



## Waived Applications for Medical Test Sites in Washington



Elizabeth Parent, MLS(ASCP)CG  
Medical Test Site Survey and Investigation Manager

# Topics covered in this presentation

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- What is required
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- How to get started
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- What do I do after the application is submitted?
- Test menu changes – adding testing to an existing license
- Reporting rules
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- “Ready, Set, Test!” CDC Resource
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# What is required

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For a Waived Medical Test Site, there are three requirements:

1. That the Medical Test Site is licensed to perform testing and only uses test kits that are deemed as waived by the FDA
2. That the Medical Test Site follows the test kit/manufacturers instructions for use (IFU's) exactly
3. That the Medical Test Site reports positive and negative Covid-19 test results to the State and/or Local Health Jurisdiction where the patient resides

# Where to find the application? Quick Tip: Google “WA LQA”

## Lab Quality Assurance – Tools and Information

The screenshot shows the top portion of the Washington State Department of Health website. On the left is the logo with the text "Washington State Department of Health". On the right are links for "Home", "Newsroom", "Publications", and "About Us". Below these are buttons for "Topics A-Z" and "Español", and a search bar with the text "ENHANCED BY Google". A navigation menu below the search bar includes: "You and Your Family", "Community and Environment", "Licenses, Permits and Certificates" (which is highlighted), "Data and Statistical Reports", "Emergencies", and "For Public Health and Healthcare Providers". A light blue banner below the menu contains the text: "Visit our [COVID-19 page](#) for the latest updates, [vaccine information](#), [testing locations](#) and [data dashboard](#)."

🏠 [Licenses, Permits and Certificates](#) > [Facilities - New, Renew or Update](#) > Laboratory Quality Assurance

Laboratory Quality Assurance
Contact Us
Forms
Frequently Asked Questions +
Laws
Licensing +
Medical Test Site Surveys +
Mission

### Laboratory Quality Assurance

Welcome to the Office of Laboratory Quality Assurance (LQA) webpage. Here you'll find information regarding the licensing of Medical Test Sites — sites that perform clinical laboratory testing for the purpose of diagnosis and treatment.

#### Tools and Information

[Application](#) | [Fees](#) | [Forms - For license updates](#) | [Frequently Asked Questions \(FAQs\)](#) | [Information on survey types](#) | [Newsletters](#) | [Program updates](#)

#### We can help you:

[Contact us](#) | [File a complaint](#) | [Verify an existing Medical Test Site license](#)

#### Current Topics

- [Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests](#)

How to get started: First, ensure testing is waived. Next, complete and submit the hard copy of the application with fee payment to the address on the upper left side of the form.

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## Laboratory Quality Assurance

### Applications

#### License Types, Requirements, and Applications

The type of testing performed determines the MTS/CLIA license category. Select from the following four options:

**Please note:** All applications require an original ink signature to be processed.

#### Waived (Certificate of Waiver)

Only tests approved as waived by the [Food and Drug Administration \(FDA\)](#) can be performed under this category of license.

If your test kit doesn't appear on the FDA-approved waived test list, you **DO NOT** qualify for this license type.

See the categorized or accredited license information below.

- Complete the [Certificate of Waiver MTS/CLIA license application \(PDF\)](#).
- Review the [CDC Ready? Set? Test! Booklet](#) for best practices in waived testing.
- [Good Laboratory Practices with Waived Test Systems \(PPT\)](#) - self-study PowerPoint presentation
- Contact the Laboratory Quality Assurance (LQA) office at 253-395-6746 if you need help determining what classification of testing you perform.

# Application

## **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:** Enter the lab director's:

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>.

## After Application is Submitted

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- Site may begin Covid-19 testing after the application has been mailed with fee payment, you do not need your CLIA or Medical Test Site license number to start testing during the Public Health Emergency
- You will get an email with your Medical Test Site and CLIA Number in approximately 6 to 8 weeks
- We will reach out if we need further information



# Adding testing to an existing license

- Medical Test Sites must notify us within 30 days of any test menu changes using a test menu change form.
- Submit the test menu change form to our credentialing department at HSQA Facilities Credentialing [hsqafc@doh.wa.gov](mailto:hsqafc@doh.wa.gov)
- The Test Menu Change Form can be found by Googling “WA LQA Test Menu Change” or at: <https://www.doh.wa.gov/Portals/1/Documents/Pubs/505088.pdf>
- Questions can be sent to [LQA@doh.wa.gov](mailto:LQA@doh.wa.gov)



## Test Menu Change Form

### License type change:

You must complete a new application form if the new or deleted tests result in a change of license type. If the change does not result in a change to your license type, then email, mail, or fax this form to the address above.

### Laboratory director change:

If the change in test menu results in a change of director, you must complete the [Credential Status Change Form](#).

Your information		
MTS Name		
Effective date of change		
MTS license #	Clinical Laboratory Improvement Amendments (CLIA) #	
List tests added to your test menu (use additional pages if needed)	Waived? (Y/N)	Estimated annual test volume
List tests deleted from your test menu (use additional pages if needed)	Waived? (Y/N)	Estimated annual test volume
List existing tests for which test volume has changed	Waived? (Y/N)	Estimated annual test volume

D0H 505-088 October 2020

# Emergency Rule

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## Addition of WAC 246-338-026(7) – Notification Requirements

During the public health emergency, as defined in 42 C.F.R. 400.200, each medical test site that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 must report SARS-CoV-2 test results to the HHS in such form and manner, and at such timing and frequency, as the department may prescribe. For the purposes of this subsection, a "SARS-CoV-2 test" means any test that is intended to detect SARS-CoV-2 or diagnose a possible case of COVID-19.

This applies to all Medical Test Site certificate types.

# Emergency Rule continued

## Changes to WAC 246-338-020, Table 020-1 – Licensure

LICENSE TYPE	REQUIREMENTS	INSPECTIONS	
		TYPE	FREQUENCY
<b>Certificate of Waiver*</b>	<ul style="list-style-type: none"> <li>Restrict testing to tests classified as waived.</li> <li>Follow manufacturers' instructions for performing the test.</li> <li>Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC <a href="#">246-338-022</a> Initial Application for Medical Test Site License; WAC <a href="#">246-338-024</a> License Renewal/Reapplication Process; WAC <a href="#">246-338-026</a> Notification Requirements; WAC <a href="#">246-338-028</a> On-site Inspections.</li> </ul>	<ul style="list-style-type: none"> <li>Complaint</li> <li>Technical Assistance</li> <li>As required to assess compliance with WAC <a href="#">246-338-026(7)</a></li> </ul>	<ul style="list-style-type: none"> <li>When indicated</li> </ul>
<ul style="list-style-type: none"> <li>There are additional rule and inspection requirements for testing under Provider Performed Microscopy Procedures (PPMP), Categorized and Accredited licenses please review <a href="#">WAC 246-338-020 in Table 020-1</a>.</li> </ul>			

In order to be equivalent with the new CMS standards, the Medical Test Site program will conduct a 5 percent sampling of Certificate of Waiver and PPMP licenses that perform SARS-CoV-2 (COVID-19) testing to verify compliance with the new reporting rules.

## Other Resources

Ready? Set? Test! Resource for waived testing published by the CDC

Find it online by Googling “ready set test” or at:

<https://www.cdc.gov/clia/docs/waived-tests/ready-set-test-booklet.pdf>

Contains information on good laboratory practice, logs and charts you may find useful



Center for Surveillance, Epidemiology, and Laboratory Services  
Division of Laboratory Systems



## How to contact us with questions:

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- For FAQ's, Applications, and information, find us on the web: Google "LQA WA" or visit <https://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/LaboratoryQualityAssurance>
- To receive the fastest response to questions, please reach out to [LQA@doh.wa.gov](mailto:LQA@doh.wa.gov) We are currently working with high volumes of inquiries

Questions?

Send us an email



To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email [civil.rights@doh.wa.gov](mailto:civil.rights@doh.wa.gov).