Welcome!
The webinar will begin at 2 p.m.

Transforming Lives

Medical Test Site Waiver Regulatory Requirements

Aging and Long-Term Support Administration

Residential Care Services

Washington State Department of Health

April 14, 2022

April 18, 2022

Washington State Department of Social & Health Services
Transforming lives

Introductions

Presenters- Washington State Department of Health:

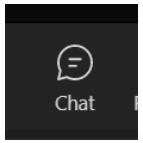
Liz Parent, Health Systems Quality Assurance

Jennifer Valverde and Rebecca Sutherland, Public Health Outbreak Coordination, Informatics, and Surveillance

Facilitator: Colleen Jensen, Residential Care Services

Information About Today's Presentation

- Informational webinar for long-term care providers and regulatory staff
- Not intended for the media
- Large number of participants- attendees will be muted
- Please submit your comments/questions in the Chat Pane. At the end of each presentation we will respond to as many as time will allow



Information About Today's Presentation

- No confidential information presented or discussed
- Presentation offered April 14 and April 18 (same content)
- April 18 presentation will be recorded
- Presentation and all supporting resources will be posted on Provider Page of ALTSA website

Presentation Agenda

Medical Test Site Requirements (2:05-2:50pm)
2:05 Explanation of MTSW
2:15 MTSW Application Instruction
2:30 Question and Answer

2:50-3:00pm BREAK

COVID-19 Reporting Requirements (3:00-3:30pm)
3:00 Reporting Methods
3:15 Question and Answer

Presenters- Medical Test Site Requirements

Elizabeth (Liz) Parent

Medical Test Site Survey & Investigation Manager

Health Systems Quality Assurance
Washington State Department of Health

Waived Applications for Medical Test Sites in Washington State

Washington State Department of Health

Office of Health Systems Oversight
Laboratory Quality Assurance
Medical Test Site Program

Agenda

- What is a "Test Site"
- What is a Medical Test Site Waived (MTSW) License?
- What are the Requirements?
- How do I apply? - Application
- After the Application is Submitted
- Is Staff Training Required?
- How to Contact Us

What is a Test Site

- In Washington, a "test site" is a location where lab tests are performed by someone other than the person the test is on

Regulatory Definition: WAC 246-338-010(25)(a)

(25) "Medical test site" or "test site" means any facility or site, public or private, which analyzes materials derived from the human body for the purposes of health care, treatment, or screening. A medical test site does not mean:

(a) A facility or site, including a residence, where a test approved for home use by the Federal Food and Drug Administration is used by an individual to test himself or herself without direct supervision or guidance by another and where this test is not part of a commercial transaction;

What is a Medical Test Site License?

It is the license required to perform lab tests in Washington.

- Medical Test Site laws and rules apply to sites in Washington instead of Federal CLIA (Clinical Laboratory Improvement Amendments), as Washington State is exempt from the Federal CLIA law.
- RCW 70.42 & WAC 246-338 licensing laws and rules apply to all Medical Test Sites.

Your Medical Test Site License will include the CLIA number.

- When you get your MTS license, a CLIA number will also be issued to you for billing purposes, to order tests from suppliers, and to report Positive Covid-19 results in SimpleReport. CMS (Centers for Medicare & Medicaid Services) also uses this number for tracking purposes.

What is the Medical Test Site Waived License?

It is the license for a site that uses "waived" tests.

- What is waived testing?
  - Waived tests are categorized as simple tests that have an insignificant risk of an erroneous result.
  - The Food and Drug Administration (FDA) determines which tests meet the criteria to be considered a waived test.

Regulatory Definition: WAC 246-338-010 (45)(a)(b)

(45) "Waived test" means a test system that is:
(a) Cleared by the Food and Drug Administration for home use; or
(b) A simple laboratory examination or procedure that has an insignificant risk of an erroneous result.

What is an Over-the-Counter (OTC) Test?

- OTC tests are authorized by the FDA for self-testing.
- You collect your own sample, perform the test, and read the result yourself without the need to send a sample to a laboratory.
- FDA authorized OTC tests are available without a prescription. Can be purchased online or at a store.
- OTC tests can also be used by licensed sites.

When is a License Required for Testing?

You will need a license if:

- Your site uses "Waived" test kits not intended for home use, or
- Your staff use an "over-the-counter" test kit on a resident.
  - With "over-the-counter" testing when your staff are directly involved in any part of the testing process including collecting the sample, helping a person understand how to run the test, helping the person complete the test, or helping them read the test result.
- Your site is giving the test results to a medical provider to possibly use for treatment decisions.

There is one exception:

- When someone is helping a child, or an adult (who is unable to test themselves due to a physical disability) and is using an "over-the-counter" test.

When is a License Not Required for Testing?

When the site is not involved in testing

- When the resident is completing an over-the-counter test on themselves without assistance.
- When an employee is given an "over-the-counter" test to take and to perform on themselves.
- When the site is not giving the test result to a medical provider to use for treatment decisions.

What are the Requirements for a Licensed Medical Test Site Waived?

Requirements:

1. The site only uses test kits approved by the FDA as "Waived" or "over-the-counter."
2. That the site follows the test kit Instructions For Use (IFU's) exactly.
3. That the site reports positive reportable disease results to the State and/or Local Health Jurisdiction where the patient resides.
4. That the site follows Medical Test Site notification requirements, including updating new contact information or new test kits being used.

Is Staff Training Required?

- Ensure staff:
  - Read and follow the testing package insert or manufacturer's Instructions For Use (IFU) exactly.
  - Train staff according to the manufacturer's test kit instructions for use.
  - If your site chooses to develop an internal policy for testing, we recommend including the instructions for use for the kit you are using.

Links to LQA Webpage & Regulatory Information

LQA Website: Quick Tip: Google "WA LQA"

- https://doh.wa.gov/licenses-permits-and-certificates/facilities-z/laboratory-quality-assurance

Information on Reporting Positive Covid-19 Test Results:

- https://doh.wa.gov/emergencies/covid-19/healthcare-providers/reporting-test-results/reporting-covid-19-test-results-point-care-testing-facilities

Requirements to update changes on a license:

- https://app.leg.wa.gov/WAC/default.aspx?cite=246-338-026

Washington State Statute and Rules:

RCW 70.42

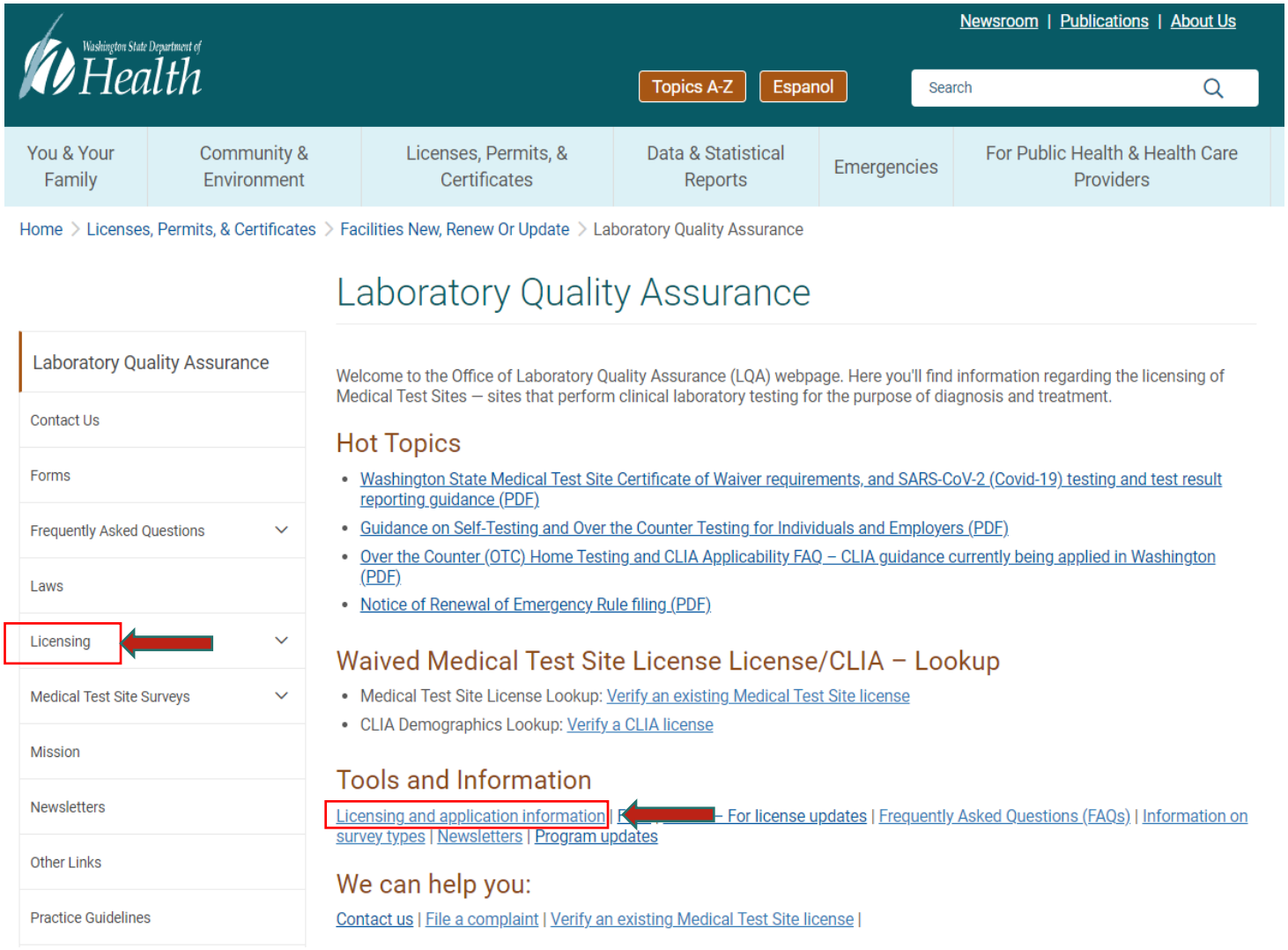
- https://app.leg.wa.gov/RCW/default.aspx?cite=70.42

WAC 246-338

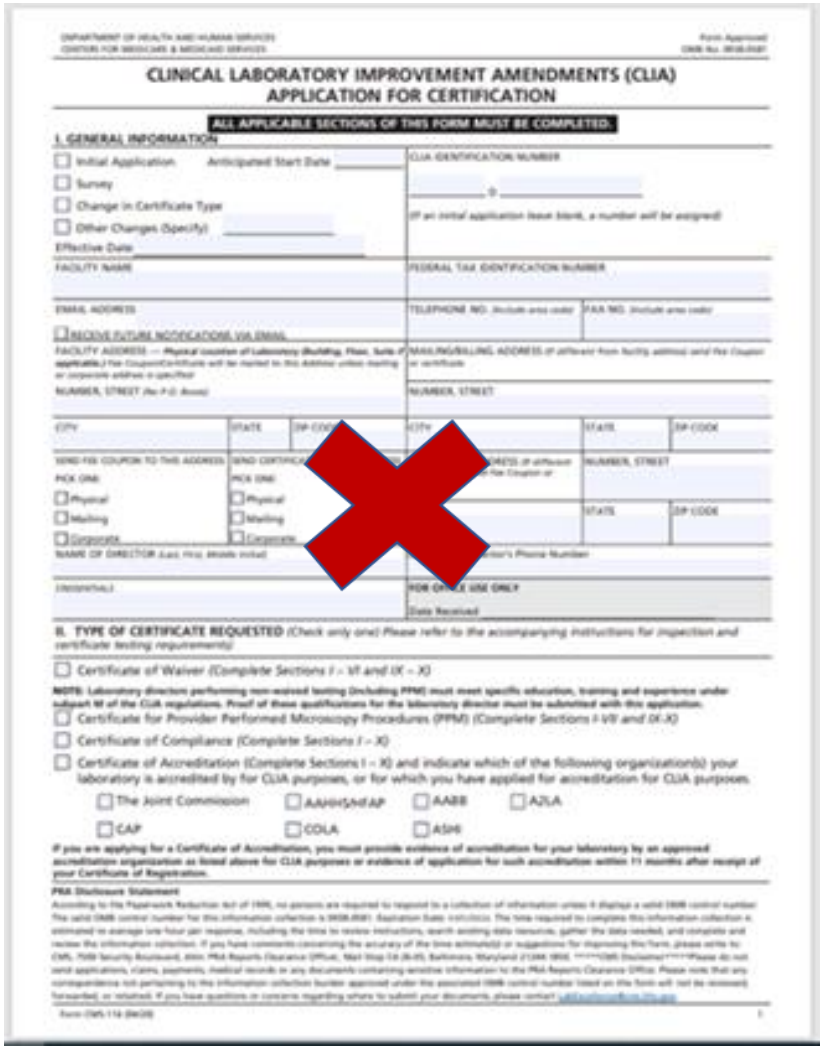
- https://app.leg.wa.gov/wac/default.aspx?cite=246-338

How Do I Apply for a Waived License?

Link to Webpage



CLIA 116 Application vs WA MTS Application



CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION

ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.

I. GENERAL INFORMATION

II. TYPE OF CERTIFICATE REQUESTED (Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)

Certificate of Waiver (Complete Sections I - VI and IX - X)

Certificate for Provider Performed Microscopy Procedures (PPM) (Complete Sections I-VII and IX-X)

Certificate of Compliance (Complete Sections I - X)

Certificate of Accreditation (Complete Sections I - X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.

The Joint Commission | AAHHS/MAP | AABB | A2LA | CAP | COLA | ASHI

PRA Disclosure Statement

Health

Revenue Section
P.O. Box 10981
Olympia, WA 98507-1098
253-395-6746

Date Stamp Here

Fee
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

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

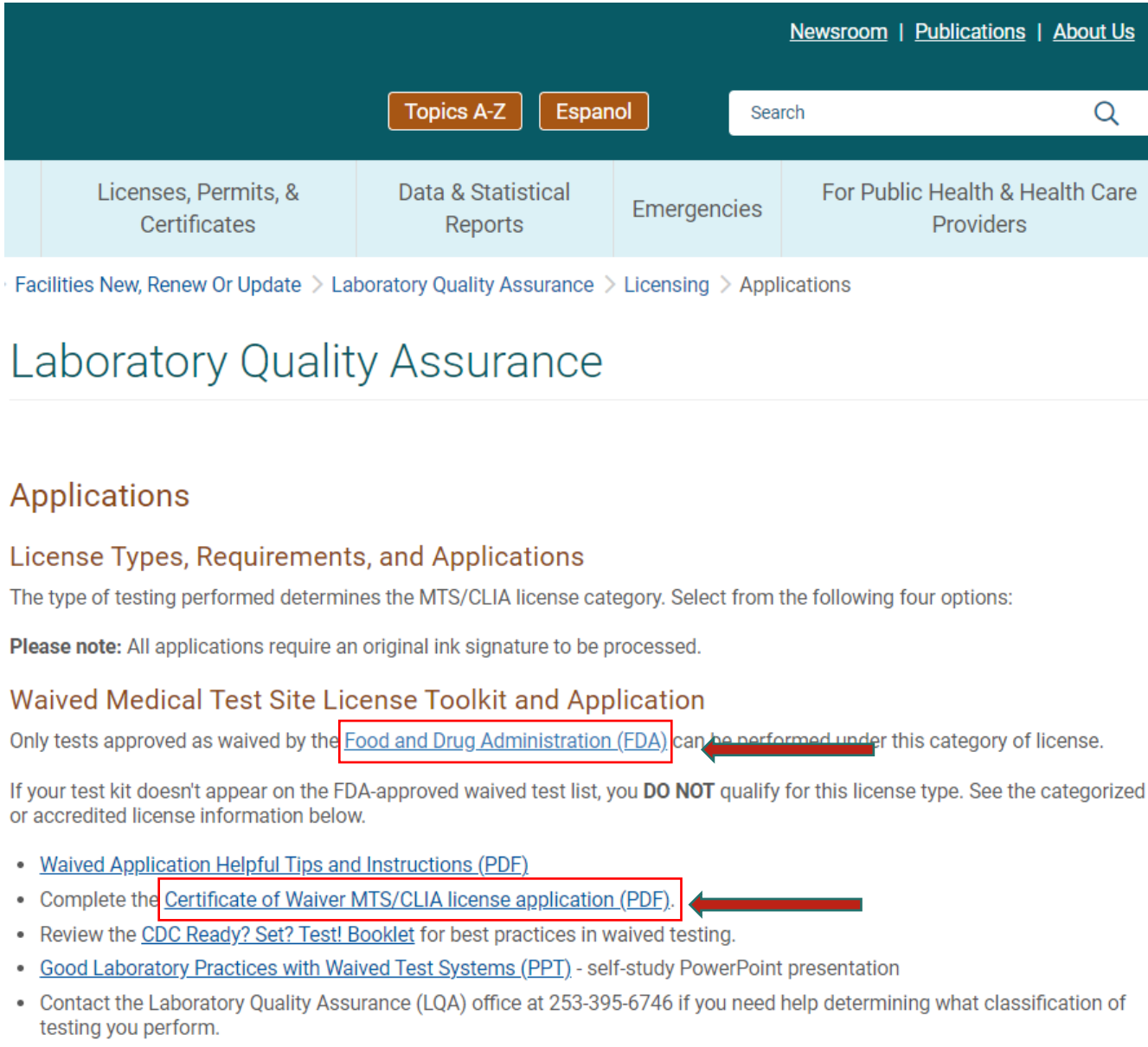
UBI # | Federal Tax ID (FEIN) #
Legal Owner/Operator Entity Name
Mailing Address
City | State | Zip Code | County
Phone (enter 10 digit #) | Fax (enter 10 digit #)
Email Address | Web Address
Facility/Agency Name (Business name as advertised on signs or website)
Facility Specific Federal Tax ID (if different than one entered above.)
Physical Address
City | State | Zip Code | County
Facility Phone (enter 10 digit #) | 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 #

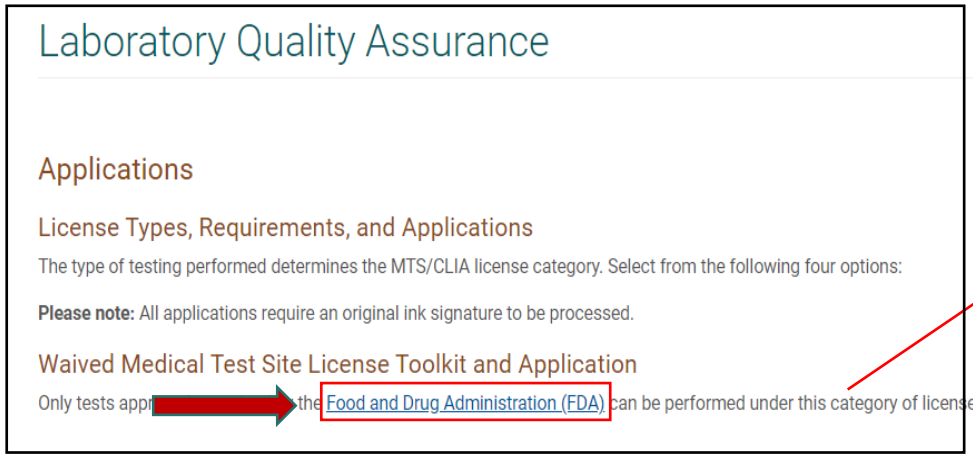
Download and Complete the Waived Application

- Click on and Complete the "Certificate of Waiver MTS/CLIA License Application (PDF)"
- Verify your tests are authorized by the FDA.
- Submit the hard copy with fee payment to the Olympia address on the application form.



Check the tests are FDA Approved as "waived" or "over-the-counter" for "home use"

For **FDA fully authorized tests** use link on LQA Applications page:



OR

For Covid tests with **FDA Emergency Use Authorization**:

Covid-19 Antigen Tests

Covid-19 Molecular tests

To look up tests authorized by the FDA for home use, click on the link, scroll down to the table, enter the test name into search bar.

Under the "Authorized Settings" column the test must be designated "Home" (over-the counter) or with a "W" for "waived" to be used under a Medical Test Site Waived license.

Application

Instructions - Listed on the first four pages of the application and in the following slides

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.

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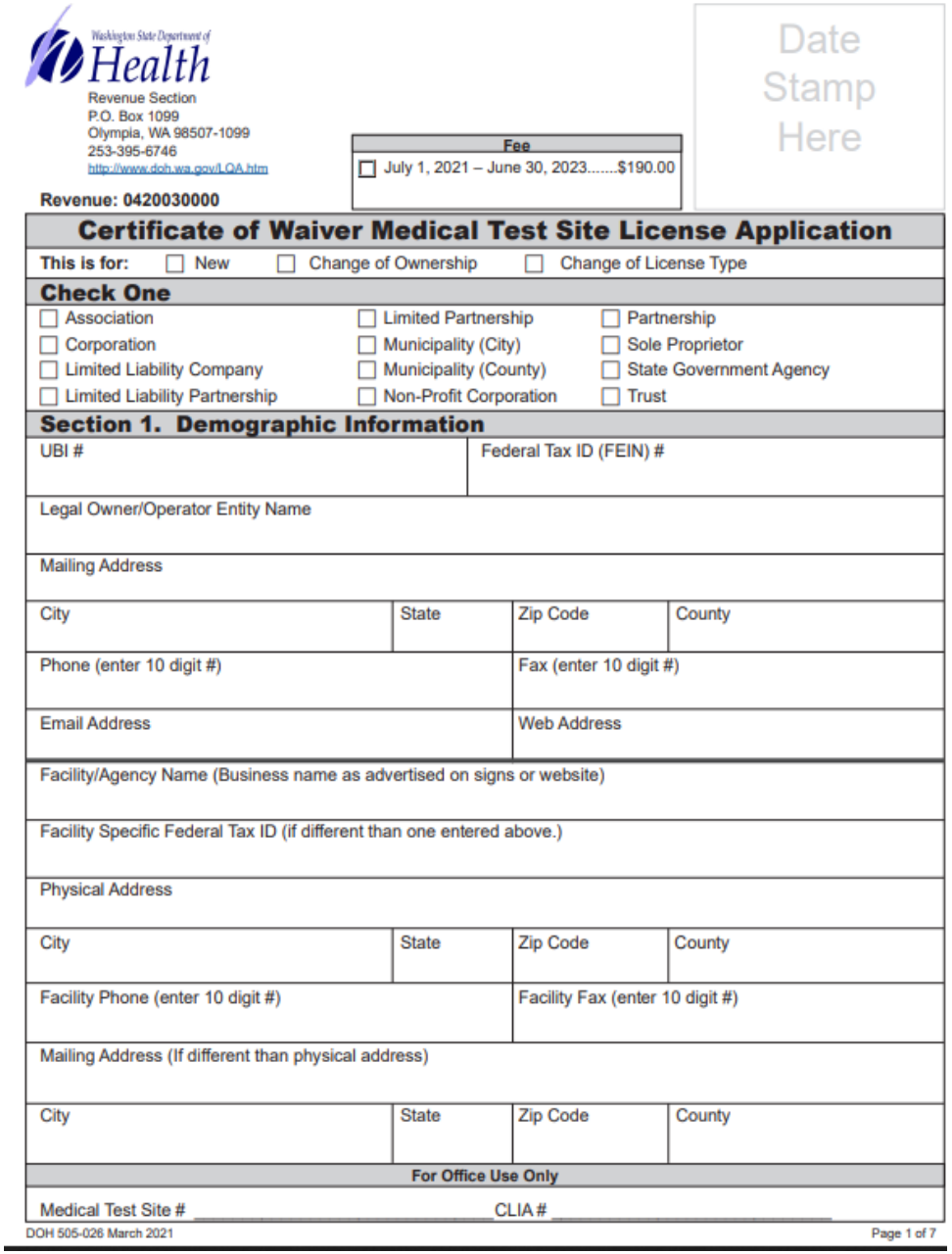
Instructions & Tips

- "New" box
  Mark "new" if this is the first time applying for an MTS license.
- "Check One" - type of business as listed on your business license (non- profit, corporation etc.)
- "Section 1. Demographic Information" - information listed on your site's business license.
  The owner information must match your business license.
- Below the bold line "doing business as" information
  This may be the same or different than above – it may be what you are advertising your business as.
- Phone Number and Email address MUST be provided in order for your application to be processed.

Please submit all seven pages of the application, even if some of the test kit pages are left blank.



Washington State Department of Health
Revenue Section
P.O. Box 1099
Olympia, WA 98507-1099
253-395-6746
http://www.doh.wa.gov/LQA.htm

Date Stamp Here

Fee
☐ 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

☐ 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 #		Federal Tax ID (FEIN) #	
Legal Owner/Operator Entity Name			
Mailing Address			
City	State	Zip Code	County
Phone (enter 10 digit #)		Fax (enter 10 digit #)	
Email Address		Web Address	
Facility/Agency Name (Business name as advertised on signs or website)			
Facility Specific Federal Tax ID (if different than one entered above.)			
Physical Address			
City	State	Zip Code	County
Facility Phone (enter 10 digit #)		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 # _____

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Section 2
Mark the site type

You must mark your specific site type or if you are not sure, please write site type in the blank area under Other Practitioner (adult family home, supportive living, etc.)

Hours of Testing

Hours testing happens, this may differ from business hours. List 24/7 if testing is performed all hours of the day.

Section 2. Facility Specific Information

Site Type (check one only)

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

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:							
To:							

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

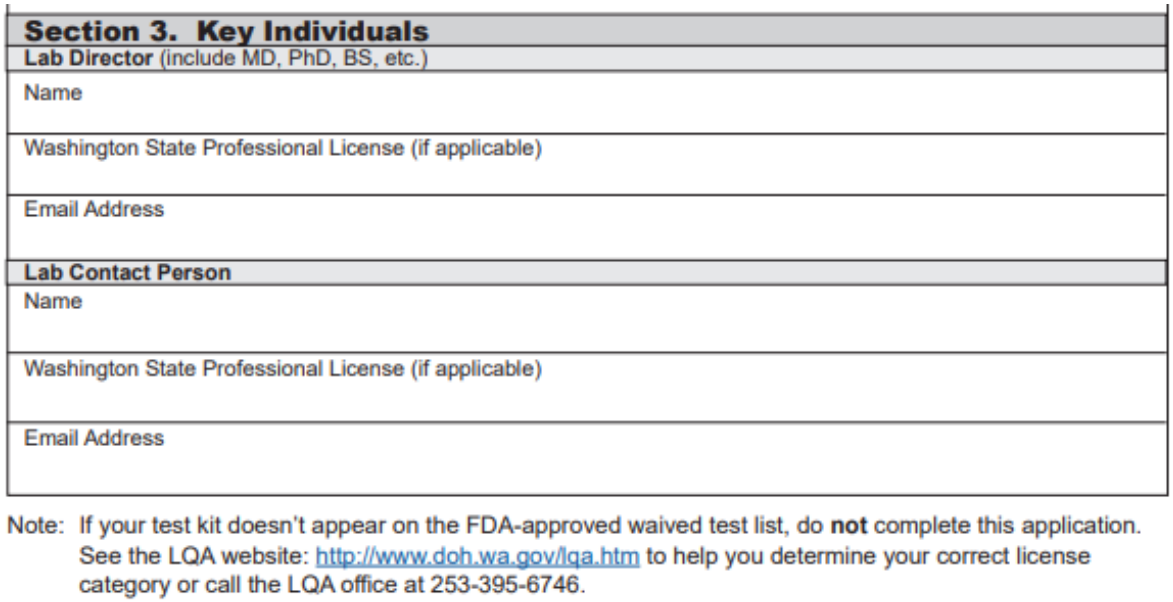
If yes: Attach a list of names, addresses and phone numbers for each site that will be included under one license, and a list of tests performed at each site. If any of the sites already have a MTS license, include the MTS and CLIA numbers of the sites that will be consolidated under this license. If 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.

Additional locations under license for Government or Not-for-Profit

If your site is Government or Not-for-Profit entity on your business license you may list different locations where testing takes place. Verification of not-for-profit status is required, please submit with application. To list additional locations, submit a separate sheet of paper, including the full addresses, building names, & phone numbers of each location.

Instructions continued

- Section 3: Key Individuals
  Laboratory Director
  List the name and email address of the person who is responsible for the site and for the testing.



Section 3. Key Individuals

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

Name

Washington State Professional License (if applicable)

Email Address

Lab Contact Person

Name

Washington State Professional License (if applicable)

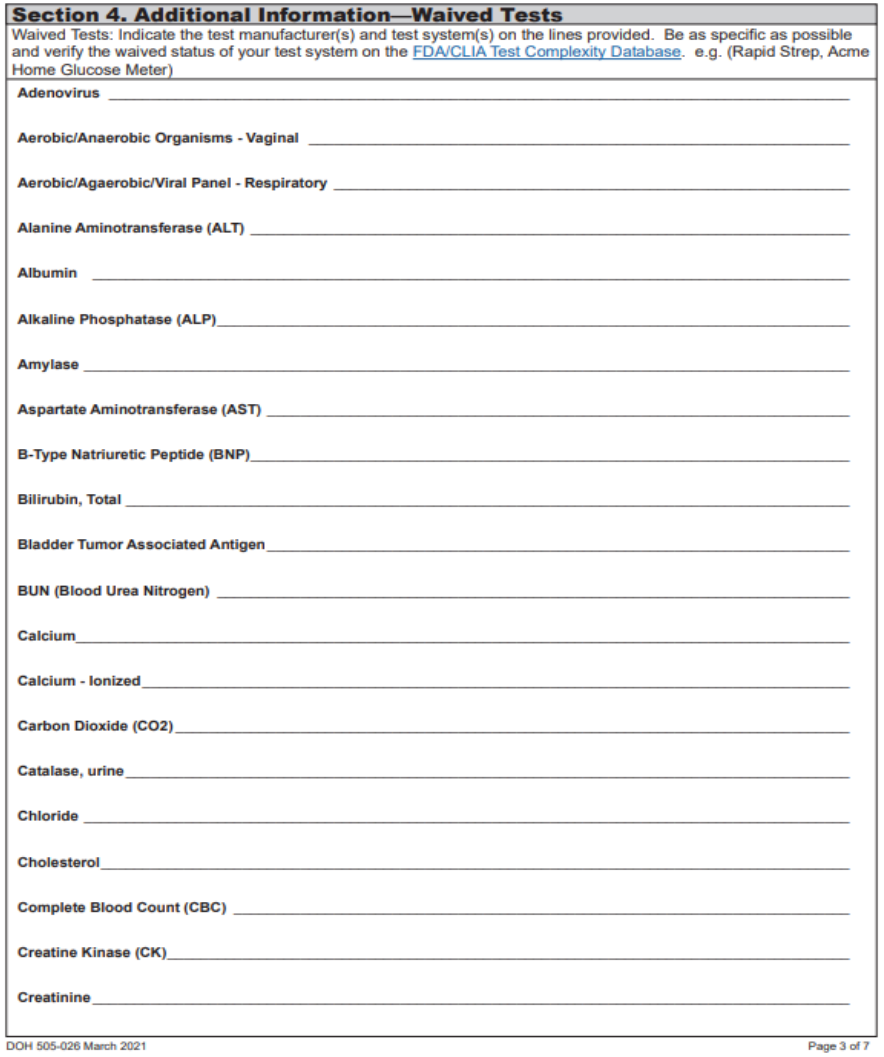
Email Address

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.

- Laboratory Director
  There are no personnel requirements to be the Lab Director for a waived site - the individual is not required to be a nurse, doctor, etc. Please list the person who is responsible for the license and testing. They do not have to have a Washington State Professional License (that can be left blank).
- Contact Person
  Please list a contact person. The contact person may be an administrative staff, a secretary, someone who can get a message to the Lab Director, or someone we can reach out to with questions.

Instructions, continued

- Section 4, Pages 3 – 6
  Waived tests are listed in alphabetic order. Please list any tests used at your site, even if the test is completed just once on one person per year.
- Please do not list tests if they are sent to an off-site lab and are only collected at your site.
- The name of the manufacturer and the name of the test should be listed.
- If staff are helping residents with their own test, such as a glucometer test, and you do not have the manufacturer information please list "Home use test -Cleared by FDA" on page 4 under "Glucose".



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/Agaerobic/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 _____

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- You will find SARS CoV-2(COVID-19) on page 5. Please list each test kit you are using.
- You must update us when you start using a new test kit within 30 days. This can be done using the Test Menu Change Form, and is free of charge, an additional application does not need to be submitted.

Instructions, continued

- Section 5 Page 7 Other Licensure
  You may add other individuals, such as Board Members or heads of the organization if you prefer, this is not required and can remain blank.
- Change of Ownership Information: This should remain blank for a new application.
- Signature
  We require the license be submitted with an original ink signed signature in order to process and approve your license. This can be an authorized representative of the business, or the signature of the person employed by the business and who has been asked to complete the paperwork. We also require the date, printed name and title of the person.

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

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

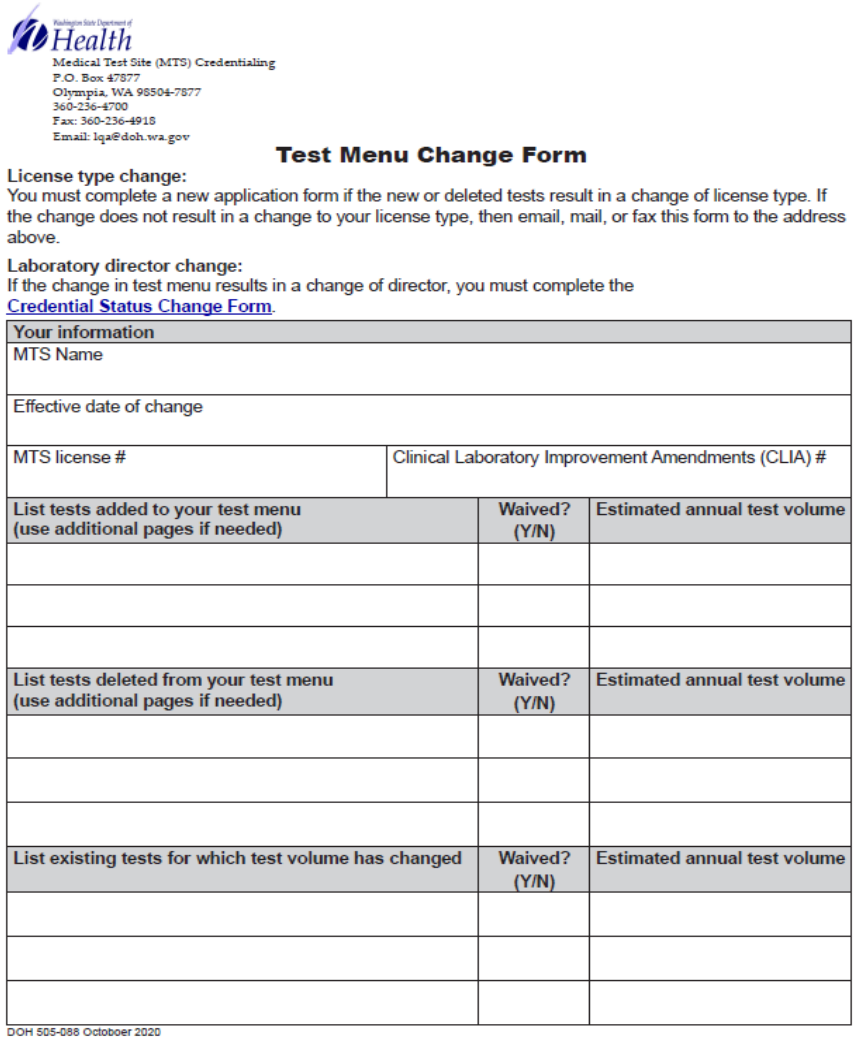
Print Title

Submit the Application

- Please mail in the fully completed original application along with a check or money order (in the same envelope) made out to the 'Department of Health' to the address listed on the left side of page one
    - Department of Health, Revenue Section
      PO Box 1099, Olympia WA 98507-1099
- Please make a copy of the application for your records.
- If you need to obtain testing products, please reach out to a supplier or contact your local county health department for test kits currently distributed by the Department of Health such as for Covid-19 testing during the Public Health Emergency.

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 – no fee is required.
- Submit the test menu change form to our credentialing department at HSQA Facilities Credentialing 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



Health

Medical Test Site (MTS) Credentialing
P.O. Box 47877
Olympia, WA 98504-7877
360-236-4700
Fax: 360-236-4918
Email: 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

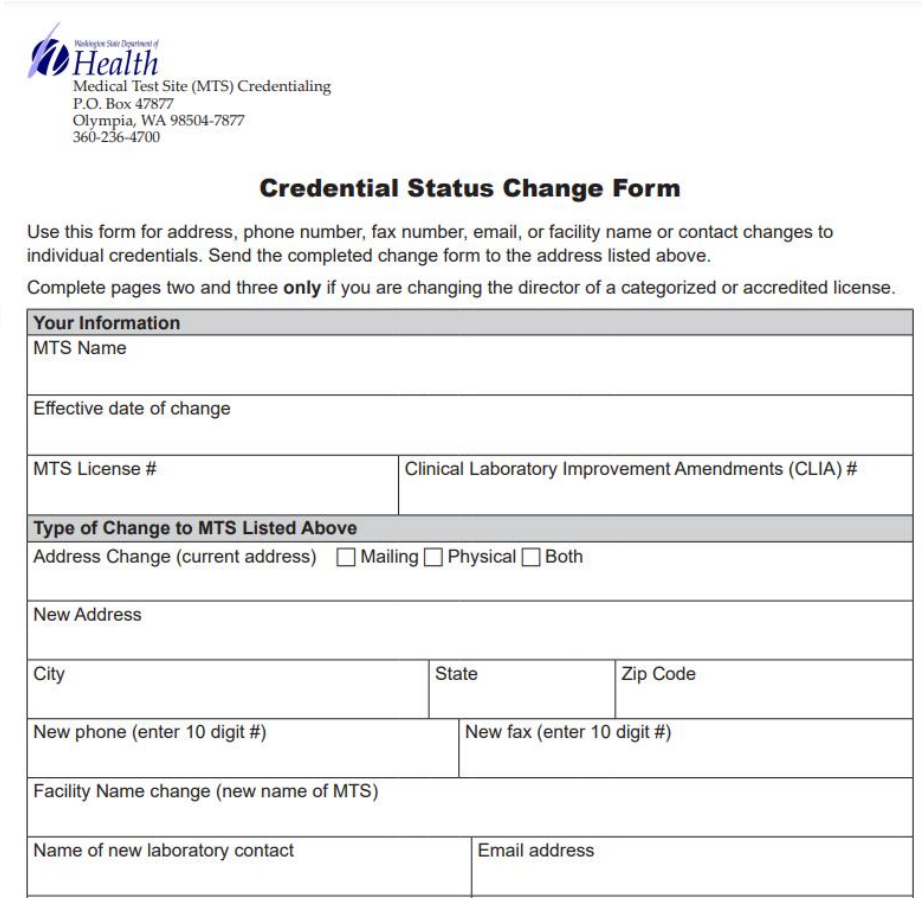
List tests deleted from your test menu (use additional pages if needed)	Waived? (Y/N)	Estimated annual test volume

List existing tests for which test volume has changed	Waived? (Y/N)	Estimated annual test volume

DOH 505-088 October 2020

Updating Contact Information on a License

- Medical Test Sites must notify us within 30 days of any change in information such as the Name of Site, the Director, Location, Tests, and Changes of Ownership.
- Submit the Credential Status Change form to our credentialing department at HSQA Facilities Credentialing hsqafc@doh.wa.gov
- The Credential Status Change form can be found by Googling "WA LQA Credential Status Change form" or at: https://doh.wa.gov/licenses-permits-and-certificates/facilities-z/laboratory-quality-assurance/forms
- Questions can be sent to LQA@doh.wa.gov



Health
Medical Test Site (MTS) Credentialing
P.O. Box 47877
Olympia, WA 98504-7877
360-236-4700

Credential Status Change Form

Use this form for address, phone number, fax number, email, or facility name or contact changes to individual credentials. Send the completed change form to the address listed above.

Complete pages two and three **only** if you are changing the director of a categorized or accredited license.

Your Information		
MTS Name		
Effective date of change		
MTS License #	Clinical Laboratory Improvement Amendments (CLIA) #	
Type of Change to MTS Listed Above		
Address Change (current address) ☐ Mailing ☐ Physical ☐ Both		
New Address		
City	State	Zip Code
New phone (enter 10 digit #)	New fax (enter 10 digit #)	
Facility Name change (new name of MTS)		
Name of new laboratory contact	Email address	

After the Application is Submitted

- Specifically, for Covid-19 testing during the Public Health Emergency Adult Family Homes may begin testing once the application and fee payment have been submitted.
- We will reach out if we need further information.
- You will get an email with your Medical Test Site and CLIA Number once the application is fully processed.

For resources, FAQ'S and more in depth information find us on the web - Google "LQA WA" or visit:

https://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/LaboratoryQualityAssurance

Resources

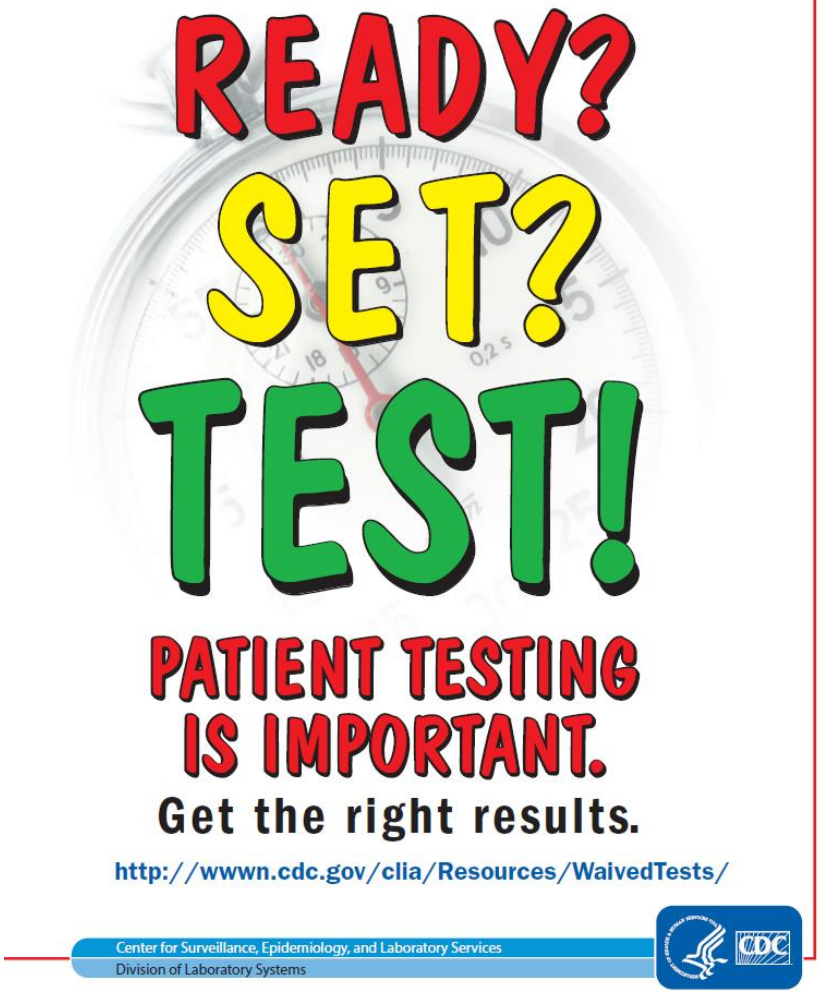
Ready? Set? Test! Resources for waived testing published by the CDC

These resources contain information on good laboratory practice, as well as logs and charts that you may find useful.

Ready Set Test Online Course

CDC Self-Assessment for Good Testing Practices

Ready Set Test Booklet
https://www.cdc.gov/clia/docs/waived-tests/ready-set-test-booklet.pdf

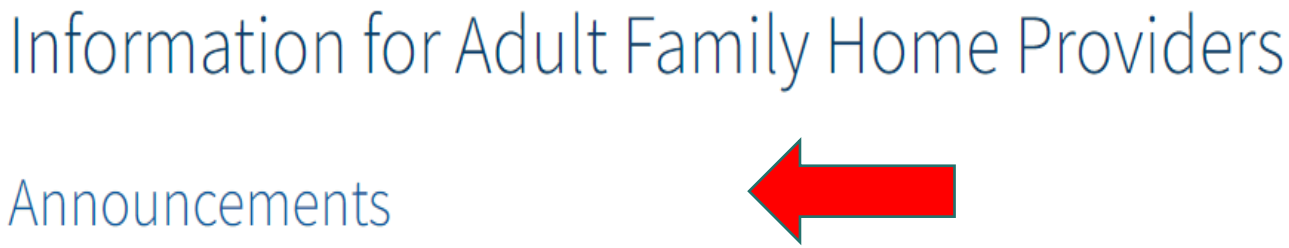


Resources

Medical Test Site Waived Test Readiness Checklist

This two-page checklist was developed for you with RCS and contains testing tips, reminders and resources. You can find it on the RCS AFH Provider webpage:

https://www.dshs.wa.gov/altsa/residential-care-services/information-adult-family-home-providers



How to Contact Us:

Once you have submitted your application you can check the status here:

Verify a Medical Test Site License or

https://fortress.wa.gov/doh/facilitysearch/

For other questions regarding testing or interpretations, or for specific questions on the MTSW application please reach out to LQA@doh.wa.gov.

We are processing a high volume of inquiries, thank you for your patience.

Questions?

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.

BREAK

Presenters- COVID 19 Point of Care Reporting Requirements

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Data Support: Outreach Unit
Public Health Outbreak Coordination, Informatics, and Surveillance (PHOCIS)
Washington State Department of Health

Washington State Department of Health

COVID-19 POINT-OF-CARE TEST REPORTING FOR ADULT FAMILY HOMES & ENHANCED SERVICES FACILITIES

WA DOH Surveillance & Data Support

Learning Objectives

1. COVID-19 Reporting Requirements

2. SimpleReport Account Set Up
   - Step 1: Create Account
   - Step 2: Add Facility/Home
   - Step 3: Add Staff/Users
   - Step 4: Add Patient/Residents
   - Step 5: Submit Results

3. Other reporting options
   - Pdf Report form
   - Local Health Jurisdiction/County Health Department

COVID-19 Reporting Requirements

- Washington Administrative Code 246-101

- Only positive results are required to be reported within **24 hours**
  - Do not report negatives

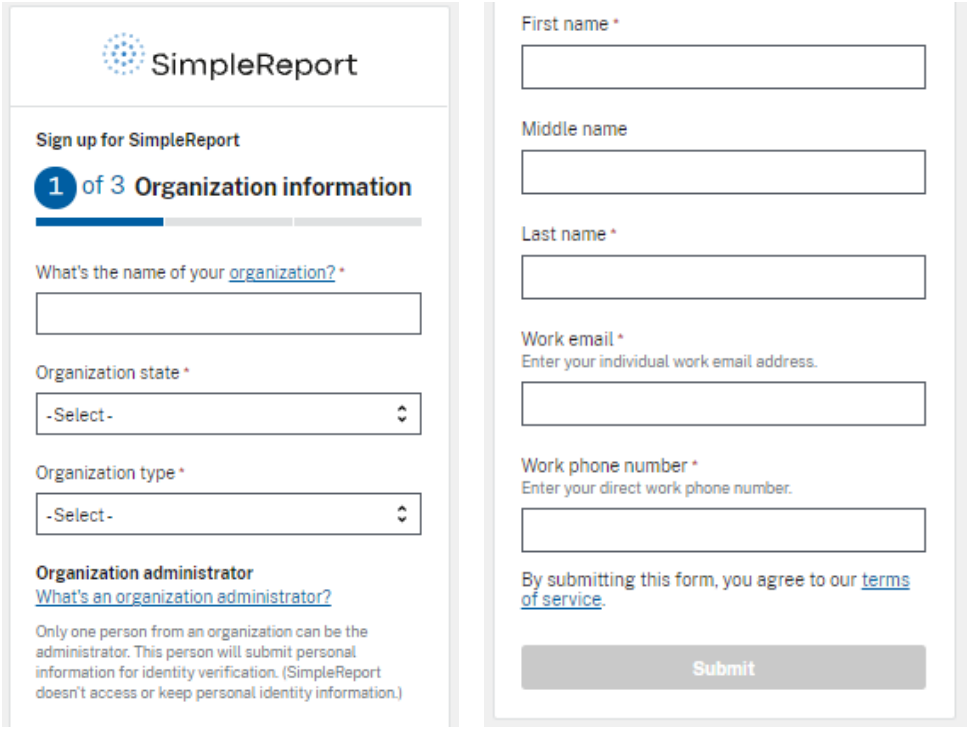
- Reporting can be done through
  - PDF Report Form
  - Through your Local Health Jurisdiction (LHJ)
  - SimpleReport (online web application)

SimpleReport

- Free, web-based application created by US Digital Services and CDC
- Offers a simple and easy to use method
- Get started at https://simplereport.gov/
  - Step 1: Create Account
  - Step 2: Add Facility/Home
  - Step 3: Add Staff/Users
  - Step 4: Add Patient/Residents
  - Step 5: Submit Results

Step 1: Create Account

- Account administrator enters organization/provider information
  - Only one person one time
- Identity verification process with Experian
  - Enter personal information
  - Personal data are not saved
- Activate your account from the link you receive via email



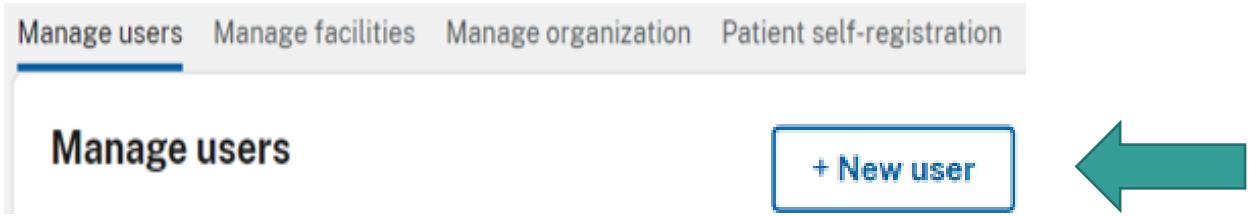
Step 2: Add Facility/Home

- Organizations/providers with more than one facility/home:
  - add each home separately (example by location)
- Organizations/providers with *only* one facility/home:
  - can be the same as the organization/provider name
- SimpleReport requires a CLIA number - you will get this when you receive your medical test site license
  - Wait to create your SimpleReport account until you receive your CLIA number. Please use the pdf form until then.
- National Provider Identifier (NPI): 0000000
- "Ordering provider" doesn't need to be a medical provider
  - Can be manager/administrator of facility
- Enter default test type in this step

Step 3: Add Users/Staff

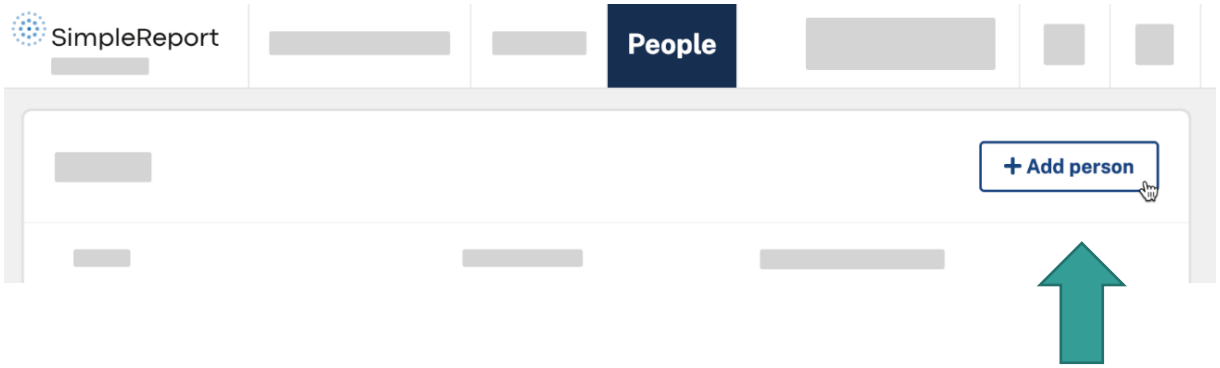
- Add users/staff to account who will be conducting tests or entering data

- Can specify access level for each user/staff member to all or certain facilities/homes
  - "Admin" (full permissions)
  - "Standard user" (manage results and profiles)
  - "Entry only" (conduct tests and submit results)



Step 4: Add a Patient/Resident

- Must add resident information before submitting results
- Enter demographics and contact information
- Primary phone number can be provider's number
- Once a resident is added, multiple tests can be entered over time



General information

Required fields are marked with an asterisk (*).

First name *

Middle name

Last name *

Role

-Select-

Facility *

-Select-

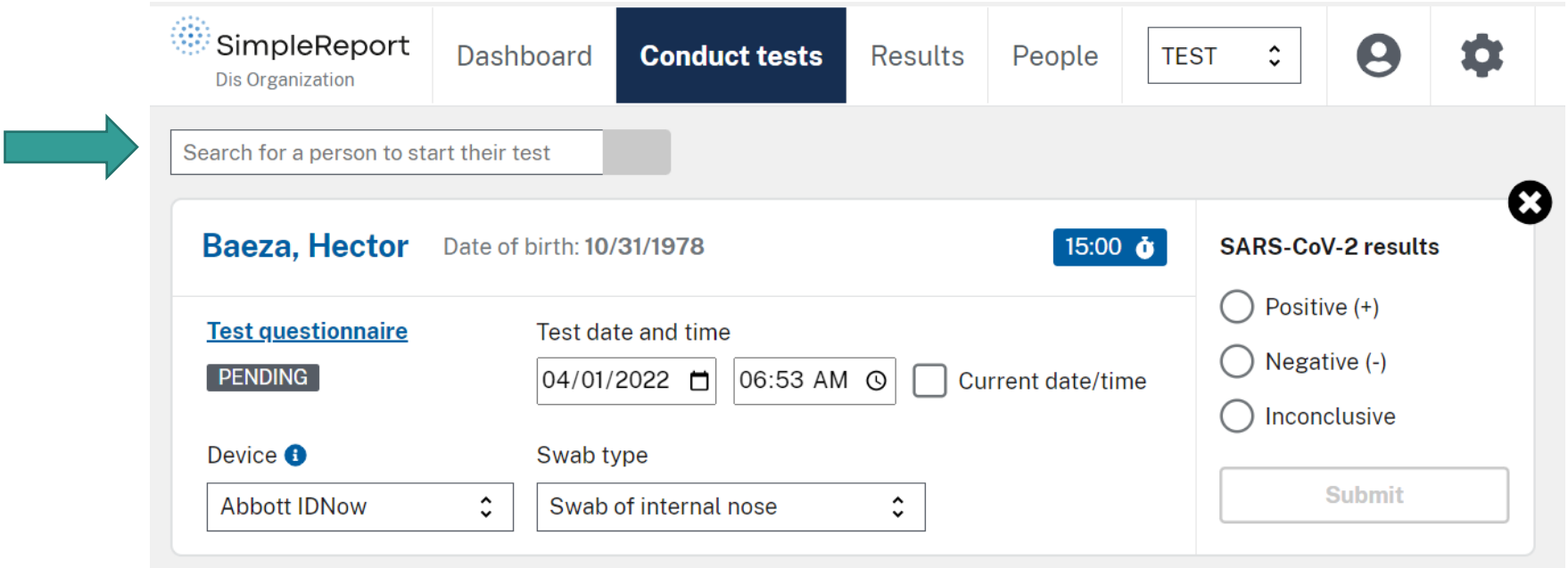
Preferred language

Date of birth (mm/dd/yyyy) *

mm/dd/yyyy

Step 5: Submit Results

1. Search for patient/resident
2. Complete questionnaire
3. Enter results and submit



Other Reporting Options

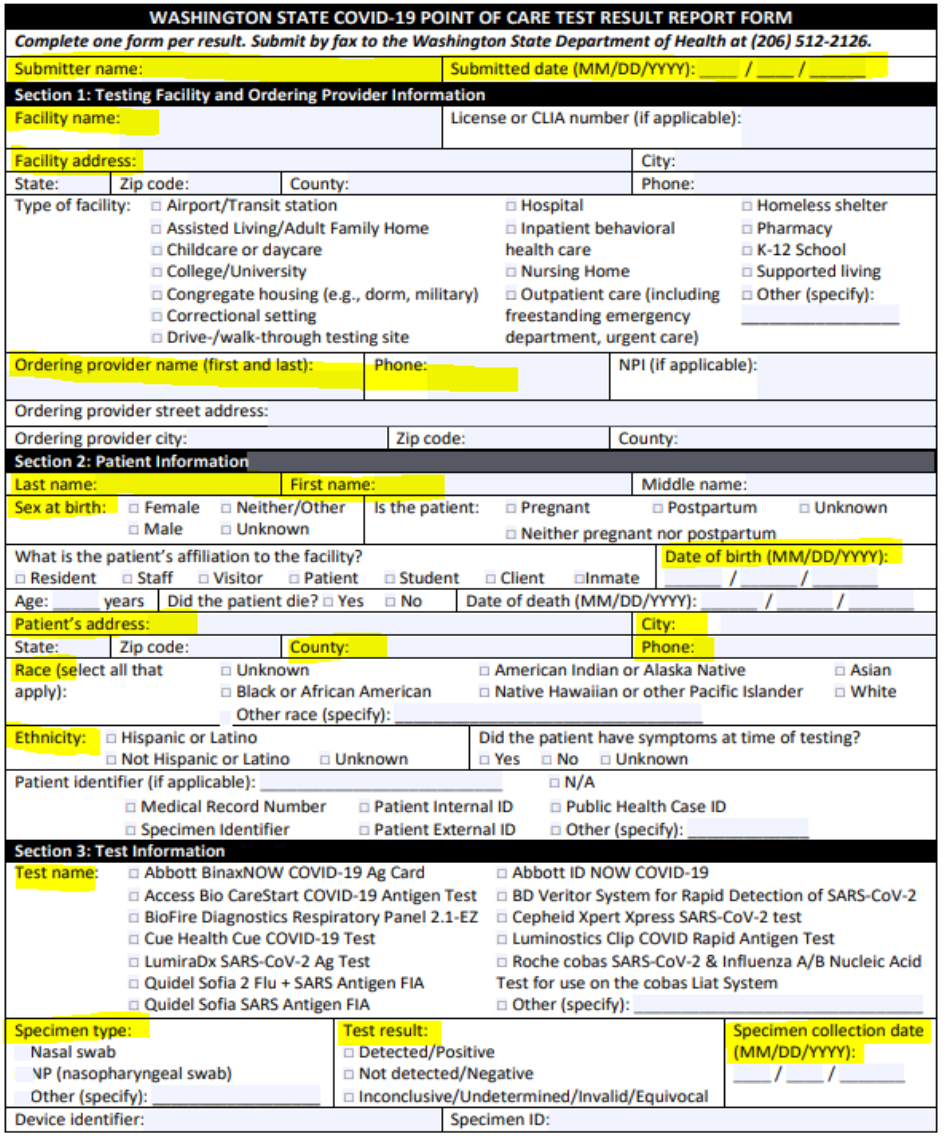
1. PDF Report Form

Fill out and fax to (206) 512-2126

Or send via secure e-mail to PHOCIS-fax@doh.wa.gov

-OR-

2. Report through your Local Health Jurisdiction (LHJ)



WASHINGTON STATE COVID-19 POINT OF CARE TEST RESULT REPORT FORM

Complete one form per result. Submit by fax to the Washington State Department of Health at (206) 512-2126.

Submitter name: | Submitted date (MM/DD/YYYY): ____ / ____ / _____

Section 1: Testing Facility and Ordering Provider Information

Facility name: | License or CLIA number (if applicable):

Facility address: | City:

State: | Zip code: | County: | Phone:

Type of facility: □ Airport/Transit station □ Assisted Living/Adult Family Home □ Childcare or daycare □ College/University □ Congregate housing (e.g., dorm, military) □ Correctional setting □ Drive-/walk-through testing site □ Hospital □ Inpatient behavioral health care □ Nursing Home □ Outpatient care (including freestanding emergency department, urgent care) □ Homeless shelter □ Pharmacy □ K-12 School □ Supported living □ Other (specify): _____

Ordering provider name (first and last): | Phone: | NPI (if applicable):

Ordering provider street address:

Ordering provider city: | Zip code: | County:

Section 2: Patient Information

Last name: | First name: | Middle name:

Sex at birth: □ Female □ Male □ Neither/Other □ Unknown | Is the patient: □ Pregnant □ Postpartum □ Unknown □ Neither pregnant nor postpartum

What is the patient's affiliation to the facility? □ Resident □ Staff □ Visitor □ Patient □ Student □ Client □ Inmate | Date of birth (MM/DD/YYYY): ____ / ____ / ____

Age: _____ years | Did the patient die? □ Yes □ No | Date of death (MM/DD/YYYY): ____ / ____ / ____

Patient's address: | City:

State: | Zip code: | County: | Phone:

Race (select all that apply): □ Unknown □ American Indian or Alaska Native □ Asian □ Black or African American □ Native Hawaiian or other Pacific Islander □ White □ Other race (specify): _____

Ethnicity: □ Hispanic or Latino □ Not Hispanic or Latino □ Unknown | Did the patient have symptoms at time of testing? □ Yes □ No □ Unknown

Patient identifier (if applicable): _____ □ N/A □ Medical Record Number □ Patient Internal ID □ Public Health Case ID □ Specimen Identifier □ Patient External ID □ Other (specify): _____

Section 3: Test Information

Test name: □ Abbott BinaxNOW COVID-19 Ag Card □ Access Bio CareStart COVID-19 Antigen Test □ BioFire Diagnostics Respiratory Panel 2.1-EZ □ Cue Health Cue COVID-19 Test □ LumiraDx SARS-CoV-2 Ag Test □ Quidel Sofia 2 Flu + SARS Antigen FIA □ Quidel Sofia SARS Antigen FIA □ Abbott ID NOW COVID-19 □ BD Veritor System for Rapid Detection of SARS-CoV-2 □ Cepheid Xpert Xpress SARS-CoV-2 test □ Luminostics Clip COVID Rapid Antigen Test □ Roche cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System □ Other (specify): _____

Specimen type: Nasal swab | NP (nasopharyngeal swab) | Other (specify): _____

Test result: □ Detected/Positive □ Not detected/Negative □ Inconclusive/Undetermined/Invalid/Equivocal

Specimen collection date (MM/DD/YYYY): ____ / ____ / _____

Device identifier: | Specimen ID:

Revised: 26-Jan-21

Summary

- Positive results are required to be reported within 24 hours

- Three options to report COVID-19 test results
  - Pdf Report form
  - Local Health Jurisdiction/County Health Department
  - SimpleReport

- If you choose to use SimpleReport to submit results to DOH
  - Step 1: Create Account
  - Step 2: Add Facility/Home
  - Step 3: Add Staff/Users
  - Step 4: Add Patient/Residents
  - Step 5: Submit Results

Contacts & Resources

SimpleReport User Guide (account set up, general 'how to', printable format)
https://simplereport.gov/user-guide/

Using SimpleReport (quick help on managing users, results, facility info, etc.)
https://simplereport.gov/using-simplereport/

USDS SimpleReport Technical Assistance (troubleshooting, software issues)
support@simplereport.gov

Washington State DOH Surveillance Section (reporting questions)
DOH-Surv@doh.wa.gov

WA DOH: Reporting COVID-19 Test Results for Point-of-Care Testing Facilities:
Reporting COVID-19 Test Results for Point-of-Care Testing Facilities | Washington State Department of Health

Questions

Thank you!

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.

Questions about the presentation?

Presentation materials will be posted on the DSHS ALTSA Provider webpage

Questions about content presented today:

- Medical Test Site Licensing: LQA@doh.wa.gov
- COVID-19 Reporting: DOH-Surv@doh.wa.gov

DSHS policy questions:

- Residential Care Services: RCSpolicy@dshs.wa.gov

Thank You

Washington State
Department of Social
& Health Services

Transforming lives

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