



Technical Bulletin



Date: September 4, 2020
Topic: COVID-19 Laboratory Reporting Requirements
Contact: Melissa Peek-Bullock, State Epidemiologist, Office of Public Health Investigations and Epidemiology
To: Laboratories and Healthcare Providers

Background:

Updated national reporting requirements from the United States Health and Human Services (HHS) for COVID-19 laboratory data went into effect on August 1, 2020. In order to ensure a rapid and comprehensive public health response to COVID-19, it is essential that laboratory data is both timely and complete. The required data is important for understanding disease trends, initiating disease investigations and contact tracing, the ability to identify and respond to inequities, and to make decisions regarding mitigation and control efforts. As reopening decisions are made across Nevada, access to complete and accurate testing data is crucial.

Data Required to be Reported:

All COVID-19 laboratory results are required to be reported. Healthcare providers should work with the laboratories to provide the required data elements upon initial order of the test by completing all the demographic information on the laboratory requisition form or the equivalent electronic laboratory order. Once laboratories have completed the testing, the below required data elements must be submitted with the laboratory result:

- Test ordered – use harmonized LOINC codes provided by CDC
- Device Identifier (Point of Care Device Type)
- Test result – use appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC
- Test result date
- Accession number/Specimen ID
- Patient age
- Patient race
- Patient ethnicity
- Patient sex
- Patient residence zip code
- Patient residence county
- Ordering provider name and NPI (as applicable)
- Ordering provider zip code
- Performing facility name and/or CLIA number, if known
- Performing facility zip code
- Specimen source — use appropriate LOINC, SNOMED-CT, or SPM4 codes, or equivalently detailed alternative codes
- Date test ordered
- Date specimen collected

Timeliness of Laboratory Reporting:

Laboratories and healthcare providers must submit **ALL** COVID-19 results (positive, negative and indeterminant) within 24 hours of analysis.

How Laboratory Results are Reported:

Report laboratory results through the electronic laboratory reporting (ELR) system. The Nevada Division of Public and Behavioral Health (DPBH), Office of Public Health Investigation and Epidemiology (OPHIE) team will assist in onboarding laboratories into the ELR system and can be contacted at dpbhelronboarding@health.nv.gov. During the onboarding process OPHIE will provide instructions on the best interim alternative mechanism to report until the completion of ELR onboarding.

Authority to Require Reporting:

The enhanced reporting is required by the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The CARES Act authorizes HHS “to prescribe the form and manner, and timing and frequency, of such reporting.” In addition, Nevada Administrative Code (NAC) also requires reporting by laboratories. According to NAC 441A.235 it is the duty of the laboratory director or other person in charge of a medical laboratory to report findings of communicable disease, causative agent of communicable disease or immune response to causative agent. The report must include:

- The date and result of the test or examination performed.
- The name, address and, if available, telephone number of the person from whom the specimen was obtained.
- The sex, age and date of birth of the person from whom the specimen was obtained, if available.
- The name of the health care provider who ordered the test or examination.
- The name and the address or telephone number of the medical laboratory making the report.
- Any other information requested by the health authority, if available. **(this is inclusive of the additional variables required to be reported by HHS).**

Non-compliance with Reporting Requirements:

Any laboratory or health care provider that is non-compliant with the outlined requirements related to reporting, will receive notification from DPBH. It is expected that upon notification a plan to correct the issue(s) is established and acted upon. If continued non-compliance occurs, DPBH will issue a formal citation for violation of NAC 441.A. Per NAC 652.530 the circumstances under which DPBH has authorization for disciplinary action are:

1. If necessary to protect the public and safety, the Division may impose such disciplinary action as it deems necessary without notice to the laboratory or with verbal notice to the laboratory.
2. The Division may suspend the license of a laboratory without or upon verbal notice if the Division finds a violation with a severity level of four where corrective action within 48 hours is necessary because the violation has caused, or if uncorrected is likely to cause, serious injury or harm or death to a patient.
3. Within 48 hours after the Division imposes disciplinary actions without written notice, the Division shall provide written notice in the manner set forth in NAC 439.345.

As previously stated timely, complete and accurate laboratory data is essential to our public health response as it allows to accurately track disease occurrence, assess trends, calculate positivity rates, timely case investigation and contact tracing, understanding the impact of marginalized and minoritized communities, and to make sound recommendations for reopening Nevada.

Resources and References:

CDC Lab Advisory: Update on COVID-19 Laboratory Reporting Requirements:

<https://www.cdc.gov/csels/dls/locs/2020/update-on-covid-19-reporting-requirements.html>

COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115:
<https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>

HHS Announces New Laboratory Data Reporting Guidance for COVID-19 Testing:
<https://www.hhs.gov/about/news/2020/06/04/hhs-announces-new-laboratory-data-reporting-guidance-for-covid-19-testing.html>

NAC 441A: <https://www.leg.state.nv.us/NAC/NAC-441A.html#NAC441ASec230>

NAC 652.530: <https://www.leg.state.nv.us/NAC/NAC-652.html#NAC652Sec530>

NAC 439.345: <https://www.leg.state.nv.us/NAC/NAC-439.html#NAC439Sec345>

For More Information: Please contact DPBH M-F 8:00 AM to 5:00 PM at (775)-684-5911. The after-hours line can be contacted at (775)-400-0333.



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