

## COVID-19 Laboratory Reporting FAQs

### *What laws govern COVID-19 laboratory test reporting to public health?*

Reporting of COVID-19 laboratory test results to the Utah Department of Health (UDOH) is mandated by state and federal law. Those laws define what is reportable, who must report, the timeframe reports must be made, the acceptable methods of reporting, and what data elements are reportable. Additional information on public health reporting regulations is available at <https://coronavirus.utah.gov/recommendations-for-providers/>.

### *What COVID-19 laboratory results are reportable?*

All test results (positive, negative, indeterminate, equivocal) for all test types performed on a device with an FDA Emergency Use Authorization (EUA) are reportable. This includes diagnostic tests, like molecular or antigen tests, and antibody, or serology, tests. Laboratory results performed on a person who lives in Utah or a person whose specimen was collected by a Utah facility should be reported to the Utah Department of Health. Laboratories located in Utah who perform testing for facilities outside of Utah should report results to the appropriate state public health agency.

### *Who must report COVID-19 laboratory results?*

All facilities that perform COVID-19 testing are required to report. This includes:

- Laboratories that perform clinical diagnostic testing under CLIA,
- Non-laboratory COVID-19 testing locations, and
- Other facilities or locations offering point-of-care testing or in-home testing related to COVID-19.

### *When should laboratory results be reported?*

Laboratory test results must be reported to the Utah Department of Health within 24 hours of test finalization.

### *What data elements are reportable?*

A number of data elements are required when reporting to public health. These data elements generally fall into three categories: patient information, diagnostic/ordering provider and facility information, and laboratory information. UDOH has mandated a set of data elements that must be reported for all laboratory results for all conditions. The U.S. Department of Health and Human Services (HHS) has mandated additional data elements that must be reported for COVID-19 test results only. Additional information is available at <https://coronavirus.utah.gov/recommendations-for-providers/>.

### *How can I report?*

State and federal law requires testing facilities to report test results electronically to UDOH. Laboratory results can be submitted via one of the following four avenues:

- HL7 direct to UDOH via SFTP
- Association of Public Health Laboratories' AIMS platform
- Direct CSV upload into UDOH's COVID-19 reporting portal
- Direct data entry into UDOH's COVID-19 reporting portal

Additional information on acceptable reporting methods is available at <https://coronavirus.utah.gov/recommendations-for-providers/>.

### *Are there penalties for not reporting?*

Utah law allows for the loss of accreditation or licensure or a monetary penalty for each reporting violation. However, UDOH prefers to work with facilities to identify and resolve reporting deficiencies. The Centers for Medicare & Medicaid Services (CMS) recently announced that they will impose monetary penalties for laboratories and nursing homes that do not comply with reporting requirements. It is not clear currently how reporting compliance will be assessed by CMS. The CMS announcement can be found at: <https://www.cms.gov/newsroom/press-releases/trump-administration-strengthens-covid-19-surveillance-new-reporting-and-testing-requirements>.

### *Do I need to report results from a research study?*

Laboratory results are still reportable even if they are not done for diagnostic purposes. Research groups assume reporting responsibility if they do not provide the appropriate patient identification information to the performing laboratory.

For additional information, contact the DCP Informatics Program at [edx@utah.gov](mailto:edx@utah.gov) or visit the "Information for Laboratories and Testing Facilities" section of <https://coronavirus.utah.gov/recommendations-for-providers/>.