

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

Testing is important to help reduce the spread of SARS-CoV-2, the virus that causes COVID-19. While testing is generally not required, testing may be useful in various ways in a non-health care setting (depending on the type of test and whether the employer has a CLIA certificate of waiver), such as:

- Determining whether a worker with symptoms has COVID-19, which impacts when they could return to work.
- Allowing workers who are asymptomatic and exposed to return to work in accordance with the 7-day quarantine option with testing no sooner than 48 hours before end of quarantine ([Isolation and Quarantine for COVID-19 :: Washington State Department of Health](#)), if this quarantine option is permitted by the local health jurisdiction.
- Routine screening for employees, especially those at higher risk due to inability to maintain distance because of the nature of their work, those who come in close contact with unmasked people of unknown vaccination status, or those who work in areas with poor ventilation.
- Screening of employees following travel.

There are various testing options for employers to consider for their workplace. One option for testing in the workplace is self-testing. This guidance provides information for employers in non-health care settings to determine potential use of self-tests and/or when developing policies about self-tests. Employers should consult with their local health jurisdiction in development of such plans and/or policies. This guidance is intended for employers in non-healthcare settings; the general public is advised to follow the [WA DOH guidance for use of self-tests](#) for information on COVID-19 testing for personal use. For more general information on testing in non-healthcare settings, please see the DOH [Guidance for Non-Health Care Businesses and Organizations](#) and the CDC's [Interim Guidance for SARS-CoV-2 Testing in Non-Healthcare Workplaces](#).

Self-tests are now available to make testing more accessible. Sometimes a self-test is also called a “home test,” an “at-home test,” or an “over-the-counter test.” These self-collection kits and self-tests are available either by prescription or over-the-counter (without a prescription) in a pharmacy or retail store. Self-tests are intended to detect current infection, and therefore can be used to determine if an employee is contagious before they enter the workplace or return to work. This can help prevent spread of COVID-19 in the workplace. Self-tests are:

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

Non-health care facilities may use and/or provide COVID-19 self-tests in a [variety of ways](#), depending on whether the facility has a [CLIA Certificate of Waiver](#). Some settings may require a different type of test, such as a molecular test, depending on the purpose of the test. Check with your company policy.

Different testing recommendations may apply in an outbreak; please consult with your local health jurisdiction.

What is a CLIA Certificate of Waiver?

All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease, are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) with the use of [CLIA Certificate of Waivers](#). To determine if you need a CLIA Certificate of Waiver for your company's intended use of self-tests, see the sections below on the details for operating [with](#) or [without](#) the CLIA Certificate of Waiver.

Employer Self-Test Use [Without](#) a CLIA Certificate of Waiver

A CLIA Certificate of Waiver (or simply, CLIA waiver) is not needed for tests used for private, individual use, such as SARS-CoV-2 self-tests (over-the-counter tests) performed and interpreted by the individual themselves.

An employer/facility/organization/agency without a CLIA waiver may *provide* self-tests to individuals so long as the self-testing is entirely self-directed by the individual and the facility meets the following requirements:

- The employer/facility/organization/agency **does not** provide and recommend self-testing to the person because they are symptomatic. An employer may recommend that a symptomatic person get tested, but not specifically using a self-test.
- The employer/facility/organization/agency **does not** provide guidance on the frequency of self-testing or require self-testing as a condition of employment or participation in the organization/activity.
- The employer/facility/organization/agency **does not** provide guidance to the individual about administering and performing the test (swab/sample collection and applying the patient sample to a test device), interpretation of the test (reading the results from the testing device), or what to do based on the test results. Additionally, facility staff may not take on the [role of reporting](#) the test results to the individual.
- If an individual does report their results to the facility of their own accord (without the facility requesting or requiring that the person report the results to the facility), the employer/facility/organization/agency or the individual should report positive results to the Washington State Department of Health (DOH) by calling 1-800-525-0127.

If an employer/facility/organization/agency provides a person with a self-test in accordance with the requirements above, they may also provide the person with a copy of the [WA DOH guidance for use of self-tests](#).

Employer Self-Test Use [With](#) a CLIA Certificate of Waiver

If the employer/facility/organization/agency directs the self-testing in any of the ways in the list below, then they are required to have a [CLIA Certificate of Waiver](#). The employer/facility/organization/agency can apply for a CLIA waiver on the [Department of Health's Certificate page](#). Other processes for supporting testing of employees, such as performing commercially packaged tests on-site, are often more appropriate than self-testing if an employer/facility/organization/agency has a CLIA waiver and intends to incorporate testing into their company practices. This is especially true for regular screening.

The employer/facility/organization/agency should direct the person performing the self-test to use the test in accordance with manufacturer's instructions. With a CLIA waiver, the employer/facility/organization/agency can:

- Provide and recommend testing to a person because they are symptomatic, were exposed, or as a condition of employment or participation in the organization or activity.
- Provide guidance on the frequency of testing, administering and performing the test, interpretation of the test, and/or what to do based on test results.
- Report the test results to the individual.

If testing is performed under a CLIA waiver, the employer/facility/organization/agency must report test results to the Washington State Department of Health (see Reporting Results below).

Reporting Results

Employers/facilities/organizations/agencies directing self-testing for COVID-19 with a CLIA Certificate of Waiver must report all COVID-19 testing results to the Washington State Department of Health (DOH). See more information about reporting can be found on the [Reporting COVID-19 Test Results for Point-of-Care Testing Facilities page](#).

Employers/facilities/organizations/agencies without a CLIA waiver must not require employees to report their results to the employer/facility/organization/agency. If an individual does report their results to the employer/facility/organization/agency of their own accord, the employer/facility/organization/agency or the individual should report to DOH by calling 1-800-525-0127.

Consider developing a policy regarding the use of self-tests

The general public is advised to follow the [WA DOH guidance for use of self-tests](#).

Employers/facilities/organizations/agencies should implement policies outlining if they will accept results from self-tests for return to work or other purposes. Individuals who test positive using a self-test should report the case to DOH by calling 1-800-525-0127 and follow the [WA DOH guidance for use of self-tests](#), which includes next steps after testing positive. When developing a policy for employee self-testing, an employer/facility/organization/agency should consider several factors including:

- [Transmission in the community](#).
- Workplace risk factors, such as, exemptions to wearing a mask/source control, ability to maintain six feet of distance, and ventilation of the workplace.
- Vulnerability of employees and customers.
- Vaccination status of the employees.
- [CLIA Waiver Regulations](#).
- [Reporting responsibilities](#).

See the WA DOH guidance for workplaces and specific non-healthcare settings [here](#) for 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.

Key Features	 Abbott BinaxNOW Self	 ellume Ellume HomeTest	 Quidel QuickVue	 AccessBio Care Start	 Abbott BinaxNOW AG Card	 BD Veritor	 Lucira Check-It	 Amazon COVID-19 Test Collection Kit DTC FDA Authorized	 Pixel by LabCorp	 Everlywell	 SalivaClear by Mirimus Clinical Labs	 cic Health Pooled Testing Kit
Method-Modality	Shallow nasal swab	Shallow Nasal Swab	Shallow Nasal Swab	Shallow Nasal Swab or Nasopharyngeal	Shallow Nasal swab	Shallow Nasal Swab	Shallow Nasal Swab	Shallow Nasal Swab	Shallow Nasal Swab	Shallow Nasal Swab	Saliva Specimen	Shallow Nasal Swab
Testing Technology	Rapid Antigen	Rapid Antigen	Rapid Antigen	Rapid Antigen	Rapid Antigen	Rapid Antigen	Molecular (Viral RNA as proxy to PCR)	Polymerase chain reaction (PCR)	Polymerase chain reaction (PCR)	Polymerase chain reaction (PCR)	Three Step: Same-Sample Reflex Pooled Testing / In-Lab Pooling followed by Individual Diagnostic (2)	Pooled (Bach) PCR
Cost	\$24 for Two	\$39	\$24 (OTC)	~\$13	<\$10 per Card (as low as \$5)	~\$350 Reader (one-time) + \$17.50 per Cartridge	\$50	\$37	\$120; Free and No Upfront Cost if Meet Guidelines	\$109, Potential Insurance Reimbursement	Enterprise	\$119 for 10 people; Bulk \$890 for 100 people
CLIA Waiver Requirement	No*	No*	No*	Yes	Yes	Yes	Yes if Healthcare Provider; No* for Home (ages 14+)	No*	No*	Lab (No)	Lab (No)	Lab (No)
Primary Use Cases (EUA)	Diagnostic-Symptomatic; Some Screening	Diagnostic-Symptomatic and Asymptomatic Screening per EUA	Diagnostic-Symptomatic and Asymptomatic Screening per EUA	Diagnostic-Symptomatic and Asymptomatic Screening per AccessBio	Diagnostic-Symptomatic; Some Screening	Diagnostic-Symptomatic; Some Screening	Diagnostic-Symptomatic and Asymptomatic Screening per EUA?	Diagnostic-Symptomatic and Asymptomatic; Screening	Diagnostic-Symptomatic and Asymptomatic; Screening	Diagnostic-Symptomatic and Asymptomatic; Screening	Asymptomatic Screening and Follow-Up Reflex Testing if Positive Pool	Asymptomatic Screening; Does not Include Follow-Up Reflex Testing
Accuracy (Sensitivity, Specificity)	Lower Sensitivity for Asymptomatic; Risk of False Negatives	96% Sensitivity per Ellume	Positive Agreement 83.5%; Negative Agreement 99.2%; 2 Tests Recommended	Positive Agreement 87%; Negative Agreement 100%; Serial Tests Indicated	Lower Sensitivity for Asymptomatic; Risk of False Negatives	Lower Sensitivity for Asymptomatic; Risk of False Negatives	98% Sensitivity per Lucira	Gold Standard; >98%	Gold Standard; >98%	Gold Standard; >98%	Gold Standard; >98%	Gold Standard; >98%
Cycle Time to Collect	<5 Minutes on Serial Basis (two tests over 36 Hrs)	<5 Minutes	<5 Minutes	<5 Minutes	<5 Minutes	<5 Minutes	<5 Minutes	<5 Minutes	<5 Minutes	<5 Minutes	Multiple Cycles; first >5 Minutes	~10 Minutes per Pool
Result Turnaround Time	15 Minutes on Serial Basis (36 Hrs)	15 Minutes	10 Minutes	10-15 Minutes;	15 Minutes	15 Minutes	30 Minutes	~1-3 days	~1-3 days	~1-3 days	24 Hours + 12 Hours + 6 Hours + Transit Time	24 Hours + Transit Time
Self-Administration and Age Limitations	Ages 2 and Older	Self-Test at Home for Ages 16+ Ages 2-15 Administered by Adult	13+ Self-Test at Home; Ages 2-13 Administered by Adult	Prescription Use Only; not for POC Screening	Only administered by a healthcare professional or school staff/volunteer trained by a healthcare professional	Self-Administration with small equipment Reader/Analyzer as a Provider	Authorized for self-collection for individuals aged 14+ and adult collection for children aged 2-13	18+ only	Ages 2 and Older	18+ Self-Test at Home; 16+ with test observer; Healthcare professional for under 16	Generally Intended for Adults as Enterprise Solution	Self-Swab Recommended for Ages ~7 and Above
Labor Requirements	Self OTC	Low – Education and Counseling for Take Home	Low – Self-Education and Counseling for Take Home	High; Extraction Vial and Sample Well Required	High; Observer and Administration of Card for Results	High; Observer and Administration of Card for Results	Low – Self-Education and Counseling for Take Home	Low – Self-Education and Counseling for Take Home	Low – Self-Education and Counseling for Take Home	Low – Self-Education and Counseling for Take Home	Lab comes to Enterprise	Enterprise collects and ships to Lab
Training Platform Available	Instructions for Use	App Required for Results	Instructions for Use	Healthcare Providers Fact Sheet and Instructions for Use	Abbott Self-Service Modules 1-4	Yes; <u>On-Demand Training BD Veritor™ Plus System</u>	Instructions for Use	Instructions for Use	Instructions for Use	Yes; Home-Based Training Video	End-to-End Solution Provided	Instructions for Use

Key Features	 Abbott BinaxNOW Self	 ellume Ellume HomeTest	 Quidel Quidel QuickVue	 AccessBio Care Start	 Abbott BinaxNOW AG Card	 BD Veritor	 Lucira Check-It	 Amazon COVID-19 Test Collection Kit DTC	 Pixel by LabCorp Pixel by LabCorp	 everlywell Everlywell	 SalivaClear by Mirimus Clinical Labs Saliva Clear	 cic Health Pooled Testing Kit
Reporting to Required Entities (State of WA, Counties)	211 Self-Reporting	Yes via Proprietary App	211 Self-Reporting	SimpleReport POC	SimpleReport POC; NAVICA Connect App	SimpleReport POC	211 Self-Reporting	Yes via Lab	Yes via Lab	Yes via Lab	No for Pool Cycles; Yes for Diagnostic	No; Deidentified Pool
Inventory Availability	Constrained; Max 6 per Order, currently out of stock	Constrained thru November – on allocation nationally	In Stock at Walgreens in Pasco and Kennewick	Inquire – See Below	Constrained in September 2021; future availability	Yes/ Robust Supply Chain	Enter Email for Future Availability	Yes	Yes	Yes	Inquire – See Below	Currently Sold Out
Business Travel Compliant	No	No	No	No	No	No	Likely	Very Likely; Download Results	Unknown	Very Likely	No	No
How to Order / Channel	https://www.cvs.com/shop/abbott-binaxnow-covid-19-antigen-self-test-2-tests-for-serial-testing-prodid-550147 (CVS)	https://www.cvs.com/shop/ellume-covid-19-home-test-digital-results-in-15-minutes-prodid-431742 (CVS) Everlywell Flyer available for larger orders	https://www.walgreens.com/store/c/quickvue-at-home-otc-covid-19-test-kit/ID=300416410-product (OTC Walgreens) https://www.quidel.com/order-request (Healthcare Professionals)	https://accessbiodiagnositics.net/carestart-covid-19-antigen/ (Click 'How to Order')	https://mms.mckesson.com/product/1186179/Abbott-Rapid-Dx-North-America-LLC-195000	https://bdveritor.bd.com/en-us/ordering-reimbursement Enterprise Channel - See Distributor e.g. McKesson (800) 654-7240 https://www.fishersci.com/shop/products/veritor-system-rapid-detection-sars-cov-2/B256082	https://checkit.lucirahealth.com/ Email when Available	https://www.amazon.com/gp/product/B08ZR5XNBM	https://www.pixel.labcorp.com/node/32051/questionnaire Covered if mild symptoms or close contact, live/work in a congregate setting, referred by a healthcare professional, contact investigator, or public health.	https://www.everlywell.com/products/covid-19-test/	Email testing@mirimus.com with subject: "SalivaClear Pool Testing Inquiry"	https://testing.cic-health.com/products/pooled-testing-kit?variant=39765717090500
Additional Resources	https://www.globalpointofcare.abbott/en/product-details/binaxnow-covid-19-antigen-self-test-us.html	https://www.ellumehealth.com/products/consumer-products/covid-home-test	https://quickvueathome.com/ (OTC) https://www.quidel.com/immunoassays/quickvue-sars-antigen-test (Healthcare Professionals)	https://accessbiodiagnositics.net/carestart-covid-19-antigen/	https://www.fda.gov/media/141570/download (Instructions for Use)	https://bdveritor.bd.com/en-us/bd-veritor-plus-system https://bdveritor.bd.com/en-us/education-training/product-training https://bdveritor.bd.com/en-us/education-training/product-training	https://checkit.lucirahealth.com/ https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-covid-19-test-self-testing-home	https://www.amazon.com/gp/product/B08ZR5XNBM	https://www.pixel.labcorp.com/at-home-test-kits/covid-19-test-home-collection-kit#additional-information	https://www.everlywell.com/products/covid-19-test/	https://www.salivaclar.com/	https://testing.cic-health.com/products/pooled-testing-kit https://testing.cic-health.com/a/faq

¹ Individuals living in Benton and Franklin Counties are encouraged to report positive tests to 509-222-2333. Individuals living in other counties please report via 1-800-525-0127

*IMPORTANT → CLIA Waiver Enterprise Rule: "If there is intention for businesses to direct the self-testing in any way, then they must apply for a CLIA Certificate of Waiver"

Please see <https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/420-360-SARSCoV2SelfTesting.pdf>

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