IDAHO DEPARTMENT OF HEALTH & WELFARE

Use of Rapid Antigen Tests in Idaho Long-term Care Facilities

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Background

The U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorizations (EUAs) for various SARS-CoV-2 antigen diagnostic tests. The U.S. Department of Health and Human Services (HHS) has been distributing some of these diagnostic test devices and test cards to eligible nursing homes and assisted living facilities throughout the United States. These tests provide rapid point-of-care testing, but have some limitations compared to SARS-CoV-2 reverse transcriptase polymerase chain reaction (RT-PCR) tests, as outlined in this document.

Purpose of this document

This document addresses the appropriate use of rapid antigen testing in the long-term care setting, interpretation of test results, and the public health reporting requirement. This document does not cover the laboratory aspects of use of these testing devices and test cards, such as obtaining a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver, specimen collection and handling, use of the instrument, etc. Some of this information can be obtained from material sent with the device or card and through training offered by the manufacturer. In addition, the Centers for Disease Control and Prevention (CDC) offers guidance on performing facility-wide SARS-CoV-2 testing in nursing homes that addresses many of these topics as well as a list of testing resources for nursing homes that all types of long-term care facilities may find helpful.

What is a rapid antigen test (RAT) and how does it differ from the reverse transcriptase polymerase chain reaction (RT-PCR) test?

Rapid antigen tests (RATs) detect the presence of a specific viral protein (an "antigen"). SARS-CoV-2 RATs are low complexity tests, can be done in a CLIA-waived laboratory, and return results in less than 30 minutes. In comparison, SARS-CoV-2 reverse transcriptase polymerase chain reaction (RT-PCR) tests are more complex tests that detect viral RNA and must be performed in a CLIA-certified laboratory. However, currently available SARS-CoV-2 RATs are less sensitive than RT-PCR tests, and therefore there is a greater chance of false negative results. In contrast, RATs have high specificity, so false positive results should be rare when the test is used in a manner consistent with the EUA.

For what purpose are RATs authorized?

According to the EUAs issued for these devices, RATs are intended for use in **individuals with COVID-19-compatible symptoms within a certain number of days of symptom onset.** (The number of days varies by type of device or card, and users should consult the manufacturer's Instructions for Use (IFU) that can be found on the FDA website or as provided by the manufacturer.)

When should RATs be used?

RT-PCR remains the gold standard for clinical diagnostic detection of SARS-CoV-2.

However, there are certain situations in which RATs may be useful, such as in settings where RT-PCR testing capacity is limited or testing results are delayed (e.g., >48 hours). The interpretation of results from RATs must consider the clinical context in which the test was taken, as discussed further below.

Can RATs be used for testing asymptomatic individuals with or without known exposure to COVID-19?

CDC has issued guidance around use of RATs in nursing homes that includes settings other than what is authorized by the EUAs. Facilities that are considering using RATs in these circumstances should familiarize themselves with this guidance.

RT-PCR testing continues to be preferred for serial testing of asymptomatic healthcare personnel (HCP) in long-term care facilities without an outbreak, if laboratory capacity allows and turn-around time for test results is < 48 hours. If RATs are used for serial testing of asymptomatic HCP, facilities should refer to CDC guidance for interpretation of results. In particular, any positive result in an asymptomatic person should be confirmed with RT-PCR within 48 hours, and the tested individual should be excluded from work pending confirmatory test.

How to interpret results?

Positive test results

Because of the high specificity of the RATs, ***positive results can generally be accepted without a confirmatory RT-PCR test*** if the test is performed on an individual with high pre-test probability (e.g., an individual exposed to COVID-19 who has COVID-19-compatible symptoms and is tested within the first 5-7 days of symptom onset). Interpretation of positive results in other clinical scenarios should follow the CDC guidance.

Negative test results

RATs are less sensitive than RT-PCR tests and therefore may generate false negative results. If pre-test probability is high, ***negative results should be treated as presumptive, do not rule out SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.*** If needed for clinical or infection control decision-making, negative results should be confirmed with a RT-PCR test.

As noted, RT-PCR tests for SARS-CoV-2 remain the gold standard for detecting SARS-CoV-2 infection. When confirmation with a RT-PCR test is necessary, it is important that the time interval between the two sample collections is less than two days, and there have not been any opportunities for new exposures between the two tests. An RT-PCR test done 3 or more days after a RAT is considered a separate, not confirmatory, test.

Can RATs be used for return-to-work considerations for healthcare personnel or to determine the duration of transmission-based precautions?

No. Decisions about returning to work should follow CDC guidance on return-to-work considerations for healthcare personnel with SARS-CoV-2 infection and for healthcare personnel with potential exposure to COVID-19. Decisions about discontinuation of transmission-based precautions should be based on CDC guidance.

How and when to report results

All positive and negative test results must be reported to public health authorities within 24 hours of test completion, on a daily basis. All positive test results should be reported immediately to the local public health district. Contact your local public health district for more information. All positive and negative test results should be submitted to the Idaho Department of Health and Welfare Division of Public Health. Contact epimail@dhw.idaho.gov for instructions.

References

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