Public Health Reporting Requirements for At-Home COVID-19 Tests

Background

Point-of-care COVID-19 diagnostic tests have been used in a variety of settings during the pandemic. These tests can provide rapid results for the identification of individuals with COVID-19. Until recently, point-of-care tests were only available with a prescription. At this time, a number of at-home testing products are available for purchase without a prescription, allowing individuals to self-administer COVID-19 tests without supervision by trained personnel. There is not, however, a current system for results from home tests to be reported to public health on a reliable basis. As described in this memo, DHS has determined that mandatory reporting should not be a barrier to use of at-home tests, that residents who use at-home tests should report all positive tests to their health care provider or local health department, and that at-home tests should not be used to inform public health decisions such as early discontinuation of quarantine or clearance for travel due to concerns about reliability of at-home test results.

COVID-19 Reporting Requirements

Reporting of all cases of COVID-19 to public health departments remains an important element of the public health response in Wisconsin. COVID-19 remains a Category I reportable condition in Wisconsin (Wis. Admin Code ch. DHS 145) and cases must be reported to local public health within 24 hours. Because of unique logistical considerations associated with different test types, and issues related to the reliability of test results, DHS has adopted different reporting requirements for laboratory-based testing, point-of-care testing, and at-home testing, as described below.

All laboratory-based and point-of-care negative and positive results from molecular tests (e.g., PCR) and all positive antigen test results conducted for diagnostic purposes should continue to be reported to public health in Wisconsin. All results, regardless of methods must be reported to HHS. Reporting is most commonly accomplished through electronic laboratory reporting (ELR) or web-based lab reporting (WLR), both of which meet Wisconsin public health and federal HHS reporting requirements. DHS has previously provided instructions for electronic reporting of POC test results in DPH Numbered Memo BCD 2021-01.

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Laboratory based tests: Includes both molecular and antigen tests conducted for diagnostic purposes in laboratories with CLIA certificates and must be reported to public health using WLR/ELR.

Point-of-care (POC) tests: Includes both antigen and molecular test methods conducted for diagnostic purposes. These tests are conducted or proctored by trained personnel outside of a laboratory setting. They are performed under a CLIA certificate, with a prescription from a licensed provider, and must be reported to public health using WLR/ELR.

At-home tests: Includes both antigen and molecular test methods. Tests are available over the counter, often without a prescription, and are performed without a CLIA certificate and without supervision by trained personnel. These tests are not subject to mandatory reporting. Patients are strongly encouraged to report any positive results to their health care provider or their local health department, for appropriate clinical and public health follow-up actions, which may include confirmatory testing.

Guidance for Health Departments and Clinicians

Health department personnel and health care providers should strive to ensure that all individuals who are interested in using an at-home COVID-19 test are aware of the need to precisely follow all instructions for performing the test and what to do if their test is positive. CDC has recently updated its self-testing guidance for patients, which includes resources about specimen collection and reporting results.

Clinicians who are notified by a patient that they had a positive at-home COVID-19 test should use their judgment to determine whether a second, or confirmatory, test is needed to determine the appropriate clinical and public health actions. For example, antigen tests results may need to be followed by a second molecular test in some circumstances because of lower test performance characteristics:

- Negative antigen test results occurring in individuals with COVID-19-like symptoms should be confirmed by a molecular test, because of the risk of false negative results.
- Positive antigen test results occurring in asymptomatic individuals (e.g. tests conducted as part of a routine screening program) should be confirmed by a molecular test, because of the risk of false positive results.
- Clinicians who wish to report a probable case of COVID-19 based on patient report of a positive at-home test can fax a completed copy of the DHS Patient Information Form (F-02700) to the local or tribal health department in their jurisdiction.

Local health departments should conduct appropriate follow-up, including confirmatory testing and investigation, for all probable and suspect cases of COVID-19 that result from at-home testing. Although there is not currently a system to ensure that all at-home test results are reported to public health, positive test results that are reported to health departments should be considered to represent a probable case, similar to results reported through other methods.

DHS recommends that at-home test results not be used to support public health decision-making without verification by a test conducted in a CLIA-authorized environment. Specifically:

- At-home tests should not be used as a sole justification for early release from quarantine.
- At-home tests should not be used to document clearance for travel.
- At-home tests should not be used as a sole means to determine whether a symptomatic student can return to school.