



CLIA Updates

January 2021

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COVID-19 RELATED UPDATES

Inside This Issue

1 COVID-19 RELATED UPDATES

On December 17, 2020, the U.S. Centers for Medicare & Medicaid Services (CMS) updated the "[Frequently Asked Questions \(FAQS\), CLIA Guidance During the COVID-19 Public Health Emergency](#)" document to provide additional clarification on the following topics:

2 COVID-19 POC UPDATES

- How CMS defines a "CLIA-waived" facility
- Developing an Individualized Quality Control Plan (IQCP) for COVID-19 test systems
- FDA authorization of the Lucira™ COVID-19 All-In-One Test Kit for home use and at the point of care

3 Frequently Asked Questions

For additional information, refer to Laboratory Outreach Communication System ([LOCS](#)) [message sent on November 12, 2020](#).

4 CMS Guidance

5 Common Deficiencies

The Centers for Medicare & Medicaid Services (CMS) posted a Frequently Asked Questions document for Nursing Home COVID-19 Testing on December 7, 2020. [Nursing Home COVID-19 Testing FAQs \(cms.gov\)](#)

Topics include:

- County positivity rates
- Testing frequency
- Outbreak testing
- Staff Testing
- False-positive antigen test results

For additional information: [Clinical Questions about COVID-19: Questions and Answers | CDC](#)

COVID-19 POC UPDATES

CDC recently published three new infographics for the [BD Veritor™ Plus System](#), [Quidel® Sofia® and Sofia 2®](#), and [Abbott BinaxNOW™](#) antigen tests for rapid detection of SARS-CoV-2. These infographics are designed to provide helpful tips to healthcare providers performing point-of-care testing for SARS-CoV-2. To ensure accurate performance of these tests, refer to the package insert or the manufacturer's instructions for use.

Cited from Centers for Disease Control and Prevention, (Dec. 28, 2020) Laboratory Outreach Communication System | Division of Laboratory Systems (DLS) Retrieved from [CDC Offers New Infographics for SARS-CoV-2 Point-of-Care Tests](#)

[Guidance for SARS-CoV-2 Point-of-Care Testing | CDC](#)

Frequently Asked Questions



Q: What is the required documentation for a Certificate of Compliance laboratory director qualifications?

A: [High Complexity: §493.1443 Standard;](#) Laboratory director qualifications.

[Moderate Complexity: § 493.1405 Standard;](#) Laboratory director qualifications.

1. Montana Licensure
2. Educational Degree
3. HHS qualified Certification Board
4. Resume with required experience

[Code of Federal Regulations \(govinfo.gov\)](#)

Q: Where can I find information regarding the complexity of a test?

A: [FDA Test Complexity](#)

**Please also check out our website for
Frequently Asked Questions.**

[CLIA \(mt.gov\)](#)

CMS Guidance

**Center for Clinical Standards and Quality/Survey & Certification Group
Ref: QSO-20-37-CLIA, NH August 26, 2020**

CLIA Citation Guidance

Failure of a CLIA-certified laboratory to report SARS-CoV-2 test results as required by the new requirements at §§ 493.41 and 493.1100(a) will result in a mandatory citation. This applies to all CLIA certificate types. A laboratory must have documentation that they have reported all SARS-CoV-2 test results.

- **D1002** (new D-Tag) must be used for noncompliance with reporting SARS-CoV-2 waived testing results; and
- **D3000** must be used for noncompliance with reporting SARS-CoV-2 nonwaived testing results

Laboratories operating under a Certificate of Waiver will be cited at D1002; all other certificate types, including PPMs, will be cited at D3000.

Imposition of Civil Money Penalties (CMPs)

The regulatory amendments at §§ 493.41 and 493.1100(a) require all CLIA-certified laboratories, including those holding a CoW and PPM, to report SARS-CoV-2 test results to the Secretary for the duration of the PHE for COVID-19, and, that failure to do so will result in a condition level violation of the CLIA regulations. If a laboratory does not report required SARSCoV-2 test results, CMS will impose a CMP as required under §§ 493.1804 and 493.1834. 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.

Please note that health care facilities using Point of Care COVID-19 testing devices under a CLIA Certificate of Waiver, including nursing homes, pharmacies, or other settings will be required to report test results under this regulation.

CMS Guidance (continued)

CLIA Survey Guidance For Certificate of Waiver (CoW) and Certificate for Provider-Performed Microscopy (PPM)

For the duration of the PHE, on-site surveys of 5% of CLIA CoW and PPM laboratories will be conducted for the purpose of determining compliance with:

- Implementing the new CLIA Condition-level regulation (493.41) pertaining to COVID19 reporting requirements;
- Confirming that laboratories hold the appropriate type of CLIA certificate (i.e., not testing outside certificate); and
- In addition, PPM laboratories will be surveyed to assess for compliance with the applicable CLIA requirements for PPM procedures.

Complaints received in CoW or PPM laboratories should be investigated according to State Operations Manual (SOM) Chapter 5 procedures after consultation with CMS operations branch locations. Complaints related to SARS-CoV-2 testing or reporting will be prioritized. Complaint surveys will count as part of the 5% of surveys. The 5% of these laboratories will be spread over the three years of the PHE, rather than 5% annually.

[QSO-20-37-CLIA, NH \(cms.gov\)](#)

Common Deficiencies

§ 493.1235 Standard: Personnel competency assessment policies. (D5209)

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

- Evaluating and documenting competency of personnel responsible for testing is required at least semiannually during the first year the individual tests patient specimens.
- Thereafter, competency assessment must be performed at least annually.
- If test methodology or instrumentation changes, an individual's competency must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

[Competency Guidelines for Laboratory Professionals | CDC](#)

References:

[CLIA \(mt.gov\)](#)
[Clinical Laboratory Improvement Amendments \(CLIA\) | CMS](#)
CMS CLIA Interpretive Guidelines
CMS CLIA Federal Regulations 42 CFR 493
QSO letters

If you would like to be added to the emailing list for future correspondence from the Montana CLIA program, please send an email to Michelle Griffin at Michelle.Griffin@mt.gov

Questions about the information discussed in this CLIA Update?

The Montana CLIA Program would love to answer them. Contact us at:

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