

Discussion With ODH and Long-Term Care (LTC) Facilities on COVID-19 Reporting Requirements

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Agenda

- Review of HHS Guidance Released June 4, 2020 and CMS QSO Released Aug. 26, 2020.
- Review of Ohio Reporting Requirements for COVID-19.
- LTCF Aggregate Count Registration and Reporting Process.
- LTCF Case Reporting Process.
- Review of Electronic Laboratory Reporting (ELR) Submission Option and Process.
- Q&A.

Review of CMS QSO-20-37-CLIA, NH Released Aug. 26, 2020

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-37-CLIA, NH

DATE: August 26, 2020

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: 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

Review of HHS Guidance Released June 4, 2020

COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115

June 4, 2020

Assuring a rapid and thorough public health response to the COVID-19 pandemic necessitates complete and comprehensive laboratory testing data, including standardized test results, relevant demographic details, and additional information that can improve both the public health response to SARS-CoV-2 and COVID-19. These data contribute to understanding disease incidence and trends: initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and identifying supply chain issues for reagents and other material. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities. As the country begins to reopen its doors, access to clear and accurate data is essential to communities and leadership as they use data to make decisions for a phased reopening. For individuals, access to personal test results improves feelings of safety, security, and awareness, and empowers them to take action, if necessary, to protect themselves, their families, and their communities.

Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires “every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19” to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS). In addition, the statute authorizes the Secretary to prescribe the form and manner, and timing and frequency, of such reporting. This document outlines the requirements for data submission to HHS as authorized under this law.

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Review of Ohio Reporting Requirements for COVID-19

- COVID-19 test results must be reported at both the case/line level AND the aggregate count level.
- Line level results must be reported to the local health department (LHD) where the patient resides within 24 hours of case identification.
- Aggregate counts must be reported daily by 11 a.m. ET for the previous day of testing.

Review of Ohio Reporting Requirements for COVID-19



FW New submission for Lab Registration..msg

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LTCF Aggregate Count Registration and Reporting Process

- Register your LTCF [here](#).
 - Registration will initiate engagement at ODH.
- Report your LTCF point-of-care (POC) antigen device COVID-19 testing results daily by 11 a.m. ET [here](#).

LTCF Aggregate Count Registration and Reporting Process

- Two reporting tabs exist for aggregate count reporting.
 - Diagnostic (PCR) COVID-19 Aggregate Test Results – **Not performed at LTCFs.**
 - **“Non-Diagnostic” (Antigen and Antibody) COVID-19 Aggregate Test Results.**
 - BOTH tabs must be completed before submission is accepted.
- Pending Tests and Tests Not Performed only refer to specimens collected, not people yet to be swabbed.

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LTCF Case Reporting Process

- Negative COVID-19 test results must be reported at the case/line level per CMS QSO and HHS requirements.
 - ODH is not yet ready to accept negative test results at the case/line level as of Sept. 20, 2020.
 - ODH anticipates GO LIVE of new IT system by end of September 2020 to start accepting negative test results.

LTCF Case Reporting Process

- LTCFs must report positive and inconclusive/indeterminate test results to the local health department.
 - Manual reporting option – Faxing results using the confidential case report form or other similar report format.
 - Electronic submission reporting option – Electronic laboratory reporting (ELR) using a CSV-supported schema.

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Review of Electronic Laboratory Reporting (ELR) Submission Option and Process

- ODH recommends LTCFs report COVID-19 test results using an electronic submission method directly to ODH.
- CSV – Comma separated values file schema format is available.
 - An **update** to the standard CSV format will be coming to address more HHS required data fields.

Review of Electronic Laboratory Reporting (ELR) Submission Option and Process

- Establish secure connection with ODH to submit COVID-19 testing results using secure file transfer protocol (SFTP).
- Begin setting up the CSV template for your LTCF to send a TEST file to ODH for review and approval.
- Participate in a brief acceptance testing period to validate the results prior to moving to PRODUCTION.

Review of Electronic Laboratory Reporting (ELR) Submission Option and Process

- LIVE demo of setting up a CSV file.

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ELR Contacts

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