

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

COVID-19 Clinical Knowledge Transfer from Vizient members and industry resources  
Updated: May 28, 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 continues to be subject to significant supply shortages across the entire spectrum of the testing process, including sample collection swabs, storage and transport media, processing reagents, test kits and lab-based instruments that run the tests. These supply issues are slowly being addressed by manufacturers and test availability has significantly improved. However, as criteria for those seeking testing is eased, demand is again significantly exceeding supply.

The accuracy of available tests is also an ongoing issue. The marketing process has initially prioritized early availability to meet supply demands over rigorous proof of accuracy. High false negative rates have been reported for PCR testing. Some of this may be attributed to technical difficulty in obtaining a good sample specimen rather than the actual test itself. Some is also likely attributable to variable viral shedding from different tissues at different times in the disease course. These types of issues are not novel, but timely data describing test characteristics are needed to help hospitals understand the limitations of their testing protocols. The FDA recently released information about **false negative results** for the Abbott ID NOW test.

Antibody tests have also seen a wide range of accuracy issues. The FDA released a revised guidance on May 5 to provide more oversight of antibody tests. The new approach will require commercial manufacturers to submit emergency use authorization (EUA) requests with validation data within 10 to 14 days and follow specific performance guidelines for test validation before marketing. These policies should help prevent fraudulent marketing claims and improve standardization of antibody tests. There remain many unknowns, however, about how to appropriately use antibody tests in the overall care paradigm.

Manufacturers and commercial labs continue to apply for FDA authorization and ramp-up production of test kits. As of May 19, there are 61 FDA EUAs for molecular tests, 28 EUAs for laboratory developed molecular tests and 12 EUAs for serology tests. The first antigen test received FDA EUA status on May 8. The first home collection kit EUA was granted on May 15. These provide a lot of different options, platforms and labs that hospitals can 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 meet their testing needs.

## COVID-19 key strategies roadmap

COVID – 19 Stage	Testing key strategies
<b>Prepare</b>	<ul style="list-style-type: none"> <li>• Determine diagnostic <b>tests</b> that will be used as well as the appropriate <b>supplies</b></li> <li>• Establish a primary and secondary vendor for tests and supplies</li> <li>• Estimate testing demand and capacity</li> <li>• Develop a triage and testing <b>algorithm</b> based on testing capacity</li> <li>• Develop plans to <b>staff</b> for triage and test follow-up activities</li> <li>• Establish plan for alternative testing <b>sites</b> with specimen courier service</li> <li>• Provide publicly available <b>education</b> on testing (how, when and where to seek testing)</li> </ul>
<b>Respond</b>	<ul style="list-style-type: none"> <li>• Implement testing triage protocols and stand-up alternative sites</li> <li>• Establish or utilize <b>telemedicine</b> for persons under investigation and/or meeting testing criteria</li> <li>• Establish <b>postmortem</b> procedure specimen criteria</li> </ul>
<b>Recover</b>	<ul style="list-style-type: none"> <li>• Monitor for updates to CDC, CMS, FEMA, FDA and other laboratory guidance <b>publications</b></li> <li>• Assess response and revise testing preparedness policies and procedures</li> <li>• Determine future testing needs and capacity</li> <li>• Establish a hierarchy of vendors for increased access to <b>molecular</b> and <b>serological</b> tests</li> <li>• Establish testing <b>protocols</b> for resuming non-emergent non-COVID-19 care pathways, including symptomatic screening and laboratory testing for staff and patients</li> <li>• Optimize test protocols based on test availability, expected test frequency and timing, test turn-around-time, accuracy and local COVID-19 prevalence rates</li> </ul>

## Emerging practices

### Resuming normal healthcare operations

In states or regions meeting established [criteria set by CMS](#) for re-opening facilities and providing non-emergent/non-COVID care, health care facilities should routinely screen staff for potential symptoms and screen all patients for potential symptoms prior to facility access. If adequate testing capability is available, staff and patients should be screened with approved laboratory testing as well.

*Added 4/23/2020*

In facilities considering resuming elective surgeries, available testing methods should be used to protect staff and patient safety. Re-opening policies should include consideration of test availability, test frequency and timing, test turn-around-time, accuracy and local COVID incidence and transmission factors. A roadmap for resuming elective surgery created by various specialty societies is available as a [resource](#).

*Added 4/23/2020*

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### Antigen tests

Perform antigen testing of respiratory specimens to rapidly screen for active COVID-19 infection. Antigen testing is a new class of diagnostic testing that differs from currently available molecular or antibody testing. Antigen tests identify proteins associated with the viral surface as compared to molecular tests which identify specific genetic material or serology tests which identify antibodies created through an immune response. Advantages of antigen testing include a low cost, simpler process and rapid availability with positive results indicated in <15 minutes. However, antigen tests may have a lower sensitivity than molecular tests and a negative result may not rule out infection. The first antigen test, from [Quidel](#), received FDA EUA on May 8. This test uses the Sofia Fluorescent Immunoassay Analyzer. More antigen tests are expected through the FDA EUA process in the near future.

*Added 5/12/2020*

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### Antibody tests

The FDA revised their [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency](#) to provide more oversight of antibody test accuracy. The new policy requires manufacturers/laboratories to submit a completed EUA request with validation data to FDA for all new tests and tests that came to market under the previous guidance. The new policy also provides guidance for test validation and performance. The new policy is effective immediately and replaces a March 16 policy.

*Updated 5/7/2020*

**Implement antibody tests** to screen patients for past exposure to SARS-CoV-2. The first antibody test kits are now passing through the FDA [EUA process](#). As of May 4, there were 12 serology antibody tests for SARS-CoV-2 with FDA EUA approval. 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. Limitations on the diagnostic use of antibody tests has been discussed by the [FDA](#).

*Updated 5/7/2020*

**Use laboratory-based antibody serology tests that run on existing lab immunoassay instruments.** These assays provide advantages associated with utilizing laboratory automation to perform large volume testing. Traditional venipuncture blood samples and conventional laboratory processing are used for these tests. Some of

these tests have currently received **FDA EUA** approval and many other manufacturers of these tests have notified FDA of their intent to pursue EUA approval in the near future.

*Updated 4/23/20*

**Monitor the FDA EUA approved listing to check for the availability of rapid point-of-care serology antibody test kits.** These antibody tests provide a testing option that is fast, simple to conduct, uses a readily obtained sample and requires no specialized lab instrumentation. 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 5/7/2020*

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### **PCR tests**

Check for new FDA **EUA approved** SARS-CoV-2 PCR tests for possible sourcing to improve the availability and turn-around-time of testing. Investigate using an alternative platform or different off-site lab which may be using a different instrument platform to explore all options.

*Updated 3/30/2020*

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### **Point-of-care PCR testing**

Concerns about point-of-care test: The Abbott ID NOW point-of-care test for SARS-CoV-2 may deliver **false negative results**, possibly due to the type of swabs or virus transport media used, the FDA said in a news release. The agency has received 15 adverse event reports about the test. The manufacturer will be conducting post marketing studies to help identify the cause of any inaccuracies. In the meantime, an FDA official said, "This test can still be used and can correctly identify many positive cases in minutes. Negative results may need to be confirmed with a high-sensitivity authorized molecular test." For example, a negative result should be confirmed if it's inconsistent with a patient's signs and symptoms.

*Updated 5/21/2020*

Rapid POC testing, e.g. from **Cepheid** or **BioFire**, can provide results in about 45 minutes for use in hospitalized patients in cases where it would improve patient management. These tests require availability of specific instrumentation.

*Added 3/30/2020*

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### **Triage and testing algorithm**

Standardize triage and testing algorithm throughout the organization utilizing a priority methodology. See updated CDC Guidance for **Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19)**.

*Added 4/2/2020*

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### **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 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*

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### **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*

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### **Screening for fever**

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

*Added 4/2/2020*

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### **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*

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### **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*

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### **Alternative testing sites**

The Office of the Assistant Secretary for Health issued new [guidance](#) under the Public Readiness and Emergency Preparedness Act authorizing licensed pharmacists to order and administer COVID-19 tests. Providing testing at retail and independent, community-based pharmacies will further expand access to testing.

*Added 4/30/2020*

Use at-home testing as an alternative to drive-thru testing for patients not requiring immediate care. The first EUA approval for an at-home SARS-CoV-2 test was [granted](#) on April 21. The LabCorp Pixel test kit uses a self-collected nasal sample shipped to the lab for PCR analysis. Patients must fill out an online form, receive approval from a physician based on provided data and self-pay to receive the test kit.

*Added 4/23/2020*

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*

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## 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*

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## 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*

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## Additional resources

- [Annals of Internal Medicine Narrative Review of Diagnostic Testing](#)
- [ACS/ASA/AORN/AHA Joint Statement: Roadmap for Resuming Elective Surgery after COVID-19 Pandemic](#)
- [CDC Evaluating and Testing Persons for Coronavirus Disease 2019 \(COVID-19\) Webpage](#)
- [CDC Information for Laboratories](#)
- [CMS CLIA Laboratory Guidance During COVID-19 Public Health Emergency](#)
- [CMS Recommendations: Re-opening Facilities to Provide Non-emergent Non-COVID-19 Healthcare: Phase I](#)
- [Duke Margolis Center Policy Roadmap to achieve widespread testing for COVID](#)
- [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](#)
- [FDA Letter to Health Care Providers: Important Information on the Use of Antibody Tests for COVID-19](#)

## Additional emerging practices

Access resource documents on other topics.

- [Emerging clinical practices and evidence](#)
- [Managing critical supplies](#)
- [Surge capacity](#)
- [Staff impact](#)
- [Visitation](#)