

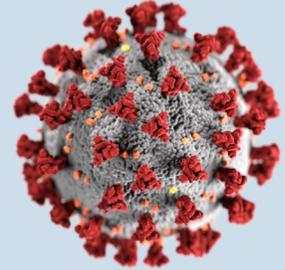
CLIA CORNER

State Hygienic Laboratory at The University of Iowa

First Quarter 2021

In This Issue...

- Requirements for reporting SARS-CoV-2 test results and other frequently asked questions



In January 2021, the Centers for Medicare & Medicaid Services (CMS) released the [QSO-21-10-CLIA](#) memo which gave surveyor guidance for the reporting of SARS-CoV-2 test results. This memo is a direct result of the President's declared national public health emergency in response to the SARS-CoV-2 virus on 3/13/2020. Due to the COVID pandemic, CMS made modifications to the Clinical Laboratory Improvement Amendments (CLIA) regulations.

New and Updated CLIA regulations:

***The new or updated language appears in italics*

- **§ 493.2 Definitions. (Modified):**

Condition level requirements means any of the requirements identified as "conditions" in § 493.41 and subparts G through Q of this part.

- **§ 493.41 Condition: Reporting of SARS-CoV-2 test results. (New):**

During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

- **§ 493.555(c) Federal review of laboratory requirements. (New):**

(c) The organization's or State's agreement with CMS that requires it to do the following:

(6) Notify CMS within 10 days of any conditional level deficiency under §§ 493.41 or 493.1100(a).

- **§ 493.1100 Condition: Facility administration. (New)**

(a) Reporting of SARS-CoV-2 test results. During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

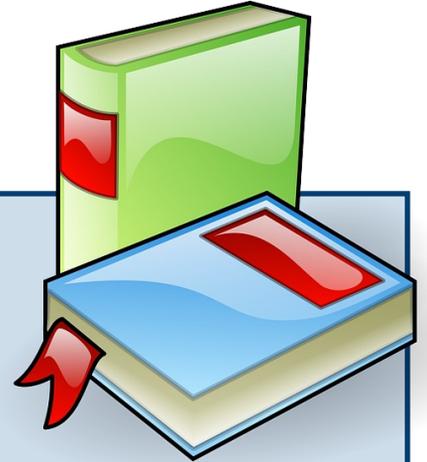
- **§ 493.1804 General considerations.** (Modified)

(c) Imposition of alternative sanctions.

(1) CMS may impose alternative sanctions in lieu of, or in addition to principal sanctions. (Except for a condition level deficiency under §§ 493.41 or 493.1100(a), CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not routinely inspected for compliance with condition-level requirements.)

- **§ 493.1834 Civil money penalty.** (New)

(d)(2)(iii) For a condition level deficiency under §§ 493.41 or 493.1100(a), a CMP of \$1,000 for the first day of noncompliance and \$500 for each additional day of noncompliance.



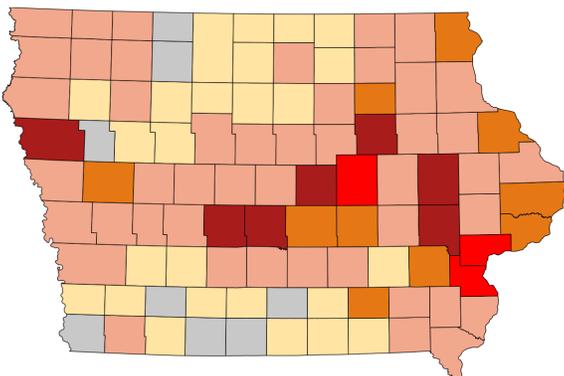
The new and updated regulations require ALL CLIA certified laboratories performing SARS-CoV-2 testing to report both **positive and negative results** to the state and/or local health department. This includes both waived and non-waived SARS-CoV-2 testing, AND applies to ALL CLIA certificate types: certificates of waiver (CoW), certificates of provider performed microscopy (PPM), certificates of registration, certificates of accreditation and certificates of compliance.

FREQUENTLY ASKED QUESTIONS:

Is the facility only required to report SARS-CoV-2 molecular testing? What if the facility is performing antigen and/or antibody testing?

All CLIA laboratories performing SARS CoV-2 testing must report both **positive and negative** test results. This includes molecular, antigen and serology testing. This is true even if the IFU only references reporting of positive results.

How will CLIA ensure all positive and negative results are being reported to the state and local health departments?



Generally, laboratories that have a CoW or PPM certificate are not routinely surveyed. Over the next three years, 5% of CLIA CoW and PPM laboratories will be surveyed for the purpose of determining compliance with the new SARS-CoV-2 reporting requirements. These special surveys will be performed either remotely or on-site. Additionally, during initial and recertification CLIA surveys, the laboratory will need to demonstrate they are in compliance with the new SARS-CoV-2 reporting requirements.

What documentation will the laboratory need to demonstrate SARS-CoV-2 results are being sent to the state and/or local health department?

- 1) The laboratory must have a policy/procedure related to SARS-CoV-2 reporting.
 - The laboratory may have a specific policy/procedure related to SARS-CoV-2 test reporting or it may be embedded in a more general policy/procedure. Either is acceptable.
 - The procedure must include the method for reporting all positive and negative SARS-CoV-2 test results, the entity to which results are reported, and the frequency with which results are reported.
- 2) The laboratory will need patient SARS-CoV-2 testing records.
- 3) The laboratory will need documentation that SARS-CoV-2 test results were reported to the state and/or local health department and that the laboratory's reporting policy/procedure was followed. Examples of acceptable reporting documentation include:



Laboratory information system reports documenting the date and time results were submitted to the state and/or local health department.



Fax machine log that documents the date and time results were submitted to the state and/or local health department.



E-mail verification documenting the date and time results were submitted to the state and/or local health department.



Manual log that documents the date and time results were submitted to the state and/or local health department.

Our hospital has a long term care (LTC) facility attached that is performing waived SARS-CoV-2 testing on their residents. How should the LTC facility report their results?

LTC facilities may submit waived SARS-CoV-2 testing data for residents and staff, including antigen testing data, to CDC's National Healthcare Safety Network (NHSN). This pathway applies only to Medicare and Medicaid-certified LTC facilities. The CLIA-waived test data submitted to NHSN will be reported to appropriate state and local health departments using standard electronic laboratory messages. The new pathway will enable certified LTC facilities, commonly known as nursing homes, to meet HHS' requirement to report data for SARS-CoV-2 POC antigen testing and other on-site COVID-19 laboratory testing. All other test results (e.g., for visitors) should be reported to the state or local health department.



What happens if I don't report my SARS-CoV-2 test results as required by the CLIA regulations?

CMS may impose civil money penalties (CMPs) for any laboratory with a Certificate of Waiver (CoW), Certificate for Provider-performed Microscopy (PPM), Certificate of Compliance (CoC), Certificate of Accreditation (CoA), or Certificate of Registration (CoR) that does not report SARS-CoV-2 test results in the manner and frequency prescribed by the Secretary. Such CMPs will be \$1000 for the first day of noncompliance with the new reporting requirements, and \$500 for each subsequent day the laboratory fails to report SARS-CoV-2 test results. For more information, please visit: [QSO-20-37-CLIA, NH](#). Exempt States (ESs) are those states that have been approved by CMS as having a State Licensure Program equal to, or more stringent than, the CLIA condition level requirements. CMS would expect the ESs to have an equivalent CMP structure to CMS and would expect the ES to impose CMPs under their State licensure program for failure to report SARS-CoV-2 results to whomever is required under State law.

Can the laboratory perform an Individualized Quality Control Plan (IQCP) for COVID testing?

During the COVID-19 public health emergency, CMS has determined that IQCP is an option for Emergency Use Authorization (EUA) tests classified as non-waived (authorized for use in moderate or high complexity settings) when manufacturers' QC is less stringent than the CLIA quality control requirements at [42 C.F.R. § 493.1256](#). The laboratory director may determine, based on risk assessment, that additional QC is necessary above what is otherwise required in the EUA Instructions for Use (IFU).



The manufacturer's QC instructions for all tests that have an EUA need to be followed. However, if the IFU indicates laboratories should perform external "QC in accordance with applicable local, state, and/or federal regulations," then for purposes of CLIA, the laboratory needs to follow the non-waived CLIA quality control requirements found at § 493.1256 or develop an IQCP, as well as any other QC instructions provided by the manufacturer. If the laboratory opts to implement an IQCP, refer to the State Operations Manual, Appendix C ([Interpretive Guidelines](#)) page 198. The Quality Control Plan must include the **number, type, frequency of testing, and criteria for acceptable result(s) of the quality control(s)**, and must be approved by the laboratory director.

Can the laboratory change the specimen type (nares swabs vs nasopharyngeal) for a SARS-CoV-2 test system?

The laboratory must follow the instructions for use for all EUA SARS-CoV-2 test systems which includes specimen type and specimen collection instructions. Any laboratory intending to modify a previously EUA-authorized COVID-19 assay, including the intended use or specimen type, must be CLIA-certified for high complexity testing, establish performance specifications (including specificity and sensitivity), and be in compliance with the high complexity requirements.

If you would like your name added to our CLIA Corner google group, send an email to:

Kristine-rotzoll@uiowa.edu or Melinda-Bochmann@uiowa.edu