

# Frequently Asked Questions

## 1. How do I know if I need CLIA certification?

CLIA certification is required for facilities that test clinical specimens for the purpose of diagnosis, treatment, or prevention of disease. If your facility only collects specimens to be sent out for testing at another facility, then CLIA certification is not required for your facility. Laboratories performing research only testing, laboratories operated directly by the Federal Government (for example VA, DOD), or laboratory testing for the hiring or termination of employees are CLIA-exempt and do not require CLIA certification. There are four certification types, depending on the type of testing performed: Certificate of Waiver, Certificate of PPM, Certificate of Compliance or Certificate of Accreditation. All certifications are valid for a 2 year period.

## 2. Where do I get the CLIA application?

The CMS-116 application is available on the CLIA website, [www.cms.gov/clia](http://www.cms.gov/clia) Click on “How to Apply for a CLIA certificate” on the left side of the screen, then the CMS-116 application is found under “Related Links” at the bottom of the page.

## 3. How does the application process work?

Once the application is completed, the application must be sent to the state agency. **Do not send the payment with the application.** You may fax or email the application to: Fax (602)364-0759 or email: [Marcie.Bentley@azdhs.gov](mailto:Marcie.Bentley@azdhs.gov) or [Denise.Barbeau@azdhs.gov](mailto:Denise.Barbeau@azdhs.gov) The application is processed by the State Agency and, once processed, the facility will receive an invoice (CLIA user fee coupon) from CMS in Maryland. Once the invoice is paid, CMS will mail the facility their CLIA certificate. The entire application process usually takes 4-6 weeks. Fee schedules can be found on the CLIA website, [www.cms.gov/clia](http://www.cms.gov/clia)

## 4. Which types of payment methods are available?

Once the laboratory receives the invoice from CMS, there are 2 ways to make a payment. The facility may mail a check to the PO Box address listed on the fee coupon:

**CLIA Laboratory Program**

**P.O. Box 530882**

**Atlanta, GA**

**30353-0882**

or pay online at [www.pay.gov](http://www.pay.gov) (enter “CLIA” in the search area). **Do not send payment to the State Agency.**

## 5. How do I make general changes to an existing CLIA Certification?

Facilities are required to notify our office of any changes to your CLIA certification within 30 days of the change.

To change the address, mailing address, phone or fax, email, facility name and/or tax ID that does not include a change of ownership, you must use the facility status change form found at [www.azdhs.gov/CLIA](http://www.azdhs.gov/CLIA).

To change the director of a Certificate of Waiver or a Certificate of PPM, use the facility status change form found at [www.azdhs.gov/CLIA](http://www.azdhs.gov/CLIA).

To change the director of a Certificate of Compliance or a Certificate of Accreditation, use a CMS-116 form found at [www.cms.gov/clia](http://www.cms.gov/clia)

For our purposes, a change in ownership occurs when the facility undergoes a change in facility name and tax ID. If you have a change in ownership, you must submit a facility status change form and a Disclosure of Ownership form found at [www.azdhs.gov/clia](http://www.azdhs.gov/clia)

To upgrade/downgrade your existing certificate type, use the CMS-116 application found at [www.cms.gov/clia](http://www.cms.gov/clia)

**6. Why haven't I received my certificate since my payment was already processed?**

The certificate renewal process is automatic for any existing CLIA. CMS will mail out the renewal invoice approximately 6 months prior to the current expiration date. There will be a total of 3 invoices mailed out, every two months, until the payment is made. Once the payment is processed, CMS will not mail the new certificate until approximately 3 weeks prior to the current expiration date, regardless of when the payment was processed.

**7. Why does my facility address not appear on the invoice?**

The invoice will only contain the mailing address of the facility. If there was a separate mailing address listed, then that will be the address shown on the invoice. If there was no separate mailing address listed, then the facility address will appear on the invoice.

**8. How do I get a copy of my CLIA certificate?**

If you need a copy of an existing CLIA certificate then you may contact our office to request a copy. Reprinted certificates are generated and mailed from our Central Office in Maryland and may take up to 3 weeks to arrive. However, reprinted certificates are not available if the request is made within 6 months of the current expiration date.

**9. Is there State licensure or phlebotomy licensure in Arizona?**

Arizona does not have State Licensure for laboratories. Clinical laboratories in Arizona are only required to be CLIA certified. There are no additional requirements for specimens that are collected in Arizona and sent to another state for testing, other than the testing laboratory must be CLIA certified in their own state, at the appropriate level for the testing performed. Each state has different regulations, so make sure to check with each state prior to collecting and testing clinical specimens.

Arizona does not have phlebotomy licensure or certification.

**10. How do I terminate an existing CLIA certification?**

If you no longer test clinical specimens and do not require CLIA certification any longer, then you must submit a letter of termination to the State Agency. The termination letter must include: the CLIA number, facility name and address, effective date of the termination and reason for termination. Please submit the termination letter on the facility's letterhead, if possible. The request must be signed by the laboratory director or authorized personnel. You may submit the termination request by fax to 602-364-0759 or by email to [Marcie.Bentley@azdhs.gov](mailto:Marcie.Bentley@azdhs.gov) or [Denise.Barbeau@azdhs.gov](mailto:Denise.Barbeau@azdhs.gov)