COVID-19 Testing

Overview and General Information

The spread of COVID-19 from the community and within the health center is challenging. COVID-19 testing will be an instrumental aspect that will assist facilities in prompt detection of cases in order to implement actions to reduce the exposure and to halt transmission within the facility whenever possible.

The Centers for Medicare & Medicaid Services (CMS) published an interim final rule (https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/interim-final-rule-ifc-cms-3401-ifc-additional-policy-and-regulatory-revisions-response-covid-19) establishing Long-Term Care (LTC) Facility Testing Requirements for Staff and Residents on August 25, 2020.

An update to the testing guidance includes: "CMS Updates COVID-19 Testing Methodology for Nursing Homes" on September 29, 2020: https://www.cms.gov/newsroom/press-releases/cms-updates-covid-19-testing-methodology-nursing-homes

CMS has added a new requirement at F886 COVID-19 Testing to include:
"The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. At a minimum, for all residents and facility staff, including individuals providing services under arrangement and volunteers, the LTC facility must:

(1) Conduct testing based on parameters set forth by the Secretary, including but not limited to:

(i) Testing frequency;

(ii) The identification of any individual specified in this paragraph diagnosed with COVID19 in the facility;

(iii) The identification of any individual specified in this paragraph with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19;

(iv) The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;

(v) The response time for test results; and

(vi) Other factors specified by the Secretary that help identify and prevent the transmission of COVID-19.

(2) Conduct testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests;

(3) For each instance of testing:

(i) Document that testing was completed and the results of each staff test; and

(ii) Document in the resident records that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test.

(4) Upon the identification of an individual specified in this paragraph with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19.
(5) Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.
(6) When necessary, such as in emergencies due to testing supply shortages, contact state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results."[1]

CMS has indicated that "healthcare facilities using Point of Care COVID-19 testing devices under a CLIA Certificate of Waiver, including nursing homes, pharmacies, or other settings will be required to report test results under this regulation."[2] In addition, CMS indicates, "All CLIA-certified laboratories that perform or analyze any test that is intended to detect SARSCoV-2 or to diagnose a possible case of COVID-19 (e.g., molecular, antigen, antibody) are required to report, regardless of the type of laboratory (type of CLIA certificate) performing the testing."[2]

Facilities will need to have knowledge regarding the types of testing. The Centers for Disease Control and Prevention indicates, "The "gold standard" for clinical diagnostic detection of SARS-CoV-2 remains RT-PCR. Thus, it may be necessary to confirm a rapid antigen test result with a nucleic acid test, especially if the result of the antigen test is inconsistent with the clinical context."[3]

Screening asymptomatic residents and staff using point of care antigen tests will provide quick turn-around times but are referred to "off label" and are not authorized for this use by the FDA. It is important to review any State specific guidance with point of care antigen testing.

The FDA has provided information on individual emergency use authorizations (EUAs) for authorized SARS-CoV-2 antigen diagnostic tests.

Competencies which may be associated with COVID-19 Testing include but are not limited to:

- Understanding of COVID-19 Types of Testing
- Proper use of Personal Protective Equipment
- Knowledge of proper hand hygiene practices
- Specimen Collection
- Use of Point-of-Care Antigen Testing Equipment
- Cleaning and Disinfection
- Reporting Antigen Testing
- Documentation

Staff Competencies with COVID-19 Testing include but are not limited to:

- Ability to follow proper hand hygiene practices
- Demonstration of ability to properly don and doff Personal Protective Equipment including proper use, removal, and storage of medical grade face masks
- Demonstration of Specimen Collection
- Demonstration of Point-of-Care COVID-19 Antigen testing
- Ability to describe actions to prevent the transmission of COVID-19 with positive results

References and Resources:

[1]Centers for Medicare & Medicaid Services. Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements and Revised COVID19 Focused Survey Tool. QSO-20-38-NH. August 26, 2020: https://www.cms.gov/files/document/qso-20-38-nh.pdf

[2] Centers for Medicare & Medicaid Services. Interim Final Rule (IFC), CMS-3401-IFC, Updating Requirements for Reporting of SARS-CoV-2 Test Results by Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency. QSO-20-37-CLIA, NH. August 26, 2020: https://www.cms.gov/files/document/qso-20-37-clianh.pdf

Centers for Disease Control and Prevention. Interim Guidance for Rapid Antigen Testing for SARS-CoV-2. September 4, 2020: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Centers for Disease Control and Prevention. Preparing for COVID-19 in Nursing Homes; June 25, 2020; https://cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html

Centers for Disease Control Prevention. Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes. August 27, 2020: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html

United States Food & Drug Administration (FDA). In Vitro Diagnostics EUAs: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-antigen

United States Food & Drug Administration (FDA). Pooled Sample Testing and Screening Testing for COVID-19: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/pooled-sample-testing-and-screening-testing-covid-19