Point-of-care antigen testing for homeless service providers

Point-of-Care COVID-19 Testing: Homeless Service Sites

November 18, 2021

Public Health
Seattle & King County

What is point-of-care testing for COVID-19?

Point-of-care tests:
- diagnostic tests performed at or near the place where a specimen is collected
- provide results within minutes rather than hours
- may be NAAT, antigen, or antibody tests

Can be utilized on site without the need for healthcare staff.

Facilities interested in performing point-of-care testing should be aware of:
- **regulatory requirements**
- **reporting requirements**
- **staffing impact**

https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html

PHSKC point-of-care testing roll out

- Checklist/guidance document on our website
- BinaxNOW Professional testing kits (40 tests per box)
- MAT "elbow" support for sites implementing testing

Behavioral Health	+
General	+
Graphics	+
Consumer materials	+
Homeless Service Providers	+
Isolation and quarantine	+
Medical/Clinical	+
Outreach Providers	+
Sanitation	+
Testing	—

- **Point-of-Care COVID-19 Testing Checklist for Homeless Service Providers**

Vaccine	+
Ventilation	+

Safer Cleaning, Sanitizing and Disinfecting

- 繁體字 (Chinese, Trad.)
- Русский (Russian)
- af Soomaali (Somali)
- Español (Spanish)
- Tiếng Việt (Vietnamese)

Sanitation & Hygiene Guide for homeless services providers

- 繁體字 (Chinese, Trad.)
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City of Seattle hygiene facilities

https://kingcounty.gov/depts/health/covid-19/providers/homeless.aspx

BinaxNOW Professional
(40 tests per box)

BinaxNOW Over-the-Counter
(2 tests per box)

Requirements to become a point-of-care testing site:

Regulatory

Reporting

Testing logistics & operations

Overview Checklist for Point-of-Care Testing

Step 1: Apply for a CLIA Certificate of Waiver
- ☐ Fill out a Certificate of Waiver MTS/CLIA license application
- ☐ Mail application and fee to DOH

Step 2: Develop a reporting process
- ☐ Contact DOH to set up a reporting mechanism for test results
- ☐ Assign the reporting process to a designated staff member

Step 3: Prepare for testing
- ☐ Order test kits from Public Health – Seattle & King County
- ☐ Order and stock site with PPE and testing supplies
- ☐ Choose and prepare a space for testing at your site

Step 4: Train staff
- ☐ Ensure staff complete required trainings
- ☐ Ensure staff are trained in PPE donning and doffing

Step 5: Test & report
- ☐ Collect patient information
- ☐ Ensure staff wear appropriate PPE
- ☐ Supervise self-swab sample collection
- ☐ Perform tests and interpret test results
- ☐ Communicate test results to individuals who were tested
- ☐ Discard test materials, doff PPE, and disinfect testing area
- ☐ Make referrals to PHSKC Isolation & Quarantine, if needed
- ☐ Report test results to DOH and PHSKC within 24 hours

Regulatory requirements

for point-of-care testing

What is a CLIA waiver?

CLIA = Clinical Laboratory Improvement Amendments

  System by which CMS regulates all clinical laboratory testing performed on human beings

CLIA waiver = permission from the State of Washington to perform waived tests

Waived tests = test systems cleared by the FDA for home use

When do I need a CLIA waiver?

- The facility or staff provide or recommend self-testing to the person because they are symptomatic.

- The facility or staff provide guidance on the frequency of testing or require testing as a condition of employment or participation in the organization or an activity.

- The facility or staff provide guidance to the individual about administering and performing the test, interpretation of the test, or what to do based on the test results.

- The facility or staff take on the role of reporting the test results to the individual.

If your organization directs self-testing in any of the ways listed above, you are required to have a CLIA Waiver and you are required to report test results to the Washington State DOH.

Can homeless service organizations use point-of-care tests for screening testing without a CLIA waiver?

No.

BinaxNOW
Professional
(40 tests per box)

BinaxNOW Over-the-Counter
(2 tests per box)

Fee
☐ July 1, 2021 – June 30, 2023. ...... $190.00

Date Stamp Here

Certificate of Waiver Medical Test Site License Application

This is for:	⌨ New	⌨ Change of Ownership	⌨ Change of License Type

Check One

⌨ Association	⌨ Limited Partnership	⌨ Partnership
⌨ Corporation	⌨ Municipality (City)	⌨ Sole Proprietor
⌨ Limited Liability Company	⌨ Municipality (County)	⌨ State Government Agency
⌨ Limited Liability Partnership	⌨ Non-Profit Corporation	⌨ Trust

Section 1. Demographic Information

UBI # 1234-1234	Federal Tax ID (FEIN) # 1234-1234		
Legal Owner/Operator Entity Name Public Health Testing Corporation			
Mailing Address 123 Main St			
City Seattle	State WA	Zip Code 98103	County King
Phone (enter 10 digit #) 206-123-1234		Fax (enter 10 digit #)	
Email Address Testing@mailbox.com		Web Address	

If I apply for a CLIA waiver, when can I start testing?

After you drop your application & application fee in the mail, and set up a reporting mechanism with DOH, you can start testing.

You don't need to wait for your application to be returned to you.

Do I need a medical provider on staff to apply for a CLIA waiver?

No.

Facilities do **not** need an Ordering Provider or medical director to apply for a CLIA waiver and do on site testing.

Sites will need to identify a program manager or lead who will agree to administering tests appropriately and reporting results to the DOH.

This person does not need to be a medical professional for point-of-care antigen testing.

Do I need medical staff to administer tests?

No.

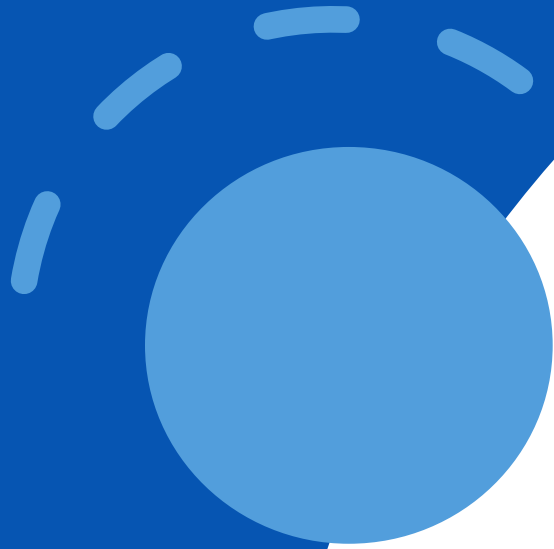Medical staff are **not** necessary to support BinaxNOW on-site testing.

What if my organization has multiple physical locations? How many CLIA waivers do I need?

Governmental agencies and nonprofits can use one CLIA waiver for multiple physical sites.

List all locations where you'll be performing point-of-care testing.

What do I need once I apply?

- Only use test kits that are waived by FDA (includes all point-of-care tests for SARS-CoV-2 that are EUA-approved)

- Follow the manufacturer's instructions for use exactly

- Train staff on use of test kit

- **Report positive and negative test results to DOH**

Reporting requirements

for point-of-care testing

Do I need to report the results of these rapid point-of-care tests?

Yes.

Point of care testing facilities **must** report COVID-19 test results because of Washington State Law. COVID-19 is a reportable disease.

The laboratory/testing site that performs the test is responsible for reporting the test result.

https://www.doh.wa.gov/Portals/1/Documents/Pubs/346124.pdf

Where do I need to report cases?
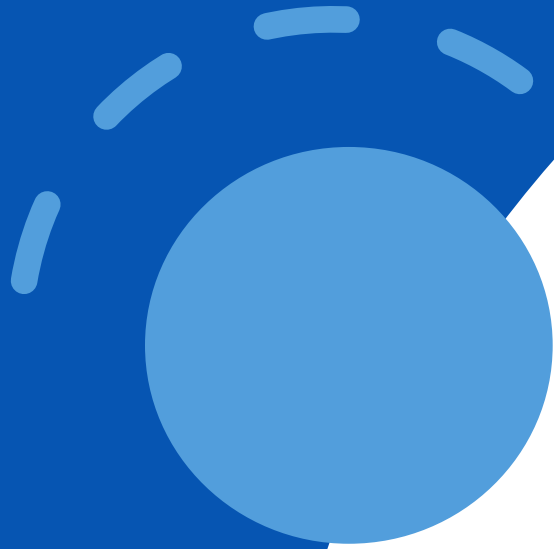
NEW

Washington State DOH

- Use reporting mechanism set up between site & DOH

Same existing process

PHSKC

- COVID-19 Intake Survey (online)
- Call a disease investigator
- King County COVID-19 Call Center: 206-477-3977

Testing logistics

for point-of-care testing

How many tests should my site order?

As a prevention strategy, screening testing of clients, staff and visitors **1-2 times per week** can improve the detection of COVID-19 and decrease the risk of large outbreaks.

Box 1. Formula for estimating the number of tests to order from Public Health

(number of staff + number of clients) x 2 tests per week x 4 weeks per month = # of tests

Example:

(20 staff + 50 residents) x 2 test per week x 4 weeks per month = 560 tests per month

Adjust orders based on testing interest and need over time. Additional orders may be submitted based on the site's needs.

Testing orders, continued

How do I order tests?

1. Reach out to a PHSKC disease investigator.

2. Submit a [COVID-19 Intake Survey](#) on our website.

3. Call the King County COVID-19 Call Center at 206-477-3977.

How quickly will they arrive?

Orders are sent to the warehouse on Tuesdays and Fridays.
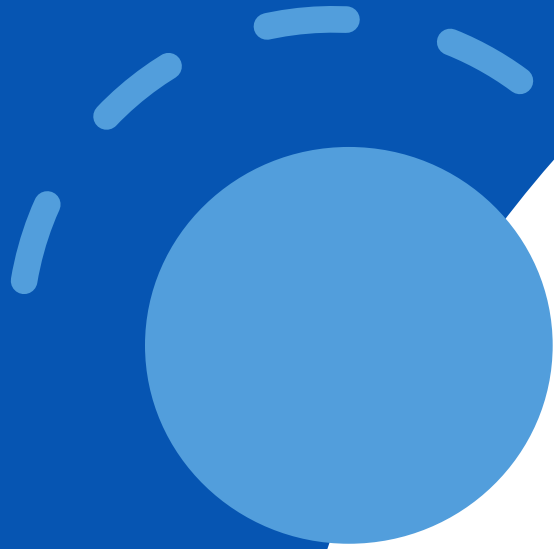
Orders submitted by Tuesday will arrive by Friday.

Orders submitted by Friday will arrive by the following Tuesday.

Before submitting the warehouse order:

Disease investigators will confirm the following with your facility:

1. The site has a CLIA waiver

2. The site has agreed to report all test results to WA DOH

3. The site is **providing services or shelter**.

   These tests are not intended for administrative offices or workplace staff-testing only. They are intended to prevent future outbreaks and address ongoing outbreaks at congregate settings.

Testing operations

for point-of-care testing

Do I need medical staff to administer tests?

No.

Medical staff are **not** necessary to support BinaxNOW on-site testing.

What PPE should my staff wear when assisting with testing?

Public Health recommends that patients <u>self-swab</u> with antigen tests whenever possible, to reduce transmission and exposure risk.

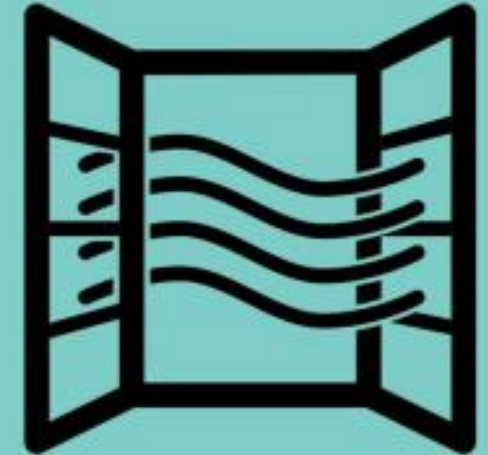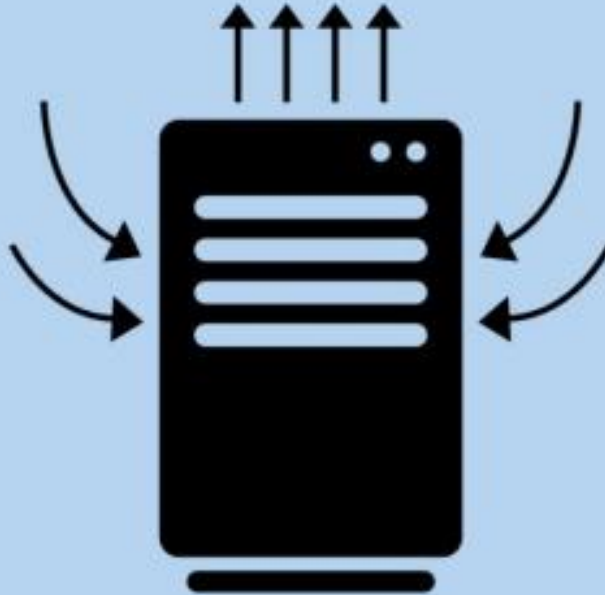## PPE for staff <u>collecting specimens</u>:

- Fit tested NIOSH-approved N95

- Eye protection

- Gloves

- Gowns

- Hand sanitizer

PPE for staff <u>handling, but not collecting specimens</u>

- A well-fitted mask that covers mouth and nose completely

- Eye protection

- Gloves

- Hand sanitizer

https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html

Where should I test at my facility?

← 6 feet of distance at all times →

When should I perform testing at my facility?

Diagnostic testing

- intended to identify **current infection** when someone has **signs** or **symptoms** consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to someone with COVID-19.

Screening testing

- intended to identify infected people who are **asymptomatic** and do not have known, suspected, or reported exposure to COVID-19. Screening helps to identify unknown cases so that measures can be taken to prevent further transmission.

Anticipating making referrals to the King County Isolation & Quarantine Facility?

King County COVID-19 Call Center
206-477-3977
Hours: 8AM -10PM

For referrals, the earlier in the day, the better!

https://www.cdc.gov/coronavirus/2019-ncov/community/homeless-shelters/testing.html

Testing should not form a barrier to services.

Testing results should not be a barrier to accessing homeless services.
SARS-CoV-2 testing should not be a pre-requisite for entrance to homeless service sites.

-CDC Interim Guidance for SARS-CoV-2 Testing in Homeless Shelters and Encampments

Do not require a negative COVID-19 viral test or proof of COVID-19 vaccination for entry to a homeless services site unless otherwise directed by local or state health authorities.

-CDC Interim Guidance for Homeless Service Providers to Plan and Respond to Coronavirus Disease 2019 (COVID-19)

Training staff

PPE donning and doffing

Test kit components & directions

How to request additional support

Need support with:

- Guidance?

- Implementation?

- Have more questions specific to your site or organization?

- An on-site demonstration?

Email:

- covid19CST@kingcounty.gov

- MAT.lead@kingcounty.gov

Submit form:

- COVID-19 Intake Form (online)

Questions?

Point-of-Care COVID-19 Testing Checklist for Homeless Service Providers

A Guide from Public Health – Seattle & King County

Updated November 10, 2021