



# CLIA Updates

June 2023

Office of Inspector General, Montana CLIA Program, 2401 Colonial Drive-2<sup>nd</sup> Floor, PO Box 202953, Helena, MT 59620  
Website: [CLIA \(mt.gov\)](https://clia.mt.gov) Email: [mtssad@mt.gov](mailto:mtssad@mt.gov) or [michelle.griffin@mt.gov](mailto:michelle.griffin@mt.gov) 406-558-9502

## Inside This Issue

1. CMS Electronic CLIA Certificate Rollout
2. Troubleshooting Electronic Certificates

3. FREQUENTLY ASKED QUESTIONS
4. Common Deficiency Review D5421 and D5469

## CMS Electronic CLIA Certificate Rollout

On March 22, 2023, the Centers for Medicare & Medicaid Services (CMS) announced that it will begin sending electronic Clinical Laboratory Improvement Amendments (CLIA) certificates to those laboratories that indicate on their CLIA application to receive email notifications. The link will enable participating laboratories to print a hard copy of their CLIA certificate. CMS plans to email certificates approximately 30 days prior to the expiration date of a current certificate.

With the electronic roll out, we can add **ONE** email to the account to receive electronic notifications.

Example of email:

Greetings!

Based on the submitted Form CMS-116, CLIA Application, your laboratory selected to receive communications electronically. As a result, CMS is providing the link to your electronic CLIA certificate. The link is **[URL provided]**. You may print your certificate from the link. In addition, your laboratory will also receive a paper copy in the US Mail.

If you have any questions or need to update laboratory information, please contact the MT CLIA PROGRAM - CERTIFICATION BUREAU. The MT CLIA PROGRAM - CERTIFICATION BUREAU contact information is listed below. Federal jurisdiction laboratories should contact their CMS locations.

MT CLIA PROGRAM - CERTIFICATION BUREAU  
OIG - DEPT PUBLIC HEALTH&HUMAN SVCS  
PO BOX 202953  
2401 COLONIAL DRIVE, 2ND FLOOR  
HELENA, MT 59620-2953  
[\(406\) 444-2099](tel:(406)444-2099)  
FAX: [\(406\) 444-3456](tel:(406)444-3456)  
EMAIL: [mtssad@mt.gov](mailto:mtssad@mt.gov)

## Troubleshooting Electronic Certificates:

1. I click on the link and cannot find downloaded file.
  - a. Check your Internet Browser's download folder.
2. URL Does not Work.
  - a. Some security software solutions disable a URL by adding a "." to the end of the URL, or by re-routing the URL to a security server that then blocks it. Different security software will do different things to prevent potential attacks on the network.
3. If Link Does Not Work and You Are on VPN
  - a. If you are on VPN, try clicking the URL with VPN turned off.
  - b. Try right mouse clicking on the certificate link, selecting Save As and select a download location.
4. Network is Blocking Download of Certificate
  - a. You can try downloading the certificate when you are outside of the company network and are not on VPN.
  - b. If you receive a message indicating the download process has been blocked, please contact your company's IT support.
5. Browser Cannot Download File
  - a. Check Internet Security Options. Do you receive a message that your browser does not allow this file to be downloaded? Then ensure that File downloads are allowed.
6. Domain is Blocked
  - a. Check with IT Admin to see if domain is allowed (ccsq.cms.hhs.gov) and (iqies.cms.gov)

## FREQUENTLY ASKED QUESTIONS

**QUESTION:** What will happen to Emergency Use Authorization (EUA) test kits after 5/11/2023.

**ANSWER:** EUAs may remain authorized and new EUAs may continue being issued so long as the applicable EUA declaration and determination remain in effect.

The EUA authorization continues until the test is approved and categorized by the FDA or the FDA ends its 564-emergency declaration. The FDA has indicated they will give 6 months' notice if they end their declaration.

**REPEAT QUESTION:** What paperwork is required to be retained for proficiency testing (PT) records?

**ANSWER:** The following documents are required and must be retained for two years:

- Test runs with PT results, including direct printouts.
- Review of results that are not evaluated or scored by the vendor and remedial actions for unsatisfactory results (**\$493.1236 Standard: Evaluation of proficiency testing performance**)
- PT intake paperwork with the date samples were received, copies of the signed PT attestation forms, and PT performance review forms.
- For nonwaived tests not listed in Subpart I, verification of test/procedure is required twice a year.
- Policies or Procedures that address PT enrollment, PT sample handling, testing, and documentation.

## Common Deficiency Review

### **D5421 42 CFR §493.1253 Standard: Establishment and verification of performance specifications**

(b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

**Interpretive Guidelines 42 CFR §493.1253(b)(1)(ii) Reference Range (Normal Values)** - The laboratory may use the manufacturer's reference range provided it is appropriate for the laboratory's patient population (i.e., a normal range that reflects the type of specimen and demographic variables such as age and sex, as applicable). If the manufacturer has not provided reference ranges appropriate for the laboratory's patient population, the laboratory may use published reference range(s).

**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.**

### **D5469 42 CFR §493.1256 Standard: Control procedures**

(d)(10) Establish or verify the criteria for acceptability of all control materials.

(d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.

(d)(10)(ii) The laboratory may use the stated value of a commercially **assayed control** material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory.

(d)(10)(iii) Statistical parameters for **unassayed control** materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

**Interpretive Guidelines 42 CFR §493.1256(d)(10)** Acceptable ranges must be verified (assayed) or established (unassayed) by the laboratory for control materials and any calibrators that are used in lieu of control materials.

**If laboratories rely on commercial companies to establish statistical limits for controls, the laboratory must have documentation to verify that its control results correlate with the established limits.**

---

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-2<sup>nd</sup> 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](mailto:Michelle.Griffin@mt.gov)

#### **References:**

[CLIA \(mt.gov\)](https://www.mt.gov/CLIA)

[Clinical Laboratory Improvement Amendments \(CLIA\) | CMS](https://www.fda.gov/oc/ohrt/clinical-laboratory-improvement-amendments-clia-cms)

[eCFR :: 42 CFR Part 493 -- Laboratory Requirements](https://www.fda.gov/oc/ohrt/clinical-laboratory-improvement-amendments-clia-cms)

[SOM- Appendix C \(cms.gov\)](https://www.cms.gov/medicare/coverage/som-appendix-c)

---