

Interim SARS-CoV-2 Self-Testing Guidance for Establishments

Summary of changes April 18, 2022

- Updated to reflect guidance from the Washington Medical Test Site Program on Medical Test Site License requirements.
 - These changes describe how establishments may use self-tests approved by the Food and Drug Administration for "over the counter" or home use without a Medical Test Site/CLIA license, as long as the tested individuals (or parents/guardians) perform and interpret the self-tests.

Introduction

Testing is important to help reduce the spread of SARS-CoV-2, the virus that causes COVID-19. Testing can be used in a variety of ways:

- Determining whether a person with symptoms has COVID-19
- Routine screening testing, especially in settings with higher risk of COVID-19 transmission due to factors such as crowding, inability to maintain distance, or limited ventilation
- Enhanced testing when a potential outbreak is identified

This guidance provides information for establishments to help determine potential use of self-tests and develop policies about self-tests. Establishments can also consult with their local health jurisdiction when developing plans or policies about self-tests. Schools and childcare facilities should consult the [separate Department of Health guidance](#) for these settings.

Self-tests are increasingly available to make testing more accessible and are an option that establishments can consider for COVID-19 testing. Sometimes a self-test is also called a "home test," an "at-home test," or an "over-the-counter test." Self-tests are usually available without a prescription (over the counter) in a pharmacy or retail store. Individuals can also request self-tests from the Department of Health [Say Yes to the Test website](#) and the federal [COVID Test](#) site.

Self-tests are intended to detect current infection, and therefore can be used to help determine if a person is contagious. This can help prevent spread of COVID-19. Self-tests are:

- Easy to use
- Quick to return results (in about 15 minutes)
- Low-cost

Establishments may use and/or provide COVID-19 self-tests in a variety of ways. Some settings may require a different type of test, such as a molecular test, depending on the purpose of the test. Different

testing recommendations may apply in an outbreak; please consult with your local health jurisdiction. In certain situations, an establishment using self-tests may need a [Medical Test Site license](#).

What is a Medical Test Site license?

A "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 test site does **not** mean 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 themselves without direct supervision or guidance by another and where this test is not part of a commercial transaction.

Facilities in Washington State that perform testing are regulated under the Washington Medical Test Site law and are required to obtain a Washington Medical Test Site license instead of a CLIA Certificate. This includes facilities using point-of-care or rapid screening tests not in a traditional laboratory setting such as long-term care facilities, schools, and correctional facilities. A CLIA number is assigned to Medical Test Sites in Washington but is only for billing, obtaining test kits, and for tracking purposes by CMS. A CLIA number is not a license in Washington as Washington State is exempt from CLIA. A Medical Test Site License would be a CLIA certificate of waiver in non-exempt states. This is important as to obtain a license in Washington a Medical Test Site Application must be filled out and not the CLIA 116 Application.

For facilities intending to use self-tests, see the sections below to determine if you need a Medical Test Site license in Washington. Healthcare facilities should also note that different requirements apply when testing patients. See [Washington Department of Health healthcare guidance](#) for more information.

When is a Medical Test Site license not needed?

A Medical Test Site license is not needed for COVID-19 self-tests performed and interpreted by individuals on themselves. The tests must be approved by the Food and Drug Administration for purchase and use by individuals.

An establishment without a Medical Test Site license may provide self-tests to individuals as long as the self-testing is performed and interpreted by the individual. More specifically, the establishment may do the following without the need for a Medical Test Site license:

- Provide the test kit to the individual along with the test manufacturer's instructions for use
- Ask the individual to carefully read and follow the package insert (following the instructions for use exactly as required)
- Allow the individual to follow the instructions to collect the sample (swab themselves), and run the test (encouraging the use of a timing device to ensure the test is read at the appropriate time is highly recommended)
- Allow the individual interpret or read the results (while being observed if the establishment requires observation of the testing process)
- Require testing as a condition of employment or participation in the organization or an activity
- Provide standard institutional guidance or published public health guidance to the individual on [self-tests](#) and [what to do if you test positive](#)

After the individual has read or interpreted the result, an employee of the establishment may then verify the results (i.e., ask to view the kit or make an observation of the result) if needed or if this is part of the establishment's policies.

An establishment, or a representative of the establishment, **may not** perform the test or interpret the test to provide the result to the individual **without** a Medical Test Site license in Washington State. Additionally, the establishment (or employees of the establishment) **may not** provide guidance to the individual about administering and performing the test (swab/sample collection and applying the sample to a test device) or guidance on interpretation of the test (reading the results from the testing device) without a Medical Test Site license.

If a representative of the establishment observes the individual making an error in performing the self-test, they may provide a new self-test kit and encourage the individual to follow the manufacturer instructions for use more closely. The establishment may also provide the individual with a copy of the [Department of Health guidance for use of self-tests](#). If an individual has a disability and needs assistance performing the test, please seek out more detailed guidance from [Department of Health Laboratory Quality Assurance](#) about assistance that may be provided.

Establishments that serve minors should note that each test is approved for specific ages. Parents or guardians may be required to supervise or collect the self-test sample for children below certain ages. Additionally, the authorized age-range varies based on the self-test. Establishments should thoroughly review and understand the self-test instructions provided with each test to understand the age requirements. See FDA's [list of In Vitro Diagnostics Emergency Use Authorizations](#) for more information about the age requirements of specific authorized tests.

If an individual tests positive, the establishment should not report the test result to public health. The establishment should encourage the individual to follow the Department of Health [guidance for use of self-tests](#) and the [guidance on next steps after testing positive](#). Establishments should notify their local health jurisdiction of suspected COVID-19 outbreaks. In the event there is a person with COVID-19 or outbreak at an establishment, the local health jurisdiction may request additional information, such as information on individuals who tested positive. Everyone is required to cooperate with public health authorities in the investigation of cases, suspected cases, outbreaks, and suspected outbreaks ([WAC 246-101](#), Governor's Proclamation 20-25 et seq. (currently [20-25.19](#))). See Labor and Industries' [reporting and outbreak notification requirements](#) for employers for additional outbreak reporting information.

When is a Medical Test Site license needed?

If an establishment wishes to perform testing, rather than having individuals self-administer tests, or interpret and provide results, the establishment is required to have a Medical Test Site license. A Medical Test Site License is required regardless of whether the establishment is using tests approved as self-tests (for individual use) or commercial point-of-care test kits. Establishments can apply for a Medical Test Site license on the [Department of Health Laboratory Quality Assurance page](#).

An establishment with multiple locations may apply for a multiple-site Medical Test Site license if the establishment is a [Not-for-Profit](#) or [State/Government agency](#) (multiple-site licenses are limited to

performing 15 waived medical test types, but this will not be an issue for establishments only offering COVID-19 testing). For-profit establishments need to apply for a separate license for each site. If an establishment is conducting mobile testing (i.e., using a vehicle to conduct testing at temporary sites), the mobile testing operation may be covered under the certificate of the designated primary site or home base, using its address. Mobile test sites should provide Department of Health Laboratory Quality Assurance (via the LQA@doh.wa.gov email box) with VIN numbers for each vehicle used for mobile testing.

Establishments that serve minors should note each test is approved for specific ages. Establishments should thoroughly review and understand the test instructions provided with each test to understand the age requirements. See FDA's [list of In Vitro Diagnostics Emergency Use Authorizations](#) for more information about the age requirements of specific authorized tests.

If an establishment has a Medical Test Site license and a representative of the establishment performs or interprets a COVID-19 test for another individual, the establishment is responsible for reporting results to the Washington State Department of Health. More information about reporting requirements and mechanisms can be found on the [Reporting COVID-19 Test Results for Point-of-Care Testing Facilities page](#). Establishments should notify their local health jurisdiction of suspected COVID-19 outbreaks. In the event there is a person with COVID-19 or outbreak at an establishment, the local health jurisdiction may request additional information, such as information on individuals who tested positive. Everyone is required to cooperate with public health authorities in the investigation of cases, suspected cases, outbreaks, and suspected outbreaks ([WAC 246-101](#), Governor's Proclamation 20-25 et seq. (currently [20-25.19](#))). See Labor and Industries' [reporting and outbreak notification requirements](#) for employers for additional outbreak reporting information.

Establishments with Medical Test Site Licenses that wish to provide self-tests for individual use

In certain situations, an establishment with a Medical Test Site license may wish to provide individuals with self-tests for their own use (for example, to perform the test at home). If the establishment provides the self-test but does not participate in performing or interpreting the test, the test result is considered a self-test result. In this situation, the establishment should not report the test result to public health. However, the establishment should encourage the individual to follow the Department of Health [guidance for use of self-tests](#) and the [guidance on next steps after testing positive](#).

Consider developing a policy regarding the use of self-tests

Establishments should implement policies outlining the expected uses of self-tests in their setting, such as clarifying whether they will accept results from self-tests for employees to return to work. When developing policies around testing, establishments should consider several factors including:

- [Transmission in the community](#)
- Risk factors in their setting, such as crowding, inability to maintain distance, or limited ventilation
- Medical vulnerability of people in their setting
- Vaccination status of people in their setting
- Medical Test Site license rules
- Reporting responsibilities

The Department of Health also publishes COVID-19 [resources and recommendations](#) for specific settings such as workplaces, other non-healthcare establishments, and healthcare facilities, which provide additional information about preventing and responding to COVID-19.

More COVID-19 Information and Resources

Stay up-to-date on the [current COVID-19 situation in Washington](#), [Governor Inslee's proclamations](#), [symptoms](#), [how it spreads](#), and [how and when people should get tested](#). See our [Frequently Asked Questions](#) for more information.

A person's race/ethnicity or nationality does not, itself, put them at greater risk of COVID-19. However, data are revealing that communities of color are being disproportionately impacted by COVID-19. This is due to the effects of racism, and in particular, structural racism, that leaves some groups with fewer opportunities to protect themselves and their communities. [Stigma will not help to fight the illness](#). Share only accurate information to keep rumors and misinformation from spreading.

- [WA State Department of Health 2019 Novel Coronavirus Outbreak \(COVID-19\)](#)
- [WA State Coronavirus Response \(COVID-19\)](#)
- [Find Your Local Health Jurisdiction](#)
- [CDC Coronavirus \(COVID-19\)](#)
- [Stigma Reduction Resources](#)

Have more questions? Call our COVID-19 Information hotline: **1-800-525-0127**

Monday – 6 a.m. to 10 p.m., Tuesday – Sunday and [observed state holidays](#), 6 a.m. to 6 p.m. For interpretative services, **press #** when they answer and **say your language**. For questions about your own health, COVID-19 testing, or testing results, please contact a health care provider.

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.