

HOW TO OBTAIN A

CLIA Certificate of Waiver

As more opportunities arise for pharmacies to provide point-of-care testing, it's increasingly important to be prepared to provide these tests. A CLIA Certificate of Waiver along with meeting state-specific requirements allows your pharmacy to perform point-of-care tests that have a degree of complexity of waived as assigned by the U.S. Food and Drug Administration according to 42 CFR 493.15(c).

This document will guide you through completing a CLIA application and provide you with state-specific instructions to obtain a CLIA Certificate of Waiver.

General Application Instructions

To apply for the CLIA Certificate of Waiver:

1. Open or download the [CLIA Application for Certification](#) CMS-116 Form.
2. Fill out Sections 1 through 6, 9, and 10.

Section 1: General Information

- If you are a first-time applicant for your location, check "Initial Application" and leave the *CLIA Identification Number* field blank.
- Fill in your pharmacy's information providing the physical address of the testing site as the *Facility Address*.
- Choose the address the fee coupon and/or certificate should be mailed to.
- Indicate the name of the lab director in the *Name of Director* field. For pharmacies, this is typically the pharmacist that will be responsible for ensuring compliance to regulations and proper testing procedures.
- For a lab director who is a pharmacist, indicate "PharmD" or "BSP Pharm" in the *Credentials* field.

Section 2: Type of Certificate Requested

- Check "Certificate of Waiver."

Section 3: Type of Laboratory

- Check option 20, "Pharmacy."

Section 4: Hours of Laboratory Testing

- List the times your pharmacy will perform laboratory testing in HH:MM format. This is typically your pharmacy's usual hours of operation.

Section 5: Multiple Sites

- If your pharmacy has multiple locations, a separate application will need to be filled out for each location that testing will occur unless your location is not-for-profit, a hospital with several labs, or using a mobile testing site.
- Check "No" and move on to Section 6 if you are applying for an individual location or if your pharmacy does not meet at least one of the regulatory exceptions.

Section 6: Waived Testing

- List the test(s) your pharmacy will perform being as specific as possible. Include the lab test name and, if available, the manufacturer's name for the test kit. The following databases or files may be helpful:
 - FDA's database of [waived test systems](#)
 - FDA's database of [waived analytes](#)
 - FDA's database of [test kits and their complexity categorization](#)
 - FDA's database of [IVD OTC lab tests](#)
 - CMS' list of [tests mapped to CPT codes](#)

Note: For COVID-19 testing, naming a specific test may be difficult due to the rapid changes in options and requirements. Some departments may accept use of "FDA authorized COVID-19 related testing" in this section while others may require you to amend the application once you have the exact test name.

- Indicate an estimated volume of waived tests that will be performed in a year.

Section 9: Type of Control

- Most pharmacies are for-profits and should check option 04, "Proprietary." Otherwise, check the type of ownership most appropriate for your pharmacy.

Section 10: Director Affiliation with Other Laboratories

- If the listed lab director oversees other testing sites, indicate the *Name of Laboratory* of those other sites along with their respective *CLIA Number*. CLIA Number may be left blank and later amended for sites that have not yet received one, i.e., an application for that site is or will be in process.

3. Print out the completed CMS-116 Form.
4. Have the lab director sign the application in ink.
5. Scan the signed CMS-116 Form into your computer to save a copy (and to have a digital file for submission via email or web, if accepted by your state).
6. Complete additional forms as required by your state. See [State-Specific Instructions](#) section.
7. Submit all forms to your [CLIA State Agency](#) contact.
8. Upon receiving a fee coupon and instructions for payment, pay the fee.
9. Once payment has been cleared, CMS will send your test site's CLIA Number.

State-Specific Instructions

Along with submitting a CMS-116 Form, each state may have additional requirements in order to obtain a CLIA Certificate of Waiver.

For your convenience, PioneerRx has gathered each state's requirements and forms that will need to be submitted with the CMS-116 Form. Click on your state from the list below to be directed to the respective section.

Alabama	Illinois	Montana	Rhode Island
Alaska	Indiana	Nebraska	South Carolina
Arizona	Iowa	Nevada	South Dakota
Arkansas	Kansas	New Hampshire	Tennessee
California	Kentucky	New Jersey	Texas
Colorado	Louisiana	New Mexico	Utah
Connecticut	Maine	New York	Vermont
Delaware	Maryland	North Carolina	Virginia
District of Columbia	Massachusetts	North Dakota	Washington
Florida	Michigan	Ohio	West Virginia
Georgia	Minnesota	Oklahoma	Wisconsin
Hawaii	Mississippi	Oregon	Wyoming
Idaho	Missouri	Pennsylvania	

If utilizing validated manufacturer assays granted Emergency Use Authorization (EUA) by the FDA to perform point-of-care testing during a public health emergency as allowed by your state, the FDA requires that the test kit's fact sheet be provided to the patient and/or provider. The fact sheets along with EUA information can be found under the [In Vitro Diagnostic Products](#) section through the FDA website. When searching for the fact sheets:

- Make sure the manufacturer of the test kit your pharmacy is using matches the *Entity* column and the name of the test kit matches the *Diagnostic* column
- Make sure the *Authorized Setting(s)* column for the test kit indicates a W for patient care settings operating under a CLIA Certificate of Waiver.
- Access the fact sheet by selecting the "+" button to the left of the table which will expand the row and reveal the Authorization Labeling documents. There will be a separate file for the healthcare provider fact sheet, patient fact sheet, and manufacturer's instructions for use.

Please be aware that state regulations and requirements may change at any time. For changes to application requirements or submission instructions, please contact your [CLIA State Agency](#).

For comments, questions, or suggestions regarding this document, please reach out to your PioneerRx account manager.

Alabama

Alabama CLIA Application Instructions

The CLIA application can be submitted via:

Email Patricia.Watson@adph.state.al.us (for use during COVID-19 emergency only)
CLIAAlabama@adph.state.al.us

Fax (334) 206-5254

Mail ALABAMA DEPARTMENT OF PUBLIC HEALTH
Division of Health Care Facilities
CLIA Program
P.O. Box 303017
Montgomery, AL 36130-3017

Upcoming Changes to Alabama Requirements

Beginning October 2020, all waived testing sites in Alabama must possess an Independent Clinical Laboratory (ICL) license in addition to the CLIA Certificate of Waiver.

Due to the processing time and to avoid interruptions in your pharmacy's ability to conduct waived testing, consider submitting the [ICL application](#) in advance of October 2020 such as at the same time as the CLIA application.

About the ICL Application

This application has a separate fee and requires additional documentation including:

- Organizational documents
 - I.e. Articles of Incorporation, LLC Agreement, Partnership Agreement, or Statement of Sole Proprietorship under which the facility will operate).
 - A copy of the registration to conduct business in Alabama if the entity was established in a state other than Alabama.
- A copy of the Certificate of Existence
- A copy of the Medical Director's license

If you have questions regarding the ICL application, please call (334) 206-5175.

Submit ICL applications via mail addressed to:

State of Alabama
Department of Public Health
Division of Provider Services
P.O. Box 303017
Montgomery, AL 36130-3017

Alaska

Alaska CLIA Application Instructions

The CLIA application can be submitted via:

Email Katherine.Ross@alaska.gov
CLIA-HSSLab@alaska.gov

Arizona

Arizona CLIA Application Instructions

The CLIA application can be submitted via:

Email Marcie.Bentley@azdhs.gov
Denise.Barbeau@azdhs.gov

Fax (602) 364-0759

Arkansas

Arkansas CLIA Application Instructions

The CLIA application can be submitted via:

Email tim.simpson@arkansas.gov
adh.hfs@arkansas.gov

California

California CLIA Application Instructions

When submitting the CMS-116 Form, also attach the following completed forms and fee:

- [LAB 155 - Application for Clinical Laboratory Registration](#)
 - Include payment for the application fee
- [LAB 183 - Director Attestation](#)

Note: Only submit completed forms with physical signatures. Copies will not be accepted. Leave fields for CLIA Number blank if applying for initial CLIA certificate and CLIA Number not yet provided.

The CLIA application and additional forms can be submitted via:

Mail California Department of Public Health
Laboratory Field Services
850 Marina Bay Pkwy, Bldg. P-1st Floor
Richmond, CA 94804-6403

About the Clinical Laboratory Registration Application

This application has a separate non-refundable fee. Refer to the [fee schedule](#) as the fee amount is subject to change with each fiscal year.

Include payment for the registration application fee when submitting the application. Payment must be in the form of a check or money order made payable to:

California Department of Public Health

Colorado

Colorado CLIA Application Instructions

When submitting the CMS-116 Form, use [Colorado's version of the CMS-116 Form](#) as it includes the Annual Test Volume Report (page 2-A) specific for Colorado.

The CLIA application can be submitted via:

Email jeff.groff@state.co.us
cdphe.lab@state.co.us

Fax (303) 344-9965

Connecticut

Connecticut CLIA Application Instructions

The CLIA application can be submitted via:

Email DPH.FLISLab@ct.gov

Fax (860) 706-5805

Additional Requirements Prior to Conducting Tests That Have Been Granted EUA

If utilizing validated manufacturer assays granted Emergency Use Authorization (EUA) by the FDA to perform point-of-care testing during a public health emergency, an approval must be obtained prior to use. The following must be submitted for each test kit in order to obtain approval:

- [FDA-EUA Approval Form](#)
- Sample test report

Based on the test kit used, the FDA requires that the fact sheet is provided to the patient and/or the provider. The fact sheet for the test kits along with EUA information can be found under the [In Vitro Diagnostic Products](#) section through the FDA website. When searching for the fact sheets:

- Make sure the manufacturer of the test kit your pharmacy is using matches the Entity column and the name of the test kit matches the Diagnostic column
- Make sure the Authorized Setting(s) column for the test kit indicates a W for patient care

settings operating under a CLIA Certificate of Waiver.

- Access the fact sheet by selecting the "+" button to the left of the table which will expand the row and reveal the Authorization Labeling documents. There will be a separate file for the healthcare provider fact sheet, patient fact sheet, and manufacturer's instructions for use.

Delaware

Delaware CLIA Application Instructions

The CLIA application can be submitted via:

Mail State of Delaware CLIA Program
 Delaware Public Health Laboratory
 30 Sunnyside Road
 Smyrna, DE 19977

District of Columbia

District of Columbia CLIA Application Instructions

The CLIA application can be submitted via:

Email DCHealth.CLIA@dc.gov
Fax (202) 442-9431
Mail DC DEPARTMENT OF HEALTH
 Health Regulations and Licensing Administration
 Health Facilities Division
 Laboratory Services
 899 North Capitol Street, NE 2nd floor
 Washington, DC 20002

Florida

Florida CLIA Application Instructions

The CLIA application can be submitted via:

Fax (850) 410-1511
Mail Bureau of Health Facility Regulation
 2727 Mahan Drive - Mail Stop #32
 Tallahassee, FL 32308

Georgia

Georgia CLIA Application Instructions

The CLIA application can be submitted via:

Email hfrd.diagnostic@dch.ga.gov
Fax (404) 463-4398
Mail GEORGIA DEPARTMENT OF COMMUNITY HEALTH
Healthcare Facility Regulation Division
Diagnostic Services Unit
2 Peachtree Street, N.W.
Suite 31-447
Atlanta, GA 30303-3142

Hawaii

Hawaii CLIA Application Instructions

When submitting the CMS-116 Form, also attach the following completed forms:

- [Form 1513 - Disclosure of Ownership and Control Interest Statement](#)
 - [Instructions for Form 1513](#)
- [OHCA 110.1 - Application for Clinical Lab Permit/License](#)
 - Include payment for the state licensing fee
 - [Instructions for OHCA 110.1](#)

The CLIA application can be submitted via:

Email paul.kuiken@doh.hawaii.gov
doh.ohcamco@doh.hawaii.gov
Fax (808) 692-7447
Mail Office of Health Care Assurance
Medicare Section
601 Kamokila Boulevard, ROOM 395
Kapolei, HI 96707

About the Clinical Lab Permit Application

This application has a separate fee and will be invoiced from the OHCA Office. Refer to the [Hawaiian Administrative Rules \(§11-103-6\)](#) for the fee amount.

For non-physician labs performing only waived tests, include payment for the Hawaii Clinical Lab Permit Class I registration application fee when submitting the application. Acceptable forms of payment include corporate check, bank, or other financial institution check, or money order.

Make checks payable to:

State of Hawaii Office of Health Care Assurance Special Fund

Send payment and a copy of the invoice to:

Office of Health Care Assurance
Medicare Section
601 Kamokila Boulevard, ROOM 395
Kapolei, HI 96707

For Class I Permits, laboratories are required to have a Laboratory Consultant who possesses a Clinical Laboratory Director or Medical Technologist license in Hawaii if the Laboratory Director on the application does not have one of these licenses. Refer to Hawaii's Department of Health website for [information on licensure](#) or the [List of Possible Laboratory Consultants](#).

Idaho

Idaho CLIA Application Instructions

The CLIA application can be submitted via:

Email LabImprovement@dhw.idaho.gov
Fax (208) 334-4067
Mail LABORATORY IMPROVEMENT SECTION
Idaho Bureau of Laboratories
2220 Penitentiary Road
Boise, ID 83712-8299

Illinois

Illinois CLIA Application Instructions

When submitting the CMS-116 Form, use [Illinois' version of the CMS-116 Form](#) as it includes additional details on personnel qualification requirements.

The CLIA application can be submitted via:

Fax (217) 782-0382
Mail IDPH CLIA Program
525 W. Jefferson St., Fourth Floor
Springfield, IL 62761

Indiana

Indiana CLIA Application Instructions

When submitting the CMS-116 Form, also attach the following completed forms:

- [Enclosure A - Disclosure of Ownership](#)
- [Enclosure I - Test Methodology and Annual Test Volume Log](#)

Note: Leave fields for CLIA Number blank if applying for initial CLIA certificate and CLIA Number not yet provided.

The CLIA application can be submitted via:

Email lswitzer@isdh.in.gov
klara@isdh.in.gov

Fax (317) 233-7157

Mail Indiana State Department of Health
Attn: CLIA Program
2 North Meridian St, Rm 4A
Indianapolis, IN 46204

Iowa

Iowa CLIA Application Instructions

The CLIA application can be submitted via:

Fax (319) 335-4174

Mail Iowa CLIA Laboratory Program
State Hygienic Laboratory
University of Iowa Research Park
2490 Crosspark Road
Coralville, IA 52241-4721

Kansas

Kansas CLIA Application Instructions

For Section 6 of the application, include the manufacturer and method for each waived analyte.

The CLIA application can be submitted via:

Email kdhe.clia2@ks.gov

Fax (785) 559-5207

Kentucky

Kentucky CLIA Application Instructions

The CLIA application can be submitted via:

Fax (502) 564-6546
Mail KENTUCKY CLIA PROGRAM
Office of Inspector General
Division of Healthcare
275 East Main Street, 5E-A
Frankfort, KY 40621-0001

Louisiana

Louisiana CLIA Application Instructions

When submitting the CMS-116 Form, also attach the following completed form:

- [Listing of Tests Performed in the Facility](#)

The CLIA application can be submitted via:

Email alexa.little@la.gov
Fax (225) 342-9349
Mail CLIA Laboratory Program
P.O. Box 3767
Baton Rouge, LA 70821

Maine

Maine CLIA Application Instructions

The CLIA application can be submitted via:

Email dale.payne@maine.gov
Fax (207) 287-9304
Mail CLIA PROGRAM
Division of Licensing & Regulatory Services
41 Anthony Avenue, Station #11
Augusta, ME 04333-0011

Additional Requirements Prior to Conducting Tests

The Maine Department of Health and Human Services also requires waived testing sites to obtain a Health Screening Permit for authorization to perform health screening tests (including occult blood, colon cancer testing, lipid profile, and glucose screenings) in addition to the CLIA Certificate of Waiver. The Health Screening Permit is not required to perform COVID-19 tests that have been granted EUA by the FDA; only the CLIA Certificate of Waiver is required.

About the Health Screening Permit Application

To request a Health Screening Permit application, please email Dale Payne (dale.payne@maine.gov). Dale can also be reached at (207) 287-9339.

Maryland

Maryland CLIA Application Instructions

When submitting the CMS-116 Form, also attach the following completed forms and documentation:

- [State Compliance Application](#)
- Copy of highest degree of education (i.e. Doctorate of Pharmacy)
- Copy of practicing license (i.e. pharmacy license)

Note: Only submit completed forms with physical signatures as a copy will not be accepted. Leave fields for CLIA Number blank if applying for initial CLIA certificate and CLIA Number not yet provided.

The CLIA application can be submitted via:

Mail MARYLAND DEPARTMENT OF HEALTH & MENTAL HYGIENE
Office of Health Care Quality - Laboratory Licensing Programs
7120 Samuel Morse Drive
Second Floor
Columbia, MD 21046-3422

About the State Compliance Application

The Maryland Department of Health requires laboratories to obtain state licensure along with a CLIA Certificate of Waiver in order to conduct waived tests. By submitting the State Compliance Application, your pharmacy will be able to receive the state laboratory license allowing pharmacists to perform CLIA-waived tests that are also listed in the [Letters of Exception](#).

There is no separate fee for this application.

Massachusetts

Massachusetts CLIA Application Instructions

When submitting the CMS-116 Form, also attach the following completed forms:

- [List of Laboratory Test Performed On-Site](#)
- [Initial Licensure/Suitability Notice of Intent to Acquire](#)
- [Clinical Laboratory Disclosure of Ownership Interest Statement](#)
- [Clinical Laboratory License Information Form](#)

Note: Only submit completed forms with physical signatures as a copy will not be accepted. Leave fields for CLIA Number blank if applying for initial CLIA certificate and CLIA Number not yet provided.

The CLIA application can be submitted via:

Mail Clinical Laboratory Program
Department of Public Health
67 Forest Street
Marlborough, MA 01752

Michigan

Michigan CLIA Application Instructions

The CLIA application can be submitted via:

Email BCHS-CLIA@michigan.gov

Minnesota

Minnesota CLIA Application Instructions

The CLIA application can be submitted via:

Email health.clia@state.mn.us

Mail Minnesota Department of Health
CLIA Program
3333 West Division Street, Suite 212
St. Cloud, MN 56301-4557

Mississippi

Mississippi CLIA Application Instructions

The CLIA application can be submitted via:

Email Nancy.Cheatham@msdh.ms.gov
CLIA.MSDH@msdh.ms.gov

Fax (601) 364-5053

Mail Mississippi State Department of Health
Licensure and Certification/CLIA
P.O. Box 1700
Jackson, MS 39215-1700

Missouri

Missouri CLIA Application Instructions

The CLIA application can be submitted via:

Email CLIA@health.mo.gov
Fax (573) 751-6158
Mail DHSS - Bureau of Diagnostic Services
CLIA Program
P.O. Box 570
Jefferson City, MO 65102

Montana

Montana CLIA Application Instructions

The CLIA application can be submitted via:

Email mtssad@mt.gov
Fax (406) 444-3456
Mail Certification Bureau-CLIA Program
2nd floor DPHHS-QAD
P.O. Box 202953
Helena, MT 59620-2953

Nebraska

Nebraska CLIA Application Instructions

When submitting the CMS-116 Form, also attach the following completed form:

- [CLIA Ownership Information Form](#)
- [List of Tests Performed](#)

Note: Only submit completed forms with physical signatures as a copy will not be accepted. Leave fields for CLIA Number blank if applying for initial CLIA certificate and CLIA Number not yet provided.

The CLIA application can be submitted via:

Mail DHHS Public Health - Licensure Unit/CLIA
P.O. Box 94986
301 Centennial Mall South
Lincoln, NE 68509-4986

Nevada

Nevada CLIA Application Instructions

When submitting the CMS-116 Form, also be prepared to upload the following completed form and

documentation:

- [Form 1513 - Disclosure of Ownership and Control Interest Statement](#)
 - [Instructions for Form 1513](#)
- Laboratory Director Proof of Identity
 - [Options for proof of identity](#)

Note: Only submit completed forms with physical signatures as a copy will not be accepted. Leave fields for CLIA Number blank if applying for initial CLIA certificate and CLIA Number not yet provided.

The CLIA application can be submitted via:

Online Portal <https://nvdpbh.athent.com/login.aspx>

About the State of Nevada Exempt Laboratory Licensure

In Nevada, pharmacists qualify as lab directors for testing sites that are only performing glucose tests. Otherwise, the lab director needs to be a medical physician for the testing site to perform other CLIA-waived tests. To perform any CLIA-waived tests (including glucose tests), a State of Nevada Exempt Laboratory License is needed.

There is a separate fee for licensure. Refer to the [Exempt Laboratory Online Initial Application Checklist](#) for payment amount.

To apply for the Exempt Laboratory License:

1. Go to the [Nevada Division of Public and Behavioral Health online licensing system](#)
2. Select the Health Care Quality & Compliance (HCQC) as the *Business Unit*
3. Select OK
4. In the section labeled "NEW APPLICANTS APPLY HERE" (bottom left column), select the link to apply for a new medical laboratory license or change of ownership
5. Register for an online account by entering in facility information, mailing address, and login account information

Note: Be sure to save the password in a secure location in case you forget it as the password is not easily retrievable by the state agency.
6. Upload the completed CMS-116 Form, Form 1513, and the lab director's proof of identity when prompted

New Hampshire

New Hampshire CLIA Application Instructions

When submitting the CMS-116 Form, also submit the following completed forms and documentation:

- [Application for Residential or Health Care License \(Laboratories and Collecting Stations\)](#)
 - Include payment for the application fee

- Floor plan of the facility
- NH Secretary of State Authority to do business in the State of NH
 - "Certificate of Authority," if a corporation
 - "Certificate of Formation," if a limited liability company
 - "Certificate of Trade Name," if a sole proprietorship
- Written disclosure from the owner(s) and the lab director containing:
 - A list of any felony convictions; and
 - An explanation of the circumstances surrounding any felony convictions
- Obtain local health, building, zoning and fire officers signed approval

Note: Leave fields for CLIA Number blank if applying for initial CLIA certificate and CLIA Number not yet provided.

The CLIA application can be submitted via:

Email CLIA@dhhs.nh.gov

Fax (603) 271-8716

About the Application for Residential or Health Care License

The State of New Hampshire requires testing sites to obtain laboratory licensure in addition to the CLIA Certificate of Waiver.

- If applying as a collection station, the lab director must meet qualifications according to [He-P 817](#).
- If applying as a laboratory, the lab director must meet qualifications according to [He-P 808](#).

There is a separate fee for this application. Refer to the application for the fee amount.

Include payment for the registration application fee when submitting the application. Payment must be in the form of a check or money order made payable to:

STATE OF NEW HAMPSHIRE, TREASURER

To expedite the submission process, email the initial application and send the original copies in the mail:

Email Marilee.Curran@dhhs.nh.gov
DHHS.HFA-Certification@dhhs.nh.gov

Mail Health Facilities Administration
129 Pleasant Street
Concord, NH 03301

Option to Obtain a Waiver of Licensing

During the COVID-19 state of emergency, the State of New Hampshire is offering to waive the Laboratory and Collection Station licensing requirements.

Pursuant to Emergency Order #47, licensed Pharmacists may initiate, order, administer, and analyze COVID-19 test kits, provided:

- 1) The pharmacist has received the adequate education and training to initiate, order, administer, and analyze COVID-19 test kits;
- 2) The COVID-19 tests are administered at a pharmacy that holds the appropriate clinical laboratory improvement amendments (CLIA) certificate and a New Hampshire laboratory license issued by the Health Facilities Administration of the New Hampshire Department of Health and Human Services (DHHS). Alternatively, tests may be administered at a pharmacy with a DHHS waiver, pursuant to DHHS' authority to waive licensure requirements when it deems appropriate health and safety standards are met; and
- 3) The pharmacy creates and implements policies and procedures to address the collection, storage, transport, and analysis of samples collected as a result of administering and analyzing COVID-19 test kits. Such policies and procedures shall be in line with the manufacturer's instructions and supplemented as needed.

To request temporary approval to conduct COVID-19 testing in accordance to Emergency Order #47, please submit your request in writing to DHHS.hfaregcorrespondence@nh.gov.

- For all pharmacies with a current laboratory license, please provide the following information when submitting your request for temporary waiver of collection site licensure:
 - 1) Name of Licensee;
 - 2) Name of Contact Person;
 - 3) Email address and phone number of Contact Person;
 - 4) Address of pharmacy;
 - 5) Proposal for collection, storage, transport, and analysis of samples collected (including the name of the EUA test).
- For ALL OTHER pharmacies, please provide the following information when submitting your request for temporary waiver of laboratory and collection site licensure:
 - 1) Name of Pharmacy;
 - 2) Name of Contact Person;
 - 3) Email address and phone number of Contact Person;
 - 4) Address of pharmacy;
 - 5) Proof of CLIA certificate;
 - 6) Proposal for collection, storage, transport, and analysis of samples collected (including the name of the EUA test).

New Jersey

New Jersey CLIA Application Instructions

The CLIA application can be submitted via mail:

By FedEx/UPS	Melanie Rinaldi Manager, NJ CLIA Program NJDOH/PHEL 3 Schwarzkopf Drive Ewing, NJ 08628
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By UPS	Melanie Rinaldi Manager, NJ CLIA Program NJDOH/PHEL P.O. Box 361 Trenton, NJ 08625-0361
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New Mexico

New Mexico CLIA Application Instructions

The CLIA application can be submitted via:

Email CLIA.DHI@state.nm.us

New York

New York CLIA Application Instructions

When submitting the CMS-116 Form, also submit the following completed forms and documentation:

- [Initial Limited Service Laboratory Registration Application](#)
 - Include payment for the application fee
- Copy of the lab director's current New York State Professional License

Note: Only submit completed forms with physical signatures (signature stamps will not be accepted). Leave fields for CLIA Number blank if applying for initial CLIA certificate and CLIA Number not yet provided.

The CLIA application can be submitted via:

Regular Mail	Clinical Laboratory Evaluation Program Wadsworth Center New York State Department of Health Empire State Plaza P.O. Box 509 Albany, NY 12201-0509
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Express Mail	Clinical Laboratory Evaluation Program Wadsworth Center
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New York State Department of Health
Empire State Plaza
P1 South - Loading Dock J
Albany, NY 12237

About the Limited Service Laboratory Registration Application

The New York State Department of Health requires testing sites to also possess a Limited Service Laboratory Registration in addition to the CLIA Certificate of Waiver for performing CLIA-waived tests.

Instructions for this application are included in the same file as the application.

There is a separate non-refundable application fee. Refer to the application file for the fee amount.

Include payment for the registration application fee when submitting the application. Payment must be in the form of a check or money order. The check or check stub should indicate the laboratory's name. Make check or money order payable to:

New York State Department of Health

North Carolina

North Carolina CLIA Application Instructions

The CLIA application can be submitted via:

Email DHSR.CLIA@dhhs.nc.gov

Fax (919) 855-4620

Mail NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
Division of Health Service Regulation/CLIA Certification
2713 Mail Service Center
Raleigh, NC 27699-2713

North Dakota

North Dakota CLIA Application Instructions

When submitting the CMS-116 Form, also attach the following completed form:

- [Laboratory Tests Performed](#)

The CLIA application can be submitted via:

Email CLIAlab@nd.gov

Fax (701) 328-1890

Mail North Dakota Department of Health
Division of Health Facilities
600 E Boulevard Avenue Dept 301

Bismarck, ND 58505-0200

Additional Requirements Prior to Conducting Tests

In North Dakota, the PIC must also notify the State Board of Pharmacy prior to performing CLIA-waived tests in accordance with North Dakota Administrative Code ([§61-04-10](#)).

Ohio

Ohio CLIA Application Instructions

The CLIA application can be submitted via:

Email CLIA@odh.ohio.gov

Fax (614) 564-2478

Mail Ohio Department of Health
Office of Health Assurance and Licensing, CLIA Program
246 North High Street
Columbus, OH 43215

Oklahoma

Oklahoma CLIA Application Instructions

The CLIA application can be submitted via:

Email medicalfacilities@health.ok.gov

Mail OKLAHOMA STATE DEPARTMENT OF HEALTH
Medical Facilities
CLIA
1000 NE 10th Street
Oklahoma City, OK 73117-1299

Oregon

Oregon CLIA Application Instructions

When submitting the CMS-116 Form, also attach the following completed form:

- [Waived Tests Performed](#)

The CLIA application can be submitted via:

Email LC.INFO@state.or.us

Fax (503) 693-5602

Mail Oregon State Public Health Laboratory (OSPHL)
Laboratory Compliance Section
7202 NE Evergreen Parkway, Suite 100
Hillsboro, OR 97124

Note: Do not send hard copies following a fax or email of a lab form. Double forms can cause duplication and extra work. You can verify receipt of your forms by calling (503) 693-4125 or by emailing LC.INFO@state.or.us.

Pennsylvania

Pennsylvania CLIA Application Instructions

When submitting the CMS-116 Form, also attach the following completed form:

- [Clinical Laboratory Permit Application for In-State Laboratories](#)
 - Include payment for the application fee
- Copies of the lab director's credentials
 - Curriculum vitae
 - Any board certifications
 - Medical license

Note: Leave fields for CLIA Number blank if applying for initial CLIA certificate and CLIA Number not yet provided.

The CLIA application can be submitted via:

Regular Mail	Bureau of Laboratories P.O. Box 500 Exton, PA 19341
Overnight Delivery Services	Bureau of Laboratories 110 Pickering Way Exton, PA 19341

About the Clinical Laboratory Permit Application

The Pennsylvania Department of Health requires testing sites to obtain a clinical laboratory permit in which the lab director must be a physician. Refer to [Understanding Clinical Laboratory Regulations in Pennsylvania](#) document for more information.

This application has a separate fee. Refer to the application for the fee amount.

Include payment for the application fee when submitting the application. Payment must be in the form of a check or money order made payable to:

Pennsylvania Department of Health

Rhode Island

Rhode Island CLIA Application Instructions

The CLIA application can be submitted via:

Email DOH.OFR@health.ri.gov
Fax (401) 222-2721
Mail RI DEPARTMENT OF HEALTH
Division of Facilities Regulation
3 Capitol Hill, Room 306
Providence, RI 02908

South Carolina

South Carolina CLIA Application Instructions

When submitting the CMS-116 Form, also attach the following completed form:

- [Disclosure of Ownership and Control of Interest Statement](#)
- [List of Tests Performed in the Facility](#)

Note: Leave fields for CLIA Number blank if applying for initial CLIA certificate and CLIA Number not yet provided.

The CLIA application can be submitted via:

Email SC_CLIA@dhec.sc.gov
Fax (803) 545-4563
Mail SOUTH CAROLINA DEPARTMENT OF HEALTH & ENVIRONMENTAL CONTROL
Bureau of Certification/Health Regulation
2600 Bull Street
Columbia, SC 29201

South Dakota

South Dakota CLIA Application Instructions

The CLIA application can be submitted via:

Email SDCLIA@state.sd.us
Fax (605) 773-6667
Mail SOUTH DAKOTA DEPARTMENT OF HEALTH
Office of Health Care Facilities Licensure & Certification
615 E 4th Street

Pierre, SD 57501-1700

Tennessee

Tennessee CLIA Application Instructions

The CLIA application can be submitted via:

Fax (615) 532-2700
Mail Office of Health Care Facilities, CLIA Certification
665 Mainstream Drive, 2nd Floor
Nashville, TN 37243
(For overnight delivery or courier mail use zip code 37228)

Additional Requirements Prior to Conducting Tests

The Tennessee Department of Health also requires waived testing sites to submit a [Waived Testing Notification](#) form. This form cannot be completed until after the CLIA Certificate of Waiver has been received.

About the Waived Testing Notification Form

The Waived Testing Notification form will requires the following:

- CLIA Number
- A copy of the CLIA Certificate of Waiver
- A copy of the supervising physician's current Tennessee medical license
- A physical signature on the form

Save a copy of the completed form and submit the original completed form via:

Fax (615) 532-2700
Mail Office of Health Care Facilities, Medical Laboratory Board
665 Mainstream Drive, 2nd Floor
Nashville, TN 37243

Texas

Texas CLIA Application Instructions

When submitting the CMS-116 Form, also attach the following completed forms:

- [Listing of Tests Performed in the Facility](#)
- [Disclosure of Ownership](#)

Submit the CLIA application and additional forms via email to the respective zone office:

Zone 1 - Central (CLIAzone1@hhsc.state.tx.us)

Counties served: Andrews, Armstrong, Bailey, Bastrop, Baylor, Bell, Blanco, Borden, Brewster, Briscoe, Burnet, Caldwell, Callahan, Carson, Castro, Childress, Cochran, Coke, Coleman, Collingsworth, Concho, Cottle, Crane, Crosby, Culberson, Dallam, Dawson, Deaf Smith, Dickens, Donley, Ector, El Paso, Fayette, Fisher, Floyd, Foard, Gaines, Garza, Gillespie, Glasscock, Gray, Hale, Hall, Hansford, Hardeman, Hartley, Haskell, Hays, Hemphill, Hockley, Howard, Hudspeth, Hutchinson, Irion, Jeff Davis, Jones, Kent, King, Knox, Lamb, Lampasas, Lee, Lipscomb, Llano, Loving, Lubbock, Lynn, Martin, Mason, McCulloch, McLennan, Menard, Midland, Milam, Mitchell, Moore, Motley, Nolan, Ochiltree, Oldham, Parmer, Pecos, Potter, Presidio, Randall, Reagan, Reeves, Roberts, Runnels, San Saba, Schleicher, Scurry, Shackelford, Sherman, Sterling, Stonewall, Swisher, Taylor, Terrell, Terry, Throckmorton, Tom Green, Travis, Upton, Ward, Wheeler, Wilbarger, Williamson, Winkler, Yoakum

Zone 2 - Arlington (CLIAzone2@hhsc.state.tx.us)

Counties served: Archer, Bosque, Brown, Clay, Collin, Comanche, Cooke, Coryell, Dallas, Denton, Eastland, Erath, Grayson, Hamilton, Hill, Hood, Jack, Johnson, Mills, Montague, Palo Pinto, Parker, Somervell, Stephens, Tarrant, Wichita, Wise, Young

Zone 3 - San Antonio (CLIAzone3@hhsc.state.tx.us)

Counties served: Aransas, Atascosa, Bandera, Bee, Bexar, Brooks, Calhoun, Cameron, Comal, Crockett, DeWitt, Dimmit, Duval, Edwards, Frio, Goliad, Gonzales, Guadalupe, Hidalgo, Jackson, Jim Hogg, Jim Wells, Karnes, Kendall, Kenedy, Kerr, Kimble, Kinney, Kleberg, La Salle, Lavaca, Live Oak, Maverick, McMullen, Medina, Nueces, Real, Refugio, San Patricio, Starr, Sutton, Uvalde, Val Verde, Victoria, Webb, Willacy, Wilson, Zapata, Zavala

Zone 4 - Houston (CLIAzone4@hhsc.state.tx.us)

Counties served: Austin, Brazoria, Chambers, Colorado, Fort Bend, Galveston, Harris, Matagorda, Montgomery, Waller, Wharton

Zone 5 - Tyler (CLIAzone5@hhsc.state.tx.us)

Counties served: Anderson, Angelina, Bowie, Brazos, Burleson, Camp, Cass, Cherokee, Delta, Ellis, Falls, Fannin, Franklin, Freestone, Gregg, Grimes, Hardin, Harrison, Henderson, Hopkins, Houston, Hunt, Jasper, Jefferson, Kaufman, Lamar, Leon, Liberty, Limestone, Madison, Marion, Morris, Nacogdoches, Navarro, Newton, Orange, Panola, Polk, Rains, Red River, Robertson, Rockwall, Rusk, Sabine, San Augustine, San Jacinto, Shelby, Smith, Titus, Trinity, Tyler, Upshur, Van Zandt, Walker, Washington, Wood

Zone 6 - State-Wide (CLIAzone6@hhsc.state.tx.us)

Utah

Utah CLIA Application Instructions

When submitting the CMS-116 Form, also attach the following completed form:

- [Ownership & Control of Interest Statement Disclosure Statement](#)

Note: Leave fields for CLIA Number blank if applying for initial CLIA certificate and CLIA Number not yet provided.

The CLIA application can be submitted via:

Email labimprovement@utah.gov
Fax (801) 536-0149
Mail Unified State Laboratories: Public Health
Bureau of Laboratory Improvement
4431 South 2700 West
Taylorsville, UT 84129

Vermont

Vermont CLIA Application Instructions

Note: Laboratories in Vermont should contact the New Hampshire State Agency.

The CLIA application can be submitted via:

Email CLIA@dhhs.nh.gov
Fax (6003) 271-8716
Mail HEALTH FACILITIES ADMINISTRATION
Department of Health & Human Services
129 Pleasant Street
Concord, NH 03301

Virginia

Virginia CLIA Application Instructions

Note: Only submit completed forms with physical signatures.

The CLIA application can be submitted via:

Mail Acute Care Division - CLIA
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Henrico, Virginia 23233

Washington

Washington CLIA Application Instructions

The State of Washington is a CLIA-exempt state and does not require a CMS-116 Form. This

exemption expires on July 31, 2021.

In order to obtain a Certificate of Waiver, submit the following completed form:

- [Certificate of Waiver MTS/CLIA License Application](#)
 - Include payment for the application fee

Note: Only submit completed forms with physical signatures.

The CLIA application can be submitted via:

Mail Department of Health
 Revenue Section
 P.O. Box 1099
 Olympia, WA 98507-1099

About the Certificate of Waiver MTS/CLIA License Application

This application has a fee. Refer to the application for the fee amount.

Include payment for the application fee when submitting the application. Payment must be in the form of a check or money order made payable to:

Department of Health

West Virginia

West Virginia CLIA Application Instructions

The CLIA application can be submitted via:

Email DHHROLSCLIA@wv.gov
Fax (304) 746-0658
Mail WEST VIRGINIA DEPARTMENT OF HEALTH
 Office of Laboratory Services
 ATTN: CLIA Section
 167 11th Avenue
 South Charleston, WV 25303-1137

Wisconsin

Wisconsin CLIA Application Instructions

The CLIA application can be submitted via:

Email DHSDQACLIA@dhs.wisconsin.gov
Fax (608) 283-7462
Mail WISCONSIN DEPARTMENT OF HEALTH SERVICES

Division of Quality Assurance
Clinical Laboratory Section
1 West Wilson Street
P.O. Box 2969
Madison, WI 53701-2969

Wyoming

Wyoming CLIA Application Instructions

The CLIA application can be submitted via:

Email DHSDQACLIA@dhs.wisconsin.gov

Fax (608) 283-7462

Mail Healthcare Licensing and Surveys
Hathaway Building, Suite 510
2300 Capitol Avenue
Cheyenne, WY 82002