

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.state.ny.us
Web: www.wadsworth.org/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 "Guide to Program Requirements and Services", particularly the section titled "Applying for a Permit." This guide is available on our website at www.wadsworth.org/clep under "Program Guide."

If your laboratory is located in New York State, 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, please complete and submit the Limited Service Laboratory Registration document available on our website at www.wadsworth.org/clep under "Limited Service Labs."

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

PAGE ONE OF THE APPLICATION

Laboratory Contact Information: Please indicate the individual designated by the director to address regulatory and compliance matters; provide the individual's telephone number and e-mail address if different from the laboratory's telephone number and e-mail address. Please also provide the approximate date when the laboratory will be prepared for an on-site survey and receipt of proficiency testing samples, if applicable.

1. General Laboratory Information

Name of Laboratory - Indicate the name of the laboratory EXACTLY as you wish it to appear on your permit. Please note that our database cannot support laboratory names greater than **70** characters in length. Under the New York State Tax Law, you are required to provide your Tax ID or Federal Employer Identification Number (EIN). The authority of the New York State Department of Health, Wadsworth Center, Clinical Laboratory Evaluation Program to request this information, and the authority to 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.

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 non-technical.

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 or municipality 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.

"Address of Principal Office" refers to the address of the principal office of the corporation, partnership or government which owns the laboratory (if applicable).

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 www.wadsworth.org/clep under "Applications and Forms."

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, New York State Secretary of State, 41 State Street, Albany, New York 12231. Questions regarding this requirement can be directed to the Division at (518) 473-2492.

3. Facility Type

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

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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, please 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), please provide your current CLIA registration number.

Questions on Medicaid enrollment should be directed to New York State Department of Health Office of Medicaid Management, Fee for Service Provider Enrollment, 150 Broadway Suite 6E, Albany, NY 12204, telephone (518) 486-9440. Questions on Medicaid policy and reimbursement issues should be directed to the Office of Medicaid Management, Bureau of Policy Development and Agency Relations, NYS Dept. of Health, 1 Commerce Plaza, Room 615, Albany, NY 12210, telephone (518) 473-2160.

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 <http://www.wcb.state.ny.us/content/main/Employers/EmployerHandbook.pdf>.

5. Other Information

If your laboratory plans to operate **PATIENT SERVICE CENTERS (COLLECTING STATIONS)**, or **LIMITED SERVICE LABORATORIES** (usually extension clinics offering waived or provider-performed microscopy testing) you must complete and return an "Application for Patient Service Center (Collecting Station)" (form DOH-1589) or "Application for Limited Service Laboratory" (form DOH-4081) for each site. If the laboratory plans to operate temporary off-site testing events (Health Fairs) a Health Fair Application (form DOH-HF) must be submitted in addition to the Patient Service Center Application. The appropriate forms available on our website at www.wadsworth.org/clep under "Applications and Forms." 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 (i.e. management contract) setting up the business relationship.

6. Laboratory Testing

Please 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. Please refer to "Test Approval" section of our website at www.wadsworth.org/clep for information on the process of notification to offer tests. Please also complete and submit the appropriate category-specific questionnaires available under the "Applications and Forms" section of our website at www.wadsworth.org/clep. This information is required to select the appropriate proficiency test samples that will be provided to your laboratory, as applicable.

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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 Certificate of Qualification, an application should be submitted along with this laboratory permit application. The application and instructions are available on our website at www.wadsworth.org/clep under "Applications and Forms." Please note, 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 is made up of the first four letters of the last name, the first letter of the first name and a sequential number and appears on the upper right-hand corner of each individual's Certificate of Qualification. If you do not yet hold a Certificate of Qualification, please 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 (i.e., 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.

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

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C. Assistant Directors - Please see the instructions for page three of this application, Laboratory Directorship. 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 www.wadsworth.org/clep under "Applications and Forms."

Please 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.

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8. Permit Categories

A description of the various permit categories offered is available on our website at www.wadsworth.org/clep under "Applications and Forms." Please note carefully the differences between categories and apply only for those categories covering the tests you perform or intend to perform on samples collected in New York State. Please also refer to the Category and Test/Analyte Index at the end of the "Guide to Program Requirements and Services" for a listing of common tests and their category section. The Guide can be found on our website at www.wadsworth.org/clep under "Program Guide."

If application is made for any category marked with an asterisk on this page, you must complete and return the appropriate questionnaire(s). Category-specific questionnaires are available at www.wadsworth.org/clep under "Applications and Forms." The laboratory director and the responsible assistant director(s) indicated on page five of the laboratory application must sign and date the questionnaire(s).

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 individuals responsible for the categories do not yet hold a Certificate of Qualification, write the last name(s) of the responsible director and any responsible assistant director(s) next to each permit category you wish to apply for.

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9. Certification

It is the responsibility of both the director and the owner to ensure that the laboratory meets all legal requirements for operation. Please refer to the "Statute and Regulations" section of our website at www.wadsworth.org/clep 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 "Guide to Program Requirements and Services found on our website at www.wadsworth.org/clep under "Program Guide."

Names of the director, all assistant directors and the owner should be printed or typed clearly at the bottom of page six and on a separate sheet if necessary. Corresponding signatures and dates must be included at the right side of the page. 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 on notification forms available from our website at www.wadsworth.org/clep under "Applications and Forms." *Please 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.*