

How to Obtain a CLIA Certificate of Waiver

START POINT-OF-CARE TESTING

Test For COVID-19 At Your Pharmacy

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 allows your pharmacy to perform point-of-care tests that have a waived degree of complexity as assigned by the U.S. Food and Drug Administration according to 42 CFR 493.15(c). **This now includes testing for SARS-CoV-2, the virus that causes COVID-19.**

This page will guide you through completing a CLIA application and provide state-specific submission instructions.

The Application Process

1

Open the CLIA Application for Certification CMS-116 Form

CMS-116 Form

2

Fill out Sections 1-6, 9, and 10

[Click Here for Instructions on Filling Out Each Section](#)

3

Print out the completed CMS-116 Form and sign it in ink

4

Scan the signed CMS-116 Form into your computer to save a copy

5

Complete additional forms and fees as required by your state and send to your State Agency contact

6

Once your application has been processed, CMS will send your test site's CLIA Number

State-Specific Instructions

For your convenience, we have gathered each state's requirements and forms that will need to be submitted with the CMS-116 Form. Click on your state for submission instructions.

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.

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 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](#)

A 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 and fee:

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 and fee:

[List of Laboratory Test Performed On-Site](#)

[Common Form: Initial Licensure/Suitability Notice of Intent to Acquire](#) (Include payment for the state license application fee)

[Clinical Laboratory Disclosure of Ownership Interest Statement](#)

[Clinical Laboratory License Information Form](#)

Articles of Incorporation or Partnership approved by the Massachusetts Secretary of State

[Criminal Offender Record Information \(CORI\) Acknowledgement Form](#)

[Instructions for the CORI Form](#)

[Suitability Disclosure Form](#) (if prompted by Common 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

About the Licensure Common Form

The Massachusetts State Department of Public Health requires testing sites to also possess a Clinical Laboratory License in addition to the CLIA Certificate of Waiver for performing CLIA-waived tests.

There is a separate application fee. Refer to the [Licensure Fee Schedule](#) for the limited clinical laboratory license type 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 payable to:

Commonwealth of Massachusetts

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 forms:

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, fee, 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

By USPS

Melanie Rinaldi
Manager, NJ CLIA Program
NJDOH/PHEL
P.O. Box 361
Trenton, NJ 08625-0361

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

Express Mail Clinical Laboratory Evaluation Program

Wadsworth Center
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, fee, and documentation:

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 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 forms:

[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 require 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

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 (603) 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 and fee:

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 608-264-9847

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 wdh-ohls@wyo.gov

Fax 307-777-7127

Mail Healthcare Licensing and Surveys

Hathaway Building, Suite 510

2300 Capitol Avenue

Cheyenne, WY 82002