CLIA Updates

September 2024

DEPARTMENT OF PUBLIC HEALTH & HUMAN SERVICES

Office of Inspector General, Montana CLIA Program, PO Box 202953, Helena, MT 59620
Website: CLIA (mt.gov) Email: mtssad@mt.gov or michelle.griffin@mt.gov

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CMS CLIA Regulation Changes

Please Note: Proficiency Testing Final Rule (CMS-3355-F) requirements effective July 11, 2024, will be implemented on **January 1, 2025**

Effective December 28, 2024

Federal Register :: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories
Search using: **CMS-3326-F**

Some points to note:

- Laboratory Director (LD) experience should be clinical in nature.
- 20 credit hours of relevant continuing education should be required for all LDs except those certified by the American Board of Pathology, American Board of Osteopathic Pathology, and American Board of Dermatology.
- LD should be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed and provide documentation of these visits.
- Modify CLIA requirements for technical consultants (TC) to include an associate degree and 4 years of training and experience.
- All testing personnel training and experience should be in a CLIA certified laboratory.

Training documentation: Documentation from a former employer would be acceptable, provided it included specific details of the individual's job description, training, and competency assessment (CA) for areas of testing performed. This documentation could be from an LD, manager, or supervisor.

CLIA Fee Changes

Biennial Certificate Fee Changes
Waived $248
PPMP $297
Accredited or Compliance $223

Link to CLIA CERTIFICATE FEE SCHEDULE (cms.gov)

The following activities require a fee to cover administrative program costs:

- Adding a specialty and determining compliance with testing in additional specialties outside of the Certificate of Compliance (CoC) survey cycle.
- Performing follow-up surveys or revisits to determine the correction of deficient practices found in either a CoC survey or a Certificate of Accreditation (CoA) validation or complaint survey.
- Performing a substantiated complaint survey.
- Conducting desk reviews of unsuccessful proficiency testing performance to ensure successful laboratory proficiency testing.

Revised or Replacement Certificate Fees

Once you have received a copy of your certificate electronically, you can pull additional electronic copies of your certificate from this website: S&C QCOR Home Page (cms.gov) [qcor.cms.gov]

On the left-hand side, click on CLIA Laboratory Lookup.

1. Enter in your CLIA ID and click on search.
2. Follow the links in blue.
3. The popup will have another http link that is a copy of your certificate.

If your changes are not present on the online version, you will have to request a revised certificate from the CLIA Program. A fee will be required.

Cost for Revised or Reissued Certificates
Waived $95
PPMP $150
Accredited or Compliance $150

FREQUENTLY ASKED QUESTIONS

QUESTION: Why do you need to know if testing personnel have a bachelor's degree versus an associate's degree to qualify testing personnel for CLIA?

ANSWER:

- The Code of Federal Regulations, Chapter 42, Section 493 does make a distinction between an associate degree versus a bachelor degree in order to qualify testing personnel listed in Subpart M for CLIA.
- CLIA requires proof of Montana licensure and education. Degrees outside of the chemical, biological, clinical or medical laboratory science, or medical technology fields will require college transcripts.

QUESTION: What is the bachelor's degree equivalency? Or the associate degree equivalency?

ANSWER:

Bachelor's degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or
At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either—

(1) Forty-eight (48) semester hours of medical laboratory science or medical laboratory technology courses; or
(2) Forty-eight (48) semester hours of science courses that include—
(i) Twelve (12) semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry,
(ii) Twelve (12) semester hours of biology, which must include general biology and molecular biology, cell biology or genetics, and
(iii) Twenty-four (24) semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination

Associate degree in a laboratory science, or medical laboratory technology from an accredited institution or
At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either—

(1) 24 semester hours of medical laboratory technology courses; or
(2) 24 semester hours of science courses that include—
(i) Six semester hours of chemistry,
(ii) Six semester hours of biology, and
(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination.

Common Deficiency Review

§ 493.1253 Standard: Establishment and verification of performance specifications.

(b)(1) Verification of performance specifications. Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results:

(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:

(A) Accuracy.

- Verify that the method produces correct results, including the approved sample matrix.

(B) Precision.

- Assess day-to-day, run-to-run, and within-run variation, as well as operator variance

(C) Reportable range of test results for the test system.

(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

- The laboratory must evaluate an appropriate number of specimens to verify the manufacturer's claims for normal values or, as applicable, the published reference ranges.

Education for LDT Labeling Requirements

FDA Webinar: Labeling Requirements for In Vitro Diagnostic Products (IVD), including LDTs, Under 21 CFR 809.10(b)

On May 6, 2024, the U.S. Food and Drug Administration (FDA) issued a final rule amending the FDA's regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. Along with that amendment, the FDA outlined a policy to phase out, over the course of four years, its general enforcement discretion approach to laboratory developed tests (LDTs). FDA expects compliance with labeling requirements for most IVDs offered as LDTs by May 6, 2025 (Stage 2 of the phaseout policy).

The U.S. Food and Drug Administration (FDA) is announcing a webinar to provide information on how to comply with labeling requirements for IVDs including LDTs. These requirements help ensure that IVD labeling has a consistent set of information critical to understanding the IVD. The focus of this webinar will be on labeling requirements for test systems, under 21 CFR 809.10(b) and will not cover labeling requirements for other types of IVDs such as collection devices and general-purpose reagents.

- **Webinar Date**: Tuesday, September 24, 2024, from 1:00 PM – 2:00 PM ET
- **Location:** webcast
- **Registration:** Not required

We anticipate high attendance for this webinar and there is limited capacity. However, due to the limited capacity we intend to post a recording and transcript as soon as possible following the webinar. We encourage you to dial in 15 minutes before the start of the call to allow time to connect.

View the Webinar Details [lnks.gd]

FDA Recall

On August 1, 2024, BD sent an urgent Medical Device Correction update [t.emailupdates.cdc.gov] regarding the removal of affected BD BACTEC™ MGIT™ 960 PZA Kits. Through internal BD complaint trending and review of internal raw material testing, lots of BD BACTEC™ MGIT™ 960 PZA Kits were identified that may intermittently produce falsely resistant results for pyrazinamide (PZA) during susceptibility testing of Mycobacterium tuberculosis isolates. The current list of affected lots can be found here [t.emailupdates.cdc.gov].

The BD BACTEC Blood Culture Media Bottle Shortage FAQs are now posted on the CLIA website under "Downloads." Please go to https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments [cms.gov] and refresh your browser to view the document.

Questions about the information discussed in this CLIA Update?
The Montana CLIA Program would love to answer them. Contact us at:

Office of Inspector General
2401 Colonial Drive-2nd Floor
PO Box 202953
Helena, MT 59620
Phone: 406-558-9502

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

References:

CLIA (mt.gov)
Clinical Laboratory Improvement Amendments (CLIA) | CMS
eCFR :: 42 CFR Part 493 -- Laboratory Requirements
SOM- Appendix C (cms.gov)