CLIA Updates

August 2020

Montana CLIA Program, 2401 Colonial Drive-2nd Floor, PO Box 202953, Helena, MT 59620
http://dphhs.mt.gov/qad/Certification/CLIA Email: mtssad@mt.gov 406-558-9502 or 406-444-2099

INSIDE THIS ISSUE

COVID-19 RELATED TESTING

All COVID-19 testing sites must:

- have a Clinical Laboratory Improvement Amendments (CLIA) certificate;
- meet all requirements to perform testing, including only using FDA-authorized test systems according to their instructions for use; and
- report the results of the COVID-19 diagnostic and screening tests that they perform to the appropriate state or local public health department.

COVID-19 testing sites are defined as:

- laboratories that perform clinical diagnostic or screening testing under CLIA;
- non-laboratory COVID-19 diagnostic or screening testing locations; and
- other facilities or locations offering COVID-19 point-of-care diagnostic or screening tests, or in-home diagnostic or screening tests.

Cited from Centers for Disease Control and Prevention, (Aug. 4 2020) How to Report COVID-19 Laboratory Data Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html

COVID-19 REPORTING

Testing sites must report **all COVID-19 diagnostic test data** in accordance with the HHS Lab Data Reporting Guidance issued June 4, 2020 and meet these reporting requirements by August 1, 2020 including providing your facility name and CLIA number when reporting results. Please visit the CDC website and Montana Department of Health and Human Services' website for more information about data reporting.

Frequently Asked Questions

Q: Does the laboratory need to verify performance specifications for qualitative (positive/negative) test systems?

A: Yes, the requirements for verification of performance specifications applies to qualitative test systems.

Q: Are there allowances for Not-for-profit or Federal, State, or local government laboratories for the number of tests performed.

A: No, these laboratories are still limited to no more than a combination of 15 moderately complex or waived tests per certificate for public health testing ***(42 CFR 493.35(b)(2), 493.43(b)(2), or 493.55(b)(2)).***

For more information regarding FAQs on Testing for SARS-CoV-2 and Test Validation FAQs, please refer to the following website: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#validation

CMS Guidance

Center for Clinical Standards and Quality/Survey & Certification Group Ref: QSO-20-21-CLIA, March 26, 2020

SUBJECT: Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency

- CMS' Exercise of enforcement discretion to ensure pathologists may review pathology slides remotely if certain defined conditions are met,
- Ensuring that laboratories located in the United States wishing to perform COVID-19 testing that apply for CLIA certification are able to begin testing as quickly as possible during the public health emergency,
- Highlighting that laboratories within a hospital/University Hospital Campus may hold a single certificate for the laboratory sites within the same physical location or street address,
- Offering enforcement discretion as to Proficiency Testing (PT) During the duration of the Public Health Emergency,
- Addressing alternate Specimen Collection Devices, and Addressing Laboratory Developed Tests,
- CMS is committed to taking critical steps to ensure America's clinical laboratories are prepared to respond to the threat of 2019 Novel Coronavirus (COVID-19) and other respiratory illnesses to ensure reliable testing as well as ensuring patient health and safety, and
- The CLIA program is unable to approve section 1135 waiver requests with respect to waivers of CLIA program requirements. The section 1135 waiver authority is only applicable to specified programs (or penalties) authorized by the Social Security Act (SSA). The CLIA program does not fall into this category of programs.

All guidance in this memorandum is applicable only during the COVID-19 public health emergency.

Proficiency Deficiencies (Non-Waived)

42 CFR §493.801 Enrollment and testing of samples (D2000)

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens.

Survey results for Compliance and Accredited laboratories in Montana

Survey Questions asked by e-mail (110 Sent):

1. Is your laboratory performing COVID-19 testing?
2. If not, are you planning to do COVID-19 testing in the future? Also include what is preventing your facility from testing.
3. Will you or are you performing PCR, Serology or both?
4. Please list the manufacture or vendor of instrument and chemistry.
5. What is your test volumes?
6. What is your biggest restriction regarding testing? (example: lack or Reagents, Personnel or Equipment)
7. Is your place of work providing screening for employees?

43% responded

Out of the laboratories that responded 47% are testing COVID-19, and 23% have plans to test.
PCR based testing is the most common chemistry.
Restrictions: 72% lack of reagents/test kits/cartridges
23% lack of personnel
15% lack of equipment

Thank you again for taking the time to reply!

References:
www.dphhs.mt.gov/qad/Certification/CLIA
www.cms.gov/CLIA
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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