

NEW YORK STATE DEPARTMENT OF HEALTH  
WADSWORTH CENTER  
CLINICAL LABORATORY EVALUATION  
PROGRAM EMPIRE STATE PLAZA, P.O. BOX 509  
ALBANY, NEW YORK 12201-0509  
Telephone: (518) 485-5378 Fax: (518) 485-5414  
E-mail: [CLEP@health.ny.gov](mailto:CLEP@health.ny.gov)  
Web: [www.wadsworth.org/regulatory/clep](http://www.wadsworth.org/regulatory/clep)

## INITIAL LABORATORY PERMIT APPLICATION INSTRUCTIONS

### GENERAL INFORMATION

These instructions should be read carefully. Incomplete or incorrectly completed applications or failure to submit additional forms as required below will result in a delay in processing. For a detailed description of the application process and program requirements, refer to our Program Guide, particularly the section titled "Application Procedures." This guide is available on our website at <http://www.wadsworth.org/regulatory/clep/clinical-labs>.

If your laboratory is located in New York State (NYS) and performs only those tests defined under the CLIA regulations as a "Waived" or "Provider Performed Microscopy Procedures", you may be eligible to register as a Limited Service Laboratory. If your laboratory services meet this definition, in place of this application complete and submit the Limited Service Laboratory Registration document available on our website at <http://www.wadsworth.org/regulatory/clep/limited-service-lab-certs>.

Section 575 of Article 5, Title V (Laboratory Services) of the Public Health Law requires that the initial application and each renewal application for a permit shall be accompanied by an application fee of \$100.00. This fee is not refundable. Chapter 103, Laws of 1981, passed by the Legislature in 1982, mandated that the Department of Health recover the cost of the State Clinical Laboratory Evaluation Program. This assessment (Inspection and Reference Fee), initially \$1,000.00, is in addition to your registration fee.

The completed application should be returned, together with the required fees of \$1,100.00, to the appropriate address below. Checks should be made payable to the New York State Department of Health.

#### Regular Mail

CLINICAL LABORATORY EVALUATION  
PROGRAM WADSWORTH CENTER  
NEW YORK STATE DEPARTMENT OF HEALTH  
EMPIRE STATE PLAZA, P.O. BOX 509  
ALBANY, NEW YORK 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, NEW YORK 12237

### INSTRUCTIONS FOR COMPLETING THE APPLICATION

**Laboratory Contact Information:** Indicate the individual designated by the director to address regulatory and compliance matters; provide the individual's telephone number and e-mail address. Provide the approximate date when the laboratory will be prepared for an on-site survey.

#### 1. GENERAL LABORATORY INFORMATION

**Name of Laboratory** - Indicate the name of the laboratory EXACTLY as you wish it to appear on your permit. Note that our database cannot support laboratory names greater than **70** characters in length. **SMALL BUSINESS** is defined as one which is independently owned and operated, and employs 100 or fewer individuals. For laboratories this means all employees, both technical and nontechnical.

#### 2. OWNERSHIP INFORMATION

All applications must list the name and address of the individual, partnership or corporation owning the laboratory. Government operated laboratories should identify the sponsoring county, city, municipality or state agency and provide the principal office address of the entity, and the name, title, and address of the administrator(s) responsible for the operation of the laboratory, in conjunction with the director.

Under the New York State Tax Law, you are required to provide your Tax ID or Federal Employer Identification Number (EIN). The authority to request and maintain such information is found in Section 5 of the Tax Law. Disclosure of this information is mandatory. This information can be used by the Department of Taxation and Finance to identify individuals, businesses and others who have been delinquent in filing tax returns or may have understated their tax liabilities and to generally identify persons affected by the taxes administered by the Commissioner of Taxation and Finance. The information can be used for tax administration purposes and for any other purposes authorized by the Tax Law.

All applications must be accompanied by a completed "Disclosure of Ownership and Controlling Interest Statement" (DOH-3486). Complete instructions are included with that form which is available on our website at <http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/application-materials>.

Non-New York State corporations may not do business in New York State until they have been authorized to do so by the New York State Secretary of State. Applications for a Certificate of Authority to do business in New York State may be obtained from the Department of State, Division of Corporations, State Records and Uniform Commercial Code, 99 Washington Avenue, 6<sup>th</sup> floor, Albany, NY 12231. Refer to the Department of State website at [www.dos.ny.gov](http://www.dos.ny.gov). Questions regarding this requirement can be directed to the Division at (518) 473-2492.

### 3. FACILITY TYPE

Indicate the facility type. Check the type that is most descriptive of your facility. If your laboratory is located in New York State and the facility type is marked with an asterisk, please provide a copy of your operating certificate or other state license/certification.

### 4. OTHER APPROVALS

All laboratories must provide their CLIA registration number in the space provided. Under our authority as a CLIA-Exempt State Program, laboratories located in New York State will be assigned a CLIA number by this office once the laboratory is placed in application for a permit. CLIA numbers will appear on your State laboratory permit and laboratories in New York State are not required to hold a separate CLIA certificate. If your laboratory is located in New York State and does not yet have a CLIA registration number, check the box marked "Requested" and a CLIA number will be issued for your facility. If you are a non-NYS laboratory that has applied directly to the CLIA program but have not yet received your CLIA Number, check "Pending." If your laboratory is currently operating as a physician office laboratory (POL), provide your current CLIA registration number.

#### Medicaid Enrollment

Refer to the webpage eMedNY ([www.eMedNY.org](http://www.eMedNY.org)) for instructions on Medicaid enrollment for New York State. The eMedNY Call Center number is 1-800-343-9000.

#### Workers' Compensation

Under the New York State Workers' Compensation Law, businesses applying for permits or licenses issued by the State must hold workers' compensation and disability benefits coverage or document their qualifying for an exemption. Information regarding this requirement and the process for submitting proof of enrollment can be found in the *New York State Workers' Compensation Board Employers' Handbook – A Guide to the Workers' Compensation System for the New York State Business Owner*, available at [www.wcb.ny.gov/content/main/Employers/EmployerHandbook.pdf](http://www.wcb.ny.gov/content/main/Employers/EmployerHandbook.pdf).

### 5. OTHER INFORMATION

If your laboratory plans to operate **PATIENT SERVICE CENTERS (collection stations)**, or **HEALTH FAIRS (temporary off-site testing events)** you must complete and return an "Application for Patient Service Center (Collecting Station)" (form DOH-1589) and/or a Health Fair Application (form DOH-HF). The appropriate forms are available on our website at <http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/patient-service-centers-health-fairs>.

If your laboratory plans to operate a **LIMITED SERVICE LABORATORY** (usually extension clinics offering waived or provider-performed microscopy procedures), you must complete and return an "Application for Limited Service Laboratory" (form DOH-4081) for each site. The appropriate forms are available on our website at <http://www.wadsworth.org/regulatory/clep/limited-service-lab-certs>.

Any laboratory that is operated and/or managed by an individual or entity on behalf of the owner must provide a copy of the written agreement (management contract) setting up the business relationship.

## 6. LABORATORY TESTING

Describe your laboratory facility by answering the questions in section A.

For Section B, all applications must be accompanied by a list of your test offerings to New York State clients. Complete and submit a Test Menu form, available on our website at <http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/application-materials>.

The laboratory must indicate the CMS-approved provider and survey module that has been determined to fulfill CMS proficiency testing requirements for tests/analytes included under CLIA Subpart I (CFR 493.909-493-959). See to the list of CMS-Approved providers at [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency\\_Testing\\_Providers.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html). An acceptable module must be chosen for each analyte on the Test Menu form where proficiency testing is required.

Refer to "Test Approval" section of our website at <http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/testapproval> for information on the process of notification to offer additional tests after this application has been submitted.

## 7. LABORATORY DIRECTORSHIP

**A. Laboratory Director** - The laboratory director must hold a New York State Certificate of Qualification (CQ) in all categories for which he or she indicates responsibility on page five of this application. If the director has not applied for a CQ, an application should be submitted along with this laboratory permit application. The application and instructions are available on our website at <http://www.wadsworth.org/regulatory/clep/certificate-requirements>. Note that NYS recognizes only one director for the laboratory; co-directors are not recognized.

The "CQ Code" is the number assigned to each individual holding a New York State Certificate of Qualification as a laboratory director. This code appears on the upper right-hand corner of each individual's Certificate of Qualification. If you do not yet hold a Certificate of Qualification, indicate whether or not you have applied for one in the spaces indicated. If you previously held a Certificate of Qualification, please record the CQ CODE in the space provided.

"Hours" refers to the time spent by the laboratory director/assistant director(s) **on-site in the laboratory** during the **actual operating hours** of the laboratory when laboratory testing is conducted. If the initial hours information provided in this application changes, notification of the change must be submitted to the Clinical Laboratory Evaluation Program in writing by the director(s). Indicate "Full-Time" status only if you work at no other laboratory and are on-site at least 37.5 hours per week.

**B. Other Employment of Director** - If the director has no other employment (whether or not in a laboratory setting), or other facilities to which he or she provides services, "none" should be written on the first line under Name of Institution/Employer.

**C. Assistant Directors** - See the instructions for item 7A of this application, Laboratory Director. Assistant Directors must hold a Certificate of Qualification in all categories for which they indicate responsibility on page five of this application. If any assistant director has not applied for a Certificate of Qualification, an application should be submitted along with the laboratory permit application. The application and instructions for a Certificate of Qualification are available on our website at <http://www.wadsworth.org/regulatory/clep/certificate-requirements>.

Note that as described in the *Clinical Laboratory Standards of Practice, Director Standard of Practice 3: Responsibilities*, the responsibilities of assistant directors must be specified in writing. If an assistant director is attesting to responsibility for a category, it is expected that documentation is available to demonstrate that the individual is actively engaged in tasks specific to the category or categories. Compliance with this requirement will be monitored during on-site survey.

## 8. PERMIT CATEGORIES

A description of the various permit categories offered is available on our website at <http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/application-materials>. Note carefully the differences between categories and apply only for those categories covering the tests you intend to perform on samples collected in New York State.

For each category, indicate the "CQ Code" for all the individuals responsible for the category. The "CQ CODE" was described previously in these instructions. If the individual responsible for the category does not yet hold a CQ, write the last name(s) of the responsible director and any responsible assistant director(s) next to each applied permit category.

## 9. CERTIFICATION

It is the responsibility of both the director and the owner to ensure that the laboratory meets all legal requirements for operation. Refer to the "Laws and Regulations" section of our website at <http://www.wadsworth.org/regulatory/clep/laws> to review all applicable statutes and regulations, which form the basis of the on-site surveys performed by the program. A description of our policies and procedures is available in the Program Guide found on our website at <http://www.wadsworth.org/regulatory/clep/clinical-labs>.

Names of the director, all assistant directors and the owner should be printed or typed clearly on the last page of the application or on a separate sheet if necessary. Corresponding signatures and dates must be included. Electronic signatures and signature stamps are not acceptable on any article enclosed in an application package.

## GENERAL INFORMATION REGARDING PERMIT CHANGES

All subsequent changes affecting laboratory name, ownership, directorship, or location, and requests for new categories or analytes must be submitted prior to the effective date of the change via eCLEP, our web-based laboratory information management system on the secure NYS Health Commerce System (HCS) website. At a minimum, the laboratory director must have completed the HCS account creation process prior to submitting changes via eCLEP. Visit our webpage at <http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce> for more information on the HCS. Telephone CLEP at (518) 485-5378 if changes must be made before the laboratory director has been granted access to HCS.

*Be advised that Article 5, Title V, Section 575 of New York State Public Health Law stipulates that a laboratory permit is automatically void upon a change of director, owner or location. This same section of Public Health Law allows us to stay the voiding of the permit for a specified period provided proper and timely notification has been made to the department and the laboratory is in good standing with the department.*

## ATTACHMENTS TO THE APPLICATION

### Required for all applications:

- ☐ Check in the amount of \$1,100 payable to the New York State Department of Health
- ☐ Completed Disclosure of Ownership and Controlling Interest Statement
- ☐ Completed HCS Affiliation Request Form
- ☐ Completed Test Menu form

### Other Attachments as Applicable:

- ☐ Certificate of Qualification Application(s) for director and assistant directors (if individuals do not already hold a Certificate), including a \$40.00 application fee for each CQ applicant, payable to the New York State Department of Health
- ☐ Copy of management contract
- ☐ Patient Service Center Application
- ☐ Limited Service Laboratory Registration form
- ☐ Health Fair application