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

(\text{number of staff} + \text{number of clients}) \times 2 \text{ tests per week} \times 4 \text{ weeks per month} = \# \text{ of tests}

\text{Example:}

(20 \text{ staff} + 50 \text{ residents}) \times 2 \text{ test per week} \times 4 \text{ weeks per month} = 560 \text{ 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.
Certificate of Waiver Medical Test Site (MTS) Application Packet

Contents:
1. 505-038 ....Certificate 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. 505-026 ....Certificate 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.
# Certificate of Waiver Medical Test Site License Application

**This is for:**
- ☐ New
- ☐ Change of Ownership
- ☐ Change of License Type

### Check One

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

## Section 1. Demographic Information

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<th>Federal Tax ID (FEIN) #</th>
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**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**

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**For Office Use Only**

Medical Test Site #

CLIA #
Section 2. Facility Specific Information

Site Type (check one only)

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

Hours of Laboratory Testing

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

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<thead>
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<th>From</th>
<th>To</th>
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<tr>
<td>Saturday</td>
<td>0800</td>
<td>1700</td>
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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)

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<tr>
<th>Test Description</th>
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<tr>
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<tr>
<td>Aerobic/Agaerobic/Viral Panel - Respiratory</td>
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<td>Albumin</td>
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<td>Alkaline Phosphatase (ALP)</td>
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<td>Erythrocyte sedimentation rate (ESR)</td>
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<tr>
<td>Esterone-3-Glucuronide</td>
</tr>
<tr>
<td>Ethanol</td>
</tr>
<tr>
<td>Follicle Stimulating Hormone (FSH)</td>
</tr>
<tr>
<td>Fructosamine</td>
</tr>
<tr>
<td>Gamma Glutamyl Transferase (GGT)</td>
</tr>
<tr>
<td>Glucose</td>
</tr>
<tr>
<td>Glycosylated HGB</td>
</tr>
<tr>
<td>HDL Cholesterol</td>
</tr>
<tr>
<td>Helicobacter pylori</td>
</tr>
<tr>
<td>Hematocrit</td>
</tr>
<tr>
<td>Hemoglobin</td>
</tr>
<tr>
<td>Hepatitis C Virus Antibody</td>
</tr>
<tr>
<td>HIV-1</td>
</tr>
<tr>
<td>Influenza</td>
</tr>
<tr>
<td>Ketones (Blood)</td>
</tr>
<tr>
<td>Lactic Acid</td>
</tr>
<tr>
<td>LDL Cholesterol</td>
</tr>
<tr>
<td>Lead</td>
</tr>
<tr>
<td>Lithium</td>
</tr>
</tbody>
</table>
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)

Protime

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
<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syphilis</td>
<td></td>
</tr>
<tr>
<td>Trichomonas</td>
<td></td>
</tr>
<tr>
<td>Triglycerides</td>
<td></td>
</tr>
<tr>
<td>TSH</td>
<td></td>
</tr>
<tr>
<td>Uric Acid</td>
<td></td>
</tr>
<tr>
<td>Urinalysis</td>
<td></td>
</tr>
<tr>
<td>Other Tests Not Listed Above</td>
<td></td>
</tr>
</tbody>
</table>
### Legal Owner Information

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

### Change of Ownership Information

<table>
<thead>
<tr>
<th>Previous Name of Legal Owner</th>
<th>Previous Name of Facility</th>
<th>Previous MTS License #</th>
<th>Effective Date of Ownership Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

### Physical Address

<table>
<thead>
<tr>
<th>City</th>
<th>State</th>
<th>Zip Code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 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: [Signature]  Date: [Date]

Print Name: [Print Name]  Print Title: [Print Title]