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CMS Electronic CLIA Updates

* **All CLIA laboratories that have received either a paper or electronic CLIA certificate since September 26, 2023 are able to print their own CLIA certificate from the Quality Certification and Oversight Reports (QCOR)** [**Clinical Laboratory Lookup Tool [lnks.gd]**](https://urldefense.com/v3/__https%3A/lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDAsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vcWNvci5jbXMuZ292L21haW4uanNwIiwiYnVsbGV0aW5faWQiOiIyMDIzMTEyMi44NjAzMzg2MSJ9.RmnkZMho9R4uNKikQnyp31RYbcSUGuXS3TB9BPWXE0o/s/1386323659/br/231467171081-l__;!!GaaboA!oqE0jNMo2pQCTefTZjdAIY_x04uGvjtgpzYiK902s95SAwocVCLReyN0-vfdCrugukgo6BM7eKOd_5YUlZF6HpHipCAJRyxsbKfA6g$)**.** The link displayed with your laboratory will be the most recently issued CLIA certificate. New changes will be updated in the next issued certificate.

**You can print your own certificate.**

* As of November 18, 2023, CMS now sends two CLIA fee coupon notices prior to the final payment date.
* On November 22, 2023, CMS will begin sending electronic fee coupon notices to those laboratories that indicated on their CLIA application (Form CMS-116) their preference to receive email notifications.
* On November 22, 2023, CMS will begin sending electronic warning letters regarding loss of accreditation to those laboratories that indicated on their CLIA application (Form CMS-116) their preference to receive email notifications.

 FREQUENTLY ASKED QUESTIONS

**QUESTION:** How do I update my email to receive electronic notifications and certificates?

**ANSWER:**

* Please provide a written notification to update your email address or opt-in to email notifications. The written notification requires the name of the facility, CLIA ID, description of change, signature, and date of the director on file. The signature needs to be either a wet signature or certified electronic.

**QUESTION**: How long is the laboratory required to retain its documentation?

**ANSWER:** **§ 493.1105 Standard: Retention requirements**.

**2 Years**

* Test requisitions and authorizations
* Test procedures
* Analytic systems records
* Proficiency testing records
* Quality system assessment records
* Test reports

**Specific to discipline:**

* Immunohematology records, blood and blood product records, and transfusion records as specified in [**21 CFR 606.160(b)(3)(ii)**](https://www.ecfr.gov/current/title-21/section-606.160#p-606.160(b)(3)(ii))**,** [**(b)(3)(iv)**](https://www.ecfr.gov/current/title-21/section-606.160#p-606.160(b)(3)(iv))**,** [**(b)(3)(v)**](https://www.ecfr.gov/current/title-21/section-606.160#p-606.160(b)(3)(v)) **and** [**(d)**](https://www.ecfr.gov/current/title-21/section-606.160#p-606.160(b)(3)(d))**.**
* Immunohematology reports as specified in [**21 CFR 606.160(d)**](https://www.ecfr.gov/current/title-21/section-606.160#p-606.160(d)).
* Pathology test reports **10 YEARS**
* Cytology slide preparations for at least **5 years** from the date of examination
	+ - see [§ 493.1274(f)](https://www.ecfr.gov/current/title-42/section-493.1274#p-493.1274(f)) for proficiency testing exception.
* Histopathology slides for at least **10 years** from the date of examination.
* Pathology specimen blocks for at least **2 years** from the date of examination.

**Please note**: Complaint Surveys are unannounced and can be at any time. The lab will be required to have two years’ worth of data at the time of the unannounced survey.

Common Deficiency Review

**D2013 42 CFR §493.801(b) Standard: Testing of proficiency testing samples**

(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory.

**The regulations divide the PT referral sanctions into three categories based on the severity and the extent of the referrals.**

1. The first category is for the most egregious violations, encompassing cases of repeat PT referral or cases where the laboratory reports another laboratory’s test results as its own.
2. The second category PT referral includes when a laboratory reports its own PT sample results but obtains test results for PT samples from another laboratory on or before cut-off date.
3. The third category of PT referral includes the scenario in which the referring laboratory does not receive test results from another laboratory prior to the event cut-off date and reports their own results. This category includes referral of confirmatory, distributive, and reflex PT samples.

FDA Recall

[**Update: October 18, 2023 [fda.gov]**](https://urldefense.com/v3/__https%3A/www.fda.gov/medical-devices/safety-communications/do-not-use-tests-manufactured-universal-meditech-inc-fda-safety-communication__;!!GaaboA!rAaf89bVrHCDgwcmsX_4cZEVt_TWHo942qAHMgFU1_lpIRs5WhbzRDMcwVsb3MDgzicqgOUm1gudJ0ejEh8SwbFO1hMUkLpaGyb9sg$)

The U.S. Food and Drug Administration (FDA) is warning consumers and patients to not use the following tests manufactured by Universal Meditech, Inc. (UMI):

* One Step Pregnancy Test
* DiagnosUS One Step Ovulation Test
* HealthyWiser UriTest 10 Parameter Reagent Test Strips for Urinalysis
* HealthyWiser UriTest UTI Test Strips
* HealthyWiser KetoFast Ketone Test Strips
* HealthyWiser pH-Aware pH Test Strips
* To Life hCG Pregnancy Urine Test
* Am I Pregnant Pregnancy Midstream Test
* DeTec hCG Pregnancy Urine Test
* PrestiBio Pregnancy Strips
* PrestiBio Rapid Detection Pregnancy Test Midstream
* PrestiBio Ovulation Strips
* PrestiBio Urinalysis Test Strip 10 Parameters
* PrestiBio Ketone Test Strips
* PrestiBio Breast Milk Alcohol Test Strips
* DiagnosUS One Step LH Ovulation Test (Strip) (added Oct. 18, 2023)
* DiagnosUS SARS-CoV-2 Antibody (IgG/IgM) Test (added Oct. 18, 2023)
* DiagnosUS One Step FSH Menopausal Test (Strip) (added Oct. 18, 2023)
* Lem Fertility hCG Pregnancy Urine Test (added Oct. 18, 2023)
* Lem Fertility LH Ovulation Test (Strip) (added Oct. 18, 2023)
* DiagnosUS hCG Pregnancy Urine Test Strip Format (added Oct. 18, 2023)
* DiagnosUS hCG Pregnancy Urine Test Cassette Format (added Oct. 18, 2023)
* DiagnosUS hCG Pregnancy Serum/Urine Test Cassette Format (added Oct. 18, 2023)
* DiagnosUS Pregnancy Test Midstream (added Oct. 18, 2023)
* DiagnosUS Ovulation Predictor Midstream (added Oct. 18, 2023)

**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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**Helena, MT 59620**

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 **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)](https://dphhs.mt.gov/qad/Certification/CLIA)

[Clinical Laboratory Improvement Amendments (CLIA) | CMS](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA)

[eCFR :: 42 CFR Part 493 -- Laboratory Requirements](https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493)

[SOM- Appendix C (cms.gov)](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf)