

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

Nashington State Department of Social and Health Services

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



Transforming lives

Washington State Department of Social and Health Services

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

Washington State Department of Social and Health 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



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 selftesting.
- 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.
- 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"

- <u>https://doh.wa.gov/licenses-permits-and-certificates/facilities-z/laboratory-</u> <u>quality-assurance</u>
- Information on Reporting Positive Covid-19 Test Results:
- <u>https://doh.wa.gov/emergencies/covid-19/healthcare-providers/reporting-test-results/reporting-covid-19-test-results-point-care-testing-facilities</u>
- 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

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

How Do I Apply for a Waived License? Link to Webpage

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Contact Us			Hot Topics Washington State Medical Test Site Certificate of Waiver requirements, and SARS-CoV-2 (Covid-19) testing and test result						
Frequently Asked Questions			 reporting guidance (PDE) <u>Guidance on Self-Testing and Over the Counter Testing for Individuals and Employers (PDF)</u> Over the Counter (OTC) Home Testing and CLIA Applicability EAC – CLIA guidance currently being applied in Washington 						
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CLIA 116 Application vs WA MTS Application

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Download and Complete the Waived Application

 Click on and Complete the "<u>Certificate of</u> <u>Waiver MTS/CLIA</u> <u>License</u> <u>Application (PDF)</u>"

- Verify your tests are authorized by the FDA.
- Submit the hard copy with fee payment to the Olympia address on the application form.

			Newsroom Publications About Us
	Topics A-Z Espar	nol se	earch Q
Licenses, Permits, & Certificates	Data & Statistical Reports	Emergencies	For Public Health & Health Care Providers

Facilities New, Renew Or Update > Laboratory Quality Assurance > Licensing > Applications

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 Medical Test Site License Toolkit and Application

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.

- Waived Application Helpful Tips and Instructions (PDF)
- 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.

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

	U.S. Department of Health & Human Services				
link on LQA Applications page:	DA U.S. FOOD & DRUG				
Laboratory Quality Assurance	Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics				
Applications License Types, Requirements, and Applications The type of testing performed determines the MTS/CLIA license category. Select from the following four options:	CLIA - Clinical Laboratory Improvement Amendments • FDA Home • Medical Devices • Databases Enter any combination of fields and select Search. You can use the Analyte Drop Down box to select a specific Analyte. For Test System Name/Manufacturer: enter a single word (e.g., Analyzer) or an exact phrase (e.g., Acme Analyzer). Learn More				
Please note: All applications require an original ink signature to be processed. Waived Medical Test Site License Toolkit and Application Only tests apprendict the Food and Drug Administration (FDA) can be performed under this category of license.	Search Database Image: Constraint of the search constraints Test System / Manufacturer Image: Constraint of the search constraints Analyte Name Image: Constraint of the search constraints Show Text Input Image: Constraint of the search constraints				

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
3.	505-026 Certificate of Waiver Medical Test Site Application

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.

DOH 505-039 March 2021

Page 1 of 2

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 <u>MUST</u> 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.

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Section 1. Demographic Info	rmation								
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Mailing Address									
City	State	Zip Code	County						
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Instructions Continued - Page 2

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 16 Industrial 5 Blood Banks 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-forprofit 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.

lude MD, PhD, BS, etc.)
Professional License (if applicable)
son
Professional License (if applicable)
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Note: If your test kit doesn't appear on the FDA-approved waived test list, do not complete this application. See the LQA website: <u>http://www.doh.wa.gov/lqa.htm</u> 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	
Vaived Tests: Indicate the test manufacturer(s) and test system(s) on the lines provided. Be as specific as p	ossible
nd verify the waived status of your test system on the FDA/CLIA Test Complexity Database. e.g. (Rapid Str	ep, Acr
iome Glucose Meter)	
Adenovirus	
Aerobic/Anaerobic Organisms - Vaginal	
Associate and a second s	
Aerobic/Agaerobic/viral Panel - Respiratory	
Alanine Aminotransferase (ALT)	
Albumin	
Alkaline Phosphatase (ALP)	
Amylase	
Aspartate Aminotransferase (AST)	
R. Type Natriuratic Deptide (RND)	
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	
0H 505-026 March 2021	Page 3

- 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 Li	icensure,	Certification	or Re	gistrat	tion Information		
Legal Owner Information	-attach add	itional sheets as ne	eded				
List names, addresses, ph	one numbers,	, and titles of corporate	officers	s, partners	, members, managers, etc.		
Name	Address		Phone	e #	Title		
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Change of Ownership Inf	formation						
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I certify that I have received, i	read, understo	ood, and agree to comp	ply with	state law	and rule regulating this licensing		
category. I also certify that the	e information i	nerein submitted is true	e to the	best of my	v knowledge and bellet.		
Signature of Owner/Authorized Representative of Medical Test Site					Date		
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			_				
Print Name				Print Title	9		

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 <u>hsqafc@doh.wa.gov</u>
- The Test Menu Change Form can be found by Googling "WA LQA Test Menu Change" or at: <u>https://www.doh.wa.gov/Portals/</u> <u>1/Documents/Pubs/505088.pdf</u>
- 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.

March Constant			
rour information			
MIS Name			
Effective date of change			
, i i i i i i i i i i i i i i i i i i i			
MTS license #	Clinical Lak	oraton (Impr	woment Amondments (CLIA) #
	Chincal Lat	oratory impre	Wernenic Americanentis (OLIA) #
	L		
List tests added to your test menu		Waived?	Estimated annual test volume
(use additional pages if needed)		(Y/N)	
			<u> </u>
List tests deleted from your test menu		Waived?	Estimated annual test volume
(use additional pages if needed)		(Y/N)	
List existing tests for which test volume has	changed	Waived?	Estimated annual test volume
		(Y/N)	
DOH ERE RES Octoboor 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 <u>hsqafc@doh.wa.gov</u>
- The Credential Status Change form can be found by Googling "WA LQA Credential Status Change form" or at: <u>https://doh.wa.gov/licenses-</u> permits-and-certificates/facilitiesz/laboratory-qualityassurance/forms
- Questions can be sent to LQA@doh.wa.gov



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)	ng 🗌 P	hysical 🗌 Both					
New Address							
City	Sta	te	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/Facilities NewReneworUpdate/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

<u>CDC Self-Assessment for Good</u> <u>Testing Practices</u>

Ready Set Test Booklet https://www.cdc.gov/clia/docs/w aived-tests/ready-set-testbooklet.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-careservices/information-adult-family-home-providers

Information for Adult Family Home Providers

Announcements



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 <u>LQA@doh.wa.gov</u>.

> 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.



Nashington State Department of Social and Health Services

Presenters- COVID 19 Point of Care Reporting Requirements

Jennifer Valverde and Rebecca Sutherland

Data Support: Outreach Unit Public Health Outbreak Coordination, Informatics, and Surveillance (PHOCIS) 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)
 - <u>SimpleReport</u> (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 <u>https://simplereport.gov/</u>
 - 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

/80	First name *
SimpleReport	
Sign up for SimpleReport	Middle name
1 of 3 Organization information	
	Last name *
What's the name of your <u>organization?</u> *	
	Work email *
Organization state *	Enter your individual work email add
-Select-	
Organization type *	Work phone number *
-Select-	
Organization administrator What's an organization administrator?	By submitting this form, you agr of service.
Only one person from an organization can be the administrator. This person will submit personal	
nformation for identity verification. (SimpleReport	Submit

e to our terms

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

General information

First name *

Middle name

Last name *

Della

Required fields are marked with an asterisk (*).

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

					Role	Role		
SimpleReport		People			-Select-	\$		
					Facility *			
				+ Add person	-Select-	\$		
-	1				Preferred language			
						~		
				_	Date of birth (mm/dd/yyyy) *			
					mm/dd/yyyy	Ö		

Step 5: Submit Results

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

SimpleReport Dis Organization	Dashboard Conduct tests	Results	People	TEST	\$	9	\$	
Search for a person to start	their test						•	
Baeza, Hector	Pate of birth: 10/31/1978		15:00	Ŏ.	SARS-Co	V-2 result	s	
Test questionnaire PENDING	Test date and time 04/01/2022			e (Positive (+) Negative (-) Inconclusive 			
Device 🕄 Abbott IDNow	Swab type Swab of internal nose	\$		(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. Submitted date (MM/DD/YYYY): ____ / ____/ Submitter nam 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 Hospital Homeless shelter Assisted Living/Adult Family Home Inpatient behavioral Pharmacy Childcare or daycare health care K-12 School College/University Nursing Home Supported living Congregate housing (e.g., dorm, military) Outpatient care (including) Other (specify): Correctional setting freestanding emergency Drive-/walk-through testing site department, urgent care) Ordering provider name (first and last): NPI (if applicable): Phone: Ordering provider street address: Ordering provider city: Zip code County Section 2: Patient Information Middle name: First name Last name: Neither/Other Is the patient: Pregnant Postpartum Unknown Male Unknown Neither pregnant nor postpartum What is the patient's affiliation to the facility? Date of birth (MM/DD/YYYY): Resident Staff Visitor Patient Student Client Inmate years Did the patient die?
Yes No Date of death (MM/DD/YYYY): Age: Patient's address: City: Zip code: State: County: Phone: Race (select all that Unknown American Indian or Alaska Native Asian apply): Black or African American Native Hawaiian or other Pacific Islander White Other race (specify): Hispanic or Latino Did the patient have symptoms at time of testing? Ethnicity: Not Hispanic or Latino Unknown 🗆 Yes 🗆 No 🗆 Unknown Patient identifier (if applicable): N/A Public Health Case ID Medical Record Number Patient Internal ID Specimen Identifier Patient External ID Other (specify): Section 3: Test Information est name: Abbott BinaxNOW COVID-19 Ag Card Abbott ID NOW COVID-19 Access Bio CareStart COVID-19 Antigen Test BD Veritor System for Rapid Detection of SARS-CoV-2 BioFire Diagnostics Respiratory Panel 2.1-EZ Cepheid Xpert Xpress SARS-CoV-2 test Cue Health Cue COVID-19 Test Luminostics Clip COVID Rapid Antigen Test LumiraDx SARS-CoV-2 Ag Test Roche cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Quidel Sofia 2 Flu + SARS Antigen FIA Test for use on the cobas Liat System Quidel Sofia SARS Antigen FIA Other (specify): Specimen collection date Specimen type: Test result: Nasal swab Detected/Positive (MM/DD/YYYY): NP (nasopharyngeal swab) Not detected/Negative 1 1 Inconclusive/Undetermined/Invalid/Equivocal Other (specify): 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) <u>support@simplereport.gov</u>

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: <u>Reporting COVID-19 Test Results for Point-of-Care Testing Facilities</u> | <u>Washington State Department of Health</u>

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: <u>LQA@doh.wa.gov</u>
- COVID-19 Reporting: <u>DOH-Surv@doh.wa.gov</u>

DSHS policy questions:

Residential Care Services: <u>RCSpolicy@dshs.wa.gov</u>

Thank You





Transforming lives

Additional Project Staff

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