



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

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*Dr. Charissa Fotinos, Associate Director Medical Services, Health Care Authority
Statewide Leader for COVID-19 Testing Initiative*

Dear Partner,

As you know, the state of Washington is set to receive 2.3 million BinaxNOW rapid antigen tests between now and December. Your organization will be receiving part of the first batch.

The [BinaxNOW™ COVID-19 Antigen](#) test has received emergency use authorization from the U.S. Food and Drug Administration (FDA). The tests are primarily approved for use in people suspected of having COVID-19 by their healthcare provider and are to be used within the first seven days of symptom onset. They are inexpensive, point of care (POC) tests with results available within 15 minutes.

This first shipment of BinaxNOW™ COVID-19 Antigen tests received by the State will be distributed to **community health centers, tribal clinics and critical access hospitals** to increase access to COVID-19 diagnostic testing in priority populations across the state. Patients who receive the tests may also download an app, NAVICA, which will allow them to store and share their test results if desired.

Any sites using these tests will need to adhere to [Washington's Medical Test Site License/CLIA waived test requirements](#), including obtaining a medical test site license if the site does not already have one. Training will be essential to successful deployment of these tests and is available through Abbott at this website, [NAVICA and BinaxNOW COVID-19 Ag Card training site](#). Both Federal and state laws require that all test results, negative and positive, be reported. At this time, sites should continue to use their current method of reporting notifiable conditions, with priority reporting of positive cases to their local health departments. Instructions on reporting COVID-19 and other notifiable conditions, including the fax number for local health departments, can be found here: [How to Report Notifiable Conditions](#). The Washington State Department of Health is also developing a streamlined process for reporting and will provide further instructions on that process when it is available.

At this point in time the tests are primarily approved for use within the first 7 days of symptom onset in persons suspected of having COVID-19. For now, the Department of Health is recommending these tests be used for this indication. Guidance regarding use of the rapid antigen tests outside of this indication, in particular in persons who are asymptomatic and live, work or attend school in congregate settings is being developed.

Please review the accompanying guidance for important details on:

- Training
- CLIA requirements and where the test can be performed
- Who can get tested
- Information about who can order the tests
- Information about who can perform the tests
- Liability protection when using these tests
- Reporting requirements
- Test interpretation

Thank you for your continued dedication to keeping the people of Washington safe during the COVID-19 pandemic.

I appreciate the opportunity to respond to your concerns. If you have questions or need additional help, please contact doh-cbts@doh.wa.gov

Sincerely,

A handwritten signature in black ink that reads "Charissa Fotinos MD". The signature is written in a cursive style with a large initial "C" and "F".

Dr. Charissa Fotinos, Associate Director Medical Services, Health Care Authority
Statewide Leader for COVID-19 Testing Initiative

Training

There are online resources, provided by Abbott, to train you and your staff on how to administer the tests properly. The [NAVICA and BinaxNOW COVID-19 Ag Card training site](#) provides access to several resources which will guide you on how to successfully employ the BinaxNOW Ag and NAVICA solution for patients at your testing location(s). Information about how to receive updates regarding training and any changes to the current Emergency Use Authorization, will be sent in a follow up email. [Learn more here](#).

To access additional support, please use the following information to email or call the Abbott Rapid Diagnostics Technical Services Team: 1-800-257-9525 between 8 a.m. – 8 p.m. EST Monday- Friday or by emailing ts.scr@abbott.com

CLIA Requirements & Where the Federally-Provided BinaxNOW Tests can be Distributed and Used

For any agencies not already possessing a CLIA certificate of waiver, applications can be accessed here: [DOH Medical Test Site/CLIA Waiver site](#). There is a \$75 certification fee until November 1st at which time it will become \$95. All MTS/CLIA licenses expire on June 30, 2021. The two year renewal fee will be \$190.

The FDA has [authorized](#) the test to be performed in CLIA-waived labs (and labs with a higher certification) and for use at the point of care, i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Entities that intend to perform only CLIA-waived labs may obtain a certificate of waiver medical test site license from the Washington State Department of Health. “Medical test site” is the term used in Washington law to denote a laboratory or “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 certificate of waiver medical test site can be essentially anywhere and needs to meet only minimal requirements. The site needs to have a director, but the person who holds the position does not need to have any particular qualifications or license. Nor do the personnel who perform tests under the certificate of waiver need to have any particular credentials. They need only perform the tests according to the manufacturers’ instructions (though see the “Who can get tested?” section below). If the medical test site is being operated by a not-for-profit or state or local government, then one certificate of waiver medical test site license can be issued to cover multiple locations. For example, one medical test site license could be issued that covers all the schools in a school district. Test results must be reported to the local health department for subsequent reporting to DOH and the federal government.

Who can get tested

The FDA’s [authorization](#) and the [manufacturer’s instructions](#) for the BinaxNOW test provide that the test is for “individuals suspected of COVID-19 by their healthcare provider within the first seven days symptom onset.” Normally, medical test sites are required by law to follow the manufacturer’s instructions in performing a test, meaning that the BinaxNOW test would be only for those suspected of COVID-19 by their provider within the first seven days of symptom onset. But, in accordance with [guidance](#) issued by the Centers for Medicare & Medicaid Services (CMS), the Washington State Department of Health’s Laboratory Quality Assurance Program (LQA) will temporarily exercise enforcement discretion for the duration of the COVID-19 public health emergency under the Medical Test Site (MTS)/CLIA rules for the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals. Specifically, LQA will not cite facilities with a MTS/CLIA Certificate of Waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals, as described in the [FDA FAQ](#). Please see the last page of the document at the following link for information on consent to testing by minors: [Testing COVID-19 in Minors](#).

Must the test be ordered by a licensed health care provider?

No, under Washington law, an individual may order their own test. A patient-specific order or a standing order by a licensed provider is not required under Washington law, and federal law defers to state law on this legal question.

Who may take the nasal swabs and who may perform the test?

The FDA authorization and instructions for the BinaxNOW test do not dictate who must take the swab, and they do not preclude an individual from taking their own swab. DOH has compiled a comprehensive table of the types of providers who are authorized to perform swabs for diagnostic testing [List of Providers Authorized to Collect Nasal Swabs for COVID-19](#).

The personnel who then perform the test do not have to have any particular qualifications or license. They need to perform the test according to the manufacturer's instructions. The FDA's authorization requires only that all operators using the test must be "appropriately trained in performing and interpreting the results of [the test]."

Who gets liability protection under the PREP Act?

The federal Public Readiness and Emergency Preparedness Act (PREP Act) provides liability protection for individuals and entities involved in implementing treatments, tests, vaccines, and other covered countermeasures designed to combat a pandemic or epidemic. As required by the Act, the HHS Secretary has issued a [declaration](#) to grant liability protection to certain covered persons engaged in ordering, administering, distributing, and other activities related to COVID-19 tests and other countermeasures meant to fight the COVID-19 epidemic. The declaration grants protection to licensed health care professionals or others authorized by state law to prescribe, administer, or dispense countermeasures and to others specified in the declaration. The HHS Assistant Secretary for Health has also [extended](#) PREP Act protection to licensed health care practitioners who prescribe or administer point-of-care COVID-19 tests, using anterior nares specimen collection or self-collection, for screening in congregate facilities. This includes licensed health care practitioners prescribing or administering FDA-authorized COVID-19 tests, like the BinaxNOW test, for off-label use to screen asymptomatic individuals on congregate facilities. The authorization defines congregate settings to mean nursing homes, assisted living facilities, long-term care facilities, and other facilities where people congregate to receive care or education or to work. Those engaged in administering and performing the BinaxNOW COVID-19 tests should consult with their legal counsel for guidance on whether they are covered under the PREP Act.

Interpreting the test results

Evaluating the results of a rapid antigen test for SARS-CoV-2 should take into account the performance characteristics of the test (e.g. sensitivity, specificity), the prevalence of COVID-19 in that particular community, and the clinical and epidemiological context of the person who has been tested. For a complete explanation on interpreting results and determining when confirmatory PCR testing is needed, see: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

Because false negative results can occur, CDC recommends confirming negative antigen test results with an RT-PCR test when the pretest probability is relatively high, especially if the patient is symptomatic or has a known exposure to a person confirmed to have COVID-19. The person should be advised to isolate themselves away from others until the results of the RT-PCR test are available. Generally, clinicians can rely upon a positive diagnostic antigen test result because the specificity of current FDA-authorized antigen tests is high in a person who has COVID-19 symptoms and a high pre-test probability of being infected with SARS-CoV-2.

The guidance above refers to the interpretation of rapid antigen test results in persons who are symptomatic. Guidance around follow-up testing and the use of rapid antigen tests for asymptomatic persons in congregate settings is being developed.

Reporting

HHS requires reporting of all test result, negative and positive, using Federal Reporting standards for SARS-CoV-2. Details on reporting requirements can be found at [CDC: How to Report COVID-19 Laboratory Data](#).

Currently, the Washington State Department of Health is working to stand up a streamlined process and guidelines to facilitate the required reporting of COVID-19 test results. Until that is complete, facilities should continue to use their current method of reporting notifiable conditions to their local health departments.