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Information for Parents for the Abbot BinaxNOW Antigen Test in Schools

Please distribute this information sheet to all parents/guardians. You are being given this information sheet because your school is participating in an antigen testing program. This is a voluntary program. This information sheet contains information to help you understand the risks and benefits of this testing program. This program is testing for the SARS CoV-2 virus that causes COVID-19. Symptoms of COVID-19 can range from no symptoms to severe respiratory illness. Symptoms can include fever, chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea. For more information see the <u>CDC Symptoms of Coronavirus</u>.

The Abbott BinaxNOW is a rapid antigen test designed to test for the SARS CoV-2 virus with results available in 15-30 minutes. The sample will be collected by your child by inserting a soft swab ½ an inch inside the nose and slowly rotating the swab for 15 seconds and then repeating on the second nostril. Even children in kindergarten can self-swab their own noses. Most people describe a ticklish sensation or feeling the need to sneeze.

The benefits of taking the test:

- The results of this test can help keep your school community healthy, along with mask wearing, social distancing, and frequent handwashing.
- This test can help limit the spread of COVID-19 to your family and your community.
- Results are available in 15-30 minutes.

The risks of taking the test:

- Possible discomfort or other complications that can arise from sample collection.
- Possible incorrect test result.

The antigen test is not as sensitive as PCR testing. PCR is a high complexity test that needs to be run in a specialized laboratory and results are not available for 24-48 hours. Because of the lower sensitivity of antigen tests, more frequent testing is recommended. Although this test was originally designed to test symptomatic people it can be a good tool for screening individuals without illness, particularly because of the quick turnaround time and lower costs. If a participant tests positive, they are likely infected with the SARS CoV-2 virus. The school will immediately contact you and inform you to take your child 42 home. A confirmatory PCR test will likely be needed. You should contact your child's medical provider to let them know about the positive result. Your child should <u>isolate</u> at home and all close contacts, such as family members, should follow CDC <u>quarantine guidelines</u>. The school will work with you and local health officials to determine the best course of action for a safe return to school. **For more information**

regarding COVID-19 and rapid testing from CDC, please visit: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-testsguidelines.html

Fact Sheet for Patients for BinaxNOW Rapid Antigen Test: https://www.fda.gov/media/141569/download

FAQs for the School Community

How will the sample be collected? To collect the specimen, the participant will insert a soft swab about ½ an inch inside the nose and slowly rotate the swab at least 5 times for a total of 15 seconds and then repeat the same steps on the second nostril.

What is self-swabbing? Self-swabbing means you collect the sample yourself. A study done at UCSF found that even young children could self-swab their own noses without difficulty. (Cooch et al., mdRxiv 2020)

What will the test feel like for my child? Most participants describe a ticklish sensation or feeling the need to sneeze.

Why was I (or my child) tested? You (or your child) was tested as part of routine screening at school to detect cases of COVID-19 to help avoid spread of the virus. This screening program does not replace the other important safety measures that help keep the school community safe, such as mask-wearing, social distancing, frequent handwashing and increasing ventilation.

What if I or my child refuses to self-swab? Your school will inform you what alternatives there are for children who refuse or who are unable to self-swab.

What does it mean if a staff or student has a positive test result? If the person currently has any symptoms of COVID-19 that began less than 7 days ago and test positive using BinaxNOW, then is the person has confirmed COVID-19 and they should isolate per CDC guidelines and get a confirmatory PCR test within 24 hours. If the person does not have any symptoms, it is highly likely that they have COVID-19 and should isolate per CDC guidelines. Because antigen tests are slightly less specific than PCR tests, there is a small chance that the test was falsely positive. For that reason, a PCR test within 24 hours was negative and the person still does not have symptoms, the antigen test was falsely positive, and isolation can be ended. The participant or the parent/guardians of a minor will be notified if there is a positive test. Please also inform your primary care doctor and let them know about your/your child's test results. The school and the department of public health will also be notified.

What does it mean to have a negative test result? A negative test means a person most likely does not have the virus that causes COVID-19, unless they have symptoms of COVID 19. If they

have symptoms of COVID 19 and test negative, then a confirmatory PCR test should be performed. It is possible, though unlikely, for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means a person could still possibly have COVID-19 even though the test results are negative. This is why individuals who test negative must still observe safety measures including mask wearing, physical distancing and handwashing and the test will be repeated on a regular basis.

How does the Abbot BinaxNOW test compare to other types of tests? The Abbot BinaxNOW test is a rapid antigen test. It works by identifying SARSCoV-2, the virus that causes COVID-19 disease in 15-30 minutes. This test is different from a PCR test. A PCR test is a high complexity test and needs to be run in a specialized laboratory and results are not available for 24-48 hours. A PCR test, like an antigen test, identifies an active infection with SARS-CoV-2. It is also different from an antibody test, which is a blood test that checks whether or not you have had a SARS-CoV-2 infection in the past.

What does self-isolate mean? People who are in isolation should stay home until it's safe for them to be around others. In the home, anyone sick or infected should separate themselves from others by staying in a specific "sick room" or area and using a separate bathroom. Don't share personal household items, like cups, towels, and utensils. Members of the household should wear masks when around other people, if possible. Isolation lasts for at least 10 days from the positive test unless otherwise instructed by your primary care doctor or public health department. (More information from the CDC on self-isolation and caring for others with COVID-19)

If I get the COVID-19 vaccine, will I test positive? No, getting the COVID-19 vaccine will not affect the result of the antigen test.

Is this test FDA approved? The FDA has authorized this test for use under an Emergency Use Authorization (EUA) for testing of symptomatic patients. The FDA states: "If highly sensitive tests are not feasible, or if turnaround times are prolonged, health care providers may consider use of less sensitive point-of-care tests, even if they are not specifically authorized for this indication (commonly referred to as 'off-label'). If less sensitive 50 tests, such as some rapid point-of-care tests, are used, health care providers should be aware of the performance of the tests and may want to consider different testing approaches, such as serial testing." (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medicaldevices/covid-19-test-uses-faqs-testing-sars-cov-2)

What is the sensitivity and specificity of this test? Positive agreement of the BinaxNOW compared a PCR assay was "99/117, 84.6% (95% CI: 76.8% - 90.6%)." Negative agreement of the BinaxNOW compared to a PCR assay was "338/343, 98.5% (95% CI: 96.6% - 99.5%)." For more information about the sensitivity and specificity of the test, please see the Abbott Instructions for Use for the COVID-19 Ag Card Rev. 2 2020/12 (https://www.fda.gov/media/141569/download).

If my child is sick, can I send him/her to school so he/she can be tested? No, please keep your child at home and seek testing at a local COVID-19 testing center. Please seek care with your child's primary care provider.

Does a deviated septum affect the test? No, a deviated septum does not affect the test.

How long after testing positive for COVID-19 should someone wait before being retested? Follow CDC guidelines as when retesting can occur following a previous positive test.