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Point of Care Testing for COVID-19

Overview

Testing at the point-of-care for COVID-19 adds a distinct advantage—rapid availability of results upon which to make treatment and infection prevention and control decisions. However, these tests are not error-proof. They need to be performed correctly, by trained personnel and in an environment where good laboratory practices are followed. Reporting of results to Pennsylvania's electronic disease surveillance system, PA-NEDSS is mandated by law and becomes the responsibility of the facility doing the testing.

Types of Tests

At present, the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for point-of-care testing for COVID-19 via two types of tests: molecular detection and antigen detection.

Molecular detection tests use nucleic acid amplification technology (NAAT) for the qualitative detection of viral nucleic acids found in the RNA of the target virus. This is the same technology used by most clinical laboratories to detect SARS-CoV-2, the virus that causes COVID-19. This type of test has high sensitivity and specificity, but test performance varies by manufacturer and depends on proper specimen collection.

Antigen detection tests will react to the detection of nucleocapsid antigens. These antigens are generally detectable in the respiratory system during the acute stage of infection. Antigen tests are very specific but not as sensitive as molecular detection tests. This means that a positive antigen test is highly accurate, but there is a greater chance of false-negative results (i.e. a person who is infected will still test negative) with this test type.

Specimen Collection

Each point-of-care test uses a different method of specimen collection and storage. Carefully follow the Instructions for Use (IFU) for the instrument. Don all required personal protective equipment including an N-95 or higher respirator or a facemask (if respirator is not available), eye protection, clean gown and clean gloves prior to specimen collection.

Interpreting Results

Clinical presentation and pretest probability should be carefully considered in evaluating results from point-of-care testing platforms. Per the FDA EUA, positive results must be used in conjunction with clinical presentation and patient history. Negative results should be treated as presumptive and do not rule out COVID-19. If there is still concern that a person has COVID-19 after a negative point-of-care test, then that person should be tested again using a different authorized molecular test.

CLIA Certification

Facilities utilizing point-of-care testing instruments for COVID-19 must have a Pennsylvania laboratory permit and a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. If you have questions about laboratory permits or CLIA certification, please notify RA-DHPACLIA@pa.gov to assure laboratory compliance.

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Training

Facilities must carefully review the instrument Instructions for Use (IFU) and must train staff on the collection of specimens and performance of the test according to the IFU. Use online training videos provided by the company or the package insert instructions. Document staff training and competency.

The Centers for Disease Control and Prevention (CDC) Booklet Ready, Set, Test is a good resource for ensuring that staff has the basic training necessary to safely and accurately perform point-of-care laboratory testing.

Reporting Results to PA-NEDSS

All positive and negative results must be reported within 24 hours to Pennsylvania's electronic surveillance system, PA-NEDSS. Do not report "invalid" results; repeat testing as per the instrument IFU. To request a PA-NEDSS account, complete the PA-NEDSS Prime Contact Information Form and send it to PA-NEDSS@pa.gov. The facility will then receive registration instructions and training materials.

A "prime contact" for the facility will need to be named; the prime contact can then add people who are designated to report on behalf of the facility. Training information will be sent with the registration information. The attached Disease Reporter Guide also provides instructions. The following fields are required:

- Patient name
- Patient date of birth
- Patient address (use the address of the facility for residents; employees must have their residential address reported)
- Patient race and ethnicity
- Patient phone number (can use facility phone number for residents)
- Patient gender
- Test name
    - For molecular detection tests, choose "2019 novel coronavirus nucleic acid detection (rRT-PCR, probe)"
    - For antigen detection tests, choose "2019 novel coronavirus ANTIGEN detection"
- Test information
    - Specimen collection date
    - Test completed date (for point-of-care testing these dates are likely to be the same)

Key training resources for PA-NEDSS include the New User Guide, Disease Reporter Guide, and Technical Bulletin which provides basic technical information for PA-NEDSS.

Additional Requirements

Follow manufacturer's instructions for performance of the test.

Resources

CMS guidance for how to receive a CLIA Certificate of Waiver
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf

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Table of Point-of-Care Tests for COVID-19

	Test Type	When to Use	Specimen Source	Specimen Type	Detects	FDA EUA Approval Letter*	Instructions for Use*	Healthcare Provider Fact Sheet*	Patient Handout*
Quidel SARS 2 Antigen TIA	Antigen	Persons suspected of having COVID-19[1] within the first five days of the onset of symptoms	Nasopharyngeal and nasal swab[2]	Direct or in viral transport media (VTM)	SARS-CoV nucleocapsid antigen[3] and SARS-CoV-2 nucleocapsid antigen	May 8, 2020	IFU	Fact Sheet	Patient Handout
BD Veritor System	Antigen	Persons suspected of having COVID-19[1] within the first five days of the onset of symptoms	Nasal swab (dual nares collection method)[2]	Direct specimen only	SARS-CoV-2 nucleocapsid antigen	July 2, 2020	IFU	Fact Sheet	Patient Handout
Abbott ID Now	Molecular	Persons suspected of having COVID-19[1]	Nasopharyngeal, nasal, or throat swab[2]	Direct specimen only	SARS-CoV-2 viral RNA	June 1, 2020	IFU	Fact Sheet	Patient Handout

*These resources were obtained from the Food & Drug Administration (FDA) website and are subject to change. This table contains information for select devices. Additional devices are listed on the FDA website. If the links provided no longer function, or you need additional information, we advise going to the FDA COVID-19 Emergency Use Authorization (EUA) website, under the section for COVID Invitro Diagnostic Products. From there, type the name of the instrument into the search box or browse the list provided.

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Footnotes

1. Individuals suspected of COVID-19 infection or exposure can be symptomatic, pre-symptomatic, or asymptomatic. Diagnostic tests authorized for use on individuals suspected having of COVID-19 by their healthcare provider may be performed on specimens from *certain* asymptomatic individuals (e.g., those who have likely been exposed to an infected individual).

   Exposure to COVID-19 could include the introduction of COVID-19 into the facility as per PA-HAN-509 or its successor, which should prompt weekly testing until no new cases are detected. The Department does not suggest the use of the Abbott ID Now system for routine testing of asymptomatic individuals without likely exposure to COVID-19.

2. Follow the collection procedure outlined in the instrument's instructions for use (IFU).

3. The Department of Health has sufficient evidence to conclude that detection of SARS-CoV will not be a significant contributor to the detection of antigen using this instrument based on the current absence of SARS-CoV in the Commonwealth at this time.