

FAQ #3 – Revised/Replacement certificates

Q #1: We cannot find our current CLIA.

Q #2: We sent notification to the CLIA State Agency for Oregon of changes to our CLIA lab. Why haven't we seen a revised certificate?

A: Effective January 2024 the federal CLIA Program is charging for replacement and revised certificates. Before a replacement or revised certificate can be delivered, all outstanding fees to the CLIA program, including the certificate fee, itself, must be paid. There is a window of time when no certificate may be generated at all. That window is 6 months prior to the expiration of a Certificate of Waiver or Certificate of Provider Performed Microscopy and 1 year prior to the expiration for a Certificate of Compliance or Certificate of Accreditation.

We do not automatically order a revised certificate after entering any changes that have been submitted to the CLIA State Agency. You must request that a new certificate be generated, whether it is a revised or replacement certificate. A replacement certificate is created when a lab requests a new certificate in the absence of changes having been made by the CLIA State Agency. A revised certificate is issued after changes have been made based on a submission to the CLIA State Agency. Requesting a new certificate indicates that you will pay the fee for it. Please see the fee schedule document on our website for the current fees being charged.

Beginning in late 2023, the federal CLIA Program started posting all CLIA certificates generated to a CMS website (S&C's Quality, Certification and Oversight Reports (QCOR)). You can find this by Googling 'CLIA Laboratory Lookup' and clicking on the link for the CMS webpage labeled 'Laboratory Demographics Lookup' or use this link:

<https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/laboratory-demographics>

With newly created CLIA certificates being posted online for download, we are no longer providing letters of documentation of the status of a CLIA certificate for the purpose of presentation to a surveying organization such as The Joint Commission, while they are performing a facility survey or a CLIA approved laboratory Accrediting Organization.

It is the responsibility of the laboratory to maintain the CLIA certificate that was mailed or emailed or obtained from the QCOR website and have it displayed according to state regulations. Any replacement or revised certificate must be paid for before it will be delivered. Certificate delivery can take up to 8 weeks, or longer, from the time it is ordered. Turn around time from ordering to delivery of a replacement/revised certificate largely depends on how quickly a lab can pay for it and whether the laboratory has selected electronic or mailed hardcopy delivery.