Utah Department of Health & Human Services

Guidelines for using point-of-care SARS-CoV-2 antigen tests in long-term care facilities

Background

Point of care (POC) antigen testing is an important tool to identify and reduce transmission of SARS-CoV-2 in the long-term care setting. This guidance addresses appropriate use of the tests, understanding results, CLIA requirements, and federal and state reporting mechanisms.

What is an antigen test and how does it differ from the PCR test?

POC antigen tests detect proteins on the surface of the SARS-CoV-2 virus while PCR tests detect viral RNA. Given the different detection methods, POC antigen tests may not detect the virus as soon as a PCR test. Consequently, false negative results can occur, particularly in the early days of infection. False positive results are rare, particularly with symptomatic individuals. Please see the CDC's antigen test algorithm to determine when a confirmatory PCR test is needed after a positive or negative POC antigen test result.

When to use the antigen test

The POC antigen test is most useful for testing symptomatic individuals. Since test results can be returned in as little as 15 minutes, a positive result can be used by the facility to quickly decide the type of care necessary for the patient or HCW to prevent transmission to others in the facility.

Antigen tests may also be used to test individuals after a known exposure to SARS-CoV-2. CDC guidance recommends a series of three viral tests after a known exposure:

- Immediately (but not earlier than 24 hours after the exposure)
- 48 hours after the first negative test and
- 48 hours after the second negative test.

CMS requires that all POC tests be used in alignment with their emergency use authorization (EUA). Only some tests are authorized for use on asymptomatic individuals. Please check the FDA list of individual EUAs to make sure you are using a test that has been authorized for the proper setting and attributes. Home tests used by employees are not subject to these rules.

While it is generally not recommended to test individuals in the 30 days after they have had a known infection, antigen tests can be used to determine readiness of HCP to return to work after an infection. Please see CDCs Return to Work Criteria for more information.

What are the CLIA requirements for using the test?

Any facility that performs laboratory tests on human specimens for the purpose of diagnosis and/or treatment is required by federal law to have a Clinical Laboratory Improvement Amendments (CLIA) certificate. There are different types of CLIA certificates; a CLIA Certificate of Waiver covers all tests that are classified as waived by the FDA. Most POC antigen tests are included on the waived list and can be found here with a 'w' in the authorized settings column. Many facilities have obtained a certificate of waiver previously. For those that have not, instructions and an application for the certificate of waiver can be found here. A CLIA waiver is valid for two years and facilities must renew their certificate of waiver prior to expiration. CLIA certificates can be found using this search tool.

How to collect a specimen safely

Most antigen tests require a swab of the anterior nares. Please follow the manufacturer's instructions for proper specimen collection. Following the manufacturer's instructions will improve reliability of results and is required under the CLIA Certificate of Waiver. Recommended PPE for specimen collection includes an N95, face shield, gown and gloves. Ideally, specimen collection should occur in a private, well-ventilated area.

How to report results to the Utah Department of Health and Human Services

All COVID-19 test results (positive, negative, equivocal, indeterminate) for all test types (PCR, antigen, serology) are reportable to the Utah Department of Health and Human Services (DHHS).

- Test results must be reported to DHHS within 24 hours of testing
- Facilities enrolled in the NHSN network, should report all antigen testing results via NHSN
- All other facilities should report to the Utah DHHS reporting portal. Please direct test result reporting questions to edx@utah.gov

References

Centers for Disease Control and Prevention. (Updated March 4, 2022). Guidance for Antigen Testing for SARS-CoV-2 for Healthcare Providers Testing Individuals in the Community. Retrieved March 28, 2022, from https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

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Centers for Medicare and Medicaid Services. (March 2019) *How to Obtain a CLIA Certificate of Waiver*. Retrieved March 28, 2022, from https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf