



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

A Guide from Public Health – Seattle & King County

Updated November 10, 2021

COVID-19 testing is an important part of a comprehensive approach to reducing COVID-19 transmission and preventing outbreaks at homeless service sites. Point-of-care testing for COVID-19 involves using tests that provide results within minutes of the test being administered and can be utilized on-site without the need for healthcare staff. Facilities interested in administering point-of-care testing for COVID-19 should be aware of and prepare for the requirements of a successful on-site testing program, including meeting certain regulatory and reporting requirements. This document offers guidance on how homeless service sites can prepare for and implement rapid point-of-care COVID-19 testing at their sites.

For questions regarding implementing testing, ordering test kits, or additional COVID-19 outbreak support, contact the Public Health – Seattle & King County (PHSKC) COVID-19 Outbreak Investigations team at covid19CST@kingcounty.gov.

In addition to phone or email support, on-site support and technical assistance may be available. Contact MAT.lead@kingcounty.gov to schedule on-site training or support during a testing event.

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Additional Guidance:

Washington State Department of Health:

[Reporting COVID-19 Test Results for Point-of-Care Testing Facilities](#)

[Washington State Medical Test Site Certificate of Waiver requirements, and SARS-CoV-2 \(COVID-19\) testing and test result reporting guidance document](#) (June 2021)

Centers for Disease Control and Prevention:

[Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing](#)

CDC [Ready? Set? Test! Booklet](#) for best practices in waived testing

[CDC Self-Assessment Checklist for Good Testing Practices](#)

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

Step by Step 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

- Download and complete the [Certificate of Waiver MTS/CLIA license application \(PDF\)](#) located on the Washington State Department of Health (DOH) [Laboratory Quality of Assurance](#) web page. A sample license application can be found in **Appendix B: Sample Certificate of Waiver Application**.
- Identify a program manager or lead who will agree to the test result reporting requirements. Of note, this person is labeled “lab director” on the application but does not need to have any medical credentials. Note their name and email address on the application.
- Provide your organization’s information on the form, including legal business name, owner, address, and license number if applicable. See additional information on the application process in Appendix A: FAQs.

Mail application and fee to DOH

- Via mail, submit your completed waiver application and fee in the form of check or money order made out to the Washington State Department of Health. The mailing address is: Department of Health Revenue Section P.O. Box 1099 Olympia, WA 98507-1099 (also located in the application).
- You do not need to wait for your application to be processed prior to beginning testing during the public health emergency; after you place the application in the mail with the fee, **and you have set up a reporting mechanism**, (see Step 2), you may begin testing.

Step 2: Develop a reporting process

Contact DOH to set up a reporting mechanism for test results

- Develop a reporting process in consultation with the Washington State Department of Health (DOH). Point-of-care testing facilities must report COVID-19 test results to the WA DOH, per Washington State Law. Follow the reporting instructions located on the [Reporting COVID-19 Test Results for Point-of-Care Testing Facilities](#) web page. See additional information on reporting in **Appendix A: FAQs**.

Assign the reporting process to a designated staff member

- Determine who will be responsible for reporting test results to the Washington State Department of Health (DOH). Positive test results must be reported to WA DOH within 24 hours.

Step 3: Prepare for testing

☐ Order test kits from Public Health – Seattle & King County

- ☐ Determine how many rapid point-of-care antigen test kits your organization needs. If you are ordering from Public Health, we encourage homeless service providers to order a 30-day supply of test kits.
- ☐ Consider offering screening testing to everyone at your facility one to two times a week. 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 larger outbreaks. Testing interest may vary from week to week.
- ☐ Submit an order to Public Health – Seattle & King County by requesting test kits directly from a Disease Investigator, by emailing covid19CST@kingcounty.gov, or by calling the King County COVID Call Center at 206-477-3977. Orders are sent to the PHSKC warehouse on Tuesdays and Fridays. The PHSKC warehouse will deliver antigen tests directly to the ordering facility in 2-3 business days.

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.

☐ Order and stock site with PPE and testing supplies

- ☐ Determine what personal protective equipment (PPE) is required for your staff that will be supporting point-of-care testing and ensure adequate supply. PPE requirements vary based on the staff's role in specimen collection and whether they will be at least 6 feet away from the person being tested. More information can be found on the CDC's [Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing](#) web page under the section "Specimen Collection & Handling of Point-of-Care and Rapid Tests".

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

- ❑ PPE for staff **collecting specimens** (e.g., swabbing patients) or working within 6 feet of individuals suspected to be infected with SARS-CoV-2 (the virus that causes COVID-19) should include:

- A fit-tested [NIOSH-approved N95 equivalent or higher-level respirator](#)
- Eye protection (goggles, safety glasses with side protection, or face shield)
- Gloves (to be changed immediately after collecting, handling, and processing a new specimen)
- Hand sanitizer (for use in between specimen collection)
- Gowns (can utilize one gown per testing event unless it becomes visibly soiled)

Note: N95 respirators require specialized fit-testing for proper use. **If your staff is not fit-tested, your staff should encourage individuals to self-swab.** When ordering gloves, keep in mind that a new pair of gloves should be used each time a specimen is collected from a new individual, and hand hygiene should be performed each time gloves are changed. Gloves are not recommended to be worn by the individual doing self-swabbing.

- ❑ PPE for staff **handling specimens but not directly involved in the collection** (e.g., when patients self-swab) and not working within 6 feet of individuals:

- A well-fitted mask that covers the mouth and nose completely
- Eye protection (goggles, safety glasses, or face shield)
- Gloves (to be changed immediately after handling and processing a new specimen)
- Hand sanitizer

- ❑ Determine what hand hygiene supplies are needed and ensure adequate supply. Staff should wash their hands or use alcohol-based hand sanitizer (at least 70%) every time gloves are donned, and after gloves are removed. Gloves should be replaced with each new specimen collection.

- ❑ Determine what cleaning and disinfecting materials are needed and ensure adequate supply. [Disinfect](#) surfaces within 6 feet of the specimen collection and handling area before, during, and after testing and at these times:

- Before testing begins each day
- Between each specimen collection
- At least hourly during testing
- When visibly soiled
- In the event of a specimen spill or splash
- At the end of every testing day

❑ **Choose and prepare a space for testing at your site**

- ❑ Pick a testing location in a low-traffic area with good ventilation, opening doors and windows when possible.

- Ideally select a location that allows for individuals to face open windows/doors while swabbing and face away from other individuals and area where test cards will be run.
- Ensure at least 6 feet of distance can be maintained between individuals in the swabbing area and the area where test cards will be run and interpreted.
- Identify a waiting area when waiting for the tests to result that has good ventilation and supports 6 feet of distance between individuals. If an adequately sized waiting area is not available, encourage individuals to return for results at a future specified time.

Step 4: Train staff

Ensure staff complete required trainings

- Ensure staff are familiar with the rapid point-of-care antigen kit components and review and understand the directions included in the test box. If using BinaxNOW COVID-19 Ag Cards, review [training videos for the BinaxNOW COVID-19 Ag Card](#) with staff. These short videos explain how to use the test kits step-by-step.
- Ensure staff are trained in how to handle specimen, how to run the tests, and how to interpret test results.
- Have staff demonstrate their understanding of the testing process.
- Consider maintaining a log of which staff are trained at your organization and the date they completed training.

Ensure staff are trained in PPE donning and doffing

- Train staff in proper donning (putting on) and doffing (taking off) of appropriate PPE (see PPE guidance based on staff role in Step 3). CDC donning and doffing guidance can be [found here](#).
- Post PPE donning and doffing instructions in the testing area for staff to review.

Step 5: Test & report

Collect patient information

- Obtain patient consent prior to testing. **Testing 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 or be used to deny services.**
- For everyone who tests, document the necessary information that will be used for reporting (see Step 2). This includes name, date of birth, race, and ethnicity. These elements are very important for case investigation and surveillance work. Individuals do not need to show identification to test.

- ❑ **Ensure staff are wearing appropriate PPE**
 - ❑ Allocate the appropriate amount of PPE for staff to use while overseeing testing, and monitor for proper donning, doffing, and use.
- ❑ **Supervise self-swab sample collection**
 - ❑ Follow the instructions in the testing kit for proper swabbing technique. For staff protection, have individuals self-swab if staff are not fit-tested to N95s.
- ❑ **Perform tests and interpret test results**
 - ❑ Following the instructions in the antigen testing kit for performing tests and interpreting test results.
- ❑ **Communicate test results to individuals who were tested**
 - ❑ Communicate test results to individuals who test and maintain confidentiality. Tests results are protected health information (PHI) and should not be disclosed to other people at the facility.
 - ❑ More guidance on whether someone needs to isolate or quarantine and for how long can be found on our [PHSKC COVID-19 quarantine and isolation](#) guidance web page.
- ❑ **Discard test materials, doff PPE, and disinfect testing area**
 - ❑ Discard all materials including test kits and PPE. Regular trash disposal is sufficient. Remove any patient identifying information (e.g., name, date of birth, bed number) from the test kit materials prior to discarding.
 - ❑ [Disinfect](#) surfaces within 6 feet of the specimen collection and handling area after testing.
- ❑ **Make referrals to PHSKC Isolation & Quarantine if needed**
 - ❑ If isolation of positive individuals is not possible at your site, referrals can be made to PHSKC Isolation & Quarantine Facilities.
 - ❑ PHSKC Isolation & Quarantine referrals may be made between the hours of 8 AM and 10 PM, 365 days a year by calling (206) 477-3977.
- ❑ **Report test results to DOH and PHSKC within 24 hours**
 - ❑ Report required test results to the WA DOH using your established reporting process (see Step 2). Positive results must be reported within 24 hours.
 - ❑ Report positive cases to Public Health – Seattle & King County using the [COVID-19 Intake Survey](#) located on our [PHSKC COVID-19 Homelessness Response](#) web page.

Appendix A: Frequently Asked Questions

CLIA WAIVERS

What is a CLIA Certificate of Waiver (CLIA Waiver)?

All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease, are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To conduct point-of-care COVID-19 screening or diagnostic testing, your facility must have a CLIA Certificate of Waiver (CLIA Waiver) and meet regulatory requirements. This will allow your facility to perform “waived tests”, which include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria.

When does my organization need a CLIA waiver?

If your organization directs testing at your facility in any of the ways listed below, your organization is required to have a [CLIA Certificate of 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.

Over-the-counter COVID-19 tests are considered point-of-care tests when they are done at the recommendation of a CLIA-waived facility. If your organization directs self-testing in any of the ways listed above, you are required to have a CLIA waiver and required to report those results to the Washington State Department of Health.

Do I need a medical director or medical staff to apply for a CLIA waiver?

No. Your organization does not need a medical director to apply for a CLIA waiver. You'll need to identify a program manager or lead who will agree to the test result reporting requirements. Of note, this person is labeled “lab director” on the application but does not need to have any medical credentials. Staff supporting on-site testing do not need to have medical credentials.

How many licenses does my organization need?

If your organization is a governmental agency or a non-profit, you can use one CLIA waiver for multiple physical sites. All physical sites under a single waiver must be part of the same parent organization.

How do I apply for the waiver?

Download and complete the [Certificate of Waiver MTS/CLIA license application \(PDF\)](#) located on the WA Department of Health [Laboratory Quality of Assurance](#) web page. A sample waiver application can be found in **Appendix B: Sample Waiver Application**.

Is there a fee to apply for the waiver? How long will my waiver last?

Yes. The fee is \$190 for a two-year waiver, and your will waiver will be valid from July 1, 2021 to June 30, 2023. You will need to renew after this time. Financial assistance may be available through Public Health – Seattle & King County. If the cost of a waiver is a barrier for your facility, please contact covid19CST@kingcounty.gov.

How soon after applying for the waiver can I begin administering tests at my organization?

Testing may begin as soon as the [Certificate of Waiver MTS/CLIA license application \(PDF\)](#) has been mailed with fee payment and you have set up a test result reporting mechanism with the WA DOH. You do not need to wait for your application to be processed prior to beginning testing during the public health emergency. You will get an email with your Medical Test Site and CLIA number in approximately 6-8 weeks.

REPORTING

Where do I need to report COVID-19 testing results?

There are two organizations that you need to report COVID-19 testing results to:

1. Report required test results to WA DOH using your established reporting process (see Step 2, or find more information on the WA DOH [Reporting COVID-19 Test Results for Point-of-Care Testing Facilities](#) page). Facilities directing self-testing for COVID-19 with a CLIA Certificate of Waiver must report all COVID-19 test results to the Washington State Department of Health.
2. Report positive cases to Public Health – Seattle & King County using the [COVID-19 Intake Survey](#) located on our [PHSKC COVID-19 Homelessness Response](#) web page.

Why do I need to report COVID-19 testing results to the Washington State Department of Health?

Washington Administrative Code [WAC 246-101](#) requires that all facilities conducting point-of-care or rapid screening tests for COVID-19 report **all** COVID-19 results (positive, negative, indeterminate, etc.) to WA DOH. Additionally, the [Washington State Board of Health's emergency rule, WAC 256-101-017](#), requires additional data elements that must be reported along with new federal requirements from the US Department of Health & Human Services.

To conduct testing at your organization, you'll need to develop a written process for reporting SARS-CoV-2 test results to the Washington Department of Health.

What other information will I need to report when reporting test results?

You will need to submit information on your facility, in addition to patient information, including but not limited to the patient's name, date of birth, race, and ethnicity.

I still have questions about point-of-care testing reporting. Who can I contact?

Email the WA State DOH Surveillance Section at doh-surv@doh.wa.gov, and DOH will be in touch with you.

Why do I need to report COVID-19 positive cases to Public Health – Seattle & King County?

Employers in King County in non-healthcare settings **must notify** Public Health – Seattle & King County within 24 hours if they suspect COVID-19 is spreading in their workplace.

How can Public Health- Seattle & King County support your site?

Public Health- Seattle & King County is here to support your organization as you manage COVID-19 activity at your homeless service site. After you report cases using our online form or by calling the COVID-19 call center, a disease investigator will call your organization to support and facilitate infection control and prevention guidance, site visit consultation, ventilation improvement, additional mobile testing needs, and other COVID-19 response assistance.

Appendix B: Sample Waiver Application



Certificate of Waiver Medical Test Site (MTS) Application Packet

Contents:

1. 505-038Certificate of Waiver Medical Test Site Application Index Page 1 Page
2. 505-039....Certificate of Waiver Medical Test Site
Application Instructions Checklist..... 2 Pages
3. 505-026Certificate of Waiver Medical Test Site Application 7 Pages

Important Information:

Laboratories licensed by the Washington Medical Test Site (MTS) licensure program are exempt from the Clinical Laboratory Improvement Amendments of 1988 (CLIA). You do not need to apply to the Centers for Medicare and Medicaid Services (CMS) for a CLIA number. Your MTS license will contain both your MTS license number and your CLIA number.

In order to process your request:

Return Completed Application (original copy) and fee in the form of check or money order (made out to Department of Health) to:

Department of
Health Revenue
Section
P.O. Box 1099
Olympia, WA 98507-1099

Certificate of Waiver Application Instructions Checklist

When your application for a Medical Test Site is received by the Department of Health, you will be notified in writing of any outstanding documentation needed to complete the application process.

All information should be printed clearly in blue or black ink. It is your responsibility to submit the required forms.



Indicate type of application:

- New
- Change of ownership
- Change of license type.



Check One:

Please check your legal owner/operator business structure type according to your Washington State Master Business License.



Section 1. Demographic Information:

Uniform Business Identifier Number (UBI #): Enter your Washington State UBI #. All Washington State businesses must have UBI #s. City, county, and state government departments also have UBI #s.

Federal ID Number (FEIN #): Enter your Federal ID Number, if the business has been issued one. If the facility FEIN # is different than the Legal Owner FEIN, enter this number on page two of the application under Facility Specific Federal Tax ID (FEIN) #.

Legal Owner/Operator Entity Name: Enter the owner's name as it appears on the UBI/Master Business License.

Legal Owner Mailing Address: Enter the owner's complete mailing address.

Phone and Fax: Enter the owner's phone and fax numbers.

Email and Web Address: Enter the owner's email and facility web addresses, if applicable.

Facility Name: Enter the lab's name as advertised on signs and web site.

Facility Specific Federal Tax ID (FEIN) #. Enter if different from the Owner FEIN listed on page one of the application.

Physical Address: Enter the lab's physical street location including city, state, zip code, and county.

Phone and Fax Numbers: Enter the lab's phone and fax number.

Mailing Address: Enter the lab's mailing address, if different than physical address.



Section 2. Facility Specific Information:

Site Type: Please check one applicable site type.

Hours of Laboratory Testing: List the days and hours of testing for this site.

Additional locations under this license: Attach a list of names, addresses and phone numbers for additional locations, if applicable, and test(s) performed at each site.



Section 3. Key Individuals:

Lab Director:

1. Name
2. Washington State professional license number, if applicable.
3. Email address

Lab Contact: Enter the lab contact's:

1. Name
2. Washington State professional license number, if applicable.
3. Email address

The lab contact will receive all information that we mail to your medical test site.



Section 4. Additional Information—Waived

Tests: Waived Tests:

Indicate the test manufacturer(s) and test system(s) on the lines provided. Be as specific as possible. Please verify the waived status of your test system at <https://www.accessdata.fda.gov>.

If you perform any tests other than the waived tests listed, do not complete this application. See the LQA website: <http://www.doh.wa.gov/lqa.htm> to help you determine your correct license category or call the LQA office at 253-395-6746.



Section 5. Other Licensure, Certification, or Registration Information:

Legal Owner: List the names, titles, addresses, and phone numbers of the corporate officers, LLC members or manager, partners, etc. Attach additional pages, if necessary.

Change of Ownership Information: If applicable, list the previous legal owner name, previous name of facility, previous MTS license number, effective date of ownership change and physical address.



Signature:

Signature of legal owner or authorized

representative Date signed

Print name of legal owner or authorized

representative Print title of legal owner or authorized

representative

Your new MTS license will expire on June 30, 2023. You will receive a renewal notice for this license approximately 60 days before the expiration date.

Please contact our Kent office at 253-395-6746 if you have any questions or need assistance in completing the application form. Additional information is available on our website at: <http://www.doh.wa.gov/lqa.htm>.



Revenue Section
 P.O. Box 1099
 Olympia, WA 98507-1099
 253-395-6746
<http://www.doh.wa.gov/LQA.htm>

Date
Stamp
Here

Fee
<input type="checkbox"/> July 1, 2021 – June 30, 2023. \$190.00

Revenue: 0420030000

Certificate of Waiver Medical Test Site License Application

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

Check One

- | | | |
|--|---|--|
| <input type="checkbox"/> Association | <input type="checkbox"/> Limited Partnership | <input type="checkbox"/> Partnership |
| <input type="checkbox"/> Corporation | <input type="checkbox"/> Municipality (City) | <input type="checkbox"/> Sole Proprietor |
| <input type="checkbox"/> Limited Liability Company | <input type="checkbox"/> Municipality (County) | <input type="checkbox"/> State Government Agency |
| <input type="checkbox"/> Limited Liability Partnership | <input type="checkbox"/> Non-Profit Corporation | <input type="checkbox"/> 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	
Facility/Agency Name (Business name as advertised on signs or website) Public Health Testing Corporation			
Facility Specific Federal Tax ID (if different than one entered above.)			
Physical Address 123 Main St			
City Seattle	State WA	Zip Code 98103	County King
Facility Phone (enter 10 digit #) 206-123-1234		Facility Fax (enter 10 digit #)	
Mailing Address (If different than physical address)			
City	State	Zip Code	County
For Office Use Only			
Medical Test Site # _____		CLIA # _____	

Section 2. Facility Specific Information

Site Type (check one only)

- | | | |
|--|--|--|
| <input type="checkbox"/> 1 Ambulance | <input type="checkbox"/> 12 Home Health Agency | <input type="checkbox"/> 23 Prison |
| <input type="checkbox"/> 2 Ambulatory Surgery Center | <input type="checkbox"/> 13 Hospice | <input type="checkbox"/> 24 Public Health Lab |
| <input type="checkbox"/> 3 Ancillary Test Site | <input type="checkbox"/> 14 Hospital | <input type="checkbox"/> 25 Rural Health Clinic |
| <input type="checkbox"/> 4 Assisted Living Facility | <input type="checkbox"/> 15 Independent Laboratory | <input type="checkbox"/> 26 Student Health Service |
| <input type="checkbox"/> 5 Blood Banks | <input type="checkbox"/> 16 Industrial | <input type="checkbox"/> 27 Skilled Nursing Facility |
| <input type="checkbox"/> 6 Community Clinic | <input type="checkbox"/> 17 Insurance | <input type="checkbox"/> 28 Tissue Bank/Repository |
| <input type="checkbox"/> 7 Comprehensive Outpatient Rehab | <input type="checkbox"/> 18 ICFMR | <input type="checkbox"/> 29 Other |
| <input type="checkbox"/> 8 End Stage Renal Disease Dialysis | <input type="checkbox"/> 19 Mobile Lab | <input type="checkbox"/> 30 Drug Treatment |
| <input type="checkbox"/> 9 Federally Qualified Health Center | <input type="checkbox"/> 20 Pharmacy | <input type="checkbox"/> 31 Clinic |
| <input type="checkbox"/> 10 Health Fair | <input type="checkbox"/> 21 Physician Office | |
| <input type="checkbox"/> 11 Health Main. Organization | <input checked="" type="checkbox"/> 22 Other Practitioner <u>ex. Homeless service provider, school, jails, etc</u> | |

Hours of Laboratory Testing

List days and times during which **laboratory testing** is performed. If testing 24/7 check here

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
From:		0800	0800	0800	0800	0800	
To:		1700	1700	1700	1700	1700	

Additional locations under this license

If you qualify as a not-for-profit laboratory or state or local government laboratory that performs limited public health testing (total of 15 or less waived or moderate complexity tests) at different locations, you may apply for one license.

This license will have additional locations under one license and the paragraph above applies: Yes No

If yes: Attach a list of names, addresses and phone numbers for each site that will be included under one license, and a list of tests performed at each site. If any of the sites already have a MTS license, include the MTS and CLIA numbers of the sites that will be consolidated under this license. If you are not a state or local government laboratory, you **must** include a copy of your federal 501(c)(3) determination letter to be licensed in this manner.

Section 3. Key Individuals

Lab Director (include MD, PhD, BS, etc.)

Name - Program Manager/Testing Manager (does not have to be a medical professional for PoC Antigen testing, must be able to discuss testing operation with DOH)

Washington State Professional License (if applicable)

Email Address

Lab Contact Person

Name

Washington State Professional License (if applicable)

Email Address

Note: If your test kit doesn't appear on the FDA-approved waived test list, do **not** complete this application. See the LQA website: <http://www.doh.wa.gov/lqa.htm> to help you determine your correct license category or call the LQA office at 253-395-6746.

Section 4. Additional Information—Waived Tests

Waived Tests: Indicate the test manufacturer(s) and test system(s) on the lines provided. Be as specific as possible and verify the waived status of your test system on the [FDA/CLIA Test Complexity Database](#). e.g. (Rapid Strep, Acme Home Glucose Meter)

Adenovirus _____

Aerobic/Anaerobic Organisms - Vaginal _____

Aerobic/Anaerobic/Viral Panel - Respiratory _____

Alanine Aminotransferase (ALT) _____

Albumin _____

Alkaline Phosphatase (ALP) _____

Amylase _____

Aspartate Aminotransferase (AST) _____

B-Type Natriuretic Peptide (BNP) _____

Bilirubin, Total _____

Bladder Tumor Associated Antigen _____

BUN (Blood Urea Nitrogen) _____

Calcium _____

Calcium - Ionized _____

Carbon Dioxide (CO₂) _____

Catalase, urine _____

Chloride _____

Cholesterol _____

Complete Blood Count (CBC) _____

Creatine Kinase (CK) _____

Creatinine _____

Waived Tests (continued)

Drugs of Abuse _____

Electrolyte Panel _____

Erythrocyte sedimentation rate (ESR) _____

Esterone-3-Glucuronide _____

Ethanol _____

Follicle Stimulating Hormone (FSH) _____

Fructosamine _____

Gamma Glutamyl Transferase (GGT) _____

Glucose _____

Glycosylated HGB _____

HDL Cholesterol _____

Helicobacter pylori _____

Hematocrit _____

Hemoglobin _____

Hepatitis C Virus Antibody _____

HIV-1 _____

Influenza _____

Ketones (Blood) _____

Lactic Acid _____

LDL Cholesterol _____

Lead _____

Lithium _____

Waived Tests (continued)

Lyme Disease _____

Lutenizing Hormone (also see ovulation tests) _____

Matrix metalloproteinases-9 (MMP-9) _____

Microalbumin _____

Mononucleosis _____

Nicotine (or its metabolites) _____

Occult Blood _____

Osmolarity _____

Osteoporosis _____

Ovulation Tests _____

PH _____

Phosphorus _____

Platelet Aggregation _____

Potassium _____

Pregnancy Test (Urine) _____

Protine _____

Protein, Total _____

RSV (Respiratory Syncytial Virus Direct Antigen) _____

SARS-CoV-2 (COVID-19) ex. BinaxNOW, B.D. Veritor. List all COVID-19 tests that you use. You'll need to file an amendment to your testing menu if you begin using a test not listed on your initial CLIA waiver.

Semen _____

Sodium _____

Strep Antigen Test _____

Waived Tests (continued)

Syphilis _____

Trichomonas _____

Triglycerides _____

TSH _____

Uric Acid _____

Urinalysis _____

Other Tests Not Listed Above _____

Section 5. Other Licensure, Certification or Registration Information

Legal Owner Information—attach additional sheets as needed

List names, addresses, phone numbers, and titles of corporate officers, partners, members, managers, etc.

Name	Address	Phone #	Title
John Smith	Chinook Building, Seattle WA	206-111-1234	Director

Change of Ownership Information

Previous Name of Legal Owner

Previous Name of Facility

Previous MTS License #

Effective Date of Ownership Change

Physical Address

City

State

Zip Code

Signature

I certify that I have received, read, understood, and agree to comply with state law and rule regulating this licensing category. I also certify that the information herein submitted is true to the best of my knowledge and belief.

Signature of Owner/Authorized Representative of Medical Test Site Date

Print Name Print Title