COVID-19 Testing

Ohio Department of Health

Frequently Asked Questions

BinaxNOW Testing (Higher Education)

Traditional Version

Why is the state providing these tests?

The Ohio Departments of Health (ODH) and Higher Education (ODHE), in close consultation with institutions for higher education (IHE) and local public health officials, recommend that any IHE with on-campus student housing should develop a screening testing program focused on testing asymptomatic individuals. These BinaxNOW COVID-19 tests are being distributed to higher education institutions as a means to increase compliance with these guidelines.

Who can administer BinaxNOW tests?

BinaxNOW tests must be administered by medical professionals (e.g., physicians, nurses, pharmacists) or trained operators proficient in performing rapid lateral flow test. Each test administrator should be properly trained in administering BinaxNOW COVID-19 tests and interpreting results. Abbot, the has provided modules and video instruction to aid in training testing administrators. Additional guidance on administration of the tests, including recommended PPE usage, is available on the Abbott support site and through the CDC.

Does my institution need a CLIA waiver to administer these tests?

The BinaxNOW test is authorized for point-of-care use in settings operating under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver, Certification of Compliance, or Certificate of Accreditation. The application to apply for a CLIA certification or waiver can be found here and additional support can be provided by contacting Abbott support, the Ohio Department of Health, or by contacting Ohio's testing team at TestingRequests@odh.ohio.gov. Once a testing site has identified a laboratory director and provided all required information on the application, a CLIA number will be assigned and the site can begin testing for COVID-19.

Can people swab themselves for these tests?

Yes, self-swabbing, to obtain the sample, is authorized but must be conducted under the supervision of a medical professional. The actual administration of the BinaxNOW test must be conducted by medical professionals or trained operators proficient in performing rapid lateral flow test.

What do we do if someone tests positive?

FDA and CDC guidance suggest that antigen test results should be considered in the context of clinical observation, patient history, and epidemiological information:

> Healthcare providers should consider pretest probability when using antigen tests as screening tests, and confirmatory testing may be required for clinical management and public health decision-making. See each test's instructions for use at FDA's In Vitro Diagnostics EUAs, and see FDA's Recommendations for healthcare providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19. Also see CMS' Enforcement discretion for the use of SARS-CoV-2 point-of-care testing on asymptomatic individuals.

> When testing a person who is asymptomatic and has not had known exposure to a person with COVID-19 within the last 14 days, indicating that the pretest probability is low, the healthcare provider generally can interpret a negative antigen test to indicate that the person is not infected with SARS-CoV-2. If the prevalence of SARS-CoV-2 infection is not low in the community, clinical judgement should consider whether this negative antigen test result should be followed by a confirmatory NAAT. See the antigen testing algorithm when pretest probability is low, Figure 4, which is excerpted directly from the full antigen testing algorithm in Figure 1.

The Emergency Use Authorization for BinaxNOW says it is to be used for symptomatic individuals. Why are you suggesting we use it for asymptomatic screening?

The current FDA authorized antigen tests, including BinaxNOW, are intended for use in symptomatic individuals within the first 5 to 7 days of symptom onset. However, antigen tests are also being used off-label for testing individuals who are asymptomatic and may have or not have known contact or specific exposure to SARS-CoV-2. The Centers for Disease Control and Prevention (CDC) have released guidance for rapid antigen testing for SARS-CoV-2.

Should tests be used for individuals who have been vaccinated?

Schools should follow CDC guidance regarding vaccinated individuals. As of March 8, 2021, the following guidance was in place for non-healthcare settings:

> Although the risk that fully vaccinated people could become infected with COVID-19 is low, any fully vaccinated person who experiences symptoms consistent with COVID-19 should isolate themselves from others, be clinically evaluated for COVID-19, and tested for SARS-CoV-2 if indicated. The symptomatic fully vaccinated person should inform their healthcare provider of their vaccination status at the time of presentation to care.
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> Fully vaccinated people with no COVID-like symptoms do not need to quarantine or be tested following an exposure to someone with suspected or confirmed COVID-19, as their risk of infection is low.
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> Fully vaccinated people who do not quarantine should still monitor for symptoms of COVID-19 for 14 days following an exposure. If they experience symptoms, they should isolate themselves from others, be clinically evaluated for COVID-19, including SARS-CoV-2 testing, if indicated, and inform their health care provider of their vaccination status at the time of presentation to care.