- Be aware that some variants may cause slightly different symptoms than the wild-type strain.

While vaccines are widely available to adults and many children and continue to be highly effective in preventing hospitalizations and deaths, breakthrough infections among the vaccinated are possible. Hospitals should test:

- Fully vaccinated symptomatic patients.
- Fully vaccinated asymptomatic patients with recent exposure to someone with COVID-19.

In the event of a testing surge, hospitals should have a plan in place with the healthcare coalition or other response partners to include community-based testing sites or designated testing clinics to supplement hospital capacity. Hospitals should:

- Be aware of federal, state, and local resources that can supplement testing supplies or personnel.
- Identify supply alternatives and have strategies for acquiring substitutes as needed.
- Establish plans to manage testing volume.

Financial sustainability and patient safety require administrative monitoring. Hospitals should:

- Maintain awareness of federal, state, and private insurer testing coverage, billing, coding, and reimbursement policies.
- Integrate timely reporting of required information to public health authorities in administrative workflows.
- Ensure staff and patients are made aware of how and when to report adverse testing events or issues with test performance and results to FDA MedWatch.
- Be aware of fraudulent activity related to COVID-19 testing products and how to report it to FDA.

Resources Related to Testing Considerations

- American Academy of Pediatrics: <u>COVID-19 Testing Guidance</u>
- American College of Emergency Physicians: <u>ACEP COVID-19 Field Guide</u>
- American Medical Association:
 - o <u>COVID-19 CPT Coding and Guidance</u>
 - o Special Coding Advice During COVID-19 Public Health Emergency
- ASPR TRACIE: <u>COVID-19 Drive-Through Testing/Community Screening Resources</u>
- Centers for Disease Control and Prevention:
 - o <u>COVID-19 Vaccine Breakthrough Case Investigation and Reporting</u>
 - Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2

- Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic
- o Interim Public Health Recommendations for Fully Vaccinated People
- o <u>Overview of Testing for SARS-CoV-2</u>
- Center for Medicare and Medicaid Services:
 - o <u>COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing</u>
 - <u>Commonly Ordered COVID-19, Influenza, and RSV Clinical Diagnostic Laboratory Tests</u> for Which Medicare Allows One Test Without a Practitioner Order During the PHE
- National Emerging Special Pathogens Training and Education Center: <u>Choosing a COVID-19 Test</u>
- University of Iowa Health Care: <u>COVID-19 Testing</u>
- University of Michigan Medicine: Indications for COVID-19 Diagnostic Testing for Patients in All <u>Clinical Settings</u>
- U.S. Food and Drug Administration:
 - FAQs on Testing for SARS-CoV-2
 - o Fraudulent Coronavirus Disease 2019 (COVID-19) Products
 - o <u>MedWatch Online Voluntary Reporting Form</u>
 - o SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests
 - o <u>Testing Supply Substitution Strategies</u>
- U.S Department of Health and Human Services:
 - <u>COVID-19 Guidance for Hospital Reporting and FAQs for Hospitals, Hospital Laboratory,</u> and Acute Care Facility Data Reporting
 - o <u>COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115</u>
- Yale New Haven Health: <u>Testing</u>

Return to Toolkit Landing Page