Hospital Operations Toolkit for COVID-19

Patient Care Policies/Processes:

Testing

November 30, 2020

Testing is critical to accurately diagnose COVID-19 infections and guide patient care. It is also crucial for understanding transmission patterns and infection control needs within a population. Accurate testing informs hospital resources, public health action, and need for additional medical support. The ability to identify current COVID-19 infections, or detect antibodies from an earlier infection, varies according to test type, stage of infection, and interpretation of results. Hospitals using proper testing protocol can better ensure targeted treatment and prevention of further illness within the community. Timely availability, processing, and communication of test results is critical to effective isolation of infected patients, limiting community transmission, informing protective measures for surgical and other procedures, and protecting healthcare workers. There are three fundamental objectives of testing:

- **Diagnostics**: intended to identify current infections in individuals exhibiting symptoms consistent with COVID-19 infection or are asymptomatic but have recent known/suspected exposure to SARS-CoV-2.
- **Screening**: intended to identify infected asymptomatic individuals without known or suspected exposure to SARS-CoV-2. Useful for congregate settings, long term care facilities, or workplace/school settings.
- **Surveillance**: intended to monitor prevalence of infection at the community/population level. Informs public health planning and mitigation efforts (e.g., monitoring essential worker positivity rates).

**COVID-19 Test Types**

As testing technology and methods evolve, it is important for hospitals to recognize general testing guidelines that affect practical use, test results, and availability versus utility (i.e., which test is best used for patient history). Test performances vary based on sensitivity (i.e., the ability of the test to correctly identify those who have the disease), specificity (i.e., the ability of the test to correctly identify those who do not have the disease), and the optimal time to conduct the test during the course of illness. Sample collection also greatly affects test performance. Each test needs to be validated to a collection technique and media. Changing swabs or sample site or failing to correctly obtain the specimen can lead to false negative results.

- **A molecular (RT-PCR) test** is the standard for identification of viral genetic material and the benchmark for accurately diagnosing infection. The need for specialized lab processing,
including pipetting, results in longer processing times and requires trained providers. Viral ribonucleic acid (RNA) in a nasopharyngeal swab should be detectable at symptom onset (and often at least one day prior) and peaks within the first week of symptom onset. Other types of specimens may be collected, but hospital staff should be aware how that may affect test accuracy.

- **Results:**
  - A positive result indicates RNA from SARS-CoV-2 was detected. Patients are deemed infected and presumed to be contagious.
  - Negative results indicate SARS-CoV-2 was not present in the specimen above the detection limit. A negative result does not mean a patient is not infected if other factors (e.g., clinical observation, exposure) indicate otherwise, particularly if the patient is more than a week from the start of symptoms.
  - RT-PCR testing is generally highly accurate with little difference in performance by test.

- **Antigen tests** are used to detect fragments of viral surface proteins. Tests are inexpensive and provide rapid results. Sampling includes collection with nasal or throat swab, or saliva. They are suggested for use as a screening tool when identification of infection within a large group is necessary to potentially recognize clusters of infection or a rapid result with minimal laboratory resources is needed. It is best to test in the early stage of infection when viral load is highest.

  - **Results:**
    - Antigen tests are highly specific and confirmatory testing via RT-PCR is generally not necessary for those who test positive.
    - Sensitivity of antigen tests varies and overall, they are less sensitive than RT-PCR. Antigen tests are most likely to detect infection early in the course of illness but may result in false negatives, especially when testing occurs beyond 5 to 7 days after symptom onset. Negative results should be considered presumptive, particularly in patients who are symptomatic or have known exposures, and should be confirmed via RT-PCR within 2 days.
    - Different antigen tests have different performance characteristics and users should understand the benefits and limitations of the test used.

- **Antibody tests** are serological assays intended to detect an immune response to SARS-CoV-2 indicating recent or prior infection. Detectable amounts of antibody usually occur within one to three weeks after symptom onset. These tests should not be used to diagnose or exclude SARS-CoV-2 infection or to determine status of infection. Instead, they are helpful in determining the proportion of a community’s population that has already been infected. As antibody tests may detect other coronaviruses aside from SARS-CoV-2, tests work best when used in a population with high rates of infection.

  - **Results:**
    - Negative antibody test results do not rule out a SARS-CoV-2 infection, especially for patients who have a history of exposure to the virus and are still within the estimated incubation period.
• A negative test result also does not rule out that the patient’s immune system responded to the virus and will be protective against later infections, as antibody levels decrease over time.

Point-of-Care (POC) platforms allow for diagnostic testing at the site of patient care. POC testing should be used to augment laboratory testing and increase testing capacity in areas where laboratory testing is limited or inundated or when the situation requires rapid results to test priority specimens, such as to investigate new case clusters. POC platforms offer faster results and are simpler to use. There are currently three models of POC testing.

• **Molecular (nucleic acid amplification) POC:**
  o Facility-based platform: Larger, ideal for use in hospitals and medical centers. Higher throughput to process more samples in a certain time period. Ideal for larger batches of testing (e.g., critically ill patients, hospital staff).
  o Mobile platform: Smaller, portable, ideal for use in remote areas or during crisis situations. Due to size, throughput is lower and processes fewer samples in a specified time period (5-30 minutes). Not ideal for areas requiring a large amount of testing. Suggested for use on highest priority symptomatic individuals in a limited resource environment.

• **Antigen POC:** Approved for use in facilities with a Clinical Laboratory Improvement Amendments, or CLIA, certificate waiver. Uses nasal cavity swab and provides results in minutes. May not detect all active infections and results may require confirmation testing.

• **Serological POC:** Currently, there are no U.S. Food and Drug Administration (FDA)-authorized serological POC tests, but they may become available in the future. Some products are currently being marketed but cannot be recommended until additional data is available.

The FDA has issued several emergency use authorizations (EUAs) for multi-analyte respiratory panels. These panels allow hospitals to simultaneously test for SARS-CoV-2 and influenza A, influenza B, respiratory syncytial virus, or other respiratory pathogens. The number and specific viruses detected varies by test. These tests may help hospitals more quickly and efficiently make differential diagnoses in patients with respiratory symptoms.

The FDA has also issued EUAs for several at-home test collection kits. Generally, patients are required to complete online assessments before receiving a kit. Guidance for sample collection (mucus or saliva) is included along with directions on mailing or submitting samples. Results return in 24-72 hours on average, with results varying based on the specific test. User error should be considered. Unlike the nasal samples, saliva samples are stable at room temperature for days.

**Interpreting Test Results**

As testing performance constantly changes due to improved technology, hospital staff should remain aware of how new testing methods should be interpreted and what can be inferred from results that are not consistent with patient presentation or exposure history.
• Understanding test results should be done in the context of clinical observations (symptomology) and awareness of community epidemiological data.
• Negative test results should not rule out COVID-19 infection if other observations or history suggest otherwise. These could be:
  o Clinical presentation - signs and symptoms consistent with COVID-19 infection.
  o Exposure history pointing to likelihood of infection.
  o Additional diagnostic test results are negative (e.g., other respiratory illnesses).
• National guidelines recommend that “presumptive” or weak positives be tested again unless there is a basis for presuming positive (e.g., clinical symptoms, history of exposure).
• False positives can lead to delayed diagnosis or treatment and unnecessary treatment or therapies.
• Knowing the sensitivity and specificity of a test is helpful but must be considered in the context of the population being sampled. The higher the prevalence of COVID-19 in the population tested, the higher the predictive value of a test. In populations with low prevalence of COVID-19, an increase in test specificity also increases the predictive value. Understanding the basics of test performance can help determine whether confirmatory testing is needed.

**Resources Related to Test Types and Interpretation**

- American Medical Association: [Seroological Testing for SARS-CoV-2 Antibodies](#)
- American Society of Health-System Pharmacists: [COVID-19 Diagnostic Testing Chart](#)
- ASPR TRACIE: [Essential Information for Use of Point-of-Care Tests for COVID-19 Diagnosis](#)
- Association of Public Health Laboratories: [Laboratory and Testing Resources](#)
- California Department of Public Health: [Testing for COVID-19: PCR, Serology and Antigen](#)
- Center for Infectious Disease Research and Policy: [Smart Testing for COVID-19 Virus and Antibodies](#)
- Centers for Disease Control and Prevention:
  o [Diagnostic Multiplex Assay for Flu and COVID-19 at Public Health Laboratories and Supplies](#)
  o [Guidance for SARS-CoV-2 Point-of-Care Testing](#)
  o [Interim Guidelines for COVID-19 Antibody Testing](#)
  o [Interim Guidance for Rapid Antigen Testing for SARS-CoV-2](#)
  o [Multiplex Assays Authorized for Simultaneous Detection of Influenza Viruses and SARS-CoV-2 by FDA](#)
  o [Using Antibody Tests for COVID-19](#)
- County of Los Angeles Public Health: [COVID-19 Testing](#)
- In-Q-Tel: [COVID-19 Testing Database](#)
- Infectious Diseases Society of America:
  o [Guidelines on the Diagnosis of COVID-19](#)
• **U.S. Department of Health and Human Services:**
  - Guidance for Proposed Use of Point-of-Care Testing Platforms for SARS-CoV-2 (COVID-19)
  - Interpreting COVID-19 Test Results

• **U.S. Food and Drug Administration:**
  - Antibody (Serology) Testing for COVID-19
  - COVID-19 Frequently Asked Questions
  - EUA Authorized Serology Test Performance
  - FAQs on Testing for SARS-CoV-2
  - In Vitro Diagnostics EUAs
  - Molecular Laboratory Developed Test (LDT) COVID-19 Authorized Tests

### Testing Practices

Hospitals, outpatient settings, and health systems have developed testing guidance based on the populations they serve and their capacity and capability relative to the current COVID-19 situation.

- Hospitals conducting COVID-19 testing should coordinate with their state, local, territorial, and tribal governments, health departments, and public health laboratories about preferred testing types for specific populations or situations based on the current status of COVID-19 in their communities.
- Whenever possible hospitals should rely on use of molecular RT-PCR tests as the standard for diagnosing COVID-19 infection in patients. If molecular tests are not available, a test prioritization strategy should be in place with indications for determining which tests are appropriate.
- While CDC provides guidance on screening for COVID-19 in patients and healthcare workers, decisions on who should be tested are at the discretion of state, tribal, local, and territorial authorities. Testing criteria should be readily available for a variety of scenarios and staff should be made aware of any changes/updates to the criteria and indications for testing.
- Collecting and testing upper respiratory specimens is recommended for all diagnostic testing; however, hospital staff should be aware of specific collection and handling protocols for each test type. As hospital testing policies are updated and availability of tests changes, ensure a clear policy exists for determining appropriate testing and sampling.
- Each test manufacturer has different guidelines for test use. New and temporary staff should be trained on individual test types and appropriate approaches for diagnostic testing.
- Administrative staff should utilize FDA’s list of EUAs that includes test instructions and fact sheets for both healthcare providers and patients.
- When interpreting results and determining diagnosis, healthcare professionals should be aware of current COVID-19 statistics and trends in their jurisdiction. Understanding virus circulation and transmission dynamics within the community supports accurate evaluation of test results to inform patient care.
• Hospitals should have a standard test result notification process for patients. Be ready to answer questions and provide handouts or other communication material that details test information and result implications. If possible, use standard scripts to reinforce the importance of isolation, identifying potential contacts, or discussing medical support services. Discuss possibility of false negatives relevant to the situation and provide information on next steps if any.
• Hospitals should be aware of testing supply alternatives and have strategies for identifying and purchasing substitutes as needed.
• Test positivity rate is an important indicator of the level of disease transmission in a community. Hospitals need to stay updated on reporting, licensing, and authorization requirements to conduct testing within their jurisdiction. Integrate these policies and workflows into the administrative process to ensure timely reporting of results to the public health authority.
• Hospital staff should be aware of testing limitations for vulnerable and at-risk populations, especially children and pregnant patients.
• Hospitals testing their staff should have clear related policies, including scenarios in which test results are inconclusive. These policies should account for staff who test positive or healthcare workers who were exposed but test negative; review and share operational standards for positive staff to return to work.

**Resources Related to Testing Practices**

- American College of Emergency Physicians: [ACEP COVID-19 Field Guide](#)
- Beth Israel Lahey Health: [COVID-19 and Influenza-like Illness Testing and Statistics](#)
- California Department of Public Health: [Updated COVID-19 Testing Guidance](#)
- Centers for Disease Control and Prevention:
  - [Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19](#)
  - [Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2](#)
  - [Overview of Testing for SARS-CoV-2 (COVID-19)](#)
- Cleveland Clinic: [Testing](#)
- COVID-19 Healthcare Coalition: [COVID-19 Decision Support Dashboard](#)
- Food and Drug Administration: [Testing Supply Substitution Strategies](#)
- Intermountain Healthcare: [Testing and Lab-Related Documents](#)
- MedStar Health: [Provider Assessment for COVID-19 Testing](#)
- National Emerging Special Pathogens Training and Education Center: [Choosing a COVID-19 Test](#)
- University of Iowa Health Care: [COVID-19 Testing](#)
- University of Michigan Medicine: [Indications for COVID-19 Diagnostic Testing for Patients in All Clinical Settings](#)
- Yale New Haven Health: [Testing](#)
Administrative Considerations

- Centers for Medicare & Medicaid Services (CMS) modifications included increasing access for Medicaid and Medicare beneficiaries to COVID-19 testing. Hospitals should maintain awareness of changing coverage requirements, and billing and coding updates.
- Many hospitals established processes to help manage their testing volume and allow physical separation between suspected COVID-19 patients and other patients. These include establishing drive-through clinics or setting up testing sites in outbuildings or tents, using telehealth technologies to identify those in need of testing and to schedule an appointment, scheduling pre-surgical or other procedural testing, or designating a facility or location within a health system for testing.
- In the event of a testing surge, there should be a plan in place with the healthcare coalition or other response partners to include community-based testing sites/designated testing clinics. Administrative personnel should be aware of federal, state, and local resources that can supplement testing supplies or other resources. Public health operated testing options may also be available.
- Report adverse testing events or issues with test performance and results to MedWatch by submitting the online FDA Form 3500 or calling 1-800-FDA-1088.
- Report the sale of fraudulent COVID-19, or suspected fraudulent products, to FDA’s Health Fraud Program or the Office of Criminal Investigations, or email FDA directly.

Resources Related to Administrative Considerations

- American Medical Association:
  - COVID-19 CPT Coding and Guidance
  - Special Coding Advice During COVID-19 Public Health Emergency
- ASPR TRACIE: COVID-19 Drive-Through Testing/Community Screening Resources
- Center for Medicare and Medicaid Services:
  - Updated Requirements for Reporting of SARS-CoV-2 Test Results
  - List of Lab Test Codes for COVID-19, Influenza, and RSV
- Kaiser Family Foundation: FAQs Medicare Coverage and Costs Related to COVID-19 Testing and Treatment
- U.S Department of Health and Human Services: COVID-19 Guidance for Hospital Data Reporting

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