LABORATORY QUICK START GUIDE TO CMS CLIA CERTIFICATION

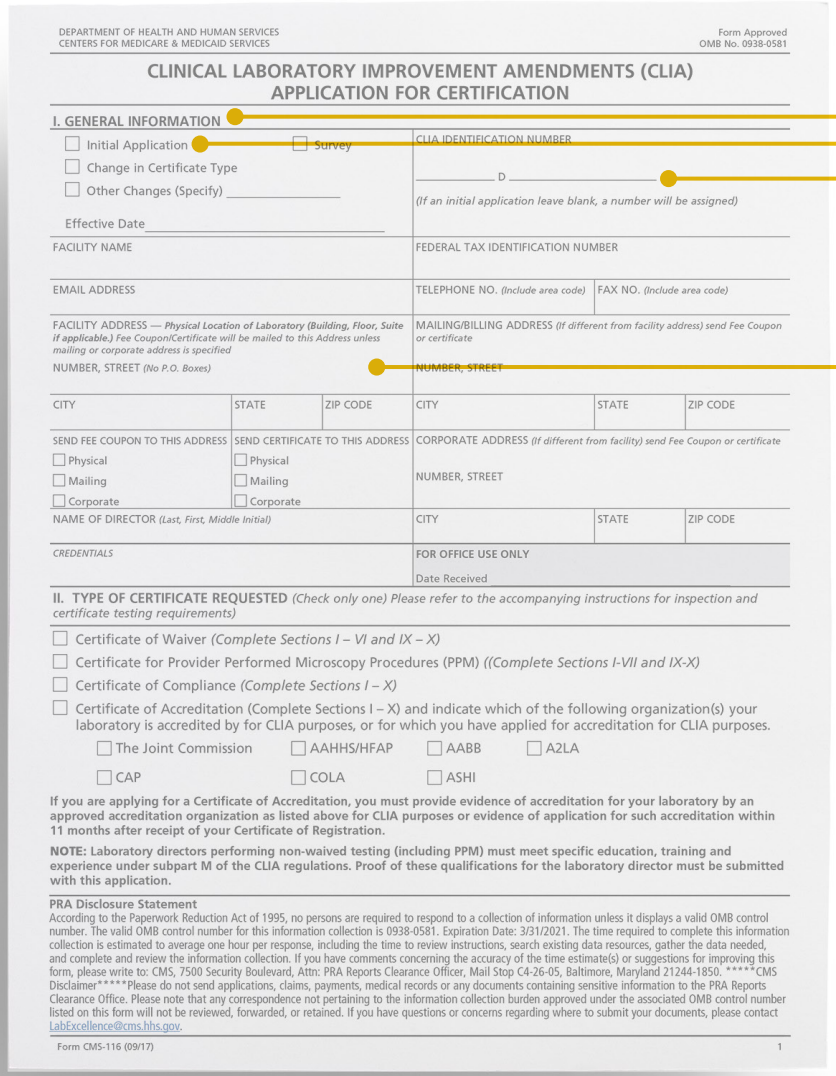
AUGUST 2020

Laboratory Quick Start Guide to CMS CLIA Certification

The Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) regulates the quality and safety of U.S. clinical laboratories to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed. CLIA has regulatory requirements for quality that all laboratories must meet. This guide helps laboratories seeking to apply for CLIA certification from CMS. More information can be found on the CMS CLIA website.

STEP 1: Download and Complete Form CMS-116

- Include information based on the date of form completion.
- All applicable sections must be completed. Incomplete applications cannot be processed.
- Print legibly or type.
- To find out if the testing your laboratory is performing is categorized as waived, moderate, or high complexity-refer to the FDA website. If you are unable to locate the test complexity of your laboratory testing, contact your State Agency.
- For a complete list of instructions, refer to page 6 of Form CMS-116.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

☐ Initial Application ☐ Survey
☐ Change in Certificate Type
☐ Other Changes (Specify) _____
Effective Date _____

CLIA IDENTIFICATION NUMBER
_____ D _____
(If an initial application leave blank, a number will be assigned)

FACILITY NAME | FEDERAL TAX IDENTIFICATION NUMBER

EMAIL ADDRESS | TELEPHONE NO. (Include area code) | FAX NO. (Include area code)

FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified
NUMBER, STREET (No P.O. Boxes) | CITY | STATE | ZIP CODE

MAILING/BILLING ADDRESS (If different from facility address) send Fee Coupon or certificate
NUMBER, STREET | CITY | STATE | ZIP CODE

SEND FEE COUPON TO THIS ADDRESS
☐ Physical ☐ Mailing ☐ Corporate

SEND CERTIFICATE TO THIS ADDRESS
☐ Physical ☐ Mailing ☐ Corporate

CORPORATE ADDRESS (If different from facility) send Fee Coupon or certificate
NUMBER, STREET | CITY | STATE | ZIP CODE

NAME OF DIRECTOR (Last, First, Middle Initial)
CREDENTIALS

FOR OFFICE USE ONLY
Date Received

II. TYPE OF CERTIFICATE REQUESTED (Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)

☐ Certificate of Waiver (Complete Sections I – VI and IX – X)
☐ Certificate for Provider Performed Microscopy Procedures (PPM) ((Complete Sections I-VII and IX-X)
☐ Certificate of Compliance (Complete Sections I – X)
☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.
☐ The Joint Commission ☐ AAHHS/HFAP ☐ AABB ☐ A2LA
☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

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 these qualifications for the laboratory director must be submitted with this application.

PRA Disclosure Statement
According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. Expiration Date: 3/31/2021. The time required to complete this information collection is estimated to average one hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. *****CMS Disclaimer*****Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact LabExcellence@cms.hhs.gov.

Form CMS-116 (09/17) 1

Complete General Information in section I.

First-time applicants check "Initial Application."

For an initial applicant, the **CLIA Identification Number** is left **blank**. When the application is processed, the number is **assigned**.

Facility Address must reflect the physical location where the laboratory testing is performed. The address may include a floor, suite and/or room location, but cannot be a Post Office box or Mail Stop.

International Lab Facilities

For CLIA purposes, 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, and that the reader should consult the relevant statutes and regulations for the full scope of the CLIA requirements.

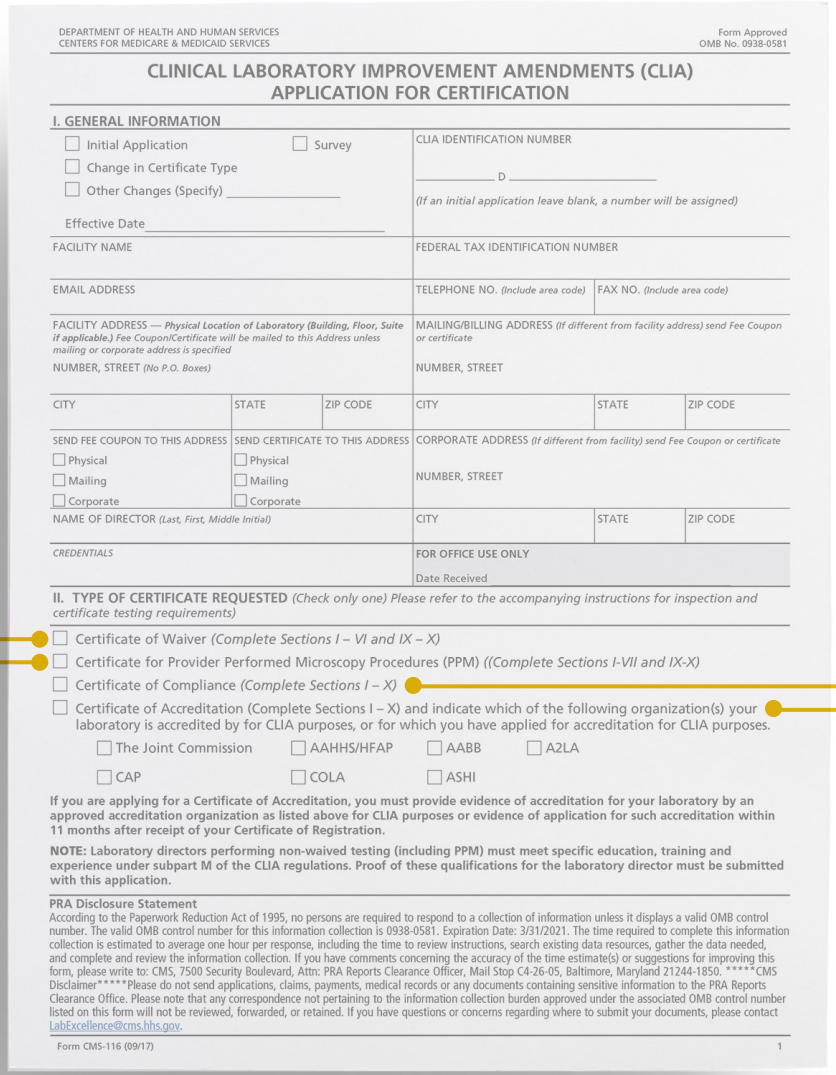
Complete Type of Certificate Requested in section II.

In section II, **Type of Certificate Requested**, select your certificate based on the highest level of test complexity performed by the laboratory (Note: all CLIA certificates are valid for 2 years):

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

More information about each certificate can be found below:

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



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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**CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
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☐ Other Changes (Specify) _____
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FACILITY NAME

FEDERAL TAX IDENTIFICATION NUMBER

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CITY | STATE | ZIP CODE

MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate*
NUMBER, STREET
CITY | STATE | ZIP CODE

SEND FEE COUPON TO THIS ADDRESS
☐ Physical ☐ Mailing ☐ Corporate

SEND CERTIFICATE TO THIS ADDRESS
☐ Physical ☐ Mailing ☐ Corporate

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NAME OF DIRECTOR *(Last, First, Middle Initial)*
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FOR OFFICE USE ONLY
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Form CMS-116 (09/17) 1

- **Certificate of Registration (COR):** A COR is temporary and permits 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.

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 an inspection by a CLIA state survey agency that finds the laboratory to be in compliance with all applicable CLIA requirements.
- **Certificate of Accreditation (COA):** Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS. A non-profit accreditation organization's requirements must equal or exceed CLIA program requirements to receive CMS approval.

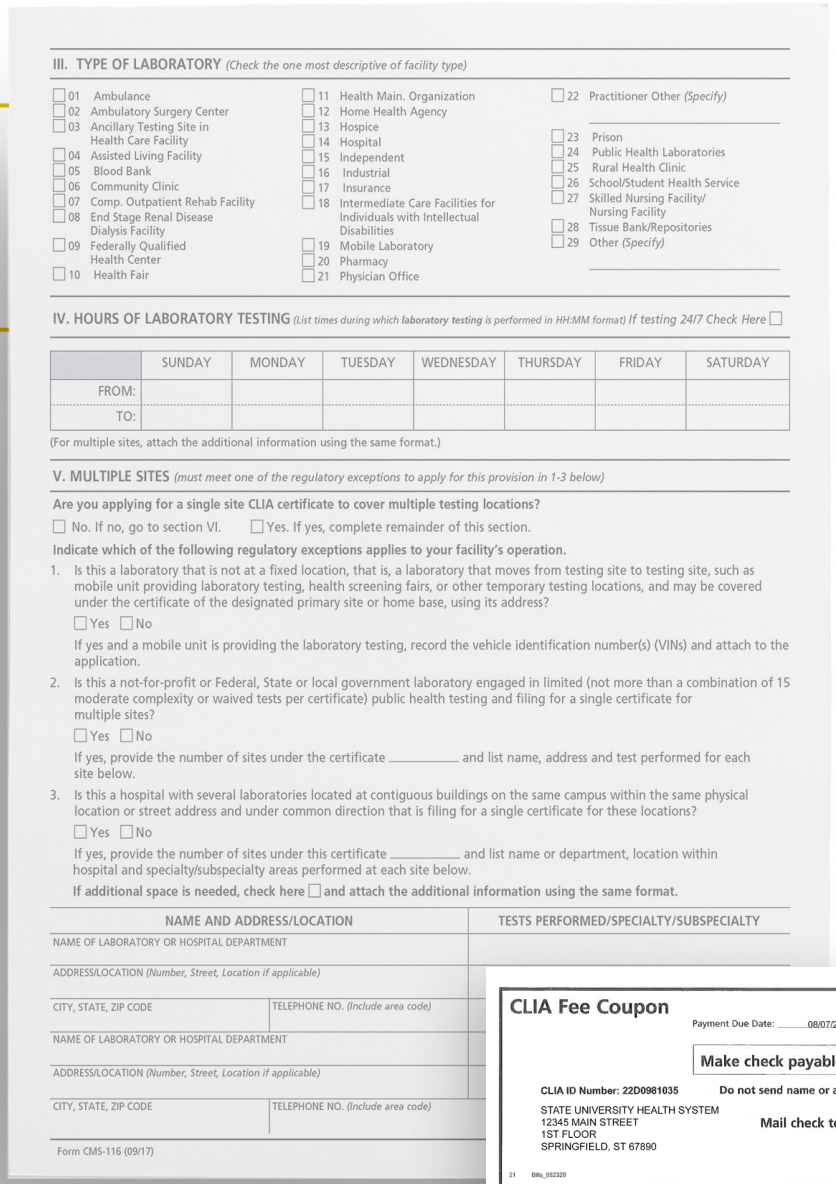
Complete Type of Laboratory in section III.

In section III, select the **Type of Laboratory** that is most descriptive of the location where the laboratory testing is performed. If you have questions, contact your State Agency.

STEP 2: Send Completed CMS-Form 116 to the appropriate State Agency

- Send via mail or email
- Include state-specific paperwork. As your local CLIA contact, the SA can answer your questions on CLIA certificates and laboratory testing. They can also advise about any state requirements that apply to your laboratory.

To help laboratories begin COVID-19 testing, CLIA has expedited its review of applications for a CLIA certificate. Once the laboratory has identified a qualified laboratory director and provided all required information on the CMS-116 application, a CLIA number will be assigned. This CLIA number will allow laboratories to begin testing before a paper certificate is mailed as long as applicable CLIA requirements have been met (e.g., establishing performance specifications).



III. TYPE OF LABORATORY *(Check the one most descriptive of facility type)*

- ☐ 01 Ambulance
- ☐ 02 Ambulatory Surgery Center
- ☐ 03 Ancillary Testing Site in Health Care Facility
- ☐ 04 Assisted Living Facility
- ☐ 05 Blood Bank
- ☐ 06 Community Clinic
- ☐ 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)*

IV. HOURS OF LABORATORY TESTING *(List times during which laboratory testing is performed in HH:MM format)* If testing 24/7 Check Here ☐

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES *(must meet one of the regulatory exceptions to apply for this provision in 1-3 below)*

Are you applying for a single site CLIA certificate to cover multiple testing locations?

☐ No. If no, go to section VI. ☐ Yes. If yes, complete remainder of this section.

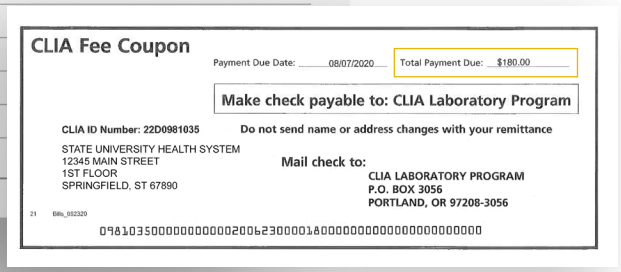
Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?
   ☐ Yes ☐ No
   If yes and a mobile unit is providing the laboratory testing, record the vehicle identification number(s) (VINs) and attach to the application.
2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?
   ☐ Yes ☐ No
   If yes, provide the number of sites under the certificate _____ and list name, address and test performed for each site below.
3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?
   ☐ Yes ☐ No
   If yes, provide the number of sites under this certificate _____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ☐ and attach the additional information using the same format.

NAME AND ADDRESS/LOCATION	TESTS PERFORMED/SPECIALTY/SUBSPECIALTY
NAME OF LABORATORY OR HOSPITAL DEPARTMENT	
ADDRESS/LOCATION *(Number, Street, Location if applicable)*	
CITY, STATE, ZIP CODE / TELEPHONE NO. *(Include area code)*	
NAME OF LABORATORY OR HOSPITAL DEPARTMENT	
ADDRESS/LOCATION *(Number, Street, Location if applicable)*	
CITY, STATE, ZIP CODE / TELEPHONE NO. *(Include area code)*	

Form CMS-116 (09/17)



CLIA Fee Coupon

Payment Due Date: 08/07/2020 Total Payment Due: $180.00

Make check payable to: CLIA Laboratory Program

CLIA ID Number: 22D0981035 Do not send name or address changes with your remittance

STATE UNIVERSITY HEALTH SYSTEM
12345 MAIN STREET
1ST FLOOR
SPRINGFIELD, ST 67890

Mail check to:
CLIA LABORATORY PROGRAM
P.O. BOX 3056
PORTLAND, OR 97208-3056

21 Bills_032320

0981035000000000002006230000180000000000000000000000

STEP 3: Receive Fee Coupon (i.e., invoice);

See coupon image below

- Refer to CLIA Fee Schedule
- Receive 10-digit alphanumeric CLIA identification number, with the "D" in the third position identifying the provider/supplier as a laboratory certified under CLIA.
- Amount due will be included on Fee Coupon as the Total Payment Due (outlined below in yellow)

STEP 4: Pay Applicable Fees

Pay CLIA certification fees by:

- **Using the U.S. Treasury online platform**—include the CLIA Identification Number and charge to a debit or credit card; this secure federal government platform applies payments nightly to outstanding fees
- **Writing a check**—include the provider number and allow 10 business days for outstanding fees to be applied

STEP 5:
Receive Certificate and Begin Testing

- View laboratory certificate data on CLIA website
- Laboratories with a Certificate of Registration will usually have an initial survey performed during the first year of testing to confirm compliance with CLIA regulations

CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS
LABORATORY
12345 MAIN STREET
SPRINGFIELD, ST 67890

CLIA ID NUMBER
22D0981035

EFFECTIVE DATE
12/02/2018

LABORATORY DIRECTOR
JACOB LEE Ph.D.

EXPIRATION DATE
12/01/2020

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

Karen W. Dyer, Acting Director
Division of Laboratory Services
Survey and Certification Group
Center for Clinical Standards and Quality

STEP 6:
Maintain Certificate

- Maintain your valid and current CLIA Certificate per the following schedule:
- Update laboratory's demographics, as needed (e.g. address, specialties)
- Laboratories must notify the appropriate State Agency (and the accreditation organization as applicable) of any of the following changes. Laboratories with a Certificate of Waiver or a Certificate for Provider Performed Microscopy Procedures must notify their State Agency immediately to perform testing outside of their current certificate.
- Laboratories with a Certificate of Waiver, Accreditation or PPMP will receive a renewal invoice 6 months prior to the certificate expiration. Laboratories with a Certificate of Compliance will receive a certificate fee invoice following their compliance survey, and a compliance fee invoice 1 year prior to the certificate expiration.

CERTIFICATE TYPE	SURVEY SCHEDULE
Certificate of Waiver (COW)	Not routinely surveyed
Certificate for Provider Performed Microscopy Procedures (PPMP)	
Certificate of Compliance	Every 2 years
Certificate of Accreditation	

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 Sup	N/A	N/A	30 days	6 mos	6 mos
Testing	Immediately	Immediately	6 mos	6 mos	6 mos