CLIA CERTIFICATION QUICK START GUIDE

November 2026

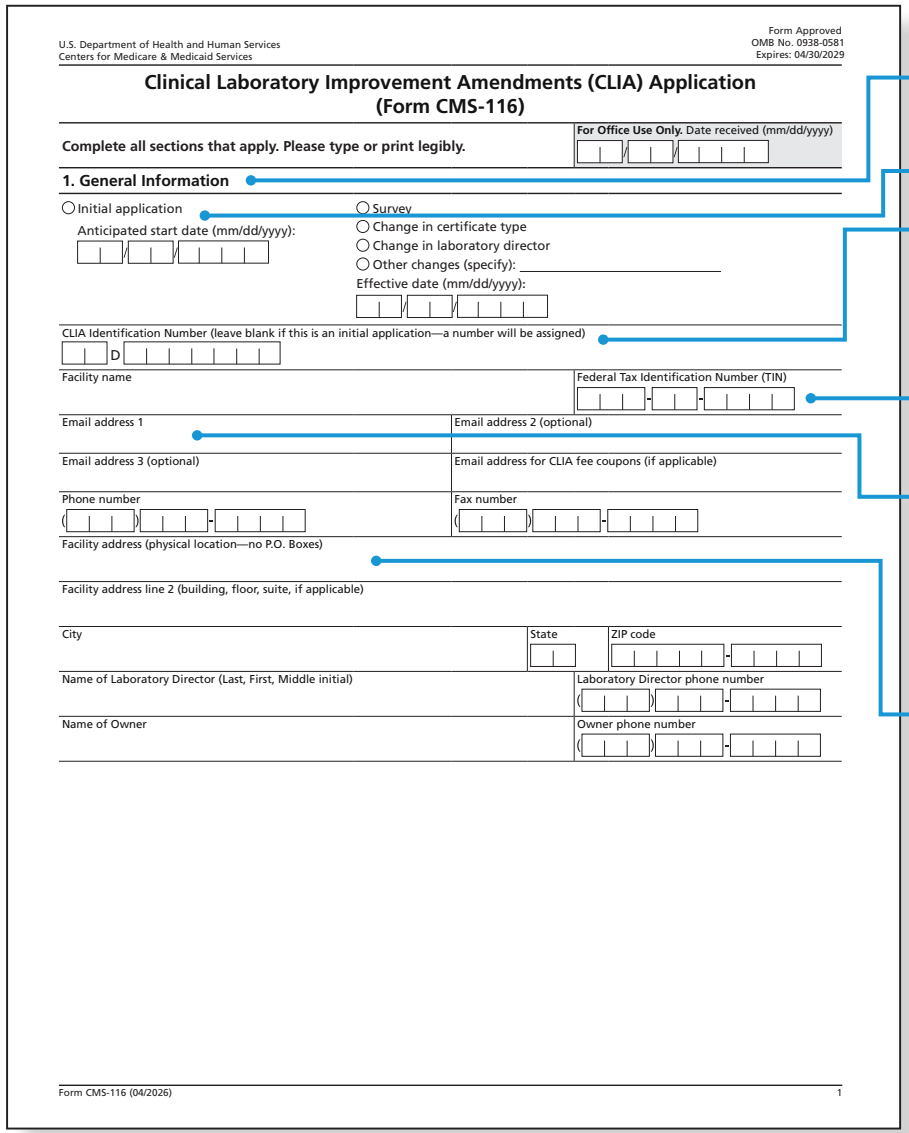
The Centers for Medicare & Medicaid Services (CMS) supports the Clinical Laboratory Improvement Amendments (CLIA) and its regulations to ensure U.S. clinical laboratories provide accurate, reliable, and timely patient test results. Under CLIA, laboratories are generally required to have the appropriate certificate before they can begin testing.

This guide explains how laboratories can apply for CLIA certification from CMS. For more information, visit the CMS CLIA website.

STEP 1

Complete Form CMS-116

- Download this fillable form and type your responses in each section. Make sure you save it as a PDF on your computer.
- Include information as of the date you complete this form.
- Complete all applicable sections. CMS cannot process incomplete applications.
- Check the FDA website to find out if your laboratory's tests are categorized as waived, moderate, or high complexity. If you can't find test complexity information, contact your State Agency.



U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0581
Expires: 04/30/2029

Clinical Laboratory Improvement Amendments (CLIA) Application
(Form CMS-116)

Complete all sections that apply. Please type or print legibly. | **For Office Use Only.** Date received (mm/dd/yyyy) ___/___/_____

1. General Information

○ Initial application
Anticipated start date (mm/dd/yyyy): ___/___/_____

○ Survey
○ Change in certificate type
○ Change in laboratory director
○ Other changes (specify): _____
Effective date (mm/dd/yyyy): ___/___/_____

CLIA Identification Number (leave blank if this is an initial application—a number will be assigned)
___ D _____

Facility name | Federal Tax Identification Number (TIN) ___-___-_____

Email address 1 | Email address 2 (optional)

Email address 3 (optional) | Email address for CLIA fee coupons (if applicable)

Phone number (___)___-_____ | Fax number (___)___-_____

Facility address (physical location—no P.O. Boxes)

Facility address line 2 (building, floor, suite, if applicable)

City | State ___ | ZIP code _____-____

Name of Laboratory Director (Last, First, Middle initial) | Laboratory Director phone number (___)___-_____

Name of Owner | Owner phone number (___)___-_____

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Complete GENERAL INFORMATION in Section 1

- First-time applicants check **"Initial Application."**
- For first-time applicants, leave the **CLIA IDENTIFICATION NUMBER** blank. When the application is processed, the number is assigned.
- Enter the 9-digit **FEDERAL TAX IDENTIFICATION NUMBER (TIN)** associated with your laboratory facility. Only enter numbers and do not use dashes, spaces, or other symbols. *Example: Enter 123456789 (not 123-45-6789).*
- Include your laboratory's most up-to-date **EMAIL ADDRESS** so you get fee notifications, electronic CLIA certificates, and important updates from CMS. You must provide at least one email address, and you may include an email address specific to billing. The remaining email fields are optional.
- **FACILITY ADDRESS** must reflect the physical location where you perform laboratory testing. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.

Tip: Include a business email address that many laboratory staff access and use.

International Lab Facilities

Under CLIA, an international laboratory is a facility outside the U.S. or its territories that performs clinical laboratory tests referred by and returned to a facility in the U.S. or its territories.

Disclaimer: This guide is a restatement of the law intended to assist people in understanding the basics about the CLIA program. The reader should consult the relevant statutes and regulations for the full scope of the CLIA requirements.

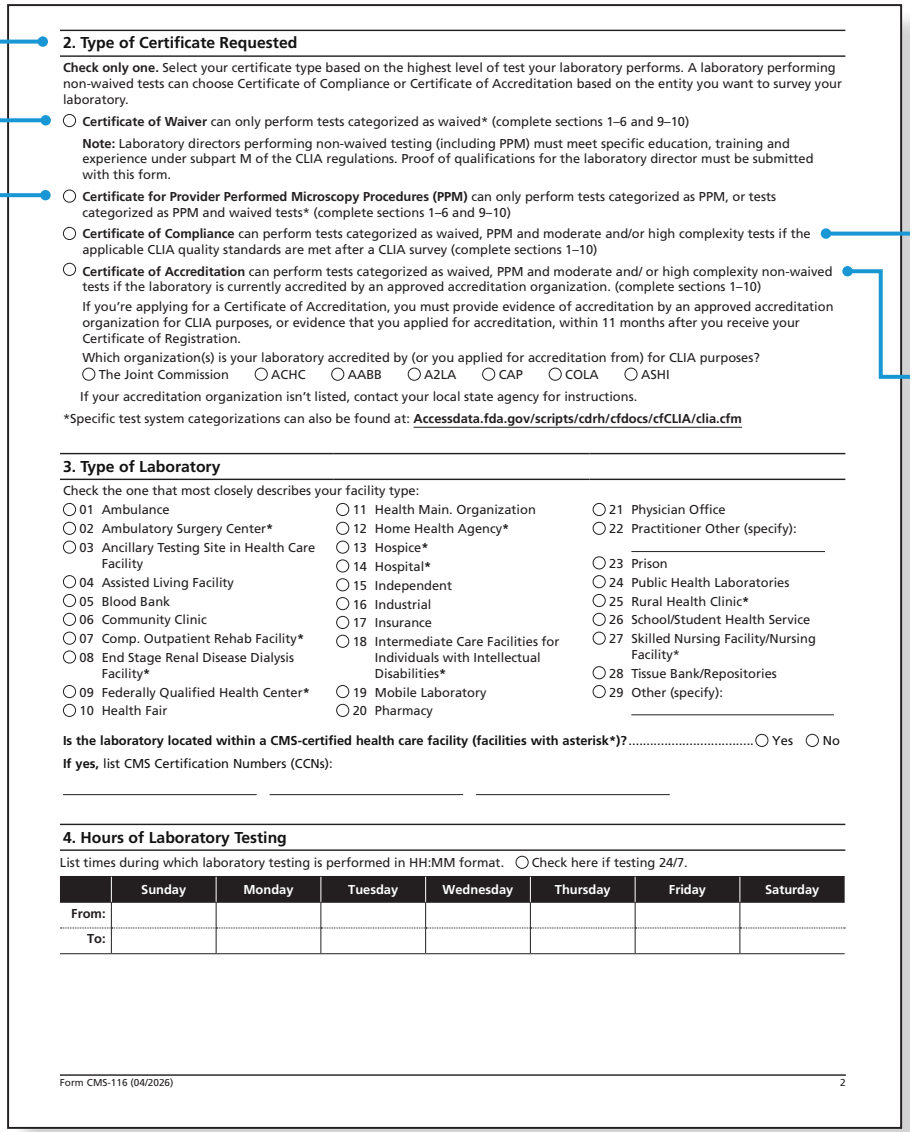
Complete TYPE OF CERTIFICATE REQUESTED in Section 2

In Section 2, **TYPE OF CERTIFICATE REQUESTED**, select the certificate that corresponds to the highest level of test complexity your laboratory performs (**Note:** all CLIA certificates are valid for 2 years):

- **Waived tests** are simple tests that have a low risk of an incorrect result. Refer to CLIA Currently Waived Analytes.
- **Moderate complexity tests** require minimal scientific and technical knowledge.
- **High complexity tests** are more difficult to perform or interpret than waived and moderate tests. Specialized scientific knowledge and training are required.

More information about each certificate type:

- **Certificate of Waiver (CoW):** Issued to a laboratory that only performs waived tests.
- **Certificate for Provider Performed Microscopy Procedures (PPM):** Issued to a laboratory in which a physician, midlevel practitioner, or dentist performs only specific microscopy procedures during a patient's visit. Refer to a listing of PPM procedures, which are a subset of moderate complexity tests.



2. Type of Certificate Requested

Check only one. Select your certificate type based on the highest level of test your laboratory performs. A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the entity you want to survey your laboratory.

- ○ **Certificate of Waiver** can only perform tests categorized as waived* (complete sections 1–6 and 9–10)

  Note: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of qualifications for the laboratory director must be submitted with this form.
- ○ **Certificate for Provider Performed Microscopy Procedures (PPM)** can only perform tests categorized as PPM, or tests categorized as PPM and waived tests* (complete sections 1–6 and 9–10)
- ○ **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests if the applicable CLIA quality standards are met after a CLIA survey (complete sections 1–10)
- ○ **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/ or high complexity non-waived tests if the laboratory is currently accredited by an approved accreditation organization. (complete sections 1–10)

  If you're applying for a Certificate of Accreditation, you must provide evidence of accreditation by an approved accreditation organization for CLIA purposes, or evidence that you applied for accreditation, within 11 months after you receive your Certificate of Registration.

  Which organization(s) is your laboratory accredited by (or you applied for accreditation from) for CLIA purposes?
  ○ The Joint Commission ○ ACHC ○ AABB ○ A2LA ○ CAP ○ COLA ○ ASHI

  If your accreditation organization isn't listed, contact your local state agency for instructions.

*Specific test system categorizations can also be found at: Accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm

3. Type of Laboratory

Check the one that most closely describes your facility type:

○ 01 Ambulance	○ 11 Health Main. Organization	○ 21 Physician Office
○ 02 Ambulatory Surgery Center*	○ 12 Home Health Agency*	○ 22 Practitioner Other (specify):
○ 03 Ancillary Testing Site in Health Care Facility	○ 13 Hospice*	
	○ 14 Hospital*	○ 23 Prison
○ 04 Assisted Living Facility	○ 15 Independent	○ 24 Public Health Laboratories
○ 05 Blood Bank	○ 16 Industrial	○ 25 Rural Health Clinic*
○ 06 Community Clinic	○ 17 Insurance	○ 26 School/Student Health Service
○ 07 Comp. Outpatient Rehab Facility*	○ 18 Intermediate Care Facilities for Individuals with Intellectual Disabilities*	○ 27 Skilled Nursing Facility/Nursing Facility*
○ 08 End Stage Renal Disease Dialysis Facility*		○ 28 Tissue Bank/Repositories
○ 09 Federally Qualified Health Center*	○ 19 Mobile Laboratory	○ 29 Other (specify):
○ 10 Health Fair	○ 20 Pharmacy	

Is the laboratory located within a CMS-certified health care facility (facilities with asterisk*)? ○ Yes ○ No

If yes, list CMS Certification Numbers (CCNs):

4. Hours of Laboratory Testing

List times during which laboratory testing is performed in HH:MM format. ○ Check here if testing 24/7.

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
From:							
To:							

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A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the agency you wish to survey your laboratory:

- **Certificate of Compliance (CoC):** Issued to a laboratory after the State Agency or CMS surveyor finds the laboratory in compliance with all applicable CLIA requirements.
- **Certificate of Accreditation (CoA):** Issued to a laboratory by a CMS-approved Accreditation Organization (AO). AOs are private nonprofits which meet all applicable federal participation requirements but may have more stringent health and safety requirements.
- **Certificate of Registration (CoR):** Issued to temporarily allow the laboratory to conduct nonwaived (moderate and/or high complexity) tests until the laboratory is inspected and found to be in compliance with CLIA regulations. The CoR is valid for no more than 2 years. Only laboratories applying for a Certificate of Compliance or a Certificate of Accreditation will receive a CoR. Under a CoR, a laboratory is also permitted to conduct waived tests.

Complete TYPE OF LABORATORY in Section 3

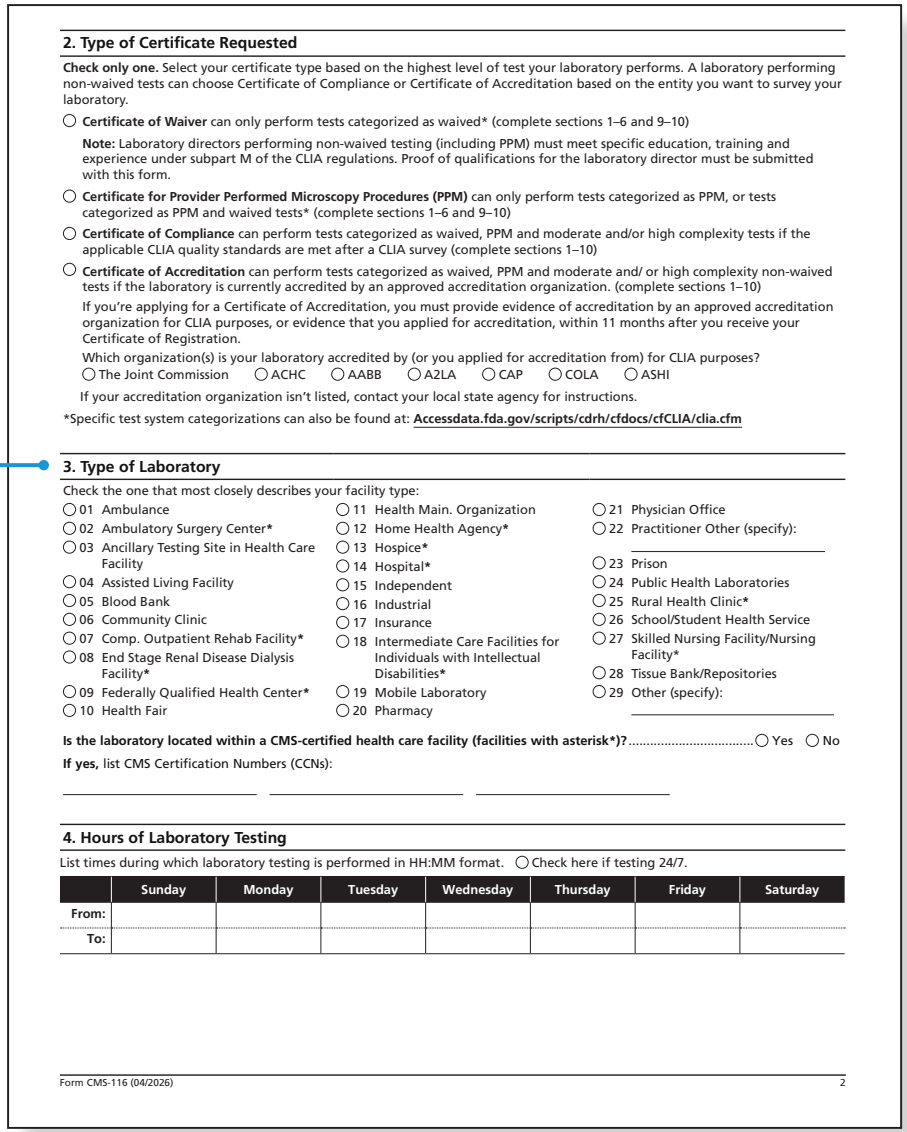
In Section 3, select the **TYPE OF LABORATORY** that best describes the facility where your laboratory performs testing. Contact your State Agency with questions.

STEP 2

Submit Completed Form CMS-116 to the Appropriate State Agency

- Submit your completed CLIA application to your State Agency.
- For PPM, CoR, CoC, and CoA, include documentation that the laboratory director's qualifications are met:
  - State licensure, as applicable
  - Education (e.g. diploma, transcript, foreign education equivalency, etc.).
  - Credentials (e.g. board certification, continuing education hours, etc.).
  - Laboratory experience

Important: Some states may have additional requirements. Contact your State Agency to find out if you need to submit additional forms or documentation with your application.



2. Type of Certificate Requested

Check only one. Select your certificate type based on the highest level of test your laboratory performs. A laboratory performing non-waived tests can choose Certificate of Compliance or Certificate of Accreditation based on the entity you want to survey your laboratory.

○ **Certificate of Waiver** can only perform tests categorized as waived* (complete sections 1–6 and 9–10)

Note: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of qualifications for the laboratory director must be submitted with this form.

○ **Certificate for Provider Performed Microscopy Procedures (PPM)** can only perform tests categorized as PPM, or tests categorized as PPM and waived tests* (complete sections 1–6 and 9–10)

○ **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests if the applicable CLIA quality standards are met after a CLIA survey (complete sections 1–10)

○ **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/ or high complexity non-waived tests if the laboratory is currently accredited by an approved accreditation organization. (complete sections 1–10)

If you're applying for a Certificate of Accreditation, you must provide evidence of accreditation by an approved accreditation organization for CLIA purposes, or evidence that you applied for accreditation, within 11 months after you receive your Certificate of Registration.

Which organization(s) is your laboratory accredited by (or you applied for accreditation from) for CLIA purposes?
○ The Joint Commission ○ ACHC ○ AABB ○ A2LA ○ CAP ○ COLA ○ ASHI

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*Specific test system categorizations can also be found at: **Accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm**

3. Type of Laboratory

Check the one that most closely describes your facility type:

○ 01 Ambulance
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○ 07 Comp. Outpatient Rehab Facility*
○ 08 End Stage Renal Disease Dialysis Facility*
○ 09 Federally Qualified Health Center*
○ 10 Health Fair
○ 11 Health Main. Organization
○ 12 Home Health Agency*
○ 13 Hospice*
○ 14 Hospital*
○ 15 Independent
○ 16 Industrial
○ 17 Insurance
○ 18 Intermediate Care Facilities for Individuals with Intellectual Disabilities*
○ 19 Mobile Laboratory
○ 20 Pharmacy
○ 21 Physician Office
○ 22 Practitioner Other (specify): _____
○ 23 Prison
○ 24 Public Health Laboratories
○ 25 Rural Health Clinic*
○ 26 School/Student Health Service
○ 27 Skilled Nursing Facility/Nursing Facility*
○ 28 Tissue Bank/Repositories
○ 29 Other (specify): _____

Is the laboratory located within a CMS-certified health care facility (facilities with asterisk*)? ○ Yes ○ No

If yes, list CMS Certification Numbers (CCNs): _____ _____ _____

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STEP 3

Receive Fee Notification (Invoice) and Pay Your CLIA Certification Fee

You'll receive a Fee Notification via email.

Your fee varies based on certificate type and test volume. Refer to CLIA Fee Schedule.

Pay your CLIA certification fee(s) on pay.gov. We accept bank account (ACH), debit, or credit cards. Your secure payment gets processed overnight.

STEP 4

Receive Certificate and Begin Testing

- You'll receive your CLIA certificate via email. Or you can view, print (and reprint) online.
- Laboratories with a CoR typically have an initial survey in the first year to determine whether the laboratory is in compliance with all applicable CLIA requirements.



CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF WAIVER

LABORATORY NAME AND ADDRESS
WESTFIELD STATE UNIVERSITY -HEALTH SERVICES
SCANLON HALL,DPT HLTH SVCS,1ST FL,WEST WING
577 WESTERN AVE
SCANLON HALL, 1ST FLOOR, WEST WING
WESTFIELD, MA 01086-1630

CLIA ID NUMBER
22D0981035

EFFECTIVE DATE
12/18/2024

LABORATORY DIRECTOR
PATRICIA C. BERUBE

EXPIRATION DATE
12/17/2026

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.
This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Gregg Brandish, Director
Division of Clinical Laboratory Improvement & Quality
Quality & Safety Oversight Group
Center for Clinical Standards and Quality

Sample certificate shown

STEP 5

Maintain Certificate

Keep your CLIA certificate current according to this survey schedule:

- Contact your State Agency when you have a change in the laboratory's demographics, such as specialties, email address, or if the laboratory stops testing or closes.
- Laboratories must notify their State Agency (and the accreditation organization, if applicable) of the following changes. ***Laboratories with a CoW or a PPM must immediately notify their State Agency before testing outside of their current certificate.**
- Laboratories with a CoW, CoA, or PPM will receive a renewal invoice 6 months before their certificate expires.
- Laboratories with a CoC will receive a certificate fee invoice after their compliance survey, and a survey fee invoice 1 year before their certificate expires.

CERTIFICATE TYPE	SURVEY SCHEDULE
Certificate of Waiver (CoW)	Not routinely surveyed
Certificate for Provider Performed Microscopy Procedures (PPM)	Not routinely surveyed
Certificate of Compliance (CoC)	Every 2 years
Certificate of Accreditation (CoA)	Every 2 years

REQUIREMENTS/ CHANGE OF:	Certificate of Waiver	Certificate for Provider Performed Microscopy Procedures	Certificate of Registration	Certificate of Compliance	Certificate of Accreditation
Ownership	30 days	30 days	30 days	30 days	30 days
Name	30 days	30 days	30 days	30 days	30 days
Location	30 days	30 days	30 days	30 days	30 days
Director	30 days	30 days	30 days	30 days	30 days
Technical Supervisor	N/A	N/A	30 days	30 days	N/A
Testing	*Immediately	*Immediately	6 months	6 months	6 months