

Question	Answer	Responder
<b>MTSW questions</b>		
If we don't have any diabetic residents and we only send out or use mobile labs or ask labs to come and get the specimen, ex: urine, blood, etc. then do we still need this license?	If your staff are not completing any test on-site, instead you are just collecting samples and sending them out to an off site lab that holds a license, then you do not need a license.	Jennifer Hopgood, Liz Parent DOH
If residents are checking their blood glucose without assistance does our site need a license?	If residents are checking their own blood glucose and independently using their test results to determine the amount of insulin/ medication to take without any guidance than a license is not required. If staff are assisting with testing or using test results for medical decisions, (such as "take this amount of insulin"), or informing residents physician of results, then a license is required. Thus if your residents are testing completely on their own then a license is not required.	Liz Parent
Can we get the slides emailed to us? There were no registrations, so how can we get the slide?	They are posted on the ALTSA Adult Family Home provider page.	Colleen Jensen
Free COVID tests from government for personal use...how do these stack up?	Some local health jurisdictions can assist AFHs with no cost testing kits. You will need to check with your county's health department. For questions about test kits and accuracy you will need to search for information on the FDA's website.	Jennifer Hopgood Liz Parent
For Section 3 on the application, can the AFH provider/ owner be listed for both Lab director and contact person?	Yes, lab director and lab contact can be the same person.	Jennifer Hopgood Liz Parent
How much is the test license fee ?	\$190 for the two year term.	Jennifer Hopgood Liz Parent
Would you remind me what to write on the glucose test?	"Blood glucometer Cleared by FDA for Home Use" under Glucose, or the name of the Glucometer and test kit if the information is available.	Jennifer Hopgood Liz Parent
To do a glucose test does the adult family home need a license for this?	If the site staff are involved in the testing, yes a license is required.	Jennifer Hopgood Liz Parent

<p>Does the Lab Director section need to be filled out? Can I leave it blank, if our staff are only testing for blood sugar?</p>	<p>Yes, the Lab Director section must be filled out, it is required to process the application. 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). The Lab Director and lab contact can be the same person, so you can put the same name in both locations.</p>	<p>Liz Parent</p>
<p>Will this power point be made available to us to use as a reference?</p>	<p>Yes</p>	<p>Colleen Jensen</p>
<p>What's the point of nurse delegation with special focus on diabetes with employee if turnover rates high, diabetic patients are not always in home now that you have to have a special license on top of that?</p>	<p>The MTSW requirement has been in effect since 1990, you need a license if you perform testing on someone else. It relates to laboratory requirements. (Liz) Nursing Delegation refers to who is doing the testing. If blood sugars are tested by caregiving (non-licensed staff), then Nurse Delegation is required. (Katherine)</p>	<p>Liz Parent and Katherine Ander</p>
<p>Section four (on the application): What do you write on the lines? (For COVID)</p>	<p>Section four (pages 3-6) is to list the tests you are using and completing at your facility. Please list the test kits next to the analyte or test ie. glucose, the name of the test kit is on the test kit box. Also for glucose on page four, you may list "Blood glucometer Cleared by FDA for Home Use" if your staff are helping residents complete a glucose test but do not know the brand of the test kit.</p>	<p>Liz Parent</p>
<p>Could you please explain a little bit about section 5 (on the application)?</p>	<p>Section 5: For Legal Owner Information just put in the required information (name, phone number, etc.) of the owner of the company. For Section 5 the Change of Ownership Information can remain blank unless the company owner/ Fed ID number/ UBI number is changing.</p>	<p>Jennifer Hopgood</p>

If I have a new admit that needs BG monitoring... can I admit and wait for you to approve? Or do I have approval for a CLIA before I even have a resident that needs the care?	A license is required before testing takes place.	Liz Parent
If we have more than one AFH Home do we need a license for each home ?	A license is required for each home/location, unless the business is a not for profit or government agency, which can have multiple sites.	Liz Parent
Do we need to fill out an application whether we do testing or not?	No, you do not need to fill out an MTS license application unless you or your staff are completing or assisting with testing.	Jennifer Hopgood
What was the contact info again? I need to change the director of the site	<a href="mailto:LQA@doh.wa.gov">email LQA@doh.wa.gov</a> or go to <a href="https://doh.wa.gov/licenses-permits-and-certificates/facilities-z/laboratory-quality-assurance/forms">https://doh.wa.gov/licenses-permits-and-certificates/facilities-z/laboratory-quality-assurance/forms</a>	Liz Parent
Aside from the provider as lab director will the caregivers be listed (on the application)?	It is not necessary to list testing personnel on the application.	Liz Parent
Blood glucose meaning blood sugar check, right? So do we need to get this license if we're doing blood sugar check before injecting insulin, right or no?	If your staff are assisting with the testing or offering medical advice (such as take this amount of insulin), or informing residents physician, then you will need the License. If the resident is completing the blood glucose testing on their own and the resident is independently determining the amount of insulin to take then a license is not required.	Liz Parent
Does the Lab Director have to be the provider?	Lab directors for waived licenses do not need to have any certification or accreditation. Anyone responsible for the testing can be listed.	Liz Parent

<p>There was a comment in the presentation differentiating physical disability from cognitive disability, could you please explain why? What differs in requirements?</p>	<p>Washington is aligning with CMS CLIA guidance that states "an individual assisting a child or adult who is unable to test themselves due to a physical disability in a home or congregate setting), to the extent authorized in the manufacturer's Instructions for Use (IFU), is considered self-testing for purposes of CLIA and would not require a CLIA certificate.". To note, the guidance specifically does not state someone who is unable to test themselves due to a cognitive disability.</p>	<p>Liz Parent</p>
<p>Do all AFHs have to apply for the license?</p>	<p>Not all AFH have to have the MTS license if there is no testing, no license is required. If your staff are assisting with the testing or offering medical advice (such as "take this amount of insulin"), or informing residents physician, than you will need the License. If your residents are testing completely on their own then a license is not required.</p>	<p>Liz Parent</p>
<p>Do we need to pay a fee yearly for the license or just one time?</p>	<p>Licenses are \$190 for a two-year term. A two-year term begins July 1st of an odd number year and ends on June 30th of the following odd year. If you apply for your license and submit your application on or after July 1st of an even numbered year, then you will only pay the prorated fee of \$95.</p>	<p>Liz Parent</p>
<p>Will AFH be surveyed for the MTSW?</p>	<p>For the Medical Test License, there will be an infection control suvey (on 5% of test sites). We reach out to set up a good time to survey. These are educational surveys, on scheduled visits. Make sure COVID-19 tests are being reported to the state or Local Health Jurisdiction and that staff performing the tests are following the instructions for use for the kit.</p>	<p>Liz Parent</p>

<p>If we provide Home Health and do not provide any test currently that would require this license should we send in for the application in case we do in the future or can we apply at any time for the license ?</p>	<p>You can apply anytime, only apply if a license is needed. We do not license facilities that are not performing testing.</p>	<p>Liz Parent</p>
<p>Just to be clear, An AFH would need a CLIA waiver and nurse delegation to perform blood sugar tests that determine if a resident needs insulin.</p>	<p>An MTSW license is required if staff are performing testing on residents. (Liz) Nursing Delegation refers to who is doing the testing. If blood sugars are tested by caregiving (non-licensed staff), then Nurse Delegation is required. (Katherine)</p>	<p>Liz Parent and Katherine Ander</p>
<p>For Enhanced Service Facilities they usually have many houses with one office. Does one CLIA cover testing for all of their associated houses? Do they need to bring all Clients to the main office to do any tests?</p>	<p>Medical Test Site licenses are site specific, if your business is for profit you will need a license for each site. A MTSW license does not cover all associated houses unless your business is not-for-profit. There are options for mobile test site licensing, but the test kits must not be kept at associated houses and are required to be kept in the mobile unit, please contact LQA@doh.wa.gov for further information.</p>	<p>Liz Parent</p>
<p>How much do we pay if I apply now? Think you said 95. I am not sure</p>	<p>Licenses are \$190 for a two-year term. A two-year term begins July 1st of an odd number year and ends on June 30th of the following odd year. If you apply for your license and submit your application on or after July 1st of an even numbered year, then you will only pay the prorated fee of \$95.</p>	<p>Liz Parent</p>
<p>If we are selling our adult family home is the license transferable</p>	<p>Yes, the license is transferrable. You would submit a new application with the change of ownership information filled out. The new owner will need to send in an application, found here: <a href="https://doh.wa.gov/sites/default/files/legacy/Documents/Pubs/505038.pdf?uid=625dc6ed47303">https://doh.wa.gov/sites/default/files/legacy/Documents/Pubs/505038.pdf?uid=625dc6ed47303</a>. The fee may be transferred only if the new owner would like to keep the existing CLIA license number.</p>	<p>Liz Parent</p>

<p>If our residents are physically disabled, are we required to get a license in order to give them COVID test or check blood glucose even though we have licensed RN' and LPN's on site at all times?</p>	<p>If the site is using the test result for medical purposes, yes a license is required. If your site is helping a person with a physical disability complete a home use covid test or blood sugar test and the site is not using the result for treatment decisions then in this situation a license is not required, as staff are helping a person with a physical disability complete a self-test, to note - the test must be approved by the FDA for home use. Also, the need for a license does not depend on if your site has licensed personnel, it depends on if your personnel are completing the tests. (Liz) If blood sugar testing is occurring on site, an MTSW is required. (Katherine)</p>	<p>Liz Parent and Katherine Ander</p>
<p>Will HCS and DDA screen homes for MTSW when making placement for residents who require BG monitoring for example?</p>	<p>After discussion with DDA and HCS it was determined no change in placement practice is anticipated related to the MTSW requirements.</p>	<p>RCS</p>
<p>I am not planning to do Covid Rapid testing right now but I might need it in the future if anyone gets an exposure. Should I add it on my license test?</p>	<p>If your facility possesses the tests already, and you most likely will be using them to test residents, then you can add them to your license. If you do not possess the test kits than please do not add them as you will not be able to provide the name of the test and manufacture.</p>	<p>Liz Parent</p>
<p>Will Home &amp; Community Services (HCS) be limiting placement of new residents who may need MTSW required testing to homes that already have this license? Will this be a consideration for placement and/or will HCS inform providers they may need a MTSW if they admit a resident needing one of these tests?</p>	<p>After discussion with DDA and HCS it was determined no change in placement practice is anticipated related to the MTSW requirements.</p>	<p>RCS</p>
<p>Will case managers with HCS and DDA consider the need for a MTSW when looking to place a resident with needs that would require testing?</p>	<p>After discussion with both DDA and HCS it was determined no change in placement practice is anticipated related to the MTSW requirements.</p>	<p>RCS</p>

<p>if we don't get CLIA because we are not comfortable doing blood glucose check and not comfortable giving insulin but the home health nurse will come to check the blood glucose , do we need to get CLIA with this situation?</p>	<p>In this situation, the staff may not be helping with testing but the HH nurse is doing testing &amp; there should be a license, it is important to check with the home health nurse to ensure they have a medical test site license to perform testing. Have them reach out to LQA@doh.wa.gov with questions.</p>	<p>Liz Parent</p>
<p>So a medication for blood pressure that requires you to take BP, which determines if and what dose is given... does this require a CLIA?</p>	<p>No, blood pressure measurements are not CLIA tests, a Medical Test Site license is for samples performed on a specimen or body fluid such as blood, urine, saliva.</p>	<p>Liz Parent</p>
<p>I take fasting blood sugar every morning, do I need CLIA?</p>	<p>Unless a staff member is involved, an individual performing blood sugar tests on themselves would not require a MTSW/CLIA license- it is self-testing. According to our WAC rules a "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;</p>	<p>Liz Parent</p>
<p>Is a RN need CLIA or only caregivers? Or everyone need one</p>	<p>Medical Test Site licenses are site specific, so sites or addresses where testing takes place need licensed. If you have a private practice, say as an RN, and go out to homes to take blood sugar tests on folks, you will need a license, likely as a mobile site.</p>	<p>Liz Parent</p>
<p>How long should we expect the license process to take?</p>	<p>Licenses are currently taking 3-4 weeks to process once WA state DOH has received the application.</p>	<p>Liz Parent</p>
<p>If a diabetic has the implant and you are using a device to read results you wouldn't need the license correct?</p>	<p>No, not unless you are using the result for medical treatment, ie. giving insulin.</p>	<p>Liz Parent</p>

<p>Are we required to obtain a CLIA license for checking blood glucose before giving insulin, right? or we don't need a license.</p>	<p>Yes, that is an activity that requires licensing at the site.</p>	<p>Liz Parent</p>
<p>So if the resident is testing their own blood glucose and telling us the level and all we do is determine the amount to give but the resident does the injection themselves, is a license required</p>	<p>Yes, a license is required if staff are involved in determining how much insulin to deliver, as this is a medical decision based off a test result.</p>	<p>Liz Parent</p>
<p>Will you provide the link with these presentations again please</p>	<p>Yes, it is on the AFH Provider webpage</p>	<p>Colleen Jensen</p>
<p>What is CLIA? What is this stand for? Is there a class for it or just application to get the license? Can we have a zoom about this? A lot of things are not clear to me? Thank you</p>	<p>Clinical Laboratory Improvement Amendments. (Jennifer) CLIA is the certificate required in most US states. WA is exempt from CLIA, we have state laws that apply in WA requiring a Medical Test Site (MTS) License. WA state medical test site licenses are issued with an MTS number as well as a CLIA number- for billing purposes. (Liz)</p>	<p>Jennifer Hopgood and Liz Parent</p>
<p>Do all staff working at the AFH need a CLIA number ?</p>	<p>A Medical Test Site License covers the facility and everyone in it. (Jennifer) Yes, a CLIA covers all testing at an address or location. (Liz)</p>	<p>Jennifer Hopgood and Liz Parent</p>
<p>Do you recommend getting a new license for testing if regulated testing will be performed after licensing?</p>	<p>Yes, and we are here to work with folks who may have already been completing testing and are currently becoming aware of the requirement. We want to improve and ensure access to testing needed to keep our communities healthy and safe.</p>	<p>Liz Parent</p>



Question	Answer	Responder
<b>MTSW questions</b>		
Can you repeat the two reporting for covid?	Any positives or negatives are reported to state. Some LHJs do not want negatives reported. Under the license, all test results are to be reported. Specifically for long-term care facility sites, do require reporting positive COVID test, no need to report negatives to the state.	Liz Parent/Jennifer Valverde
If residents are at the hospital or ER and the are tested positive, will the home need to report again?	The home will not need to report the result again to the state because the hospital or ER where the resident was tested will be the one to report this result. If the result is reported twice it will cause a duplicate record.	Jennifer Valverde
How do you report if you don't need a license?	Positive POC COVID results for self-tests can be reported to the Department of Health (DOH) by calling 1-800-525-0127	Jennifer Valverde
Can you please review the reporting requirements for each test?	Any positives or negatives are reported to state. Some LHJs do not want negatives reported. Under the license, all test results are to be reported. Specifically for long-term care facility sites, do require reporting positive COVID test, no need to report negatives to the state.	Jennifer Valverde
Simple Report is applicable to an Assisted Living as well?	Yes, if an assisted living facility is using point-of-care (rapid) tests, they can use SimpleReport to report their positive COVID test results.	Jennifer Valverde
What is the benefit of using a Simple report rather than reporting directly to the LHJ?	LHJs have access to Washington Disease Reporting System to search for residents who have tested positive for COVID - if LHJs need to keep track of folks in their county who have tested positive, they can run a report in WDRS for the results. Depending on how the facility is reporting (pdf or spreadsheet) this can cut down on time it takes to collect and report the information. It goes straight to the state.	Jennifer Valverde

<p>Are Covid tests the only tests that are required to be reported? If not, what other test results need to be reported? Thank you</p>	<p>There is a list of notifiable conditions. <a href="https://doh.wa.gov/public-health-healthcare-providers/notifiable-conditions/list-notifiable-conditions">https://doh.wa.gov/public-health-healthcare-providers/notifiable-conditions/list-notifiable-conditions</a>. Any test not performed at your site does not need to be reported, the laboratory reports tests they perform. Any test ran on site - and immediate results are returned on site, then consult list of reportable conditions. i.e. test kits beyond COVID. If doing any tests done at the home, assisting the resident, a MTSW license is required. (Liz)</p> <p>There is there is a difference between reporting lab results and being required to report notifiable conditions as a healthcare setting. Some things you are required to report even if not doing the test such as an infectious disease. As a health care setting you must notify an "occurrence" or outbreak. In other circumstances, if running tests in home and getting results, the lab results need to be reported. EXAMPLES: COVID-19 test, HIV test</p> <p>If your resident tests positive at another facility (like the hospital) &amp; returns to you, you do not need to report. The</p>	<p>Liz Parent and Amy Abbott</p>
--	---	----------------------------------