

Discussion With Higher Education Institutions on COVID-19 Reporting Requirements

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Agenda

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

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 electronically to ODH within 24 hours of case identification.
 - Until electronic files are approved by ODH, these results must be reported to the local health department (LHD) where the patient resides.
- 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

- ODH Guidance on Electronic Submission of COVID-19 Testing Results published on [ODH Electronic Laboratory Reporting \(ELR\) webpage](#).
- Direct [download file](#).

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Aggregate Count Registration and Reporting Process

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

Aggregate Count Registration and Reporting Process

- Three reporting tabs exist for aggregate count reporting.
 - **PCR or Molecular – Not performed at Higher Education Institutions.**
 - **Antigen Testing (Point of Care).**
 - **Antibody or Serology Testing – Not performed at Higher Education Institutions.**
 - **ALL** tabs must be completed before submission is accepted.

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Case Reporting Process

- Higher Education Institutions must report ALL COVID-19 test results must be reported electronically to ODH within 24 hours of test being performed.
 - Includes ALL test results (e.g., negative, positive, inconclusive/indeterminate, invalid) to the LHD where the patient resides until the electronic file is approved.
 - Manual reporting option – Faxing results using the confidential case report form or the Human Infection with 2019 Novel Coronavirus Case Report Form.
 - Electronic submission reporting option – Electronic laboratory reporting (ELR) using Ohio's custom CSV file.

Case Reporting Process

- Negative COVID-19 test results must be reported at the case/line level per federal and state regulations.
 - Do not report negatives to the local health department (LHD).
 - Once ODH approves the electronic file, institutions must provide a backfill file of all negative test results as of 10/20/2020.

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

- ODH requires electronic reporting of COVID-19 test results.
- 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

- Create account to submit COVID-19 testing results using authenticated web portal.
- Step by Step Instructions for Creating an Account and for Requesting Access to **ELR File Upload** application.
- Begin setting up the CSV template for your Institution 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 and submitting to authenticated web portal.

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ELR Contacts

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