



COVID 19 Laboratory Reporting FAQs September 11, 2020

1. Who is required to report?
According to the interim final rule: All CLIA-licensed laboratories including those with a certificate of waiver are required to report data.
2. Which tests should be reported?
The Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS) guidances, plus the interim final rule, have been clear that all tests for SARS-CoV-2 including molecular, antigen and antibody tests should be reported under these requirements.
3. What needs to be reported?
The interim final rule says that all CLIA-licensed laboratories *are required to report data in the format and manner that the Secretary of HHS prescribes*. The CAP received clarification from CMS that June 4 guidance while providing information on current CLIA regulations for reporting test results, also provides extensive guidance regarding other information, such as data transmission and reporting language via Logical Observation Identifiers Names and Codes and Systemized Nomenclature of Medicine that, at this time, will not be enforced by the agency. CMS requires clinical laboratories to report positive and negative results for all COVID-19 testing performed.
4. When should results be reported?
HHS and CDC requirements are “daily” or “within 24 hours of being known or determined on a daily basis.”
5. How should the data be reported?
Guidance is not clear on the finer points of this yet. The CAP is seeking further clarity. The interim final rule says that all CLIA-licensed laboratories *are required to report data in the format and manner that the Secretary of HHS prescribes*. They reference the June 4 requirements and CDC FAQs, but this also allows HHS and CDC to make changes.
6. To whom should results be reported?
Guidance on this question is conflicting because the original June 4 requirements and the interim final rule say to the department of public health of the patient’s residence, but the CDC FAQ at <https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html> adds that you can report to the ordering provider’s department of public health if the patient is out-of-state. The CAP is in conversations with the HHS and CDC to address the issues associated with this requirement.

On August 31, CMS stated on a call that CMS will only enforce the CARES ACT which requires laboratories to report positive and negative testing results to state and local health departments. While the June 4 guidance is required, CMS stated on the August 31 call that they will not enforce it.

The June 4 guidance document referenced in the IFC includes the following:

- Submission of laboratory testing data directly to state or local public health departments, as required by state and/or local law or policy. These entities will then submit deidentified data to the CDC daily using either Health Level 7 (HL7) messaging or the CDC-provided CSV format.
- Submission of laboratory testing data to state and local public health departments through a centralized platform (such as the Association of Public Health Laboratories’ AIMS platform) where such data will then be routed to the appropriate state and local authorities and routed



to CDC after removal of elements to achieve de-identification according to applicable rules and regulations.

- Submission of laboratory testing data through a state or regional Health Information Exchange (HIE) to the appropriate state or local public health department and to the CDC as directed by the state.
7. What is the date by which I must be compliant?
CMS recently clarified that there is a three-week grace period, which begins once the federal register notice is published (which is expected on Wednesday, September 2, 2020).
 8. What are the penalties for non-compliance?
CLIA is being revised to allow CLIA to impose penalties, including monetary penalties, for non-compliance with the reporting requirements. On August 31, 2020, CMS stated that CMS will only enforce the CARES ACT which requires labs to report positive and negative test results to state and local health departments. While the June 4 guidance is required, CMS will not enforce it. In addition, CMS indicated that enforcement will occur for COVID-19 reporting *during the normal inspection process or a complaint investigation*.
 - \$1000 for the first day of offense.
 - They add \$500 per day to the fine per additional violation (e.g., second day of violation would be a fine of \$1500, third day \$2000, etc.) up to a maximum of \$10,000 per day for non-compliance.
 9. When do the penalties for non-compliance go into effect?
This is unclear, and the CAP is seeking further clarification. Information will be updated here as soon as it is confirmed.

References

- June 4 HHS requirements: <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>.
- June FAQ on laboratory test reporting requirements: <https://www.hhs.gov/sites/default/files/laboratory-data-reporting-for-covid-19-testing-faqs.pdf>
- Online CDC FAQ on laboratory reporting last updated July 29, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html> (last accessed July 30, 2020)
- July 10 HHS requirements: https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf?utm_source=newsletter&utm_medium=email&utm_content=HHS+memo&utm_campaign=GOVT_HHS_COVID_reporting_requirement (last accessed July 30, 2020)
 - Only laboratory-related information and information which overlaps or is duplicative with the information laboratories were asked to report in the June 4 requirements were extracted from this reporting requirement and put into the information below.
- July 31 CDC laboratory advisory update on laboratory reporting requirements with detailed technical specifications for each data element: <https://www.cdc.gov/csels/dls/locs/2020/update-on-covid-19-reporting-requirements.html> and <https://www.hhs.gov/sites/default/files/hhs-guidance-implementation.pdf>
 - Three columns suggest different requirements for federal, state/local, and ordering provider reporting. Response values in these columns include “Yes”, “No”, blank (no value), “Yes as applicable”, “Yes; if known”, “Requested” and “Optional”. It is unclear what “Requested” means relative to “Optional” or “Yes; if known” as alternatives. Current understanding is that these all represent optional requirements, but further clarification is pending.