



# CLIA Updates

June 2019

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## Fee Increases

The Centers for Medicare and Medicaid (CMS) Clinical Laboratory Improvement Amendments (CLIA) program increased all program fees as of 1/7/19 by 20% due to program budget shortfall. The previous fee amounts were determined in 1992 to cover the costs of administering the CLIA program. Due to the financial obligations outpacing the fees collected, a fee adjustment was required for continued program operations.

All new bills sent out after 1/7/19 reflect the fee increase. Certificates remain effective for two years.

Certificates of Waiver are now \$180.

Certificates of Provider Performed Microscopy (PPM) are now \$240.

Certificates of Registration remain at \$100.

Certificates of Compliance and Accreditation bills are tiered based on annual test volumes. If you are interested in the exact amount of the new fees, please contact the Montana CLIA Program.

For further information regarding the fee increase, please reference the Federal Register action notice at

<https://www.federalregister.gov/documents/2018/12/31/2018-28359/medicare-program-clinical-laboratory-improvement-amendments-of-1988-clia-fees>.

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## Determining Test Complexity

The Food and Drug Administration (FDA) maintains a website for the public to research CLIA test complexity. The database may be searched by test system, manufacturer, analyte, or specialty.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm>

## Proposed Proficiency Testing Revisions

CMS and the Centers for Disease Control and Prevention (CDC) released document CMS-3355-P “Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance” with proposed updates to the proficiency testing regulations.

The proposal includes updating the analytes which require proficiency testing to add current analytes, remove analytes rarely tested, and address newer technologies. Additionally, there are proposed technical changes to subspecialties such as microbiology.

The public may review the proposed updates on the Federal Register at:

<https://www.federalregister.gov/documents/2019/02/04/2018-28363/clinical-laboratory-improvement-amendments-of-1988-clia-proficiency-testing-regulations-related-to>.

Comments may be submitted to:

[https://www.regulations.gov/comment?D=CMS\\_FRDOC\\_0001-2552](https://www.regulations.gov/comment?D=CMS_FRDOC_0001-2552).

The public comment period has been extended from the original deadline of April 8, 2019 to the new deadline of June 4, 2019 at 11:59 p.m. ET.

CMS and CDC agencies will review all submitted comments.

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## Now You Know

### Providing Information to Laboratory Clients

- 42 CFR §493.1242 Specimen submission, handling, and referral (D5317)  
*(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory’s clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) (see below).*
- 42 CFR §493.1242 Specimen submission, handling, and referral (5311)  
*The laboratory must establish and follow written policies and procedures for each of the following, if applicable:*
  - (a)(1) Patient preparation.*
  - (a)(2) Specimen collection.*
  - (a)(3) Specimen labeling, including patient name or*

*unique patient identifier and, when appropriate, specimen source.*

*(a)(4) Specimen storage and preservation.*

*(a)(5) Conditions for specimen transportation.*

*(a)(6) Specimen processing.*

*(a)(7) Specimen acceptability and rejection.*

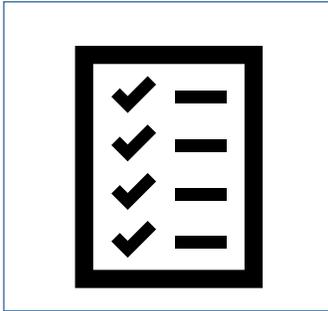
Non-staff members collecting samples at another facility must be able to access this information from the laboratory. Example formats include a worksheet, flier, or website. The name and contact information of the testing facility must be available to the collection facility.



## Patient Test Report Requirements

The test report requirements are located at 42 CFR §493.1291.

- 42 CFR §493.1291 Test report (D5805)
  - (c) The test report must indicate the following:*
    - (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.*
    - (c)(2) The name and address of the laboratory location where the test was performed.*
    - (c)(3) The test report date.*
    - (c)(4) The test performed.*
    - (c)(5) Specimen source, when appropriate.*
    - (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both.*
    - (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.*
  - (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.*



Test reports which fail to meet these regulations frequently occur when the laboratory implements a new electronic medical record system (EMR), after updates to the EMR or laboratory information system (LIS), incomplete fields for printing, or system problems.

The most frequently missing required information include the address of the performing facility and the reference interval information.

Many EMR and LIS systems offer multiple options to print patient results with only certain print options showing all the required information on the report.

The laboratory is not required to issue patient results directly from the laboratory. Each facility determines the most appropriate system for issuing patient test results, such as the Medical Records department.

Quality assessment (QA) projects monitoring for missing/changed information on printed patient test reports prevent test report deficiencies.



## Most Frequently Cited - 2018

Proficiency testing enrollment and failure to follow manufacturer directions for correctly calculating the International Normalized Ratio (INR) shared the top spot for the most frequently cited deficiencies in the 2018 calendar year for Montana. There was also a tie for second place between failure to perform accuracy verification and competency assessments.

Tied for Most Frequently Cited:

- 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.*
  
- 42 CFR §493.1252 Test systems, equipment, instruments, reagents, materials, and supplies (D5411)  
*Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under §493.1253.*

Tied for Second Most Frequently Cited:

- 42 CFR §493.1236 Evaluation of proficiency testing performance (D5217)  
*(c)(1) At least twice annually, the laboratory must verify the accuracy of the following: Any test or procedure it performs that is not included in subpart I of this part.*
  
- 42 CFR §493.1451 Technical supervisor responsibilities (D6128)  
*(b)(9) The procedures for evaluation of the competency of the staff must include, but are not limited to-- Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.*

Other pertinent deficiency themes in the most cited list included unsigned procedures, Individual Quality Control Plan (IQCP), and problems with blood storage temperatures.

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*Incorrect calculation  
of patient INR values  
tied for most cited  
deficiencies in 2018.*

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## Questions and Answers (Q & A)

**Q: The lab wants to start using a new kit, but the manufacturer states it is not CLIA classified. What is the test complexity if the FDA has not classified it?**

A: Any test unclassified by the FDA as waived, moderate, or high complexity is automatically categorized as a high complexity test (42 CFR §493.17(c)(4)). All regulations pertaining to high complexity testing must be met.

**Q: Can the laboratory throw away the IQCPs?**

A: No, Individual Quality Control Plans (IQCPs) must be retained for two years after discontinuing the test to meet the retention requirements at 42 CFR §493.1105(a)(2). This includes retaining the risk assessment, quality control plan, quality assessment plan, and all supporting data. After discontinuing the test, label the IQCP as discontinued/retired and retain the IQCP for two more years.

**Q: There is a new address on the billing statement. Where should the payment be sent?**

A: A new lockbox bank is processing CLIA financial payments as of March 13, 2019. All bills mailed out after this date will automatically be addressed to the new address. Mail sent to the old address will be overnighted to the new address. The new address is:

CLIA Laboratory Program  
PO Box 3056  
Portland, OR 97208-3056

The new address is only for mailed-in payments. All correspondence to update certificate information must continue to be sent separately to the Montana CLIA Program.

### References:

[www.dphhs.mt.gov/qad/Certification/CLIA](http://www.dphhs.mt.gov/qad/Certification/CLIA)  
[www.cms.gov/CLIA](http://www.cms.gov/CLIA)  
CMS CLIA Interpretive Guidelines  
CMS CLIA Federal Regulations  
QSO Memos

If you would like to be added to the emailing list for future correspondence from the Montana CLIA program, please send an email to Joyce Shepard at [jshepard@mt.gov](mailto:jshepard@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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