

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

A. BACKGROUND AND GENERAL INFORMATION

The New York State Department of Health's Clinical Laboratory Evaluation Program has been authorized under the federal Clinical Laboratory Improvement Amendments (CLIA) to provide oversight to facilities performing laboratory tests in New York State, even if only one or a few basic tests are performed, and even if you are not charging for testing. These facilities are considered Limited Service Laboratories and must register with the Department as described in this registration package. **NOTE: WAIVED TESTS ARE NOT EXEMPT. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST REGISTER AS A LIMITED SERVICE LABORATORY.**

B. HOW TO DETERMINE IF YOUR FACILITY QUALIFIES FOR THE 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 practitioners 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. POLs 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 are not included within the POL exemption and must obtain a permit. If you have any question about whether a permit is required, contact the program at 518-402-4253 (voice), 518-485-5414 (fax), or via e-mail at clepltd@wadsworth.org.

C. ADDITIONAL RESOURCES

This Program provides educational materials and technical support to staff from Limited Service Laboratories to assist 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

These instructions should be read carefully, as submission of incomplete or incorrectly completed applications may result in a delay in processing your application. The completed application should be returned to the address above along with the application fee of \$100.00. Please make checks payable to the New York State Department of Health-Clinical Laboratory Evaluation Program.

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. GENERAL LABORATORY INFORMATION

CLIA Number: If you have already obtained a CLIA certification number, please indicate “yes” and enter the number in this section. If you have not obtained a CLIA certification number, indicate “no” in this section. A CLIA number will then be assigned to your facility.

Laboratory Name: Indicate the legal name and address exactly as you wish it to appear on your 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: Indicate the New York State county 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.

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.

2. 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.

3. OWNERSHIP INFORMATION

All applications must list the name and address of the individual, partnership or corporation that owns the laboratory. “Address of Principal Office” refers to the address of the principal office of the corporation, partnership or government entity, which owns the laboratory. Government operated facilities should identify the sponsoring county, city or municipality and provide the name, title, and address of the administrator responsible for the operation of the laboratory. Information must also be provided to document government or not-for-profit status.

Laboratories indicating not-for-profit status must provide proof by submitting a copy of the organization’s IRS letter of determination for nonprofit status or a copy of the organization’s NYS Charities Registration Filing. Please note that the form used for making a tax exempt purchase is not acceptable proof of not-for-profit status.

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.

4. AFFILIATION

If your facility is affiliated with a laboratory, 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.**

5. MANAGEMENT

If the laboratory testing performed on-site in your facility is performed by an agency other than your own, and 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.**

6. LABORATORY FACILITIES

Please include all locations at which testing is performed, including community screenings. *In the case of community screenings, you must also supply this office with a list of locations that you intend to visit, and a calendar of events (as well as a protocol for all laboratory testing to be performed). You are to give this Program advance notice of any additions/deletions to the list of sites. Advance notice of locations at which testing will be offered will enable CLEP to respond to any inquiries or concerns.*

List and briefly describe the laboratory equipment and instruments used (e.g. microscopes, incubators, water baths, sterilizers, centrifuges, glucometers). If needed, use a separate sheet of paper.

7. 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).** Indicate if the individual holds a New York State Certificate of Qualification as a laboratory director. **Indicate whether the individual is full-time or part-time, and provide their days and hours on-site in the laboratory.**

8A. TESTING CATEGORIES REQUESTED: WAIVED TESTING

Indicate the *Waived* tests that you wish to perform. **Waived* testing includes tests performed using a kit, device or procedure, which has been designated by the Food and Drug Administration as *Waived* for the purposes of CLIA '88. 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:

By Test System: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/testswaived.cfm

By Analyte: 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

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

8B. TESTING CATEGORIES REQUESTED: PROVIDER-PERFORMED MICROSCOPY PROCEDURES

Indicate the *Provider-performed Microscopy Procedures* that you wish to perform. **Provider-performed Microscopy Procedures (PPMP)* 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 *PPMP* 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.

9A. TECHNICAL INFORMATION: WAIVED TESTING

For each *Waived* test indicated in the Testing Categories Requested (Section 9a), complete the appropriate Technical Information section(s) on page 4.

- Indicate the test procedure (i.e. blood glucose, dipstick urinalysis, fecal occult blood, etc.);
- Indicate the name of the kit, instrument, and manufacturer;
- Indicate the number of tests performed annually (i.e. How many tests do you do per year?). If you do not have an actual figure, please provide an estimate;
- Indicate if a package insert is available;
- Indicate if quality control is performed;
- Indicate if quality control is documented.

9B. TECHNICAL INFORMATION: PROVIDER-PERFORMED MICROSCOPY PROCEDURES

For each Provider-performed Microscopy Procedure indicated in the Testing Categories Requested (Section 9b), complete the appropriate Technical Information section(s) on page 5.

- Indicate the test procedure (i.e. Wet Mounts, KOH Preps, etc.);
- Indicate the number of tests done annually (i.e. How many tests do you do per year?). If you do not have an actual figure, please provide an estimate;
- Indicate the type of personnel performing the test (i.e. M.D., N.P.).

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).

CLIA REGISTRATION

Once your application is approved, we will issue an initial CLIA registration number, if you do not already hold one. You will be sent a registration document, which will serve to verify your enrollment with this program and will also provide documentation of your CLIA registration number. This registration will be valid for two years from the date it is issued. Approximately three months before it expires, you will receive an application to renew your registration.

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, etc.). You have 30 days to notify our office of such changes. Failure to do so may void your Limited Service Laboratory Registration. Change forms may be downloaded from our website at:

<http://www.wadsworth.org/labcert/clep/Administrative/ChangeForms.htm>