

TO: Vermont Health Care Providers and Health Care Facilities
FROM: Jennifer S. Read, MD; Medical Epidemiologist

Use of SARS-CoV-2 Antigen Testing in Vermont

The following information was reviewed in the September 2, 2020 HAN addressing types of testing for SARS-CoV-2, the etiologic agent of coronavirus disease 2019 (COVID-19):

1. The Council of State and Territorial Epidemiologists (CSTE) updated case definition for COVID-19 includes the following:
 - Detection of SARS-CoV-2 by antigen test in a respiratory specimen is considered **presumptive** laboratory evidence of SARS-CoV-2 infection.
 - Detection of SARS-CoV-2 ribonucleic acid (RNA) in a clinical or autopsy specimen using a molecular amplification test (PCR) is classified as **confirmatory** laboratory evidence of SARS-CoV-2 infection.
2. Characteristics of SARS-CoV-2 antigen tests:
 - A SARS-CoV-2 antigen test is used to detect specific proteins on the surface of the virus.
 - Such tests are less sensitive than PCR assays, so there are **more false negative** results. Therefore, a negative test generally requires confirmation with a PCR assay.
 - Antigen tests are intended for people with symptoms of COVID-19. Antigen tests are particularly helpful when used to test people in the early stages of SARS-CoV-2 infection (within the first 5 to 12 days, depending upon the test, of symptoms compatible with COVID-19) when the SARS-CoV-2 viral load is generally the highest.
 - In general, antigen tests should not be used to diagnose asymptomatic persons, but they might be informative in diagnostic testing situations in which the person has a known exposure to a confirmed case of COVID-19.
 - Antigen tests might produce **false positive results** when disease prevalence is low.
 - At this time, there are limited data available on the correlation between SARS-CoV-2 antigen test positivity and the likelihood of the patient to be infectious.
 - An advantage of antigen tests is that the results are usually available much more rapidly than results of PCR assays (i.e., within an hour versus same day or up to a week).

On August 25, 2020, CMS published an interim final rule establishing long-term care facility SARS-CoV-2 testing requirements for staff and residents based on parameters set forth by the HHS Secretary. The Vermont Department of Health Laboratory is able to perform the necessary testing (with reporting within the required 48 hours) for long-term care facilities in the short

term, and the state will be contracting with a private laboratory through the end of December 2020 to conduct PCR testing within 48 hours. After December 31, 2020, circumstances may change and the availability of PCR testing may decrease. If that happens, SARS-CoV-2 antigen testing may be necessary to meet the CMS testing requirements.

As noted in the September 2, 2020 HAN, HHS announced a large-scale procurement of FDA-authorized antigen test instruments and tests to be distributed to long-term care facilities across the U.S., including some facilities in Vermont. Antigen tests may be used for screening in high-risk congregate settings in which repeat testing (i.e., at least weekly) could quickly identify persons with a SARS-CoV-2 infection to inform infection prevention and control measures, thus preventing transmission within the congregate setting. When used for screening in congregate settings, antigen test results should be considered **presumptive**.

- When the pretest probability is low, those persons who receive a positive antigen test should isolate until they can be **confirmed** by RT-PCR.
- Confirmatory nucleic acid testing following a positive antigen test **might not be necessary** when the pretest probability is high, especially if the person is symptomatic or has a known exposure.

REQUESTED ACTIONS:

- When available, use PCR testing for SARS-CoV-2 infection.
- When PCR testing is not available, or when very rapid turn-around is required, use SARS-CoV-2 antigen testing (especially for symptomatic patients), e.g., in the following circumstances:
 - Symptomatic patients in a primary care setting
 - Patients being admitted to hospitals with limited availability of PCR testing
- Antigen tests could be informative for screening asymptomatic residents and staff of a long-term care facility if antigen tests were performed frequently, i.e., at least weekly. This may mitigate the effects of their lower sensitivity than PCR tests.
 - If used in this way, positive antigen tests would be considered presumptive and would need confirmation by PCR.
 - Infection prevention and control measures should be implemented pending confirmation.
- If antigen tests are used for screening, the Health Department will monitor the performance of these tests and will adjust guidelines as needed.

If you have any questions, please contact the HAN Coordinator at 802-859-5900 or vthan@vermont.gov.

HAN Message Type Definitions

Health Alert: Conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: Provides important information for a specific incident or situation may not require immediate action.

Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.

Info Service Message: Provides general correspondence from VDH, which is not necessarily considered to be of an emergent nature.