

How to apply for a



CLIA Certificate of Waiver

Clinical Laboratory Improvement Amendments (CLIA) Background

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. The Centers for Medicare and Medicaid Services (CMS) is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, approvals of proficiency testing (PT) providers, accrediting organizations and exempt states. The FDA is responsible for test categorization.

Completing the application form

Section 1 - General Information

- > The CLIA application form (CMS-116) can be obtained at the CMS website:
www.cms.gov/cmsforms/downloads/cms116.pdf.

You must have Adobe Acrobat Reader installed on your computer in order to view and print this document. A link on the CMS site has been provided for obtaining the free viewing software if it is not already installed on your computer system.

Name of Director

- > This person should be identified as the principle party responsible for overseeing testing programs, ensuring that facility personnel administering testing are fully trained, and documentation is maintained to the meet CLIA standards. States deemed as "State Licensure" or "Exempt" may require additional accreditation within their individual states to qualify (e.g. medical director with licensed medical degree, etc.). Refer to state listing for the states that may apply.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES
Form Approved
OMB No. 0938-0581

**CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION**

I. GENERAL INFORMATION

Initial Application Survey
 Change in Certification Type
 Other Changes (Specify)

CLIA IDENTIFICATION NUMBER
Leave Blank for New Applications
D

(If an initial application leave blank, a number will be assigned)

FACILITY NAME
The Family Health Center of PA

FEDERAL TAX IDENTIFICATION NUMBER
12-3456789

EMAIL ADDRESS

TELEPHONE NO. (Include area code) FAX NO. (Include area code)
(610)345-6789 **(610)345-6788**

FACILITY ADDRESS — Physical Location of Laboratory (Building, Floor, Suite
if applicable.) Fee Coupon/Certificate will be mailed to this Address unless
mailing address is specified

MAILING/BILLING ADDRESS (If different from street address)
**The Family Health Center of PA
Attn: Accounts Payable**

NUMBER, STREET (No P.O. Boxes)
123 East First Street - Suite 100

NUMBER, STREET
123 East First Street - Suite 100

CITY STATE ZIP CODE CITY STATE ZIP CODE
Reading PA 12345 Reading PA 12346

NAME OF DIRECTOR (Last, First, Middle Initial)
Taylor, John, S.

FOR OFFICE USE ONLY
Date Received _____

II. TYPE OF CERTIFICATE REQUESTED (Check only one)

Certificate of Waiver (Complete Sections I – VI and IX – X)

Section 2 - Type of Certificate

Certificate of

- > Check box indicated.

II. TYPE OF CERTIFICATE REQUESTED (Check only one)

Certificate of Waiver (Complete Sections I – VI and IX – X)

Certificate for Provider Performed Microscopy Procedures (PPM) (Complete Sections I – 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 AOA AABB
 CAP COLA ASHI

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

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application.

Section 3 - Type of Laboratory

Facility Identification

- > This should be checked off from the description that best describes the type of facility and services provided.

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

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

Is this a shared lab? Yes No

IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format)

Section 4 - Hours of Laboratory Testing

Hours of Operation

- > Indicate when testing services will be available at the test site. This may or may not mirror site location's operating hours.

IV. HOURS OF LABORATORY TESTING (List times during which laboratory testing is performed in HH:MM format)

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:		9:00	9:00	9:00	9:00	9:00	8:00
TO:		5:00	5:00	5:00	5:00	5:00	3:30

(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)

Are you applying for the multiple site exception?
 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.

- Is this a laboratory that has temporary testing sites?
 Yes No

Section 5 - Multiple Sites

Multiple Locations

- > Most applications will respond "NO" to this question. Check off as indicated if applicable and immediately go to Section 6.

For applications that have multiple location sites, contact your local CMS office to ensure that the regulatory exceptions for this provision are met prior to completing this form. Additionally, Section 5 will require that each location's testing hours are identified.

V. MULTIPLE SITES (must meet one of the regulatory exceptions to apply for this provision)

Are you applying for the multiple site exception?
 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.

- Is this a laboratory that has temporary testing sites?
 Yes No
- 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.
- 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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Section 6 - Waived Testing

Annual Test Volume

- > This number represents the total estimate number of tests that will be performed at the testing facility annually. Under CLIA Application of Waiver submission, the fee charged for a two-year certificate is \$150.00, regardless of the volume of CLIA waived tests conducted within a facility. Whereas, CLIA Certificates for Moderate Complexity and High Complexity are fee rendered by this number indicated as well as the type of testing performed as identified under Section 7.

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

VI. WAIVED TESTING
 Identify the waived testing performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.
 e.g. (Rapid Strep, Acme Home Glucose Meter)

Indicate the estimated **TOTAL ANNUAL TEST** volume for all waived tests performed 1,500

Check if no waived tests are performed

VII. PPM TESTING
 Identify the PPM testing performed.

**Skip Section 7 & 8
 IF YOU ARE ONLY CONDUCTING WAIVED TESTING**

Section 9 - Type of Control

Facility Overseer

- > Indicate which code closely identifies with your organization. This would be understood by how you are identified currently with the IRS for tax filing purposes.

IX. TYPE OF CONTROL

VOLUNTARY NONPROFIT <input type="checkbox"/> 01 Religious Affiliation <input checked="" type="checkbox"/> 02 Private Nonprofit <input type="checkbox"/> 03 Other Nonprofit _____ (Specify)	FOR PROFIT <input type="checkbox"/> 04 Proprietary	GOVERNMENT <input type="checkbox"/> 05 City <input type="checkbox"/> 06 County <input type="checkbox"/> 07 State <input type="checkbox"/> 08 Federal <input type="checkbox"/> 09 Other Government _____ (Specify)
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X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

Section 10 - Director Affiliation with Other Laboratories

Other Affiliations

- > Many identified Directors may have affiliations with other facilities and/or programs within each state. This section must be completed if the Director identified for this application has been registered to other site locations and/or organizations.

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
41D1234567	Eastern Pennsylvania Health Center

ATTENTION: BE CAREFUL WITH THIS SECTION

Section 10 - Director Affiliation with Other Laboratories

Contractual Obligation

- > The Laboratory Director must sign and complete the application. By signing this application, the Director agrees to permit the Secretary, or any Federal officer or employee designated by the Secretary to inspect the laboratory, operations and all records at any reasonable time to determine applicants eligibility or continued eligibility for a CLIA certificate and continued compliance with CLIA requirements are met.

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION	
<p>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.</p> <p>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.</p>	
SIGNATURE OF OWNER/DIRECTOR OF LABORATORY <i>(Sign in ink)</i>	DATE
John S. Taylor	03/02/2011
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Mail

Completed Application

- > Once the application is completed, it should be mailed directly to the local CMS office in your state. No check or money order should be sent at this time. The application is then entered into a national database. Within the next two (2) weeks, a bill with a detachable coupon will be mailed to the attention of the Director. Fees for a Certificate of Waiver for two years will be \$150.00. Detach the coupon and send along with payment to the address provided. Be sure to reference the assigned CLIA certificate number on your check should the coupon be lost or separated from payment.

CLIA Certificate of Waiver

- Processing for a new certificate may take up to two months, however calling your local office may or may not yield information on the progress of your application. Your CLIA certificate number is established on your original invoice. Only once your payment is credited with your application approval may you begin testing within your facility. The CLIA certificate will arrive approximately two (2) weeks following credited payment.

Renewal

- Anticipate ten months prior to renewal date of your CLIA Certificate, a coupon voucher to arrive directed to the listed Director of the facility. Payment should be made by expected due date. Any changes from the original application should also be indicated. Once payment is received a renewal Certificate will be sent one month prior to the expiration date.

For additional information, contact your local CMS office.

State Survey Agencies (CLIA Contact List)

Region	Agency Name	Address	Contact	CLIA	State	Licensure	Exempt
REGION I - Boston	CLIA LABORATORY PROGRAM DEPARTMENT OF PUBLIC HEALTH P. O. Box 340308 410 Capitol Avenue, MS#12 HSR Hartford, CT 06134-0308 (860) 509-7400 FAX: (860) 509-7543 Contact: John J. Murphy			•			
	BUREAU OF HEALTH CARE SAFETY AND QUALITY MASS. DEPT. OF PUBLIC HEALTH CLINICAL LABORATORY PROGRAM 99 Chauncy Street, 11th Floor Boston, MA 02111 (617) 753-8438 or 8439 FAX: (617) 753-8240 Contact: Roberta Teixeira			•			
	DIVISION OF FACILITIES REGULATION RI DEPARTMENT OF HEALTH 3 Capitol Hill, Room 306 Providence, RI 02908 (401) 222-4526 FAX: (401) 222-3999 Contact: Nancy Hines			•			
	CLIA PROGRAM DIVISION OF LICENSING & REGULATORY SERVICES 41 Anthony Avenue, Station #11 Augusta, ME 04333-0011 (207) 287-9339 FAX: (207) 287-9304 Contact: Dale Payne			•			
	HEALTH FACILITIES ADMINISTRATION DEPARTMENT OF HEALTH & HUMAN SERVICES 129 Pleasant Street Concord, NH 03301 (603) 271-4832 FAX: (603) 271-4968 Contact: Rodney Bascom			•			
	CLIA LABORATORY PROGRAM VERMONT DEPARTMENT OF HEALTH 108 Cherry Street Burlington, VT 05401 (802) 652-4145 FAX: (802) 865-7701 Contact: Carol Drawbaugh			•			
	REGION II - New York	CLINICAL LABORATORY IMPROVEMENT SVC STATE OF NEW JERSEY DEPARTMENT OF HEALTH & SENIOR SERVICES P. O. Box 361 Trenton, NJ 08625-0361 (609) 292-0016 FAX: (609) 292-0424 Contact: Marilou Mallada			•		
	For Physician Office Laboratories in New York: STATE OF NEW YORK DEPARTMENT OF HEALTH PHYSICIAN OFFICE LABORATORY EVALUATION PROGRAM Empire State Plaza P. O. Box 509 Albany, NY 12201-0509 (518) 485-5352 Contacts: Dr. Michael P. Ryan			•			
	For All Other Laboratory Facility Types in New York: CLINICAL LABORATORY EVALUATION PROGRAM Empire State Plaza P. O. Box 509 Albany, NY 12201-0509 (518) 485-5378 Contacts: Stephanie Shulman			•			
	COMMONWEALTH OF PUERTO RICO PUERTO RICO HEALTH DEPARTMENT OFFICE OF CERTIFICATION & LICENSURE FORMER-RUIZ SOLER HOSPITAL Road No. 2 Bayamon PR 00619 (787) 782-0120 Ext. 2222 FAX: (787) 781-2088 Contact: Julia Colón			•			
	REGION III - Philadelphia	DELAWARE STATE PUBLIC HEALTH LABORATORY 30 Sunnyside Road Smyrna, DE 19977 (302) 223-1392 FAX: (302) 653-2877 Contact: Donna Phillips-DiMaria			•		
DC DEPARTMENT OF HEALTH Health Regulations and Licensing Administration Health Facilities Division - Laboratory Services 899 North Capitol Street, NE-2nd Floor Washington, DC 20002 (202) 727-1740 FAX: (202) 442-9431 Contact: Semret Tesfaye			•				
MARYLAND DEPARTMENT OF HEALTH & MENTAL HYGIENNE OFFICE OF HEALTH CARE - LABS Bland Bryant Building Spring Grove Hospital Center 55 Wade Avenue Catonsville, MD 21228 (410) 402-8025 FAX: (410) 402-8213			•				
PENNSYLVANIA DEPARTMENT OF HEALTH BUREAU OF LABORATORIES 110 Pickering Way Exton, PA 19341-0500 (610) 280-3464 Ext. 3233 FAX: (610) 594-9763 Contact: Melissa Sealie			•				
VIRGINIA DEPARTMENT OF HEALTH OFFICE OF LICENSURE AND CERTIFICATION 9600 Mayland Drive, Suite 401 Richmond, VA 23233 (804) 367-2107 FAX: (804) 527-4504 Contact: Sarah Pendergrass			•				
WEST VIRGINIA DEPARTMENT OF HEALTH OFFICE OF LABORATORY SERVICES 167 11th Avenue South Charleston, WV 25303-1137 (304) 558-3530, extension 2103 FAX: (304) 558-2006 Contact: Jerry Gross			•				
REGION IV - Atlanta	ALABAMA DEPARTMENT OF PUBLIC HEALTH DIVISION OF HEALTH CARE FACILITIES CLIA PROGRAM, P.O. Box 303017 Montgomery, AL 36130-3017 (334) 206-5120 Contact: Faye Allen			•			
STATE OF FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION LABORATORY LICENSING UNIT 2727 Mahan Drive, Mail Stop 32 Tallahassee, FL 32308 (850) 412-4500 FAX: (850) 410-1511 Contact: Karen Rivera			•				
DEPARTMENT OF COMMUNITY HEALTH HEALTHCARE FACILITY REGULATION DIVISION DIAGNOSTIC SERVICES UNIT 2 Peachtree Street, N.W., Suite 31-447 Atlanta, GA 30303-3142 (404) 657-5447 FAX: (404) 657-5442 Contact: Sheela E. Puthumana			•				
KENTUCKY CLIA PROGRAM Office of Inspector General 275 E Main Street 5E-A Frankfort, KY 40601 (502) 564-7963 Contact: Connie Barker, Ext. 3280			•				
LICENSURE AND CERTIFICATION MISSISSIPPI DEPARTMENT OF PUBLIC HEALTH P. O. Box 1700 Jackson, MS 39215-1700 (601) 364-1115 Contact: Theresa Irwin			•				

CLIA
State
Licensure
Exempt

• NORTH CAROLINA DEPARTMENT
OF HEALTH AND HUMAN SERVICES
DIVISION OF FACILITY SERVICES/
CLIA CERTIFICATION
2713 Mail Service Center
Raleigh, NC 27699-2713
(919) 855-4620
FAX: (919) 733-0176
Contact: Azzie Conley

• SOUTH CAROLINA DEPARTMENT OF HEALTH
& ENVIRONMENTAL CONTROL
BUREAU OF CERTIFICATION/ HEALTH
REGULATION
2600 Bull Street
Columbia, SC 29201
(803) 545-4291
FAX: (803) 545-4563
Contact: Lakeisha N. Wright

• TENNESSEE HEALTH CARE FACILITIES
227 French Landing, Suite 501
Heritage Place Metro Center
Nashville, TN 37243
(615) 741-7023
FAX: (615) 532-2700
Contact: Sandra Bogard

REGION V - Chicago

• ILLINOIS DEPARTMENT OF PUBLIC HEALTH
DIVISION OF HEALTH CARE FACILITIES
& PROGRAMS
525 W Jefferson Street
Fourth Floor
Springfield, IL 62761
(217) 782-2343
FAX: (217) 782-0382
Contact: Juan Garcis, Supervisor

• INDIANA STATE DEPARTMENT OF HEALTH
DIVISION OF ACUTE CARE SERVICES
2 North Meridian Street, Room 4A
Indianapolis, IN 46204
(317) 233-7502
FAX: (317) 233-7157
Contact: Lorraine Switzer

• MICHIGAN DEPARTMENT OF COMMUNITY
LABORATORY IMPROVEMENT SECTION
611 W. Ottawa Street, First Floor
Lansing, MI 48909
(517) 241-2648
FAX: (517) 241-3354

• MINNESOTA DEPARTMENT OF HEALTH
LICENSING & CERTIFICATION CLIA PROGRAM
85 East 7th Place
P. O. Box 64900
St. Paul, MN 55164-0900
(651) 215-8420
FAX: (651) 215-9697
Contacts: Bridget Woitas

• OHIO DEPARTMENT OF HEALTH
LABORATORY CLIA LABORATORY PROGRAM
246 N. High Street, 3rd Floor
Columbus, OH 43215
(614) 644-1845
FAX: (614) 387-2762
Contact: Drema Phelps

• DEPARTMENT OF HEALTH SERVICES
DIVISION OF QUALITY ASSURANCE
CLINICAL LABORATORY SECTION
1 W. Wilson Street, Room 1151
Madison, WI 53701-2969
(608) 261-0653
FAX: (608) 264-9847
Contact: Barbara Saar

REGION VI - Dallas

• HEALTH FACILITY SERVICES Slot H9
ARKANSAS DEPARTMENT OF HEALTH
AND HUMAN SERVICES
5800 West 10th Street, Suite 400
Little Rock, AR 72204-9916
(501) 661-2201
Contact: Liz Davis

• DEPARTMENT OF HEALTH & HOSPITALS
HEALTH STANDARDS SECTION
500 Laurel Street, Suite 100
Baton Rouge, LA 70801
(225) 342-9324
Contact: Staci Glueck

• HEALTH FACILITY LICENSING
AND CERTIFICATION BUREAU
Bank of the West Building
5301 Central Avenue NW, Suite 400
Albuquerque, NM 87108
(505) 222-8646
Fax: (505) 841-5834
Contact: Julie Aragon

• OKLAHOMA STATE DEPARTMENT OF HEALTH
PROTECTIVE HEALTH SERVICES
MEDICAL FACILITIES
1000 NE 10th Street
Oklahoma City, OK 73117-1299
(405) 271-6576
Contact: Dean Bay

• TEXAS DEPARTMENT OF STATE
HEALTH SERVICES
ATTN: Charles Peck
P. O. Box 149347
Austin, TX 78714-9347
(512) 834-6792

REGION VII - Kansas City

• IOWA CLIA LABORATORY PROGRAM
STATE HYGIENIC LABORATORY
Research Park
The University of Iowa
Iowa City, IA 52242
(319) 335-4500
FAX: (319) 335 4174
Contact: Nancy Grove, Sr. Laboratory Consultant

• KANSAS DEPARTMENT OF HEALTH
& ENVIRONMENT
LABORATORY CERTIFICATION
Building 740
Forbes Field
Topeka, KS 66620-0001
(785) 296-3811
Contact: Ruby Brower

• MISSOURI DEPARTMENT OF HEALTH AND
SENIOR SERVICES
CLIA Section
P. O. Box 570
Jefferson City, MO 65102
(573) 751-6318
Contact: William Nugent

• NEBRASKA STATE HEALTH & HUMAN SERVICES
LICENSURE UNIT-DIVISION OF PUBLIC HEALTH
Office of Acute Care Facilities
P. O. Box 94986
Lincoln, NE 68509-4986
(402) 471-3484
Contact: Joann Erickson

REGION VIII - Denver

• COLORADO DEPARTMENT OF PUBLIC HEALTH
& ENVIRONMENT
LABORATORY SERVICES DIVISION
8100 Lowry Blvd.
Denver, CO 80230-6928
(303) 692-3681
FAX: (303) 344-9965
Contact: Jeff Groff

• MONTANA CLIA PROGRAM - DIVISION
OF QUALITY ASSURANCE - DEPARTMENT
OF PUBLIC HEALTH & HUMAN SERVICES
2401 Colonial Drive, 2nd Floor
P. O. Box 202953
Helena, MT 59620-2953
(406) 444-1451
FAX: (406) 444-3456
Contact: Ed Adams

• HEALTH RESOURCES SECTION
NORTH DAKOTA DEPARTMENT OF HEALTH
STATE CAPITAL
600 East Boulevard Avenue/DEPT 301
Bismarck, ND 58505-0200
(701) 328-2352
FAX: (701) 328-1890
Contact: Bridget Weidner

• SOUTH DAKOTA DEPARTMENT OF HEALTH
OFFICE OF HEALTH CARE FACILITIES
LICENSURE AND CERTIFICATION
615 E. 4th Street
Pierre, SD 57501-1700
(605) 773-3694
FAX: (605) 773-6667
Contact: Connie Richards

• UNIFIED STATE LABORATORIES-PUBLIC HEALTH
BUREAU OF LABORATORY IMPROVEMENT
4431 South 2700 West
Taylorsville, UT 84119
(801) 965-2531
FAX: (801) 965-2544
Contact: Jan Case

• OFFICE OF HEALTHCARE
LICENSING AND SURVEYS
400 Qwest Building
6101 North Yellowstone Road
Cheyenne, WY 82002
(307) 777-7123
FAX: (307) 777-7127
Contact: Russ Forney

CLIA
State
Licensure
Exempt

REGION IX - San Francisco

• ARIZONA DEPARTMENT OF HEALTH
SERVICES
DIVISION OF PUBLIC HEALTH SERVICES
Office of Laboratory Services
250 N. 17th Avenue
Phoenix, AZ 85007
(602) 364-0741
FAX: (602) 364-0759
Contact: Odalys Hinds

• DEPARTMENT OF PUBLIC HEALTH
DIVISION OF LABORATORY SERVICES
LABORATORY FIELD SERVICES
320 West 4th Street, Suite 890
Los Angeles, CA 90013-2398
(213) 620-6160
FAX: (213) 620-6565
Contact: Donna McCallum, Examiner III

• HAWAII DEPARTMENT OF HEALTH
CLIA Program
601 Kamokila Blvd., Room 395
Kapolei, HI 96707
(808) 692-7420
FAX: (808) 692-7447
Contact: Susan O. Naka

• **FOR LABS IN AMERICAN SAMOA (64), CONTACT
THE HAWAII STATE AGENCY (12) FOR LABS IN
SAIPAN (66) AND GUAM (65), CONTACT REGIONAL
OFFICE IX, SAN FRANCISCO**

• STATE OF NEVADA DEPARTMENT OF HEALTH
AND HUMAN SERVICES
HEALTH DIVISION
BUREAU OF HEALTH CARE QUALITY & COMPLIANCE
727 Fairview Dr., Ste E
Carson City, NV 89701-5493
(775) 684-1060
FAX: (775) 684-1073
Contact: Vicki Estes, MT (ASCP)

REGION X - Seattle

• OFF. OF LABORATORY QUALITY ASSURANCE
DEPARTMENT OF HEALTH
1610 NE 150TH Street
Shoreline, WA 98155-9701
(206) 418-5418
FAX: (206) 418-5505
Contact: Susan Walker

• OREGON HEALTH AUTHORITY
OREGON STATE PUBLIC HEALTH DIVISION
LABORATORY COMPLIANCE SECTION (LCS)
3150 NW 229th Avenue, Suite 100
Hillsboro, OR 97124-6536
(503) 693-4121
FAX: (503) 693-5602
Contact: Rita A. Youell

• LABORATORY IMPROVEMENT SECTION
BUREAU OF LABORATORIES
2220 Old Penitentiary Road
Boise, ID 83712-8299
(208) 334-2235 x245
FAX: (208) 334-4067
Contact: David Eisentrager

• ALASKA CLIA PROGRAM
ALASKA STATE PUBLIC HEALTH LABORATORY
5455 Dr. Martin Luther King Jr. Avenue
Anchorage, AK 99507
(907) 334-2583
FAX: (907) 334-2161
Contact: Doris Thompson

CLIA
State
Licensure
Exempt

CLIA Important Information

State Licensure or Exemption

- > Prior to the introduction of the Clinical Laboratory Improvement Amendments of 1988, numerous states had already adopted quality procedures and protocols by which laboratories operating within the state had to maintain. Many of these already established guidelines were deemed more stringent than the new protocols established under the new federal law (42 CFR Part 493). Petitions were heard and granted that allow for states with already existing protocols that proved to be “equal to or more stringent” may apply for a CLIA “Exemption”. To date, New York and Washington are the only two states operating under exemption whereas there are 17 states that have “State Licensure” in addition to CLIA. The previous chart assists in identifying these. Under State Licensure however, additional guidelines may be required in order to perform CLIA waived testing within the given state. These may include Proficiency Testing, Training Requirements, Quality Assurance Programs and Testing Procedures, Record Keeping Requirements, etc. For any application within these states, contact your local office to determine what additional steps and filings may be required to perform CLIA waived testing.

Additions or Changes to Issued Certificates

- > During the two-year certificate period, information supplied on the original certificate application may change (e.g., lab director, add-on site location, etc). It is important that this information be communicated in a prompt manner to the local State Reporting office. The local states maintain the database for each issued certificate within the state. For questions concerning changes to the current certificate status, it is best to contact your local CMS office for clarification. Most often a simple letter is all that is required. This will be kept on file at the state office. A new certificate **will not** be issued reflecting these changes. Only upon renewal application will the changed information be indicated.

Facility Inspections

- > The local state offices of CMS inspect facilities from time to time to monitor and ensure that each is operating under the CLIA guidelines. While these inspections are not punitive in nature, inspectors will check to see that Manufacturers’ Guidelines are followed within each facility. Additionally, reported complaints in the field will prompt a mandatory inspection of any facility. A report will be written for both random and mandated inspections that will advise any inconsistencies and recommendations to bring a facility up to compliance. Timelines for compliance adherence will be established. What can this mean potentially to a CLIA waived testing site? If a second follow-up inspection reveals that conformance has not been established, the local CMS office can cease CLIA testing operations for a given time to that facility or site until conformance has been satisfactorily met. Similarly, if additional complaints are filed against the facility, CLIA certification can be permanently revoked and punitive action can take place dependent on the nature of the complaint.



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