

NEW YORK STATE DEPARTMENT OF HEALTH  
WADSWORTH CENTER  
CLINICAL LABORATORY EVALUATION PROGRAM  
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INITIAL LIMITED SERVICE LABORATORY  
REGISTRATION APPLICATION  
INSTRUCTIONS

Please follow the instructions carefully since submission of incomplete applications will delay processing and issuance of the registration. **NOTE: You must enclose a \$200.00 application fee payment with your application. Your check or money order should be made payable to: New York State Department of Health.** The check or check stub should indicate the laboratory's name. This fee is non-refundable.

#### A. BACKGROUND AND GENERAL INFORMATION

The New York State Department of Health's Clinical Laboratory Evaluation Program has been authorized under Section 579 of Article 5, Title V of the Public Health Law to provide oversight to facilities performing waived and/or provider-performed microscopy procedures in New York State. These facilities are considered Limited Service Laboratories and must register with the Department as described in this registration package in order to obtain a federal CLIA number and authorization to perform patient testing. **Not-for-profit, state or local government laboratories or programs engaged in limited public health testing not exceeding fifteen types of test per registration may be eligible to apply for a multi-site CLIA number.**

#### B. PHYSICIAN OFFICE EXCEPTION

The only facilities that are exempt from Limited Service Laboratory Registration are private physician office laboratories (POLs) operated by individual practitioners or as part of a legally constituted, independently owned and managed partnership or group practice, or the independent practice of a nurse practitioner operating under a practice agreement with a licensed physician. The tests performed must be conducted by the providers or by their own employees, utilizing their own reagents and instrumentation, solely as an adjunct to the practice of medicine for their patients. Laboratories that meet the criteria above for a POL must apply to the Physicians Office Laboratory Evaluation Program (POLEP) in order to receive a CLIA number. Information and applications may be obtained by calling POLEP at 518-485-5352.

Laboratories which are set up as a joint venture of several practitioners, partnerships or practices and practices which are owned, managed and/or operated by managed care organizations, hospitals or consulting firms do not qualify for the POL exemption and must obtain a Limited Service Laboratory Registration. If you have any question about whether a permit is required, contact our program at 518-402-4253 (voice), 518-449-6902 (fax), or via e-mail at: [clepltd@wadsworth.org](mailto:clepltd@wadsworth.org)

#### C. ADDITIONAL RESOURCES

Technical support is available from our program to assist Limited Service Laboratory staff in implementing a quality testing program within these facilities. An additional resource available to Limited Service Laboratory staff is a document published by the Centers for Disease Control and Prevention (CDC) in November 2005 entitled "Good Laboratory Practices for Waived Testing Sites." This publication is available on the CDC website at: <http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf>

#### COMPLETING THE REGISTRATION APPLICATION

Please note that the authority for the New York State Department of Health, Wadsworth Center, Clinical Laboratory Evaluation Program to request personal information from you, including identifying numbers such as federal Employer Identification Number (EIN), and the authority to maintain such information, is found in Section 5 of the New York State Tax Law. Disclosure of this information by you is mandatory. These numbers are routinely used only as identifiers within our Program. They may only be released for tax administration purposes and other purposes authorized by the Tax Law. The Administrator of the Clinical Laboratory Evaluation Program is responsible for maintaining the records of such information. The administrator can be reached by writing to the Clinical Laboratory Evaluation Program at the address indicated at the top of this page.

## 1. CLIA STATUS AND APPLICATION TYPE

**CLIA Number:** If you have already obtained a CLIA certification number, please indicate the number in the area provided. If you do not already have a CLIA certification number, one will be assigned to your facility.

**Multi-Site Network Registration:** Not-for-profit, state or local government laboratories or programs engaged in limited public health testing not exceeding fifteen types of tests per registration may be eligible to apply for a Limited Service Laboratory Multi-Site Network Registration and Multi-Site CLIA number. One location must be designated as the primary location; this application should be completed for that site. To include secondary locations, complete and include with this application a Limited Service Laboratory Registration Notification to Add Permanent Testing Location to Multi-Site Network Registration (form, DOH-4081MS). Note that the laboratory director listed on this application will be responsible for all sites operating under a Limited Service Laboratory Multi-Site Network Registration and Multi-Site CLIA number.

## 2. GENERAL LABORATORY INFORMATION (Note: If you are completing this application for the primary site in a multi-site network, provide the information for that site).

**Laboratory Name:** Indicate the legal name exactly as you wish it to appear on the Limited Service Laboratory Registration Certificate.

**Federal Employer ID Number:** Under the New York State Tax Law, you are required to provide your federal Employer Identification Number. A CLIA registration number cannot be issued without this information.

**County/Borough:** Indicate the New York State county or borough that the laboratory is physically located in.

**Laboratory Address:** The laboratory address must be the actual physical location where testing is performed, including floor, suite and/or room, if applicable.

**Mailing Address:** Indicate if the laboratory has a separate mailing address. Our office will use the mailing address for all correspondence with your facility.

**Contact Person Name, Telephone Number and E-Mail Address:** The contact person is the individual designated by the Laboratory Director as the liaison with our Program. This is the individual that you would like us to direct correspondence to and/or follow-up with should questions arise regarding any of the answers provided in your registration materials. If you are applying for a multi-site network registration, this individual will be the point of contact for all sites within the network.

**Laboratory Telephone and Fax Numbers, E-mail Address:** These sections are self-explanatory.

**Days & Hours of Testing:** Indicate the days and hours when laboratory testing will be performed.

**Community Screening:** Indicate whether your laboratory or laboratory network will perform community screening events. Laboratories seeking approval to operate community screening events must maintain a protocol describing in detail how laboratory testing will be performed.

Permanent off-site locations performing testing should be registered under a Limited Service Laboratory Multi-Site Network Registration and Multi-Site CLIA number using form DOH-4081MS.

## 3. LABORATORY TYPE

This information is needed to assign and maintain your CLIA certification. Indicate your laboratory type from the list provided. Please check the type that is most descriptive of your facility.

#### 4. OWNERSHIP INFORMATION

All applications **must** list the name and address of the individual, partnership or corporation that owns or operates the laboratory or laboratory network. "Address of Principal Office" refers to the address of the principal office of the corporation, partnership or government entity, which owns or operates the laboratory. Government-operated facilities should identify the sponsoring county, city or municipality and provide the name, title, and address of the administrator.

**Small Business:** A small business is defined as one, which is located in New York State, independently owned and operated, and employs 100 or fewer individuals. This includes all employees, both technical and non-technical.

#### 5. AFFILIATION

If your facility is affiliated with a laboratory holding a New York State permit, please provide the name, address, and NYS laboratory permit PFI Number (if known). Affiliation refers to actual involvement in the technical performance of the testing performed at your facility, or common staff, supplies, etc. **Do not report the name of your reference laboratory.**

#### 6. MANAGEMENT

If the laboratory testing performed under this registration is provided under a management or consulting contract, indicate the name and address of the company that you contract with to perform this testing. **Do not report the name of your reference laboratory.**

#### 7. LABORATORY DIRECTORSHIP

Supply information concerning the individual who provides technical and clinical direction of your laboratory testing (i.e. the medical director). **The laboratory director designee must be a licensed health care practitioner (Physician, Dentist, PA, NP, or CNM only) or a Ph.D. holding a New York State Department of Health Certificate of Qualification.** Indicate if the individual holds a Certificate of Qualification. If the director is a health care practitioner, a license number must be provided. **\*NOTE: The laboratory director must include a copy of their current New York State professional license with the completed Limited Service Laboratory Registration Application package.** Indicate whether the individual is employed at the laboratory on a full-time or part-time basis.

#### 8. WAIVED TEST PROCEDURES REQUESTED

Indicate the *Waived* tests that you wish to perform and provide the combined estimated annual test volume for all *Waived* test procedures indicated. *Waived* testing includes tests performed using a kit, device or procedure, which has been designated by the Food and Drug Administration (FDA) as *Waived* for the purposes of CLIA '88. Non-DOT breath alcohol testing must be performed using an FDA approved IVD Over-The-Counter device. Sites performing these tests shall maintain a copy of the documentation that the tests in use have been so designated. Listings of waived tests are available at the following websites:

To Search By Test System: [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/testswaived.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/testswaived.cfm)

To Search By Analyte: [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/analyteswaived.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/analyteswaived.cfm)

To Search a Particular Kit/Mfr.: [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm)

To Search FDA's IVD Over-The-Counter Lab Test Database: [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm)

**IMPORTANT NOTE:** Limited Service Laboratories seeking approval to perform lead, and/or rapid HIV screening(s) **must** provide CLEP with a written protocol detailing how testing is performed in accordance with the manufacturer's requirements.

Additional guidance with protocol development for lead, and/or rapid HIV testing is available at the following websites:

For Lead Testing: [www.wadsworth.org/labcert/limited/index.htm](http://www.wadsworth.org/labcert/limited/index.htm)

For HIV Testing: [www.health.state.ny.us/diseases/aids/testing/rapid/index.htm](http://www.health.state.ny.us/diseases/aids/testing/rapid/index.htm)

## 9. PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES REQUESTED

Indicate the *Provider-performed Microscopy (PPM) Procedures* that you wish to perform and provide the combined estimated annual test volume for all PPM Procedures indicated. \**Provider-performed Microscopy (PPM) Procedures* includes tests personally performed as part of physical examinations by health care providers, licensed and currently registered in New York State, including physicians, dentists, podiatrists, physician assistants, nurse practitioners and certified midwives operating within the scope of practice for their profession and which have been designated as *PPM Procedures* by the Centers for Disease Control. Sites performing these tests shall maintain a copy of the documentation that the tests in use have been so designated.

## 10. CERTIFICATION

This section must be completed & signed by the individual indicated in Section 7–Laboratory Directorship as responsible for the technical and clinical direction of your laboratory testing and the individual completing the application (if different from the Laboratory Director).

## OUR MAILING ADDRESS

Application documents must be returned to our office at the address below:

### 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

## LIMITED SERVICE LABORATORY REGISTRATION

Once the Limited Service Laboratory Registration application is approved, an initial registration certificate will be issued. The certificate will serve to verify your enrollment with this Program and will also provide documentation of your CLIA registration number. If you are applying for a multi-site network registration, registration certificates for all locations in the network will be sent to the primary location. Certificates are valid for two years from the date issued. Approximately three months before the registration expires, you will receive materials to renew your registration or multi-site network registration.

Registrants may only perform the tests listed on the registration certificate issued by the Department. Multi-site network registrants may only perform the tests listed on the registration certificate issued to the Primary Site.

## CHANGES IN STATUS

Once approved, you must keep our Program informed of any changes which may affect your registration status (i.e. laboratory name, address, director, test menu, owner, additional testing sites, etc.). Be advised that Limited Service Laboratory registrations are void upon change in the laboratory location or the owner. In addition, registrants must inform our Program of any change in location or laboratory director within 30 days of the change. Limited Service Laboratory Change forms may be downloaded from our website at:

<http://www.wadsworth.org/labcert/limited/>