

## COVID-19 Community Testing Project

### Testing Guidance

Version 4 | Updated October 21, 2021

#### Background

North Sound ACH is working with community-based organizations throughout the region to expand access to testing among essential community workers and communities disproportionately impacted by COVID-19. The COVID-19 Community Testing Project is framed by targeted universalism, while aligning with the [Centers for Disease Control and Prevention](#), [Washington State Department of Health](#), [Health Commons Project](#) and [Medical Teams International](#) testing strategies, North Sound ACH is prioritizing:

- Community-based organizations who serve Latinx, BIPOC, farmworkers, and/or low-income families
- Early learning and childcare providers, especially those serving children 11 and under
- Long-term care facilities, including skilled nursing facilities, assisted living facilities, adult family homes, supported living agencies, residential habilitation centers, and intermediate care facilities for individuals living with intellectual disabilities
- Supportive housing organizations and facilities

The tests are provided by the Washington State Department of Health. The U.S. Food and Drug Administration (FDA) has granted emergency use authorization (EUA) for antigen tests that can identify SARS-CoV-2. The rapid BinaxNOW antigen test turnaround time (15 minutes) facilitates earlier isolation of infectious persons and is an important tool in reducing community transmission. Contact North Sound ACH for more information either via email [team@northsoundach.org](mailto:team@northsoundach.org) or by phone at (888) 438-7330.

#### Requirements & Expectations

- Organizations must report all test results (**positive and negative**) to the state Department of Health via SimpleReport, unless other arrangements have been discussed and agreed upon with North Sound ACH.
- Organizations requesting BinaxNOW tests from North Sound ACH will need to have a CLIA waiver or agree to operate under the North Sound ACH's CLIA waiver as a satellite test site.
- Technical assistance is available to organizations interested in becoming their own medical test site and obtaining the required CLIA waiver. North Sound ACH will reimburse organizations for the license application fee (currently \$190) if they choose that approach.
- Organizations operating under the North Sound ACH CLIA waiver as a testing site, thereby operating under the state order for testing, are only permitted to use the tests for operational screening purposes among staff and clients. The tests are not intended to be used only for

COVID-19 unvaccinated individuals, travel related purposes, nor as a tool to bypass any existing state vaccine mandates. Failure to comply could jeopardize future testing support.

- Organizations are encouraged to develop an agency testing plan. Resources will be made available by North Sound ACH to assist organizations in developing those plans.

## **Testing Checklist for BinaxNOW COVID-19 Antigen Test**

### **Step 1: Determine your CLIA waiver approach**

#### **What is a CLIA waiver?**

A CLIA waiver (Clinical Laboratory Improvement Amendment) is a certification that allows a facility to legally examine a person through waived tests for the purpose of diagnosis, treatment, or prevention of disease. Waived tests are simple laboratory examinations and procedures, like a rapid antigen test, that have an insignificant risk of an erroneous result. The antigen tests provided by North Sound ACH and DOH require that any facility administering these tests obtain a CLIA waiver in order to legally perform the test. If you perform a test and do not have a CLIA certificate, you will be in violation of federal law.

#### **Do I need my own CLIA waiver to provide COVID-19 Antigen Tests?**

All rapid antigen testing must be performed under a CLIA waiver. However, you have options:

1. You can operate under North Sound ACH's CLIA waiver as an ACH Testing Site
2. You can apply for your own CLIA waiver number

If you plan to use your test kits to bypass existing state vaccine mandates, or for travel testing requirements, you must apply for and use your own CLIA waiver.

### **Step 2: Apply for your CLIA waiver number (if necessary based on Step 1)**

#### **How to check if my organization has a CLIA waiver or not?**

To check if your organization has a CLIA waiver:

1. Go to DOH's [Credential Search for Health Facilities](#)
2. Enter the name of your agency into the "Facility Name" field and click search

If you see the name of your agency, it means your district has a CLIA waiver already. You will still need to confirm that your CLIA waiver covers COVID-19 testing, as CLIA waivers can cover a wide variety of waived tests. The CLIA waiver should name the specific types of tests being administered by your agency.

If your agency has a CLIA waiver in place for COVID-19 testing, you do not need to apply for another waiver.

If your agency has a CLIA waiver for different kinds of testing, you can amend the CLIA waiver to include COVID-19 rapid antigen testing using DOH's [Test Menu Change Form](#).

### **What is the CLIA waiver application process?**

1. Print, fill out, and sign Washington's [Medical Test Site License/CLIA Certificate of Waiver test site application packet](#)
2. Submit a copy of the application via email to [lqa@doh.wa.gov](mailto:lqa@doh.wa.gov) and [hsqafc@doh.wa.gov](mailto:hsqafc@doh.wa.gov)
3. To complete the application process, send the hard copy ink signed original application with payment to the address on the top left-hand corner of the application form. Include all 7 pages of the application, even pages left blank. With the completed application, also include the CLIA waiver fee of \$190 (check or money order).

CLIA application support can be directed to North Sound ACH at [team@northsoundach.org](mailto:team@northsoundach.org).

### **What is the cost?**

CLIA waiver certificate cost is \$190. The fee received will cover the time period from the application date until the license expires in two years.

If you are a non-profit agency or government entity, your CLIA number will be applied at the organization level, and can cover the numerous locations your agency may operate at (e.g. multiple stations within a fire department). Just list these locations as additional testing sites on your application. There is no additional fee.

North Sound ACH will reimburse your agency for the \$190 application fee.

## **Step 3: Request BinaxNOW COVID-19 AG Card Tests**

**My organization does not have a CLIA number, plans to use North Sound ACH's CLIA number and will follow North Sound ACH's testing policy expectations and requirements:**  
Requests your tests from [North Sound ACH's Resource Request Form](#).

**My organization does not have a CLIA number and plans to apply for our own CLIA number and design our own testing program:**

First request your tests from [North Sound ACH's Resource Request Form](#).

Once you have submitted your CLIA application, you can order test kits from WADOH here:

<https://app.smartsheet.com/b/publish?EQBCT=7fd800a357f24fb490226c26b6d313a3>

**My organization has a CLIA number and is approved to perform COVID-19 tests and design our own testing program:**

Requests your tests from [North Sound ACH's Resource Request Form](#).

You can also request test kits from WADOH here:

<https://app.smartsheet.com/b/publish?EQBCT=7fd800a357f24fb490226c26b6d313a3>

## **Step 4: Identify Test Site Supervisors & Watch BinaxNOW Training Videos**

### **What is a test site supervisor?**

BinaxNOW is a rapid antigen test that can be self-administered while under observation by a trained test supervisor/observer. This trained test supervisor needs to be 18 years or older, but does not need to be a healthcare professional. The key responsibilities of the test supervisor are to provide the test kit to the individual, observe the sample collection, run the test, and report the test results.

### **How are test site supervisors trained?**

1. Supervisors must watch training modules 1-4 on the [Abbott Lab's training website](#)
2. Supervisors can also review the [BinaxNOW Instructions for Use](#) document as an additional training resource
3. Supervisors should keep documentation of training completion. Your organization should consider how to keep and maintain these records.

### **What additional training resources are available?**

The CDC provides an overview of testing for COVID-19 and Interim Guidance for Antigen Testing for COVID-19.

[Overview of Testing for SARS-CoV-2 \(COVID-19\)](#)

[Interim Guidance for Antigen Testing for SARS-CoV-2](#)

## **Step 5: Perform Quality Control Procedure on BinaxNOW Test Kits**

### **What should I do with test kits once they arrive?**

When you receive your test kits, the test site supervisor should perform a quality control test on one of the test cards. This ensures the test kit is working as anticipated and to demonstrate testing administrator competency before officially launching. If you have

more than one test site supervisor, we recommend coming together as a group to practice and perform quality control.

You can find quality control procedure instructions on the [Abbott Lab's training website](#) (module 2).

**How should I store my BinaxNOW test kits?**

The BinaxNOW test kits should be stored between 35.6 and 86 degrees Fahrenheit. Ensure all test components are at room temperature before use.

**When will my test kits expire?**

Abbott extended the expiration dates for nearly all tests, please review their [BinaxNOW COVID-19 Ag Card Product Expiry Update](#) for the new expiration dates. These are the test kit lot numbers with new expiration dates that North Sound ACH has distributed:

Lot Number	Original Expiry	12 Month Expiry
126138	March 10, 2021	September 12, 2021
129360	April 11, 2021	October 11, 2021
130445	April 21, 2021	October 21, 2021
139575	June 3, 2021	December 3, 2021
137514	June 11, 2021	December 8, 2021
138917	June 18, 2021	December 18, 2021

**Step 6: Personal Protective Equipment – Order or Organize what you need**

**What level of PPE should our test site supervisors wear?**

Whether testing is done indoors or outside, test administrators should wear proper PPE for testing, typically including a facemask, face shield, gown, and gloves.

**What level of PPE should our test takers wear?**

The person being tested should be wearing a mask prior to testing. They can remove it fully during specimen collection or you can ask them to lower it below their nose and continue to cover their mouth. The BinaxNOW test is a self-administered shallow nasal test. Although it is very easy to perform, sometimes it may tickle the test-taker who may sneeze.

If conducting the test outside, such as through a drive-up option, you can add an extra layer of protection by asking the driver to only roll their window down a couple of inches while you give them instructions and the swab to collect their sample. Do not pass them the test kit card as that must remain flat during processing.

### **How do we order more PPE?**

Organizations can request PPE from [North Sound ACH's Resource Request Form](#) and we will do our best to assist you.

## **Step 7: Develop a Testing/Screening Plan for your organization**

### **How often should we test our clients/employees/etc.?**

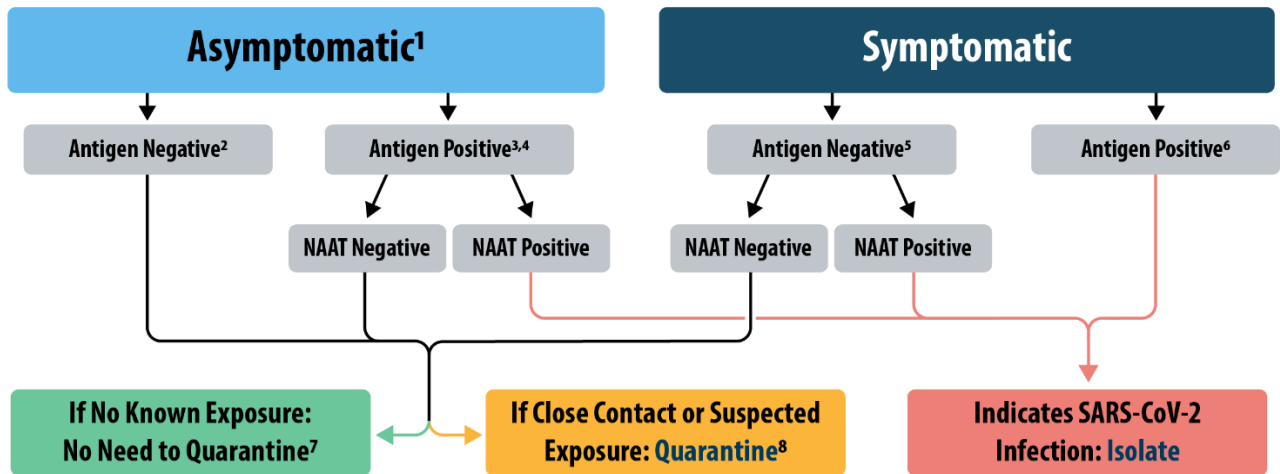
There are various recommendations which can differ based on community transmission rates, your organization and the level of exposure or contact you may have to COVID-19. Use these resources to help guide your decision-making:

- [Guidance for Non-Health Care Businesses and Organizations during COVID-19](#)
- [Guidance for Daily COVID-19 Symptom Screening of Staff and Guests](#)
- [Antigen Testing in Non-Healthcare Settings: A tool to prevent the spread of COVID-19](#)
- [COVID-19 Critical Infrastructure Sector Response Planning](#)
- [Implementing Safety Practices for Critical Infrastructure Workers Who May Have Had Exposure to a Person with Suspected or Confirmed COVID-19](#)
- [Testing Strategy for Coronavirus \(COVID-19\) in High-Density Critical Infrastructure Workplaces after a COVID-19 Case Is Identified](#)
- [Long-Term Care Facility Testing for Staff and Residents](#)
- [Testing Guidelines for Nursing Homes](#)

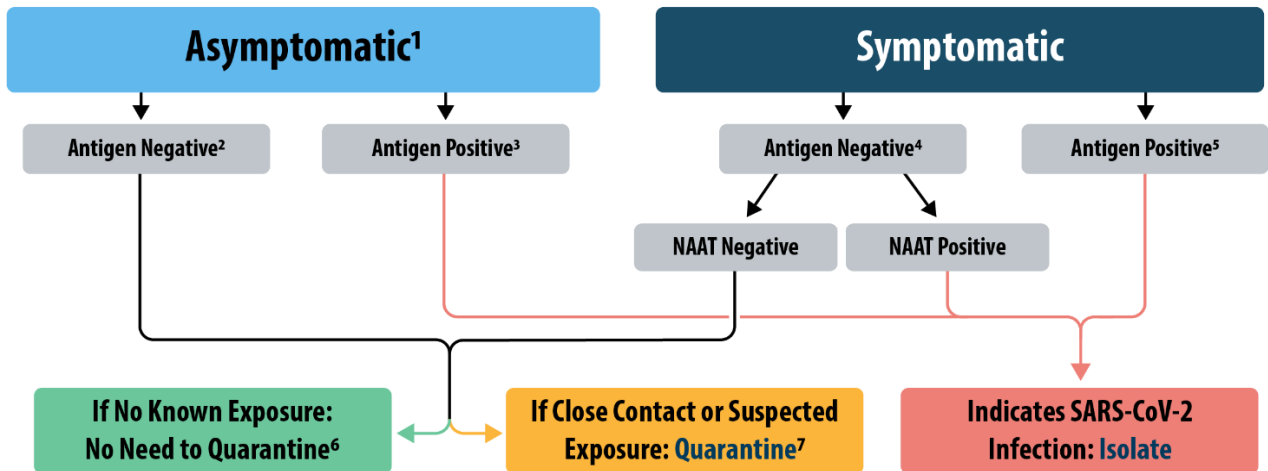
### **What testing procedures are recommended for rapid antigen tests like BinaxNOW?**

There are two CDC recommended [antigen testing algorithms](#) to accommodate two broad categories of use for antigen tests (rapid test) and how to determine when confirmatory testing (NAAT/PCR) is recommended.

**Option 1: Antigen Test Algorithm for Congregate Living Settings**



**Option 2: Antigen Test Algorithm for Community Settings**



**What is a confirmatory test and why is it needed on occasion?**

Antigen tests like BinaxNOW are highly accurate among symptomatic individuals. However, there is always a slight chance that the test could return a false positive or negative. If someone is symptomatic and their test result is negative, public health officials recommend referring that person for a NAAT/PCR test. NAAT/PCR tests are often processed in a lab setting and are highly reliable.

**I'd like more support developing a testing plan, who can I contact?**

You can request 1:1 testing support from North Sound ACH by emailing [team@northsoundach.org](mailto:team@northsoundach.org).

**Step 8: Launch Testing****When do we need to begin testing?**

We recommend starting testing as soon as you have your testing strategy developed. You may consider doing a “dry run” with your testing planning implementation team to confirm you have the right workflow and tools in place.

**Should I collect consent for testing?**

Yes, it is a best practice to collect signed, verbal, or informed consent prior to observing a test. Templates are included in the appendix of this toolkit.

**Where should I administer BinaxNOW tests?**

Ideally, testing should take place outside, prior to entering a shared, indoor space. The test card must be flat when performing testing and should not be performed with the test card in any other position.

**What supplies should I have on hand in order to test?**

- Consent forms
- PPE for test site supervisors
- Timer (avoid using personal cell phone to avoid contamination)
- Flat surface
- Pens / permanent marker
- A result reporting tracking sheet
- Hand sanitizer
- Disinfectant
- Biohazard bags



**How should I associate a test card with a particular test taker while I wait the required 15 minutes for results?**

We recommend using a marker to write the individual's initials and DOB on the outside of the test card along with the time the results should be read.

**How should I administer the test?**

Administer test using BinaxNOW COVID-19 rapid antigen tests according to [Abbott BinaxNow COVID-19 Ag Card Instructions](#) & [CDC CDC BinaxNow Testing Infographic](#).

**How should I interpret and confirm the results?**

Use the [Abbott BinaxNow COVID-19 Ag Card Instructions](#) & [CDC BinaxNow Testing Infographic](#) to correctly result the test kit card.

**Can we dispose of waste from the BinaxNOW test kits in the regular trash?**

Unless your local health jurisdiction requires otherwise, BinaxNOW test kit trash can be bagged up and put in your normal trash; you are no longer required to dispose of it as biohazardous waste.

**Step 9: Report Results to Public Health Officials & the Test Taker**

**9A: Reporting to Public Health Officials:**

**Who do I need to report results too?**

All rapid antigen test results (positive and negative) conducted by CLIA-certified sites are required to be reported to a local public health department, the Washington Department of Health (WADOH), or North Sound ACH.

- [Reporting Guidance on COVID-19 Test Results for Point-of-Care Testing Facilities](#)
- [Local Health Department Disease Reporting Line & Fax numbers](#)
- Instructions on how to securely send results via [SimpleReport](#) will be provided to test site supervisors.
- SimpleReport training from CDC and USDS  
<https://www.youtube.com/playlist?list=PL3U3nqqPGhab0sys3ombZmwOpIRYIBOBF>

**When do I need to report results?**

All test results must be reported within 24 hours.

**How do I report results to WADOH?**

North Sound ACH is using SimpleReport, which reports results securely to the appropriate public health jurisdiction and the state Department of Health. Site supervisors will be sent email instructions on how to set up their SimpleReport account, and how to report results. Enrolling in SimpleReport is required among organizations operating under the North Sound ACH CLIA waiver.

## **9B: Reporting to Test Takers:**

### **What is the best way to return results to the test taker?**

If your client is not immediately available to review the results with you, you should contact them to report their test results. Results can be sent via text message through SimpleReport if desired.

### **What recommendations should I share with test positive?**

Recommendations will vary based on vaccination status, presence of symptoms, and working environment. Suggested resources to support individuals who need to isolate due to testing positive include:

- WADOH [What to do if you have confirmed or suspected COVID-19](#).
- CDC [Spanish](#) and [English](#) “When you are sick”
- WADOH [Spanish](#) and [English](#) “I tested Positive: What will they ask me?”
- CDC [Guidance for Businesses and Employers Responding to Coronavirus Disease 2019 \(COVID-19\)](#)

You can also leverage this script from Health Commons Project, a DOH-funded COVID-19 testing partner based in Washington state:

### **Positive or Negative: Stay home!**

#### **If You Test Positive – This means you have COVID-19:**

- Avoid people who have not tested positive for COVID-19.
- You do NOT need to avoid the people in your house who have already been diagnosed with COVID-19.
- Stay in isolation, following this guidance:
  - If you have no symptoms, stay in isolation for:
    - At least 10 days after you tested.
    - **AND** limit contact with others, wear a mask or face covering, and continue to stay 6 feet away from others for another 3 days.
  - If you have or develop symptoms, stay in isolation for:
    - At least 10 days after symptoms first appeared

- **AND** wait until you have not had a fever for at least 3 days (72 hours) without the use of medicine that reduces fever, such as Tylenol or ibuprofen
- **AND** your cough and breathing are improved.

### **Negative test**

- If you test negative for COVID-19, and you have symptoms of COVID-19, you should get a follow up molecular test, also known as a PCR test.
- If you test negative for COVID-19 and do not have symptoms, you probably were not infected at the time of your test. That does not mean you will not get sick. It is possible that you were very early in your infection when you were tested. You could also be exposed after your test.
- Please continue to practice social distancing, and wear a mask in public.

## **Appendix I: Forms**

**Example 1 – Consent Form**

**Example 2 – Consent Form**

## Example 1

I, \_\_\_\_\_ (print patient name), consent to receive COVID-19 testing from the North Sound ACH testing team during the COVID-19 outbreak.

Since COVID-19 is a new and highly contagious disease, it is considered a “reportable illness.” I am aware that due to the highly contagious and novel nature of COVID-19, the results of my COVID-19 test will be shared with the local health department. I am aware that if I test positive for infection, I will be contacted by the health department who will conduct contact tracing and may need to disclose any recent close contacts who may be at risk for infection. I understand that these efforts are necessary to contain and reduce the spread of disease in my community.

I understand that based on what is currently known about COVID-19, the virus is thought to spread mostly from person-to-person via respiratory droplets among close contacts. I understand that close contact can occur from being within approximately 6 feet of someone with COVID-19 for a prolonged period of time, or by having direct contact with infectious secretions from someone with COVID-19.

I understand that carriers of COVID-19 may not show symptoms, but may still be highly contagious.

Patient/Guardian Signature:

Date:

## Example 2

### **Acknowledgement**

By receiving this test, I agree to the following:

1. I understand that my COVID-19 testing will be conducted through an Abbott Laboratories BinaxNOW antigen test provided by the Washington State Department of Health.
2. I understand the entity performing the test is not acting as my medical provider. Testing does not replace treatment by a medical provider. I assume complete and full responsibility to take appropriate action with regards to the test results, including seeking medical advice, care, and treatment from a medical provider or other health care entity if I have questions or concerns, if the above-named person develops symptoms of COVID-19, or if the above-named person's condition worsens.
3. I understand that, as with any medical test, there is the potential for a false positive or false negative COVID-19 test result.
4. I understand it is my responsibility to inform my health care provider of a positive test result, and that a copy will not be sent to my health care provider for me.
5. I understand that the antigen test result will be available in 15-30 minutes.
6. I understand and acknowledge that a positive antigen test result is an indication I need to self-isolate to avoid infecting others.
7. I have been informed of the test purpose, procedures, and potential risks and benefits. I will have the opportunity to ask questions before proceeding with a COVID-19 test.
8. I understand that to ensure public health and safety and to control the spread of COVID-19, the test results may be shared without my individual authorization.
9. I understand that the test results will be disclosed to the appropriate public health authorities and as otherwise permitted or required by law.
10. I understand that I may withdraw my consent to the testing at any time before it is performed.

Patient/Guardian Signature:

Date:

## Appendix 2: Additional Resources

### Additional Resources

1. CDC Interim Guidance for Antigen Testing for SARS-CoV-2.  
<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html#general-guidance>
2. CDC Testing Overview.  
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>
3. Antigen Testing in Non-Healthcare Settings: A tool to prevent the spread of COVID-19.  
<https://www.cdc.gov/coronavirus/2019-ncov/community/workplaces-businesses/antigen-testing.html>
4. CDC BinaxNOW Testing Infographic.  
<https://www.cdc.gov/csels/dls/preparedlabs/documents/Lessons-Learned-Antigen-Test-BinaxNOW-Ag-Card.pdf>
5. Abbott BinaxNOW COVID-19 Ag Card Training Materials (Complete Modules 1-4).  
<https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html>
6. Abbott BinaxNOW COVID-19 Ag Card Instructions.  
<https://www.fda.gov/media/141570/download>
7. WADOH Reporting Guidance on COVID-19 Test Results for Point-of-Care Testing Facilities.  
<https://www.doh.wa.gov/Emergencies/COVID19/HealthcareProviders/ReportingTestResults/ReportingCOVID19TestResultsforPointofCareTestingFacilities>
8. COVID-19 Test Results for Point-of-Care Testing Facilities Form.  
<https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/POC-COVIDReportingForm.pdf>
9. Washington State Standing Order for COVID-19 Screening in Certain Congregate Facilities and Agencies.  
[https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/LTCF\\_Standing\\_Order.pdf](https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/LTCF_Standing_Order.pdf)
10. Washington State COVID-19 Antigen Letter to Partners.  
<https://www.hca.wa.gov/assets/program/covid-19-antigen-letter-to-partners.pdf>
11. BinaxNOW: What You Need to Know (Step-by-Step video)  
<https://www.abbott.com/corpnewsroom/diagnostics-testing/BinaxNOW-what-you-need-to-know.html>
12. Schulte PA, Piacentino JD, Weissman DN, et al. Proposed framework for considering sars-cov-2 antigen testing of unexposed asymptomatic workers in selected workplaces. *Journal of Occupational & Environmental Medicine*. 2021 May 19.  
doi:10.1097/jom.0000000000002269