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To: Local and Tribal Health Departments and Health Care Providers

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## Considerations for Confirmatory Testing of COVID-19 Point-of-Care Tests

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#### Background

Point-of-care diagnostic tests can detect SARS-CoV-2 infection and inform strategies to prevent SARS-CoV-2 transmission in long-term care, correctional, educational, and other settings. Defined as a CLIA waived diagnostic test performed at or near the place where a specimen is collected and able to provide results within minutes, point-of-care tests are designed to detect either viral RNA (i.e., “molecular”, Reverse Transcription Polymerase Chain Reaction (RT-PCR), or Nucleic Acid Amplification Test (NAAT)) or viral proteins (i.e., antigen tests).

While laboratory-based RT-PCR/NAAT tests are still considered the “gold standard” for diagnosis because of their high sensitivity and specificity, point-of-care tests are an increasingly popular alternative strategy because they are relatively inexpensive, can be used at the point of care, and can provide rapid results in about 15 minutes. Providers and other organizations planning to use point-of-care testing for diagnostic or screening purposes must be aware of the limitations of these tests, which are less accurate than lab-based tests, when using these results for clinical or public health decision making.

The purpose of this memo is to communicate revisions to DHS guidance for point-of-care testing originally published on Sept 24, 2020, as [HAN #17](#). This memo references regulatory updates to the COVID-19 case definition and data on point-of-care test performance in Wisconsin residents. **DHS now recommends, but no longer requires, confirmatory lab-based molecular testing in symptomatic people with a negative point-of-care test result or asymptomatic people with a positive point-of-care test result.** The rationale for this change, which is expected to increase the reliance on point-of-care tests for public health decisions, is described below. Importantly, there are still situations when confirmatory, lab-based RT-PCR/NAAT testing may be needed to rule out false positive and false negative results, including when the public health risk or consequences of a false result are high, or for individuals who receive unexpected results given their likelihood of infection.

**The recommendations in this memo DO NOT apply to at-home tests**, and do not replace the recommendations related to at-home tests described in numbered memo [BCD 2021-03](#). For information on the use of at-home tests for public health decision making, see [BCD 2021-03](#).

### **Point-of-care tests are now authorized for screening asymptomatic people**

Since HAN #17 was published in September 2020, the U.S. Food and Drug Administration has authorized multiple point-of-care tests for screening asymptomatic individuals under updated Emergency Use Authorizations. Using point-of-care tests for screening asymptomatic individuals is of particular value in settings where lab-based tests are not available, or if turnaround times for lab-based tests are prolonged. The CDC notes in its [Interim Guidance for Antigen Testing for SARS-CoV-2](#) that using point-of-care antigen tests for screening individuals in congregate living settings, such as nursing homes, has “quickly identified people with COVID-19, informing infection prevention and control measures, thus preventing transmission.” They conclude that “In this case, and where rapid test turnaround time is critical, there is value in providing immediate results with antigen tests, even though they may have lower sensitivity than NAATs.”

### **The revised COVID-19 surveillance case definition incorporates results from point-of-care tests**

In August 2021, the Council of State and Territorial Epidemiologists revised the [surveillance case definition](#) for COVID-19, citing rapid advancements in the science of COVID-19 disease and SARS-CoV-2 infection. Under the updated COVID-19 case definition, an individual who meets the clinical criteria for COVID-19 and has an epidemiologic link to a case (e.g., had close contact to a person with COVID-19) **is no longer considered a probable case if they receive a single negative molecular or antigen test for SARS-CoV-2**. A case definition is a set of standard criteria used to define a disease for public health surveillance. Case definitions enable public health departments to classify and count cases consistently across reporting jurisdictions and should not be used by healthcare providers to determine how to meet an individual patient’s health needs. Revisions to the COVID-19 case definition included an update to the clinical criteria indicative of SARS-CoV-2 infection; inclusion of genomic sequencing as laboratory evidence of infection; and distinguishing between tests performed by Clinical Laboratory Improvement Amendments (CLIA)-certified providers or without CLIA oversight (e.g., at-home tests).

### **Point-of-care tests perform well overall for Wisconsin patients, but have limitations**

A review of data from over 15,000 people with paired point-of-care antigen and lab-based, RT-PCR/NAAT test results who were tested through the K-12 School Testing Program revealed a relatively low overall rate of false results. During this evaluation period, when the overall disease prevalence was 9% and 77% of people who underwent testing had symptoms consistent with COVID-19, point-of-care tests yielded the same result as lab-based RT-PCR testing 97% of the time. However, the accuracy of identifying people with RT-PCR-confirmed COVID-19 was imperfect, with an overall sensitivity of 75%. In practice, confirmatory RT-PCR testing resulted in identification of 280 people with falsely negative point-of-care tests, allowing for isolation and potentially preventing additional spread of COVID-19. Specifically:

- Of 1,408 people who had confirmed COVID-19 by RT-PCR, 352 people had a falsely negative point-of-care antigen test. This represents an overall **sensitivity of 75%**.
- Of 14,270 people who had a negative point-of-care antigen test, 13,918 were true negatives by RT-PCR. This represents an overall **negative predictive value of 97.5%**.
- In this context, the practice of obtaining a confirmatory RT-PCR on all symptomatic people with negative point-of-care test results would reduce the proportion of false negative results from 25% to 5%.

Data from the K-12 School Testing Program also show that the rates of false positives are high, especially among asymptomatic people. About 13% of asymptomatic and 9% of symptomatic people

who received a positive point-of-care antigen test result were not truly infected with the virus when tested by RT-PCR. The impact of false positive test results may be significant, especially in school settings, as they can lead to the unnecessary exclusion of students and staff from in-person instruction for extended periods of time. Confirming point-of-care test positives with lab-based molecular testing would reduce the number of people required to isolate or quarantine due to false positive results.

Specifically:

- Of 14,033 people confirmed to not have COVID-19 by virtue of a negative RT-PCR test, 115 people had a falsely positive point-of-care test. This represents an overall **specificity of 99.2%**.
- Of 1,171 people who had a positive point-of-care antigen test, 1,056 were true positives by RT-PCR. This represents an overall **positive predictive value of 90.2%**.
- The positive predictive value of point-of-care antigen tests was lower for asymptomatic people, suggesting a greater role for confirmatory testing when positive point-of-care test results occur when there is low clinical suspicion.

### **The reliability of point-of-care tests depends on test type and prevalence of COVID-19**

The sensitivity and specificity of point-of-care tests vary according to test-type and manufacturer, but all available point-of-care tests consistently have lower accuracy than lab-based RT-PCR tests. False results can occur for a variety of reasons including random test error, user error, and contamination. In general, the lower the prevalence of infection in the community, the higher the proportion of false positive point-of-care test results; conversely, the higher the prevalence of infection in the community, the higher the proportion of false negative point-of-care test results. In addition, when the prevalence of SARS-CoV-2 is low and the prevalence of other respiratory diseases is high, SARS-CoV-2 will be a relatively rare cause of symptoms. In these situations, people who receive a positive point-of-care test result should strongly consider confirmatory lab-based, RT-PCR/NAAT testing to confirm that they are truly infected.

### **Recommendations**

**Point-of-care SARS-CoV-2 tests perform best when used for diagnosis of COVID-19 in patients with symptoms of acute respiratory infection and when pre-test probability of infection is high** (e.g., in outbreak settings or among close contacts of exposed cases). It is acceptable to use point-of-care tests for screening asymptomatic people when lab-based RT-PCR testing with acceptable turnaround time is not feasible, but providers and organizations should expect some level of false results, which will vary according to COVID-19 prevalence in the community.

**For asymptomatic people who test POSITIVE on a point-of-care COVID-19 test: A confirmatory RT-PCR/NAAT test collected within 48 hours of the initial test is strongly recommended, but not required.** Confirmatory testing is important for asymptomatic people with positive point-of-care test results, due to the lower positive predictive value in that setting. Confirmatory testing may also be considered for symptomatic people with positive point-of-care test results if the pre-test probability of COVID-19 is considered low (e.g., when [disease prevalence is low](#), in fully vaccinated people or, if there has been no known contact with a COVID-19 case, or if other diagnoses are considered more likely). Asymptomatic and symptomatic people who test positive by a point-of-care test must isolate and close contacts must quarantine. If a confirmatory NAAT test is collected within 48 hours and is negative, the person may be released from isolation and close contacts released from quarantine.

**For symptomatic people who test NEGATIVE on a point-of-care COVID-19 test: A confirmatory lab-based, RT-PCR/NAAT test collected within 48 hours of the initial test is recommended, but not required.** Confirmatory testing should be strongly considered if a symptomatic person has a high

likelihood of infection (e.g., is a close contact to a COVID-19 case, is not fully vaccinated, has not had COVID-19 in the past 90 days, or when [disease prevalence is high](#)). Symptomatic people who test negative by point-of-care test should stay home until they have been fever-free without the use of fever-reducing medications for at least 24 hours and until other symptoms have improved. Close contacts of people with negative point-of-care test results do not need to quarantine as long as they remain asymptomatic and follow-up testing, if performed, is negative. If confirmatory testing is performed and the test is positive, the person is considered a confirmed case and should isolate at home for at least 10 days since their first symptoms began and until they have been fever-free without the use of fever-reducing medications for 24 hours and until other symptoms have improved. Unvaccinated close contacts should quarantine and get tested 5-7 days after last contact with the case, and fully vaccinated close contacts should get tested 5-7 days after last contact with the case and wear a mask in all public indoor settings for 14 days after exposure or until a negative test result.

**The above recommendations shall apply to all settings including school settings.** The DHS guidance document, Comprehensive Guidelines for the Prevention, Investigation, and Control of COVID-19 Outbreaks in K-12 Schools in Wisconsin, will be updated to reflect these changes.

**All positive point-of-care results should be reported to local public health departments.** Providers and organizations using SARS-CoV-2 point-of-care tests should be aware of all reporting requirements for COVID-19. Negative point-of-care test results are not required to be reported to the state but still need to be reported to the U.S. Department of Health and Human Services.