CLIA Updates

May 2022

Office of Inspector General, Montana CLIA Program, 2401 Colonial Drive-2nd Floor, PO Box 202953, Helena, MT 59620
Website: CLIA (mt.gov) Email: mtssad@mt.gov or michelle.griffin@mt.gov 406-558-9502 or 406-444-2099

Inside This Issue

FREQUENTLY ASKED QUESTIONS

QUESTION. Do I need to notify CLIA of changes to my certificate?

ANSWER: Yes.

§ 493.39 Notification requirements for laboratories issued a certificate of waiver.
§ 493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures.

Within 30 days of any change(s) in - (1) Ownership; (2) Name; (3) Location; or (4) Director.

§ 493.51 Notification requirements for laboratories issued a certificate of compliance. (Notify HHS representative)
§ 493.63 Notification requirements for laboratories issued a certificate of accreditation.(Notify accreditation agency)

Within 30 days of any change in - (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only).

Testing Changes

No later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined.

No later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance.

Make sure to notify the Montana CLIA Program of any changes to the mailing address on file. A CMS-116 form (Certificate of Compliance or PPMP) or written notification (Certificate of Waiver) is required for all address updates. NOTE: Your written notification must include the name of the facility, CLIA ID#, description of change, signature and date of the laboratory director or owner on file.

QUESTION. Where is my renewal bill?

ANSWER: Bills for existing CLIA certificates are automatically printed and mailed 6 months prior to the CLIA certificate expiration date.

QUESTION. I have not received my certificate. Where is my new certificate?

ANSWER: If payment has been processed to renew the CLIA certificate, a new certificate will be automatically printed and mailed three to four weeks prior to the expiration of the current certificate.

CLIA FAQs (mt.gov)

HOW TO NOTIFY FDA

Below is the current information for notifying the FDA of a Transfusion Fatality:

HOW TO NOTIFY FDA

Section 606.170(b) states that you may report a fatality by telephone, facsimile, express mail, or electronically transmitted mail (email). We recommend that you submit the initial notification by email, if possible, and if you do so, you will receive an email confirmation receipt from us. If email is not feasible, please notify us by telephone or facsimile. We cannot access notification outside of customary working hours unless you use email or telephone. Similarly, we recommend that you submit 7-day follow up reports by email, facsimile, or express mail.

- Email: fatalities2@fda.hhs.gov
- Telephone/voice-mail number: 240-402-9160
- Fax number: 301-837-6256, Attn: CBER Fatality Program Manager
- Express mail address: Office of Compliance and Biologics Quality/CBER
  Attn: Fatality Program Manager
  10903 New Hampshire Ave. Bldg. 71, Rm. 3128
  Silver Spring, MD 20993-000

Notifying FDA of Fatalities Related to Blood Collection or Transfusion – Guidance for Industry, gcc02.safelinks.protection.outlook.com] updated in August 2021.

TEST RECALL

The following list are links to test recall announcements:

1. Celltrion USA Recalls Certain Point of Care DiaTrust COVID-19 Ag Rapid Test Kits Labeled for Research Use Only
2. Celltrion USA Recalls Certain Point of Care DiaTrust COVID-19 Ag Rapid Test Kits Which May Have Been Distributed to Unauthorized, Non-CLIA-Certified Users
3. SD Biosensor Recalls STANDARD Q COVID-19 Ag Home Tests That Are Not Authorized, Cleared, or Approved by the FDA and May Give False Results
4. LuSys Laboratories, Inc Recalls COVID-19 Antigen Tests (Nasal/Saliva) and COVID-19 IgG/IgM Antibody Tests Because They Are Not Authorized, Cleared, or Approved by the FDA
5. Mesa Biotech Recalls Accula SARS-CoV-2 Tests for False Positive Risk (govdelivery.com)

Please refer to the following link for additional recalls: Medical Device Recalls | FDA

SARS-CoV-2 Reporting Guidance Update

On March 8, 2022, the U.S. Department of Health and Human Services (HHS) updated its Laboratory Data Reporting Guidance.

Beginning April 4, 2022, COVID-19 testing facilities are no longer required to report NEGATIVE results for tests authorized for use under a CLIA certificate of waiver. This includes rapid and antigen testing performed for screening testing at schools, correctional facilities, employee testing programs, long-term care facilities, and rapid testing performed in pharmacies, medical provider offices, and drive-through and pop-up testing sites. In addition, testing facilities are no longer required to report POSITIVE or NEGATIVE antibody test results.

The updated guidance still requires laboratories to report both POSITIVE AND NEGATIVE results for laboratory-based nucleic acid amplification tests (NAATs) that are performed in a facility that is certified under CLIA to perform moderate- or high-complexity tests.

Updated Reporting Requirements

CLIA Certificate Type	**Authorized Laboratory Setting/Test complexity** Waived (W), Moderate (MC) or High complexity (HC)	**Test platform**	**Reporting of SARS-CoV-2 positive results**	**Reporting of SARS-CoV-2 negative and inconclusive results**
COW/PPM	W	Antigen	Required	Optional
		Molecular (NAAT)	Required	Optional
		Serology (Antibody)	Optional	Optional
COC/COA/COR	W, MC or HC	Antigen	Required	Optional
	MC or HC	Molecular (NAAT)	Required	Required
	W	Molecular (NAAT)	Required	Optional
	W, MC or HC	Serology (Antibody)	Optional	Optional

QSO-21-10-CLIA, revised

Lab Advisory: HHS Updates COVID-19 Laboratory Reporting Guidance (cdc.gov)

COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 March 8, 2022 Effective date: April 4, 2022 COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 (cdc.gov)

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 or 406-444-2099
Email: Michelle.Griffin@mt.gov

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