QUICK START GUIDE TO CLIA CERTIFICATION FOR COVID-19 TESTING IN THE WORKPLACE

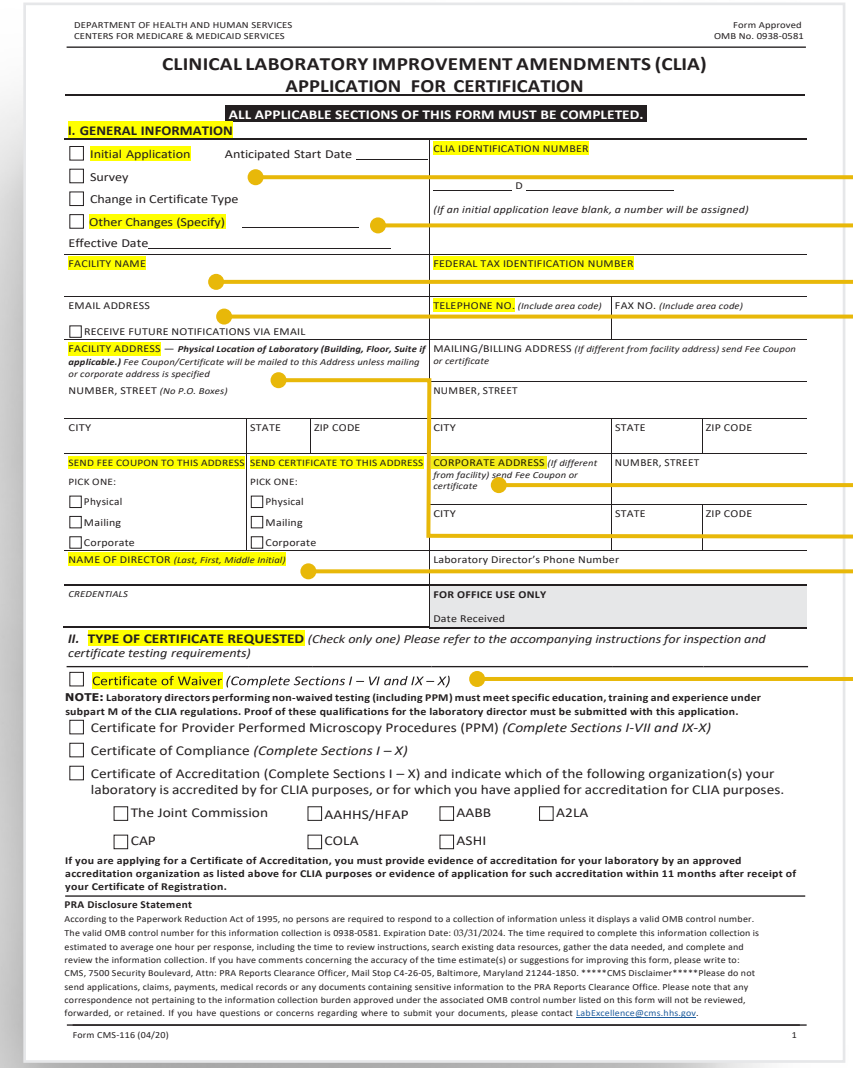
OCTOBER 2021

Facility 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. This guide helps employers and other non-healthcare entities apply for a CLIA Certificate of Waiver to conduct COVID-19 testing. Items that employers must complete are highlighted in yellow, accompanied by directions specific to workplace COVID-19 testing.

STEP 1: Download and Complete Form CMS-116

- The CLIA application (Form CMS-116) collects information about your facility's (e.g. workplace) operation to issue a CLIA number.
- Include information based on the date of form completion.
- All applicable highlighted sections/fields must be completed. Incomplete applications cannot be processed.
- Print legibly or type.
- Waived tests are not exempt from CLIA. Facilities that perform only those tests categorized or authorized as waived must apply for a CLIA Certificate of Waiver.



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

ALL APPLICABLE SECTIONS OF THIS FORM MUST BE COMPLETED.

I. GENERAL INFORMATION

☐ Initial Application Anticipated Start Date _____
☐ 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)*

☐ RECEIVE FUTURE NOTIFICATIONS VIA EMAIL

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)*

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

CITY | STATE | ZIP CODE

CITY | STATE | ZIP CODE

SEND FEE COUPON TO THIS ADDRESS
PICK ONE:
☐ Physical
☐ Mailing
☐ Corporate

SEND CERTIFICATE TO THIS ADDRESS
PICK ONE:
☐ 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)*

Laboratory Director's Phone Number

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)*

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.

☐ 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.

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: 03/31/2024. 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.

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Complete General Information in section I.

If you do not have a CLIA certificate and this is the first time you are applying for a certificate, check "**Initial Application**."

For all other changes, check "**other changes**" and provide the effective date of the change. Some examples of "other changes" are address, phone number, or laboratory director.

Facility Name should be specific. NOTE: The information you provide will appear on your certificate. The Facility Name should be specific to the employer.

Providing an **Email Address** to receive notifications is optional.

Corporate Address is the main office of the employer.

Facility Address is the physical location of a workplace where the lab testing is performed.

For **Name Of Director**, enter the name of the individual responsible for overall operation of the facility, including testing ("Facility Director"). For a Certificate of Waiver, this does not have to be a physician or medical professional.

"**Check Certificate of Waiver**" for Type of Certificate.

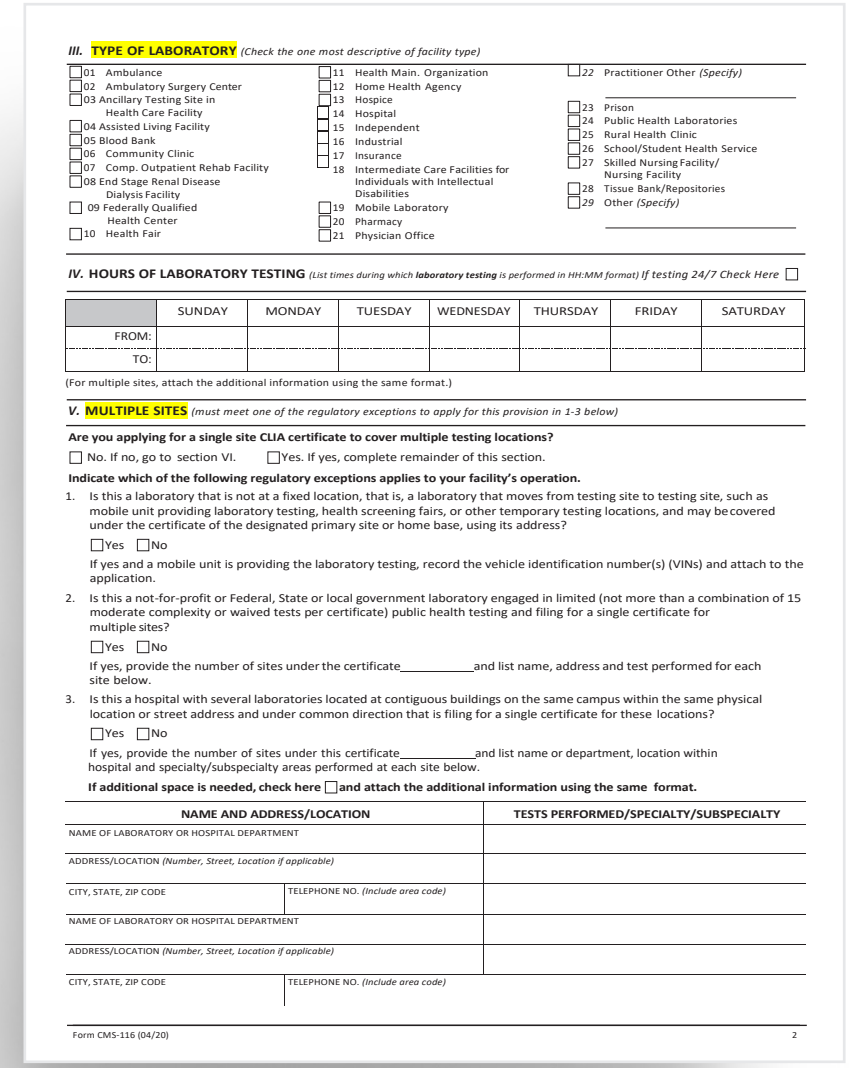
Disclaimer: This guide is a restatement of the law intended to assist people in understanding the basics about the CLIA program, and that the reader should consult the relevant statutes and regulations for the full scope of the CLIA requirements.

Complete Type of 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. Check 29 "Other." If you have questions, contact your State Agency.

Complete Multiple Sites in section V

If you are applying for multiple locations for a single employer, please attach a list of the sites, including each site's name, address, and tests performed. Please also answer questions 1 – 3 under Section V.



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)*	

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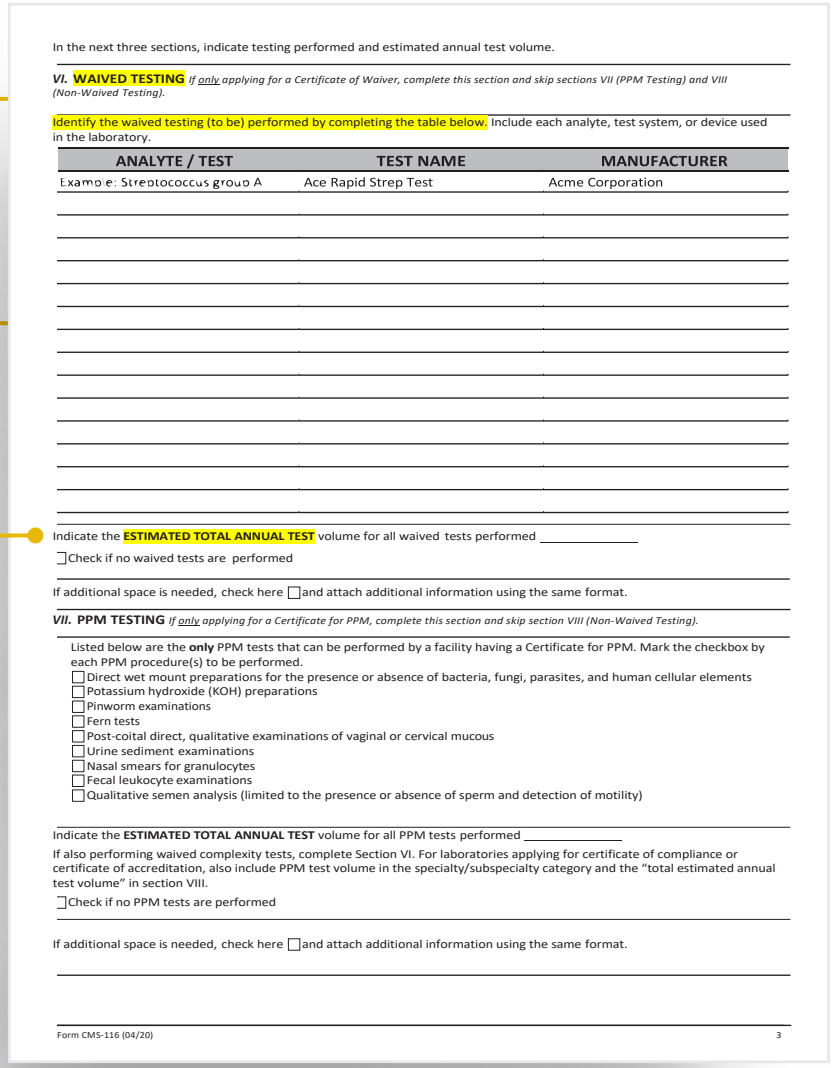
Complete Waived Testing in section VI

As an example:

TEST	TEST NAME	MANUFACTURER
COVID-19	BINAXNOW COVID-19 Ag 2 CARD	ABBOTT

Complete Estimated Total Annual Test

Please add the total number of tests that you think will be performed by all the workplace locations under this CLIA certificate in a year. This number is used to know how many tests you are performing each year.



In the next three sections, indicate testing performed and estimated annual test volume.

***VI.* WAIVED TESTING** *If only applying for a Certificate of Waiver, complete this section and skip sections VII (PPM Testing) and VIII (Non-Waived Testing).*

Identify the waived testing (to be) performed by completing the table below. Include each analyte, test system, or device used in the laboratory.

ANALYTE / TEST	TEST NAME	MANUFACTURER
Example: Streptococcus group A	Ace Rapid Strep Test	Acme Corporation

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed _____

☐Check if no waived tests are performed

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

***VII.* PPM TESTING** *If only applying for a Certificate for PPM, complete this section and skip section VIII (Non-Waived Testing).*

Listed below are the **only** PPM tests that can be performed by a facility having a Certificate for PPM. Mark the checkbox by each PPM procedure(s) to be performed.

- ☐Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- ☐Potassium hydroxide (KOH) preparations
- ☐Pinworm examinations
- ☐Fern tests
- ☐Post-coital direct, qualitative examinations of vaginal or cervical mucous
- ☐Urine sediment examinations
- ☐Nasal smears for granulocytes
- ☐Fecal leukocyte examinations
- ☐Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed _____

If also performing waived complexity tests, complete Section VI. For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.

☐Check if no PPM tests are performed

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

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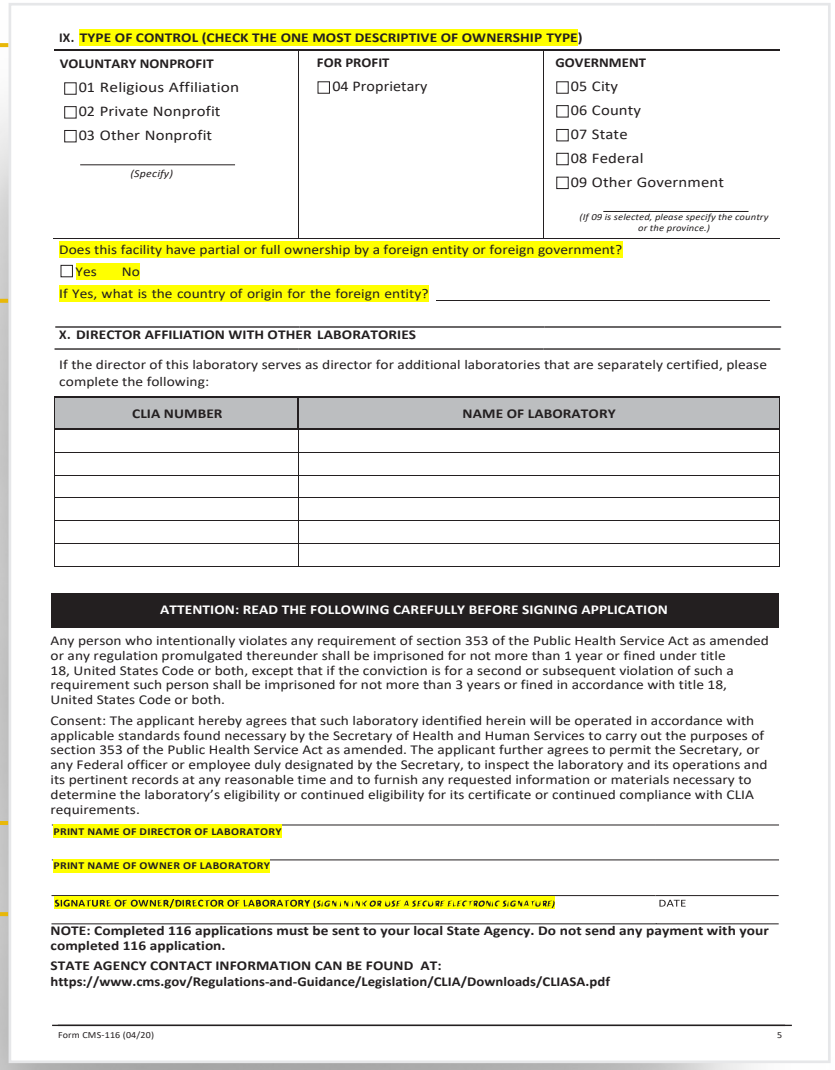
Complete Type of Control in section IX and sign application



IX. TYPE OF CONTROL (CHECK THE ONE MOST DESCRIPTIVE OF OWNERSHIP TYPE)

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT
☐01 Religious Affiliation	☐04 Proprietary	☐05 City
☐02 Private Nonprofit		☐06 County
☐03 Other Nonprofit		☐07 State
_____ (Specify)		☐08 Federal
		☐09 Other Government
		_____ (If 09 is selected, please specify the country or the province.)

Does this facility have partial or full ownership by a foreign entity or foreign government?

☐Yes No

If Yes, what is the country of origin for the foreign entity? _____

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

PRINT NAME OF DIRECTOR OF LABORATORY _____

PRINT NAME OF OWNER OF LABORATORY _____

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY (SIGN IN INK OR USE A SECURE ELECTRONIC SIGNATURE) DATE _____

NOTE: Completed 116 applications must be sent to your local State Agency. Do not send any payment with your completed 116 application.

STATE AGENCY CONTACT INFORMATION CAN BE FOUND AT:
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

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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 State Agency can answer your questions on CLIA certificates. They can also advise about any state requirements that apply.

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

See coupon image below

- You will receive a 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

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

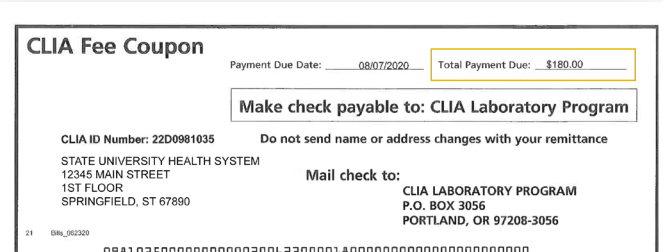
LABORATORY DIRECTOR
JACOB LEE Ph.D.

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



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_062320

0981035000000000002006230000 1A0000000000000000000000000

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:

Apply to State Agency (SA) for a Certificate of Waiver and begin COVID-19 testing*

**if permitted by local/state laws*