Mandatory Reporting of COVID-19: Point-of-Care Testing in Educational Settings Within 24 Hours

October 15, 2020

The U.S. Department of Health and Human Services (HHS) recently announced that it will begin distribution of Abbott BinaxNOW™ COVID-19 Ag Card tests to states. The BinaxNOW™ COVID-19 Ag Card test is a point-of-care (POC) test. Information regarding the POC allocation to states can be found on the HHS website (www.hhs.gov/coronavirus/testing/rapid-test-distribution/index.html). Florida is committed to protecting vulnerable populations and will be prioritizing distribution of these POC tests to include public school districts and state university health clinics.

BinaxNOW™ COVID-19 Ag Card test

- The BinaxNOW™ COVID-19 Ag Card test can be performed by a health care provider and have results available within 15 minutes without sending specimens to a laboratory.
- The BinaxNOW™ COVID-19 Ag Card test uses nasal swabs and is simple to use, inexpensive, and can be easily employed by medical personnel or trained personnel to non-clinical environments operating through a Clinical Laboratory Improvement Amendments (CLIA) certificate.
- To perform the test, personnel must operate under a CLIA certificate.

Reporting of Test Results

Health care practitioners, facilities and laboratories are subject to mandatory reporting to the Florida Department of Health (FDOH) under section 381.0031, Florida Statutes, and Chapter 64D-3, Florida Administrative Code.

- All positive, negative and indeterminate COVID-19 laboratory results, including point-of-care test results, must be reported to FDOH via electronic laboratory reporting or by fax within 24 hours. This includes all COVID-19 test types: polymerase chain reaction (PCR), other RNA, antigen and antibody tests. For a list of county health departments and their reporting contact information, please visit: www.FLhealth.gov/chdepicontact.
- Health care providers and facilities must report by fax all COVID-19 cases and negative test results to their county health department within 24 hours until they are successfully reporting results electronically.

If your facility is conducting in-house COVID-19 testing, please report results electronically. To establish electronic reporting through a web portal, please begin the enrollment process by emailing the COVID-19 Reporting Portal team at COVID19PortalEnrollment@flhealth.gov. Until you have access to the reporting portal, please fax results to your local county health department within 24 hours. For a list of county health departments and their reporting contact information, please visit www.FLhealth.gov/chdepicontact.

Reporting of Outbreaks

Suspected or confirmed outbreaks of COVID-19 in primary, secondary and postsecondary schools must be reported immediately and are defined as:

- Two or more laboratory-confirmed COVID-19 cases among individuals with onset dates or specimen collection dates within a 14-day period, who are epidemiologically linked, and were not identified as close contacts of each other in another setting during standard case investigation or contact tracing.
- Two or more acute respiratory infection (ARI) cases within 72 hours who are epidemiologically linked and were not identified as close contacts of each other in another setting during standard case investigation or contact tracing.

Antigen Test Result Interpretation

While antigen tests produce more timely results than laboratory-based PCR tests, they also have lower sensitivity and specificity than PCR assays. When comparing the results of antigen tests to PCR tests, it is important to consider the pre-test probability of infection and the likelihood that an antigen test result may be falsely positive or falsely negative. Please refer to the following table for guidance based on recommendations from the Centers for Disease Control and Prevention:

Pre-test probability of infection	**Considerations**	**Guidance**
Probability of infection is low	• Asymptomatic student • No known exposure • Not part of an outbreak • Low community COVID-19 activity • County positivity rate is less than five percent	If an antigen test result is positive, perform confirmatory PCR test within 48 hours. If the PCR test result is negative, treat as a negative result.
Probability of infection is high	• Symptomatic student • Known exposure • Part of an outbreak • High community COVID-19 activity • County positivity rate is greater than five percent	• If an antigen test result is positive, a confirmatory PCR test is unnecessary. • If a PCR test is also performed and the result is negative, facilities should base their infection prevention and control actions on the positive antigen test result.

Additional Resources

- Interim Guidance for Rapid Antigen Testing for SARS-CoV-2
- Factsheet for the Abbott BinaxNOW™ COVID-19 test can be found here
- For access to training videos and documents, please visit the BinaxNOW™ COVID-19 Ag Card and NAVICA™ App Set-Up and Training portal.
- For CLIA FAQs and information, click here.

- For policy regarding performance of antigen tests authorized by the Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) at the point-of-care or inpatient care settings operating under a CLIA Certificate of Waiver, please refer to the Centers for Medicare and Medicaid Services' (CMS) policy here and Public Readiness and Emergency Preparedness (PREP) Act guidance here.
- For FDA recommendations to health care providers who are ordering authorized tests outside their authorization (e.g., antigen tests for asymptomatic individuals), please see FDA's FAQ on Testing for SARS-CoV-2.