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

COVID-19 Clinical Knowledge Transfer from Vizient members and industry resources
Updated: April 9, 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.

Contents

Practice trends .................................................................................................................. 2
Emerging Practices ....................................................................................................... 3
Additional resources ..................................................................................................... 5
Additional emerging practices ....................................................................................... 5

DISCLAIMER: VIZIENT IS COMPILING INFORMATION AND EMERGING PRACTICES FROM MEMBERS TO AID IN KNOWLEDGE TRANSFER DURING THE COVID-19 RESPONSE. DECISIONS REGARDING WHETHER AND HOW TO UTILIZE ANY OF THESE PRACTICES SHOULD BE MADE BY HEALTH CARE PROVIDERS, AT THEIR OWN RISK, WITH CONSIDERATION OF INDIVIDUAL CIRCUMSTANCES. AS INFORMATION IS CHANGING RAPIDLY, VIZIENT ENCOURAGES YOU TO ALWAYS REFER TO THE CDC, YOUR STATE’S DEPARTMENT OF HEALTH, AND YOUR LOCAL PUBLIC HEALTH AUTHORITY FOR GUIDANCE. VIZIENT DOES NOT PROVIDE LEGAL, REGULATORY, OR MEDICAL ADVICE AND DISCLAIMS LIABILITY OR RESPONSIBILITY FOR THE ACCURACY, COMPLETENESS, AND/OR CLINICAL EFFICACY AND SAFETY FOR THE PRODUCTS OR PROCESSES CONTAINED HEREIN. MEMBERS SHOULD SEEK THEIR LEGAL COUNSEL’S ADVICE ON LOCAL, STATE, AND FEDERAL LEGAL/REGULATORY MATTERS. THE LINKS TO INFORMATION REFERENCED IN THIS DOCUMENT ARE THE PRODUCTS OF THE NAMED ORGANIZATIONS AND THEY ARE SOLEY RESPONSIBLE FOR THEIR CONTENT. FOR THE MOST UP-TO-DATE INFORMATION, PLEASE VISIT VIZIENT’S DISASTER PREPAREDNESS PAGE. TO SUBMIT PRACTICES YOUR ORGANIZATION IS USING TO PREPARE FOR COVID-19, PLEASE EMAIL DISASTERRESPONSE@VIZIENTINC.COM.
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 recipes 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 8, there are now 30 FDA Emergency Use Authorizations (EUAs) for PCR tests and 5 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 eagerly 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

Rapid antibody tests

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

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 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; thus, requires approval by hospital experts in laboratory medicine.

Updated 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 availability of the ID NOW benchtop instrument.

Added 4/2/2020

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.

See updated CDC Guidance for Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19)

Added 4/2/2020
Test swabs

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

**Additional emerging practices**

Access resource documents on other topics.

- Emerging clinical practices and evidence
- Managing critical supplies
- Surge capacity
- Staff impact
- Visitation