

Diagnostic COVID-19 Testing in Oregon's K-12 Schools

“Return-to-school” testing protocol for school nurses



Contents

Contents	2
Introduction	4
Registration	5
How to register	5
Liability	5
Privacy.....	6
Training	7
Abbott BinaxNOW point-of-care antigen training	7
Personal protective equipment (PPE) use	8
PPE Components.....	8
Putting on personal protective equipment.....	8
Extended use of eye protection and mask.....	9
Taking off personal protective equipment, hand hygiene, and disinfecting eye protection	9
Cleaning face shield or goggles	9
Storage of face shield or goggles	10
Testing	11
When to perform return-to-school testing.....	11
Test storage	11
Quality control.....	11
Built-in quality control	11
Positive and negative control swabs	12
Specimen collection and handling	13
Specimen testing	13
Result Interpretation.....	14
Specimen disposal	14
Reporting requirements	15
Logging tests performed.....	15
Daily reporting of all positive and negative results through the OHA K-12 Reporting Portal	15
Consent forms	15
Understanding test results	16
How to interpret negative test results.....	16

Students or staff with symptoms who have had close contact to a case of COVID-19 within the last 14 days and have a negative BinaxNOW test	16
Students or staff with symptoms without a known exposure to COVID-19 and have a negative BinaxNOW test	16
How to interpret positive test results.....	16
Appendices	17

Introduction

The Oregon Department of Education (ODE), in collaboration with Oregon Health Authority (OHA), has published the [Ready Schools, Safe Learners](#) resiliency framework to outline health and safety requirements to reduce the risk of COVID-19 transmission in Oregon's K-12 schools. To further mitigate the risk of COVID-19 transmission in Oregon's K-12 schools, OHA supports onsite diagnostic COVID-19 testing in public and private K-12 schools in Oregon offering partial or full in-person instruction for students and staff who display symptoms of COVID-19 or who have been exposed to COVID-19 in the school setting. The [core K-12 diagnostic testing program](#) allows testing of individuals who develop symptoms while at school, but does not allow students or staff with symptoms to return to school for testing.

For some students, COVID-19 testing in K-12 schools may represent their only access to a COVID-19 test and the importance of this access cannot be overstated. **This protocol supports K-12 schools with school nurses to allow symptomatic individuals to return to school for diagnostic testing at the school nurse's discretion.**

This program is intended to test symptomatic students and staff only. The Abbott BinaxNOW tests should not be used to screen asymptomatic individuals or those without a known exposure to COVID-19.

Registration

How to register

All return-to-school testing will be performed under the umbrella of a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver and a standing physician order held by OHA. This CLIA will be separate from the CLIA held for onsite diagnostic and exposure testing. In order to offer return-to-school testing for COVID-19 under this waiver, school nurses must register by completing and returning the COVID-19 Testing K-12 Registration Form (see Appendix A) via email to Schooltesting.covid@dhssoha.state.or.us.

OHA will send a confirmation of registration via email. Nurses may use the same BinaxNOW tests as the onsite diagnostic testing program. School nurses may begin return-to-school COVID-19 testing using the Abbott BinaxNOW once personal protective equipment (PPE) is available, staff training is completed, and other testing plan elements are in place per this guidance. All COVID-19 testing performed under this CLIA waiver must be performed in accordance with the procedures outlined in this guidance. Nothing in this guidance is intended to change the manufacturer's instructions or the provisions of the Emergency Use Authorization under which Abbott BinaxNOW may be used.

School nurses must notify OHA via email to schooltesting.covid@dhssoha.state.or.us regarding any changes made to the information provided on the initial registration form.

Only a registered nurse practicing in the school setting (referred to as “school nurse” in this guidance) may perform return-to-school COVID-19 testing. The school nurse must complete all required online training modules for the BinaxNOW point-of-care antigen test and carefully review all training regarding personal protective equipment (PPE) use included in this guidance. If school nurses follow the instructions in this guidance, they would not be considered a close contact of an individual who tests positive and they would not be required to quarantine.

The school nurse may identify a school testing reporter to perform all COVID-19-related reporting requirements or may perform this themselves. The school testing reporter should be a member of the school administration or staff and can be the same school testing reporter as the onsite diagnostic COVID-19 testing program.

Liability

School nurses should contact their district legal counsel or employer's legal counsel, but school nurses are likely to be entitled to immunity for claims of loss resulting from performing COVID-19 testing under the Public Readiness and Emergency Preparedness (PREP) Act, except for acts of willful misconduct. For additional information about the PREP Act, visit: <https://sharedsystems.dhssoha.state.or.us/DHSForms/Served/1e3529.pdf>, and <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>.

Privacy

Student and staff test results, both positive and negative, shall be kept confidential. Student test results may be shared with the student and their legal guardian only. However, student and staff test results will be reported to public health, as required under ORS 433.004 and ORS 433.008. As outlined in the [Ready Schools, Safe Learners](#) guidance, schools must train staff on confidentiality requirements under FERPA, HIPAA, and local policy regarding student and staff health information, including a COVID-19 diagnosis.

Training

Abbott BinaxNOW point-of-care antigen training

The Abbott BinaxNOW test is most accurate when an individual is tested in the early stages of infection, when the amount of virus in the respiratory tract is generally highest. **Under OHA’s return-to-school CLIA waiver, the Abbott BinaxNOW test may only be used to test students or staff with symptoms consistent with COVID-19.**

The Abbott BinaxNOW test may not be used for asymptomatic screening (i.e., testing students or staff without symptoms or known exposure) in schools.

The Abbott BinaxNOW point-of-care antigen test produces a COVID-19 test result in 15 minutes. The test does not require a machine or device to operate and can be administered by any person who has completed all required training modules for the Abbott BinaxNOW point-of-care antigen test and carefully reviewed all training regarding personal protective equipment (PPE) use included in this guidance. The test requires a shallow nasal swab which **must** be self-administered under observation. **If a student or staff member is not able to self-collect the specimen under observation, the school nurse should refer the student or staff member to their healthcare provider for COVID-19 testing.**

The Abbott BinaxNOW training modules are available [here](#). The following modules must be completed by the school nurse:

- Module 1: Getting Started
- Module 2: Quality Control
- Module 3: Specimen Collection and Handling
- Module 4: Patient (Individual) Test

Modules 5 and 6 relate to the NAVICA smartphone App and are not required training. **OHA does not recommend use of the NAVICA smartphone App.**

These modules provide a detailed step-by-step guide to the test process. All four modules must be completed in their entirety prior to performing tests on individuals. We recommend that the school nurse watch each training module several times.

Further information about the proper use of the Abbott BinaxNOW test kits can be found on the package insert and [here](#). This includes detailed information regarding specimen collection, handling, transportation, and storage.

This [video](#) by Dr. Susan Coffin provides an excellent overview of the Abbott BinaxNOW testing process from start to finish, and must be reviewed by all school nurses in addition to the Abbott BinaxNOW training modules prior to performing tests.

Personal protective equipment (PPE) use

Abbott BinaxNOW specimens are collected by nasal swab. For most students and staff, these swabs can be self-administered (i.e., the person being tested can place the swab into their own nose) under observation by the testing administrator at a distance of greater than 6 feet. **Students and staff who are unable to self-collect the specimen under observation by the school nurse should be referred to their healthcare provider for COVID-19 testing.**

Personal protective equipment (PPE) refers to equipment worn to minimize exposure and protect the wearer from infection. Because the Abbott BinaxNOW swabs can be self-administered, the PPE required for testing is minimal.

PPE Components

School testing administrators should wear the following components:

1. A disposable medical-grade surgical mask (an N95 respirator may also be used)
2. Reusable eye protection (goggles or face shield)
3. Disposable gloves.

Because specimens are self-collected, a gown is not required. The single-use medical-grade mask and gloves should be discarded once testing is completed. The eye protection should be set aside for cleaning and disinfection. Discarded PPE does not have to be treated as biohazardous waste and can be disposed of into a regular garbage can.

We recommend that the following [handout](#) for putting on and taking off PPE be printed and posted in the area where PPE is stored and testing performed.

School districts will be responsible for securing PPE. The Department of Administrative Services (DAS) and ODE have published a list of all the state price agreements districts or schools can use to purchase PPE. That list is available for download [here](#).

Putting on personal protective equipment

Before collecting the specimen(s) for testing, personal protective equipment (PPE) should be put on in the following order:

1. Perform hand hygiene by washing hands with soap and water or using an alcohol-based hand sanitizer.
2. Remove cloth face mask and put on medical-grade mask.
3. Put on face shield or goggles.
4. Put on disposable gloves.

Best practice recommendations for PPE use include:

- Medical-grade mask and eye protection should cover the eyes, nose, and mouth at all times.
- Staff must perform hand hygiene before and after touching, readjusting, or taking off mask or eye protection.

Extended use of eye protection and mask

When multiple people are being tested in one time period, the same medical-grade mask and eye protection can be worn during multiple specimen collection events (e.g., in the case of group testing). This will optimize school PPE supply and minimize contact with contaminated PPE. However, gloves should be changed after each test is completed. A new pair of disposable gloves should be worn for each test performed.

Taking off personal protective equipment, hand hygiene, and disinfecting eye protection

After all specimens have been collected and all tests have been completed, PPE should be taken off in the following order:

1. Remove gloves and discard into a trash can.
2. Perform hand hygiene by washing hands with soap and water or using an alcohol-based hand sanitizer.
3. Remove face shield or goggles by carefully grabbing the strap and pulling upwards and away from the head without touching the front of the face shield or goggles.
4. Put on a new pair of disposable gloves.
5. Clean and disinfect eye protection disinfection, following manufacturer labeling directions. For more details, see below “Cleaning face shield or goggles.”
6. Remove gloves and discard into a trash can.
7. Perform hand hygiene by washing hands with soap and water or using an alcohol-based hand sanitizer.
8. Put away clean eye protection in a bag or container labeled with your name.
9. Remove medical-grade mask by carefully untying or unhooking and pulling away from the face without touching the front of the mask.
10. Perform hand hygiene by washing hands with soap and water or using an alcohol-based hand sanitizer.
11. Put on your personal non-medical face covering.

Cleaning face shield or goggles

When manufacturer instructions for cleaning and disinfection are unavailable, consider the

following steps according to the [CDC](#):

1. Cleaning: while wearing gloves, carefully wipe the inside, *followed by the outside* of the face shield or goggles using a clean cloth saturated with neutral detergent solution or cleaner wipe.
2. Disinfection: carefully wipe the *outside* of the face shield or goggles using a wipe or clean cloth saturated with EPA-registered hospital disinfectant solution. Leave wet for the amount of time specified on the disinfectant label.
3. Final wipe down: wipe the outside of face shield or goggles with clean water or alcohol to remove residue.
4. Drying: air dry or use clean absorbent towels until fully dry.
5. Remove gloves and perform hand hygiene.

Storage of face shield or goggles

After cleaning, disinfecting and drying, eye protection can be stored in a clean bag or container. Eye protection and storage bag/container should be labeled with staff name to prevent sharing and should not be stored with other belongings or other PPE.

Testing

The school nurse **must** follow the instructions provided in the Abbott BinaxNOW package insert regarding test storage, quality control, specimen collection and handling, and specimen disposal as detailed [here](#). The Abbott BinaxNOW testing instructions detailed in this section must be followed exactly to ensure an accurate result.

When to perform return-to-school testing

A school nurse may consider allowing a student or staff member who has symptoms consistent with COVID-19 to return to school grounds to provide an onsite COVID-19 test. The need for return-to-school testing may be considered on a case-by-case basis and consent from the parent and/or guardian must be on file for testing to occur. The school nurse may only consider this option under the following conditions:

1. The school nurse is actively enrolled in the OHA K-12 Diagnostic COVID-19 “Return to School” Testing Program, AND
2. The school nurse is available to support the return-to-school testing process and protocols, AND
3. The school nurse determines that return-to-school testing is warranted due to both symptoms and limited testing access, AND
4. The return-to-school testing does not pose an additional risk to the rest of the school population, e.g., testing is conducted in a designated location apart from the rest of the school population or as a drive-through or after-hours event

Test storage

Test kits (test cards and reagent) must be stored at room temperature (between 59 and 86°F).

Quality control

The Abbott BinaxNOW tests have a built-in quality control system which must be verified each time a test is run. In addition, quality control testing using a positive and negative control swab should be performed once as training, and upon receipt of each new shipment of BinaxNOW tests.

Built-in quality control

Each time an Abbott BinaxNOW test is performed, the school nurse must verify that the built-in quality controls are functional. There are two built-in quality controls.

1. Each card test has a blue line present at the control line position which should be visible when the test package is opened.
2. If this blue line is not present, the test card should be discarded.
3. During each test, the blue line should change its color to pink/purple.
4. If the blue quality control has not changed to pink/purple at the time the test result is read, the test card should be discarded and the result recorded as inconclusive.



Blue line should be present before test is performed.



Blue line will turn pink/purple during test.

Positive and negative control swabs

Each BinaxNOW test kit includes 40 tests plus a positive control swab. A blank sterile swab can be used as a negative control swab. Each of these control swabs (i.e., both a positive and negative swab) should be run once with each new shipment of test kits to confirm that the test is working as anticipated and to demonstrate school testing administrator competency. The blue control line must be present prior to performing the quality control swabs. If the blue line is not present, discard the test and contact schooltesting.covid@dhsoha.state.or.us for OHA BinaxNOW testing support. The positive control swab should result as positive. The negative control swab should result as negative. If the positive or negative control swabs do not result as anticipated, contact schooltesting.covid@dhsoha.state.or.us for OHA BinaxNOW testing support. You may also contact the Abbott BinaxNOW Technical Support Advice Line at 1-800-257-9525 between 8 a.m. and 8 p.m. EST or by emailing ts.scr@abbott.com.

Specimen collection and handling

Specimens must be collected by the person being tested, under observation by the school nurse. The person being tested should be instructed to insert the swab gently into the nostril until resistance is encountered and not more than one inch deep. The person being tested should then be instructed to rotate the swab 5 times around the outer edge of the nostril. Using the same swab, this process should be repeated in the other nostril. While many students and staff will be able to self-collect specimens using this method, not all students or staff will feel comfortable doing so. While students may be encouraged through this process, **they should never be forced or coerced**. It should be recognized that age, certain medical conditions (e.g., anxiety, ADHD) or disabilities may prevent swabs from being collected safely. If there is any doubt as to whether a specimen may be safely self-collected by an individual, the individual should be referred to their health care provider for COVID-19 testing.

Specimens should be tested as soon as possible after collection. The specimen should not be returned to its paper wrapper, but may be stored in a clean, unused plastic tube labeled with the student or staff member's name and date of birth for up to one hour. If the specimen cannot be tested within one hour of collection, it cannot be tested and should be discarded.

Return-to-school testing should be administered in a private setting such that it does not pose an additional risk to the school population. School nurses should consider drive-through or outdoor walk-up testing events, in a location that is safe and not in traffic. Specimen collection should also occur in a covered area protected from precipitation (rain, snow, sleet, etc.).

Abbott BinaxNOW test kits should not be stored in the same room as tests are performed to avoid the possibility of contamination of test materials. Surfaces of testing rooms should be regularly cleaned and disinfected, including between persons being tested.

Specimen testing

To perform the test, the following steps should be observed:

1. Open kit and lay it flat—do not use if the pouch is damaged or open
2. Verify presence of blue line at control line position
3. Hold the extraction reagent bottle $\frac{1}{2}$ inch above the top hole—do not allow the bottle to touch the test card
4. Slowly add 6 drops of reagent to the topmost hole of the swab well
5. Insert specimen swab into the bottom hole and firmly push upwards so that the swab tip is visible in the top hole
6. Rotate the swab clockwise 3 times in the reagent liquid
7. Peel off adhesive liner and close and seal the test card

The test should be read promptly at 15 minutes. A dedicated stopwatch or timer should be available for testing. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes and not before. Results should not be read after 30 minutes.

Result Interpretation

Test card window	How to interpret	
One pink/purple colored line in the top half of the window, in the Control Line position	Test is negative	
Two pink/purple colored lines in both the Control & Sample Line positions ¹	Test is positive	
If no lines are seen, or if just the sample line is seen, the test is invalid. Invalid tests should be repeated on a new test card.	Test is inconclusive	<p>Invalid Result</p>

Specimen disposal

All components of the test kit may be discarded into a trash can. Additional information about the proper disposal of medical waste exposed to COVID-19 may be found here:

<https://www.oregon.gov/deq/FilterDocs/COVID19MedicalWasteFS.pdf>

¹ Note that any visible second pink/purple line in the sample line position should be considered a positive test regardless of how faint the second pink/purple line appears.

Reporting requirements

Logging tests performed

Results of each test must be promptly logged in the Abbott BinaxNOW Testing Log which can be found [here](#). Testing logs must be kept in a secure location and may be audited by OHA.

Daily reporting of all positive and negative results through the OHA K-12 Reporting Portal

OHA requires all COVID-19 test results, both positive and negative, to be reported daily. Schools must submit all test results through the OHA K-12 Reporting Portal available at <https://epiweb.oha.state.or.us/fmi/webd/k12%20Reporting%20Portal?homeurl=https://www.oregon.gov/ode/students-and-family/healthsafety/Pages/COVID-19-Reporting.aspx>.

All positive cases should be reported immediately to the local public health authority.

Consent forms

All students must have written consent (see Appendix B) on file prior to COVID-19 testing. OHA requires written consent from a parent and/or guardian for all students under the age of 15 receiving the BinaxNOW test. Schools may choose to allow 15 – 17-year-olds to consent to receiving a test under ORS 109.640(2)(a). Staff may give verbal consent at the time of testing. Staff are not required to have a consent form on file in order to be tested for COVID-19.

Understanding test results

How to interpret negative test results

All COVID-19 tests are imperfect and false negative results may occur. A negative COVID-19 test result should never be interpreted as evidence that a student or staff member is not infected with COVID-19, especially when symptoms compatible with COVID-19 are present. Any symptomatic student who is tested (even if that test is negative) must leave school immediately and not return until allowed by the [Planning for COVID-19 Scenarios in Schools](#) toolkit. A follow-up molecular test (also known as a “COVID-19 PCR test”) is not required following a negative BinaxNOW test but may be recommended by a healthcare provider.

Students or staff with symptoms who have had close contact to a case of COVID-19 within the last 14 days and have a negative BinaxNOW test

Students or staff with symptoms compatible with COVID-19 *and* who have had close contact with a case of COVID-19 within the last 14 days may meet criteria as a “presumptive case” of COVID-19. Any student or staff with symptoms compatible with COVID-19 *and* who has had close contact with a case of COVID-19 within the last 14 days should be sent home and asked to contact their local public health authority for instructions.

Students or staff with symptoms without a known exposure to COVID-19 and have a negative BinaxNOW test

Students or staff with symptoms compatible with COVID-19 who have not had close contact with a case of COVID-19 within the last 14 days should be asked to contact their healthcare provider and isolate from others until their symptoms improve. They should be instructed to isolate at home until 24 hours after fever is resolved, without the use of fever-reducing medication, and symptoms are improving.

How to interpret positive test results

Every positive test result should be reported directly to the local public health authority immediately so that local public health can provide appropriate follow-up with the family, link the family to quarantine and isolation support and manage transmission within the school cohort. A positive COVID-19 test result means that a student or staff member is infected with COVID-19 and should follow local public health instructions regarding isolation. The typical duration of isolation is 10 days from the onset of symptoms. If a person has no symptoms, the duration of isolation is 10 days from the date of the positive test. Patients with severe illness (e.g., hospitalized patients) or severely immunocompromised patients are asked to isolate for 20 days. Ultimately, local public health will determine the appropriate period of isolation. All students and staff who test positive for COVID-19 should contact their healthcare provider for additional recommendations.

Appendices

[Appendix A. COVID-19 return-to-school testing K-12 registration form](#)

[Appendix B. COVID-19 minor testing consent form](#)

[Appendix C. Understanding your positive COVID-19 result](#)

[Appendix D. Understanding your negative COVID-19 result](#)

[Appendix E. COVID-19 general testing consent form](#)

You can get this document in other languages, large print, braille, or a format you prefer. Contact the Coronavirus Response and Recovery Unit (CRRU) at 503-979-3377 or email CRRU@dhsosha.state.or.us. We accept all relay calls or you can dial 711.