

# Waived Medical Test Site License Application Helpful Tips & Instructions



## Important Note:

Only tests approved as a waived test by Food and Drug Administration (FDA) can be performed under this category of license. A "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. Tests can be looked up at the FDA's test/analyte search page found here: [FDA Analyte Search](#)

To look up tests approved under an Emergency Use Authorization (EUA) for SARS-Cov-2 (Covid-19) use on the following links: [Antigen-diagnostic-tests-sars-cov-2](#) , [Molecular-diagnostic-tests-sars-cov-2](#). Tests in the table authorized as only "W" or "Home" can be performed at a waived testing site. These tests will not be found on the FDA Analyte search page as they have not obtained a full FDA Authorization.

If your test kit doesn't appear on the FDA-approved waived test list, or appears as "H" or "M" on the EUA list you **DO NOT** qualify for this license type and are required to obtain a Categorized or Accredited license.

## Waived application Instructions - Applying for a Waived Medical Test Site License in Washington

- Complete the Waived Medical Test Site Application with Instructions found here: [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.

## Instructions

The first four pages are the official instructions for filling out the application and are meant to help fill out the application. We require that each of the seven pages of the application are returned, even if some pages are left blank (and excluding the first four pages of instructions).

Here is guidance for filling out the application which may or may not be applicable in different circumstances.

On the top of page one (above the bold line) the owner information needs to match information is listed on your site's business license.

- Mark the "New" box if this is the first time applying for a license.
- Under the **Check One** heading, mark the type of business listed on your business license (non- profit, corporation etc.)
- Below the bold line refers to the “doing business as” information. This may be the same or different as above - Whatever you are advertising your business as.

On Page two, **Section 2**, mark the site type. If you are not sure, you can write your specific site type in a blank area, we do not provide guidance on the site type.

- Actual hours of Testing (which may differ from business hours). List 24/7 if testing is performed all hours of the day.
- Additional locations under this license: If your site is a government entity or not-for profit, you may list any/every building where testing might occur. On a separate sheet of paper, include a list of the building names, full addresses & phone numbers. Verification of not-for-profit status will be required.

Section 3: Key Individuals - List the name and email address of the person(s) overlooking/responsible for the testing program (they don't have to perform the tests). For a waived site there are no personnel requirements to be the Lab Director, ie. the individual is not required to be a nurse, doctor, ect. You may list whomever oversees testing as the lab director. Also, we ask for a contact person, because lab directors are often too busy to receive calls. The contact person may be an admin/secretary or someone who can get a message to the director if necessary or may be the director.

Pages 3 – 6 are a list of waived tests in alpha order by category. If at least one test is completed on one person per year at your location, then the test should be listed. For example: Glucose on page 4. Since each diabetic will have their own glucometer, it would be difficult to list each manufacturer, so write “Cleared by FDA for Home Use”. You will find SARS CoV-2(COVID-19) on page 5. If available, write the name of the manufacturer and the name of the actual test (example: Abbott, Binax Now). If you don't have that information or may be using several different tests, you may write “SARS Antigen and Molecular Tests”.

Page 7:

- Section 5 (Other Licensure . . .) You may add other individuals, such as Board Members or heads of the organization, however, if you feel that this isn't necessary it can remain blank.
- Change of Ownership Information: This should remain blank for a new application.
- Signature: We need an original ink signed signature on the application in order to approve your license. We require a signature of a person in a position of responsibility for the business, and require a signature, date, printed name and title.

If you need a CLIA number to receive the testing products, then scan and email the signed seven pages LQA@doh.wa.gov with an explanation of the circumstances. We will do our best to expedite your license but must follow our process to ensure we are assigning CLIA numbers in the order applications are received. Your business is still required to mail in the original application with a fee payment to receive license (a

license may be assigned in a pending status initially then changed to an active license when the hard copy is received).

Mail in the 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.