COVID-19 Q&A Hour for Long Term Care





WASHINGTON STATE DEPARTMENT OF HEALTH

Healthcare-Associated Infections (HAI) Program Shoreline, WA

Housekeeping



Attendees will be in listen only mode



Self-mute your lines when not speaking



Type questions into the question window. Please include the type of facility you are from in your question (e.g., NH).



Nursing Home

Participants from long-term care, regulatory, public health



No confidential information presented or discussed. This is an educational webinar and does not constitute legal advice.



Local guidance may differ, please consult with your Local Health Jurisdiction (LHJ):

https://www.doh.wa.gov/AboutUs/PublicHealthSystem/LocalHealthJurisdictions

This is the LTC COVID-19 Q&A Hour!

A chance to connect, ask questions, and learn about the COVID-19 response and infection prevention guidance



Where Can I Find the Q & A Document?

Posted every Wednesday

Washington Health Care Association:

https://www.whca.org/washington-department-of-health-covid-19-<u>qa-session/</u>

Washington LeadingAge:

https://www.leadingagewa.org/ill_pubs_articles/copy-resourcespreparing-your-community-staff-residents-and-families-for-thecoronavirus/

• Adult Family Home Council:

https://adultfamilyhomecouncil.org/department-of-health-gawebinars/

Panelists















OF WASHINGTON STATE



Send Us Your Questions Ahead of Time

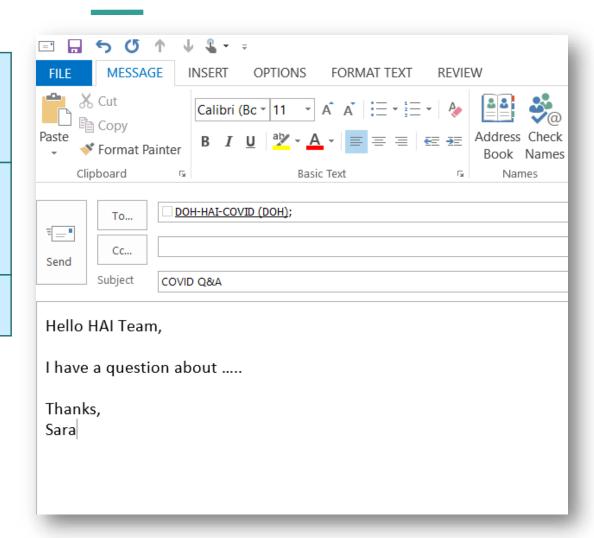
Subject Line:

COVID Q&A

Email:

HAI-COVID@doh.wa.gov

Due by: COB Tuesday



Infection Control Assessment & Response (ICAR) Program

Free, non-regulatory ICARs are a great opportunity for skilled nursing facilities, adult family homes, and assisted living facilities to:

- Ask a Department of Health infection prevention expert questions.
- Get help finding gaps in your infection control protocols.
- Receive personalized advice and recommendations for your facility.

There are multiple ways to schedule an ICAR:

- Visit https://fortress.wa.gov/doh/opinio/s? s=ICARconsultation
- Email Maria Capella-Morales maria.capella-morales@doh.wa.gov
- Email Melissa Feskin Melissa.Feskin@doh.wa.gov

In partnership with:

- Local Health Jurisdictions
- LeadingAge Washington
- Washington Health Care Association
- Adult Family Home Council of WA State
- Washington State Hospital Association



LONG-TERM CARE FACILITY STAFF:

Reasons to Get Vaccinated Against COVID-19 Today

- You are on the front lines and risk being exposed to people with COVID-19 each day on the job.
- Protecting you also helps protect your residents and your family, especially those who may be at higher risk for severe illness from COVID-19.
- You matter to us and play an essential role in keeping your community healthy.



Lead the way!

Encourage your coworkers, residents, family, and friends to get vaccinated.



www.cdc.gov/coronavirus/vaccines

Videos:

Long-Term Care Community Champions: Voices From the Front Line

Nursing home staff are on the FRONT LINES with their residents every day

Protected staff means PROTECTED RESIDENTS and a protected community

https://www.youtube.com/watch?v=k0WbAhveyDY

Vaccine Resources in multiple languages:

Resources and Recommendations :: Washington State Department of Health

> 1-833-VAX-HFIP for vaccine information

Long-Term Care COVID-19 Immunization Champion Award Summer 2021

Congratulations to the LTC facilities receiving awards!



Summer 2021 Recognition Program	Facilities Awarded
Gold Level – 90%+ Staff Vaccinated	26
Silver Level – 80-89%	18
Bronze Level – 70-79%	12

List of awardees: https://www.doh.wa.gov/Portals/1/Documents/Pubs/820228-LTC-COVID-19ImmunizationChampionAwardees.pdf

https://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/PublicHealthSyst emResourcesandServices/Immunization/LongTermCareFacilities/LongTermCareCOV ID19ImmunizationChampionAward

Long-Term Care COVID-19 Immunization Champion Award

You can apply for next quarterly award and be recognized for your work and accomplishments to protect against COVID-19 in your facility by responding to a short survey!

Deadline: December 1

- Any Long-Term Care facilities can participate <u>https://redcap.doh.wa.gov/surveys/?s=KFRMW8JN4P</u>
 - Skilled Nursing Facilities use NHSN to report staff rates
- For questions about the awards, contact covid.vaccine@doh.wa.gov
- For questions about the survey, contact <u>LTC-COVID-Vaccination-Survey@doh.wa.gov</u> using subject line: LTC COVID-19 Vaccination Survey.

Upcoming LTC Q&A Schedule

Please plan to attend these upcoming sessions!

October 21 and 28: Influenza Preparedness and Response

November 4: How to do a Risk Assessment

November 11: closed for Veteran's Day – no Q&A call

November 18: How to do a Risk Assessment

November 25: closed for Thanksgiving Day – no Q&A call



Waived Applications for Medical Test Sites in Washington 2021

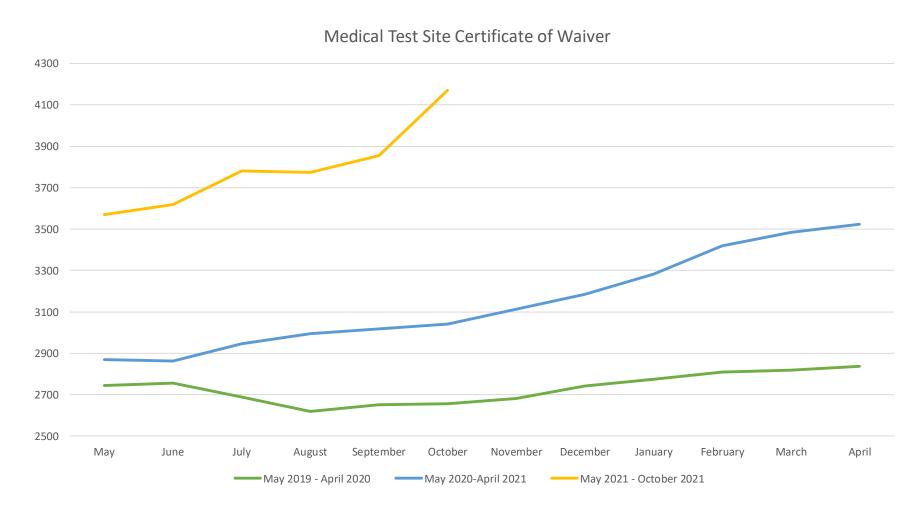


Elizabeth Parent, MLS(ASCP)CG - Acting Medical Test Site Survey and Investigation Program Manager

Topics covered in this presentation

- Growth of Certificate of Waivers in Washington
 - Where we were and where we are now
- What is required
- Where do I find the Waived Medical Test Site application?
- How to get started
- **Application**
- What to do after the application is submitted
- Test menu changes adding testing to an existing license
- Reporting rules
 - Rule writing to align WAC with CMS-3401-IFC
- "Ready, Set, Test!" resource CDC
- Information and how to contact us

Growth of Certificate of Waivers



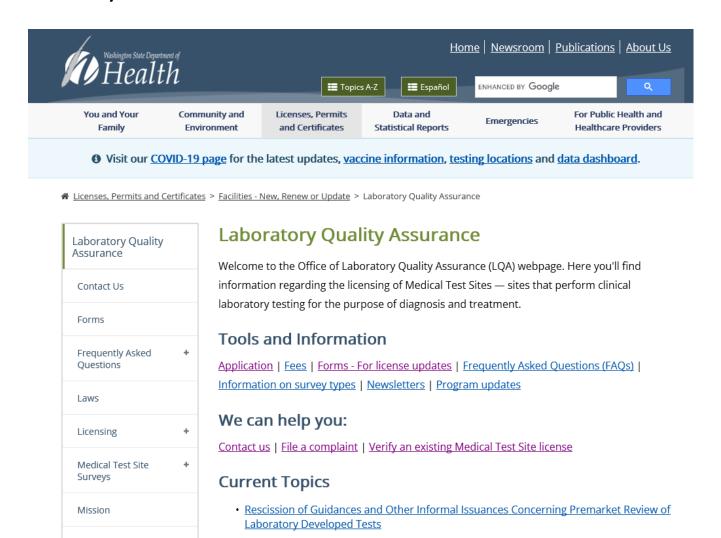
What is required

For a Waived Medical Test Site there are three requirements:

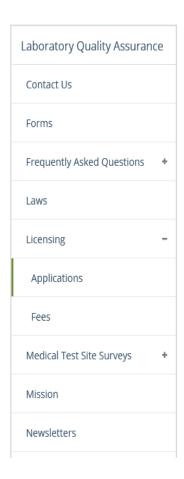
- 1. That the Medical Test Site is licensed to perform testing and only uses test kits that are waived by the FDA
- 2. That the Medical Test Site follows the test kit/manufacturers instructions for use (IFU's) exactly
- 3. That the Medical Test Site reports positive and negative Covid-19 test results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



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 upper left side of the form



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 <u>Food and Drug Administration (FDA)</u> 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 <u>CDC Ready? Set? Test! Booklet</u> 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

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

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 Section 3. Key Individuals: Lab Director: Enter the lab director's: Name Washington State professional license number, if applicable. Email address Lab Contact: Enter the lab contact's: 1. Name Washington State professional license number, if applicable. 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/lga.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/lga.htm.

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

	Fee	
July 1, 2021	– June 30,	2023\$190.00

Date Stamp Here

Revenue: 0420030000				
Certificate of Waiver Medical Test Site License Application				
This is for: New Change of	f Ownership	☐ Change of Li	cense Type	
Check One				
☐ Association ☐	Limited Partne	rship 🔲 Part	nership	
☐ Corporation ☐	Municipality (C	ity) 🗌 Sole	Proprietor	
☐ Limited Liability Company ☐	Municipality (C	County) 🗌 Stat	e Government Agency	
Limited Liability Partnership	Non-Profit Cor	poration 🗌 Trus	t	
Section 1. Demographic Info				
UBI#	Fe	ederal Tax ID (FEIN) #	‡	
Legal Owner/Operator Entity Name	<u>'</u>			
Mailing Address				
City	State	Zip Code	County	
Phone (enter 10 digit #)		Fax (enter 10 digit #)		
Email Address	Email Address Web Address			
Facility/Agency Name (Business name as ad	vertised on sig	ns or website)		
Facility Specific Federal Tax ID (if different th	an one entered	d 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 !	les Only		
For Office Use Only				
Medical Test Site #		CLIA#		

Section 2. Facility Specific Information							
Site Type (check one only) 1 Ambulance							
5 Blood Banks16 Industrial27 Skilled Nursing Facility6 Community Clinic17 Insurance28 Tissue Bank/Repository7 Comprehensive Outpatient Rehab18 ICFMR29 Other							
	f Laboratory 1						
List days				erformed. If tes			
	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
From:							
To:							
Addition	al locations (ınder this lice	ense				
				al government la mplexity tests) a			
This licen	se will have add	ditional locations	s under one lice	nse and the par	agraph above a	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.							
		Individuals					
	ctor (include Mi), PhD, BS, etc.)				
Name							
Washington State Professional License (if applicable)							
Email Address							
Lab Contact Person							
Name							
Washington State Professional License (if applicable)							
Email Add	Iress						

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.

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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)
Alkalile i liospitatase (ALI)
Amylase
Aspartate Aminotransferase (AST)
B-Type Natriuretic Peptide (BNP)
- type management space (p.m.)
Pilotic Total
Bilirubin, Total
Bladder Tumor Associated Antigen
BUN (Blood Urea Nitrogen)
Calcium
Carolini,
Calcium - Ionized
Carbon Dioxide (CO2)
Catalase, urine
Charita
Chloride
Cholesterol
Complete Blood Count (CBC)
Creatine Kinase (CK)
\-\
Creatinine

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Section 5. Other Licensure, Certification or Registration Information						
Legal Owner Information-attach additional sheets as needed						
List names, addresses, pho	one numbers,	and titles of corporate			, members, managers, etc.	
Name	Address		Phone	e#	Title	
Change of Ownership Inf	ormation				•	
Previous Name of Legal Own						
Previous Name of Facility		Previous MTS Licens	se #		Effective Date of Ownership Change	
Physical Address						
City		State		Zip Code		
		Signature	е			
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	•	

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After Application is Submitted

- 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

- It is required that Medical Test Sites 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
- The Test Menu Change Form can be found by Googling "WA LQA Test Menu Change" or at: https://www.doh.wa.gov/Portals/1/Docu ments/Pubs/505088.pdf
- Questions can be sent to LQA@doh.wa.gov



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

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 Lat	boratory Impro	ovement 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		Waived?	Estimated annual test volume
(use additional pages if needed)		(Y/N)	
1:-4	ah an mad	Waived?	Estimated annual test volume
List existing tests for which test volume has	cnanged	(Y/N)	Estimated annual test volume

DOH 505-088 Octoboer 2020

Emergency Rule

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, "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	
Certificate of Waiver*	 Restrict testing to tests classified as waived. Follow manufacturers' instructions for performing the test. 	TYPE • Complaint • Technical Assistance	FREQUENCY •When indicated
	• Meet the requirements of WAC 246-338-020 Licensure—Types of Medical Test Site Licenses; WAC <u>246-338-022</u> Initial Application for Medical Test Site License; WAC <u>246-338-024</u> License Renewal/Reapplication Process; WAC <u>246-338-026</u> Notification Requirements; WAC <u>246-338-028</u> On-site Inspections.	 As required to assess compliance with WAC 246-338-026(7) 	
	e additional rule and inspection requirements for testing under Prores (PPMP), Categorized and Accredited licenses please review WAC		

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

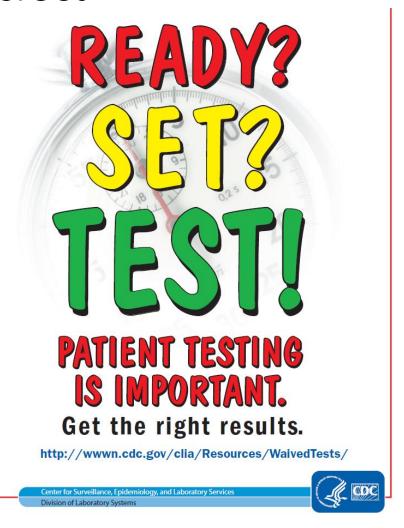
Other Resources

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-testbooklet.pdf

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



How to contact us with questions:

- For FAQ's, Applications, and information find us on the web: Google "LQA WA" or visit https://www.doh.wa.gov/LicensesPermitsandCertificates/Faci litiesNewReneworUpdate/LaboratoryQualityAssurance
- In order to receive the fastest response for questions, please reach out to LQA@doh.wa.gov We are currently working with high volumes of inquiries
- Medical Test Site Program Consultants
 - Kim Moseng (253) 395-6746
 - Anitha Santhosh (253) 395-6785

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.

Point of Care Test Reporting

Results of POC test results need to be reported to DOH:

- 1. Via NHSN (SNFs, AL)
- 2. Directly to DOH

For information about NHSN reporting: https://www.cdc.gov/nhsn/ltc/covid19/index.html





COVID-19 POINT-OF-CARE TEST REPORTING FOR LONG-TERM CARE FACILITIES

WA DOH Surveillance Section

Outline

- Reporting Requirements
- SimpleReport Account Set Up
 - Step 1: Create Account
 - Step 2: Add Facility
 - Step 3: Add Users
 - Step 4: Add Patients
 - Step 5: Submit Results

Reporting Requirements

- Washington Administrative Code 246-101
- Results are required to be reported within 24 hours
 - Only positive results need to be submitted
 - Please hold negatives until bulk upload is available
- Over-the-counter tests that are done at the direction or recommendation of the facility are required to be reported like point-of-care tests
- Required fields include patient demographics, facility information, and test data
- Reporting done through SimpleReport

SimpleReport

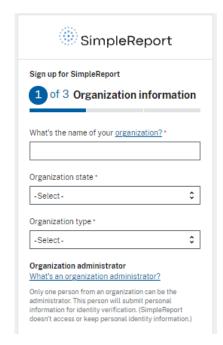


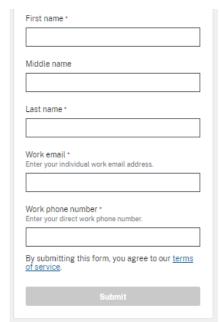
- Free, web-based application created by US Digital Services and CDC
- Offers a simple and easy to use method
- Get started at https://simplereport.gov/
 - Step 1: Create Account
 - Step 2: Add Facility
 - Step 3: Add Users
 - Step 4: Add Patients
 - Step 5: Submit Results



Step 1: Create Account

- Account administrator enters organization information
- Verify your identity with Experian
 - Enter personal information
 - Personal data are not saved
- Activate your account from the link sent via email





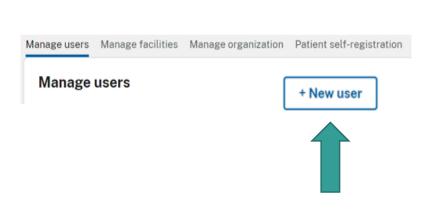
Step 2: Add Facility

- Add each point-of-care test site as separate facilities
- Facility name can be the same as the organization name
- Enter default test type



Step 3: Add Users

- Add users to account who will be conducting tests or entering data
- Can specify permission for each user



■ Remove user	Save changes
No more facilities left to select	
Testing Site	•
Access all facilities	
Facility access All users must have access to at least one facility	
Encility access	
Entry only (conduct tests)	
Standard user (manage results and profiles)	
Admin (full permissions)	
and users	

Admins have full access to conduct tests, manage results and profiles, and manage settings

Step 4: Add a Patient

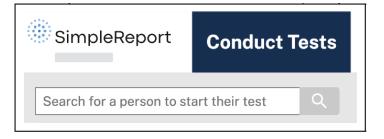
- Must add patients before submitting results
- Enter demographics and contact information
- Reminder: only need to submit positive results, so we recommend adding patients after identifying any positives

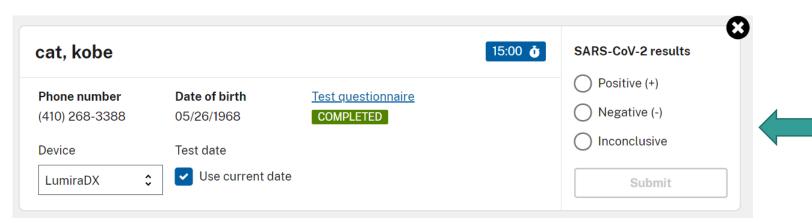


General information Required fields are marked with an asterisk (*). First name * Middle name Last name * Role -Select -Facility * -Select -Preferred language Date of birth (mm/dd/yyyy) * mm/dd/yyyy

Step 5: Submit Results

- Search for patient
- Complete questionnaire
- Enter results and submit





Separating Patient and Staff Results

- If you need to separate patient and staff results for confidentiality...
 - Create separate facilities for staff and patients
 - "Lakewood Center STAFF"
 - "Lakewood Center PATIENTS"
 - Specify user permissions for each facility

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/

Washington State DOH Surveillance Section (reporting questions)

DOH-Surv@doh.wa.gov

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

Summary

- Results are required to be reported within 24 hours
- Only positive results need to be submitted
- Use SimpleReport to submit results to DOH
 - Step 1: Create Account
 - Step 2: Add Facility
 - Step 3: Add Users
 - Step 4: Add a Patient
 - Step 5: Submit Results

Questions



Thank you!



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