

COVID-19 Self-Testing Guidance for Establishments

Summary of changes May 23, 2023

- Updated information about accessing self-tests
- Added information for K-12 schools and child cares
- Added information about use of self-tests in children under 2 years of age
- Updated information about how self-tests can be used

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 if a person with symptoms has COVID-19
- Determining if someone who was exposed to COVID-19 has COVID-19, even if they do not have symptoms
- Screening testing of people without symptoms who have no known exposure to COVID-19, in accordance with public health recommendations
- 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.

Self-tests 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. This [fact sheet](#) provides information about insurance coverage for COVID-19 tests. Individuals should check with their insurance providers to verify coverage of costs associated with at-home test purchases.

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 the 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](#).

Who Can Test?

Anyone can get tested for COVID-19, no matter your age. Washington State Department of Health (DOH) guidance allows the safe use of at-home rapid antigen testing for children under 2 years of age. At this time, the US Food and Drug Administration (FDA) has not approved or authorized any at-home COVID-19 rapid antigen test for use in children under 2 years of age. However, at-home rapid antigen tests may be safely used in children under 2 years of age after being exposed, if a child is experiencing symptoms, or to identify COVID-19 infection to begin isolation. Parents or guardians deciding to test children under 2 years of age should administer the at-home rapid antigen test themselves.

Because the FDA has not approved or authorized at-home COVID-19 rapid antigen tests for use in children under 2 years of age, establishments with a waived Medical Test Site (MTS) license are not permitted to perform at-home rapid antigen tests on children under 2 years of age. Establishments may provide at-home rapid antigen test kits to parents or caregivers for their use.

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 FDA 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 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. Health care facilities should also note that different requirements apply when testing patients. See [COVID-19 Infection Prevention in Health Care Settings](#) 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 or their children. The tests must be approved by the FDA 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 to 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 request to verify the results (i.e., ask to view the kit or observe the result) if needed or if this is part of the establishment's policies. For establishments serving minors, including K-12 schools and child cares, a parent or guardian may need to collect the sample, run the test, and interpret or read the test results.

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 [DOH 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 the [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 when performing and interpreting a test on themselves or their children, the establishment should not report the test result to public health. The establishment should encourage the individual to follow the DOH [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. K-12 schools and child care facilities are required to report outbreaks or suspected outbreaks to their local health jurisdictions ([WAC 246-101-420](#) and [WAC 246-101-415](#)). In the event there is a person with COVID-19 or an 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, outbreaks, and suspected outbreaks ([WAC 246-101-425](#)).

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 waived 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. K-12 schools should use Simple Reports to report all test results and see the [COVID-19 Point-of-Care Test Reporting for K-12 Schools](#) page for additional information. Establishments should notify their local health jurisdiction of suspected COVID-19 outbreaks. K-12 schools and child care facilities are required to report outbreaks or suspected outbreaks to their local health jurisdictions ([WAC 246-101-420](#) and [WAC 246-101-415](#)). In the event there is a person with COVID-19 or an 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, outbreaks, and suspected outbreaks ([WAC 246-101-425](#)).

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

In certain situations, an establishment with a waived 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 DOH [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 or for students and children to return to school or child care. When developing policies around testing, establishments should consider several factors including:

- Current COVID-19 transmission in the facility
- COVID-19 transmission and health impacts in the community
- Risk factors in their setting, such as crowding or limited ventilation
- Medical vulnerability of people in their facility
- Vaccination status of people in their facility
- Medical Test Site license rules
- Reporting responsibilities

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

Mental and Behavioral Health Resources

Please visit the DOH [Behavioral Health Resources and Recommendations](#) webpage.

More COVID-19 Information and Resources

Stay up-to-date on the [current COVID-19 situation in Washington](#), [symptoms](#), [how it spreads](#), [how and when people should get tested](#), and [where to find vaccines](#). 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 accurate information with others to keep rumors and misinformation from spreading.

- [WA State Department of Health COVID-19 Response](#)
- [Find Your Local Health Department or District](#)
- [CDC Coronavirus \(COVID-19\)](#)

Have more questions? Call DOH at **1-800-525-0127**.

For interpretative services, **press #** when they answer and **say your language**. For questions about your own health 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.