Emerging Practices to Combat Coronavirus Disease (COVID-19): Testing

COVID-19 Clinical Knowledge Transfer from Vizient members and industry resources
Updated: April 16, 2020

Vizient is committed to ongoing research of Vizient members’ emerging practices and other related updates to federal and regulatory guidelines in support of efforts to combat the COVID-19 pandemic. The purpose of this document is to assist our members with critical information to supplement this work. As new information surfaces, updates will be provided.

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Practice trends

Like other areas, the testing domain has been subject to significant supply shortages across the entire spectrum of the testing process, including sample collection, storage and transport, RNA extraction, processing reagents, test kits and lab-based instruments to run the tests. Hospitals with critical shortages of nasopharyngeal swabs continue to implement protocols to collect samples from alternate sites in the mouth, nose and upper respiratory tract and some are creating their own transport media based on formulas provided by the FDA/CDC or their lab provider when they can’t obtain these supplies.

Manufacturers and commercial labs continue to apply for FDA approval and ramp-up production of test kits. As of April 14, there are 32 FDA Emergency Use Authorizations (EUAs) for PCR tests and 10 EUAs for laboratory developed molecular tests. These provide a lot of different options, platforms and labs that hospitals continue to explore when their current testing process does not provide timely results. Developing in-house testing, using point-of-care testing and working with suppliers to increase test kit availability are practices many hospitals are currently applying to increase their test capabilities.

The widespread availability of serology tests for antibodies to SARS-CoV-2 is one of the most anticipated developments in the testing domain. This type of test uses a blood sample, often as small as a few drops from a finger prick, and a simple, self-contained test kit similar to a home pregnancy test with results typically available in < 5 to 15 minutes. The first IgG/IgM antibody test kit received FDA EUA clearance on April 1. Other antibody test manufacturers have notified the FDA that they have developed, validated and are beginning to offer their tests while they pursue the EUA process. Some hospitals have begun to use the serology antibody tests in select patients. While antibody tests alone are not used for definitive diagnosis of active COVID-19, usage within new protocols in conjunction with other tests is being used to improve patient management decisions.
Emerging Practices

Lab based antibody tests

Laboratory based antibody tests are under development by several traditional laboratory manufacturers. These assays offer the advantages of utilizing laboratory automation to perform large volume patient tests on existing Immunoassay instruments. Manufacturers are following the Emergency Product designations and plan to submit for EUA approval. Traditional venipuncture blood samples and laboratory processing will provide testing for the same antibodies as below under Rapid antibody tests.

Added 4/16/20

Rapid antibody tests

Monitor the FDA EUA approved listing to check for the availability of rapid serology antibody test kits. These tests are in development from many manufacturers. Some manufacturers/laboratories have notified the FDA that they have validated and are offering serology tests as set forth in Section IV.D of the FDA’s Policy for Diagnostic Tests for Coronavirus Disease-2019. However, the accuracy and risk-benefit profile for non-EUA approved serology tests is not yet entirely known. To utilize these new tests, the Laboratory Director, Pathologist or Medical Director responsible for the laboratory CLIA license must approve of their use.

Updated 4/16/2020

Implement rapid antibody tests to screen patients for current or past exposure to SARS-CoV-2. The first rapid qualitative IgG/IgM antibody test kits are passing through the FDA EUA process and one from Cellex is the first to receive EUA authorization as of April 1. These antibody tests provide a testing option that is fast, simple to conduct, uses a readily obtained sample and requires no specialized lab instrumentation. Antibody testing, however, differs from RT-PCR diagnostic tests that detect viral RNA. For example, product labeling for antibody testing states that a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment, patient management decisions or to rule out active infection. A positive test indicates previous exposure to the virus but may not mean that a patient’s current symptoms are due to COVID-19 infection.

Added 4/2/2020

PCR tests

Check for new FDA EUA approved SARS-CoV-2 PCR tests for possible sourcing to improve the availability of testing. Investigate using an alternative off-site lab which may be using a different instrument platform with current test availability.

Updated 3/30/2020

Point of Care (POC) testing

Consider using rapid POC testing from Abbott, which provides results in <15 minutes, in hospitalized patients in cases where it would improve patient management. Note that this test requires use of the ID NOW benchtop instrument, and there have reportedly been significant limitations in the early roll-out and availability of tests.

Updated 4/16/2020

Consider using rapid POC testing, e.g. from Cepheid or BioFire, which provide results in about 45 minutes, in hospitalized patients in cases where it would improve patient management. These tests require availability of specific instrumentation.

Added 3/30/2020
Triage and testing algorithm

Standardize triage and testing algorithm throughout the organization utilizing a priority methodology.


Added 4/2/2020

Test swabs and specimen collection

The FDA recommends a nasopharyngeal specimen when possible, however oropharyngeal, mid-turbinate and anterior nares specimens collected by a healthcare provider may be acceptable depending on swab availability. Some tests are labeled and validated for alternate specimen collection sites.

Updated 4/16/2020

Consider alternate specimens. A test from Rutgers using saliva as a primary specimen received EUA approval on April 10. This EUA is for a specific lab and instrument. Use of an easily obtained saliva sample has potential advantages over some other sample collection methods. In a novel application, it may be possible to obtain this specimen at home using telemedicine to supervise collection; thus, avoiding exposure of healthcare personnel. Be aware that use of sample types outside of your reference lab requirements or the Package Insert or the Instructions for Use will require Medical Director approval.

Added 4/16/2020

Consider anterior nares round foam swabs for specimen acquisition when nasopharyngeal flock swabs are not available. These may be more comfortable for patients, allow self-testing and could reduce the consumption of PPE. See FDA recommendations for specimen collection alternatives.

Updated 3/30/2020

Transport media

Create your own viral transport media or use sterile saline to cope with shortages of conventional transport media. These transport media may stabilize the SARS-CoV-2 RNA without meaningful degradation. See FDA recommendations for viral transport media alternatives.

Updated 3/30/2020

Screening for fever

Practice shared by Vizient members: screen for fever using non-contact infrared thermometers at hospital entrances.

Added 4/2/2020

Alternative staff for triage

Attempt to repurpose underutilized primary care clinicians from other departments that may have less volume now due to canceled appointments. These staff have been used for triage and test follow-up activities by some hospitals.

Added 4/2/2020
Postmortem specimens
The CDC has provided interim guidance on: Collection and Submission of Postmortem Specimens from Deceased Persons with Known or Suspected COVID-19
Added 4/2/2020

Alternative testing sites
In a rural hospital setting, consider home-based testing for patients with respiratory illness. In one model, the hospital will send a staff member out to the home to test patients. The patient will remain at home until the test results are available, unless their condition changes.
Added 3/30/2020

Develop alternate sites to conduct testing to reduce exposure to patients and staff in facilities. Develop drive-through testing. See the Drive-Through Medicine template posted by the American College of Emergency Physicians.
Updated 3/23/2020

Create patient segregation/cohorting plan for locations where patients will be tested: ED, ICU and other areas.
Added 3/23/2020

Telemedicine
Establish or utilize telemedicine services for persons under investigation for COVID-19 patients and/or meeting criteria for testing (as well as drive through).
Added 3/16/2020

Public education
Provide publicly available education on testing (how, when and where to seek care) and the process to expect (include alternative testing sites). Use the hospital web site, COVID phone hotlines and hospital PR capabilities.
Added 3/23/2020

Utilize the CDC coronavirus self-checker to help patients self-guide through appropriate testing considerations.
Added 3/30/2020

Additional resources
- CDC Information for Laboratories
- FDA Emergency Use Authorizations
- FDA FAQs on Diagnostic Testing for SARS-CoV-2
- FDA Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency
• FDA Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons with COVID-19
• Duke Margolis Center Policy Roadmap to achieve widespread testing for COVID
• CMS CLIA Laboratory Guidance During COVID-19 Public Health Emergency
• Annals of Internal Medicine Narrative Review of Diagnostic Testing

Additional emerging practices
Access resource documents on other topics.
• Emerging clinical practices and evidence
• Managing critical supplies
• Surge capacity
• Staff impact
• Visitation