CLINICAL LABORATORY PERMIT APPLICATION

NEW YORK STATE DEPARTMENT OF HEALTH
Clinical Laboratory Evaluation Program
Wadsworth Center
Empire State Plaza
Albany, NY 12237

E-mail: CLEP@health.ny.gov
Web: www.wadsworth.org/regulatory/clep

FOR OFFICE USE ONLY

Rec'd: _____

Fee No: _____

PFI: _____

CLIA No: _____

Please review all application materials for completeness prior to submission. Incomplete or incorrect applications, or failure to submit all required forms and application fees will result in delayed processing. For a detailed description of the application process and program requirements, refer to the CLEP Program Guide, particularly the section titled "Application Procedures." Our program guide is available on our website at http://www.wadsworth.org/regulatory/clep/clinical-labs.

Section 575 of Article 5, Title V (Laboratory Services) of the Public Health Law requires that the initial 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 for operating the Clinical Laboratory Evaluation Program. This assessment (Inspection and Reference Fee), initially $1,000.00, is in addition to your application 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
ALBANY, NEW YORK 12237

Courier Mail Address
CLINICAL LABORATORY EVALUATION PROGRAM
NEW YORK STATE DEPARTMENT OF HEALTH
EMPIRE STATE PLAZA
P1 SOUTH, LOADING DOCK J
ALBANY, NEW YORK 12237

ATTACHMENTS TO THE APPLICATION
Required for all applications:

- ☐ **Check in the amount of $1,100.00 payable to the New York State Department of Health**
- ☐ **Completed Disclosure of Ownership Interest, Controlling Interest, and Corporate Membership Statement, available on our website**
- ☐ **Completed HCS Affiliation Request Form, available on our website**

Other Attachments as Applicable:

- ☐ **Copy of Management Contract**
- ☐ **Limited Service Laboratory Registration Application**
- ☐ **Copy of New York State Department of Health Article 28 Operating Certificate**

GENERAL LABORATORY INFORMATION

Name of Laboratory: (Please limit number of characters to 70)

Address: (Number and Street)

City, Town or Village:	State:	Zip Code:	County:

Telephone Number:	Fax Number:

Email Address:

Testing Hours: (Please clarify hours as AM or PM)

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
From:							
To:							

CLIA Number: ☐ Approved ☐ Pending ☐ Requested (New York State Laboratories Only)

If you currently operate a Limited Service Laboratory (LSL) at the applying location, please provide your LSL's CLIA number above.

To be completed by laboratories holding a NYS Medicaid Provider ID Number for New York State ONLY:

NYS Medicaid Number: ☐ Approved ☐ Pending ☐ Not Requested

LABORATORY POINT OF CONTACT

It is in the best interest of the laboratory to include a contact person other than the laboratory director.

Contact Person Name: (first name, last name)

Contact Person Telephone Number:

Contact Person Email:

FACILITY TYPE

If your laboratory is located in NYS and the facility type is marked with an asterisk, please provide a copy of your Article 28 operating certificate or other state license/certification.

- ☐ 1-14 Hospital
- ☐ 2-03 Ancillary Testing Site in Health Care* Facility/Hospital Extension Clinic
- ☐ 3A-06 D/T Center-Community Clinic*
- ☐ 3B-02 D/T Center-Ambulatory Surgery Center*
- ☐ 3C-08 D/T Center-End Stage Renal Disease* Dialysis Facility
- ☐ 3D-09 D/T Center-Rural Health Clinic/Federally* Qualified Health Center
- ☐ 3E-29 D/T Center-Other*
- ☐ 4-03 Comprehensive Rehabilitation Facility* (Drug/Alcohol Treatment)
- ☐ 5-29 WIC Programs
- ☐ 6-23 Correctional Facilities
- ☐ 7-11 HMO*
- ☐ 8-12 Home Health Agency*
- ☐ 9-13 Hospice*
- ☐ 10 Psychiatric Hospital*
- ☐ 11-15 Independent
- ☐ 12-16 Industrial
- ☐ 13-17 Insurance
- ☐ 14-18 Intermediate Care Facility for the Mentally Retarded*
- ☐ 15-19 Mobile Laboratory
- ☐ 16-20 Pharmacy
- ☐ 17-26 School/Student Health Service
- ☐ 18-27 Skilled Nursing Facility/Nursing Home*
- ☐ 19-21 Physician Office
- ☐ 20-22 Other Practitioner
- ☐ 21 Shared Laboratory
- ☐ 24-01 Ambulance
- ☐ 25-04 Assisted Living Facility*
- ☐ 26-05 Blood Bank
- ☐ 27-24 Public Health Laboratories
- ☐ 28 Tissue Bank/Repositories
- ☐ 99-29 Other (Describe) _____

FACILITY DESCRIPTION

1. Is all laboratory space contiguous? ☐ Yes ☐ No
If the laboratory space is not contiguous, please indicate other location(s) on a separate sheet.
Contiguous space means being in actual contact, adjoined or located in the same building.

2. Is the laboratory located within a shared space? ☐ Yes ☐ No
If the laboratory is located in a shared space, please explain on separate sheet.
Shared space is space occupied by any other health service provider (e.g. physician office, clinic).

OTHER INFORMATION

	YES	NO
1. Is the laboratory currently operating a Limited Service Laboratory? If yes, please provide your laboratory's PFI number. _____	☐	☐
2. Is the laboratory planning to operate a Limited Service Laboratory? If yes, you must complete a separate application. The application can be found at: https://www.wadsworth.org/regulatory/clep/limited-service-lab-certs	☐	☐
3. Is the laboratory planning to operate a fixed transfer station? If yes, a separate application is required and is available upon request.	☐	☐
4. Is the laboratory accredited by other agencies (e.g., Joint Commission, CAP, AOA, AABB, COLA, ASHI)? If yes, please identify agency(ies): _____	☐	☐

LABORATORY DIRECTORSHIP

There must be a doctoral-level individual named as the laboratory director. The laboratory director must hold a New York State Certificate of Qualification (CQ) in all categories for which they indicate responsibility on pages 6 & 7 of this application. If the proposed laboratory director does not already hold a CQ in one or all proposed categories of testing, the CQ application can be found on our website at : https://www.wadsworth.org/regulatory/clep/certificate-requirements. ***Submitting your CQ application at the same time as your Clinical Laboratory Permit application, can delay the Clinical Laboratory Permit application process by eight to twelve weeks.***

CQ Code:	Last 4 digits of Social Security Number:
If you do not have a CQ, have you applied? ☐Yes ☐No	

Degree(s) Held: ☐M.D. ☐D.O. ☐D.D.S. ☐D.V.M. ☐Ph.D. ☐Sc.D.

Director's First Name:	Middle Initial:	Last Name:

Home Address: (Number and Street)

City, Town or Village:	State:	Zip Code:

Laboratory Director Email:

Please enter the average number of hours and frequency of your on-site presence at the laboratory. We assume that the laboratory director may be remotely accessible to the laboratory 24/7. Therefore, do not include remote access hours in the reported hours of on-site presence.

If on-site presence is less frequent than every other week, please choose "Other" and describe your schedule in the Hours Note field below. Note that all reported hours are subject to review and approval by the Department.

_____ Hours ☐Weekly ☐Every Other Week ☐Other

Hours Note:

OTHER EMPLOYMENT OF THE DIRECTOR

If the director of this laboratory serves as director for additional laboratories, please provide the following information.

PFI	CLIA Number	Name of Laboratory

ASSISTANT DIRECTORS

Excluding the director, list personnel serving the laboratory as assistant directors who hold or can qualify for Certificate(s) of Qualification and who will be designated to assume responsibility for tests performed. Note that the responsibilities of assistant directors must be specified in writing.
****A person should not be designated as an assistant director if they do not hold responsibility for a category indicated on pages 6 & 7.***

CQ Code:	Last 4 digits of Social Security Number:
If you do not have a CQ, have you applied? ☐ Yes ☐ No	

Degree(s) Held: ☐M.D. ☐D.O. ☐D.D.S. ☐D.V.M. ☐Ph.D. ☐Sc.D.

Assistant Director's First Name:	Middle Initial:	Last Name:

Home Address: (Number and Street)

City, Town or Village:	State:	Zip Code:

Please enter the average number of hours and frequency of your on-site presence at the laboratory. We assume that the laboratory assistant director may be remotely accessible to the laboratory 24/7. Therefore, do not include remote access hours in the reported hours of on-site presence.

If on-site presence is less frequent than every other week, please choose "Other" and describe your schedule in the Hours Note field below. Note that all reported hours are subject to review and approval by the Department.

Hours ☐Weekly ☐Every Other Week ☐Other

Hours Note:

ASSISTANT DIRECTORS

CQ Code:	Last 4 digits of Social Security Number:
If you do not have a CQ, have you applied? ☐Yes ☐No	

Degree(s) Held: ☐M.D. ☐D.O. ☐D.D.S. ☐D.V.M. ☐Ph.D. ☐Sc.D.

Assistant Director's First Name:	Middle Initial:	Last Name:

Home Address: (Number and Street)

City, Town or Village:	State:	Zip Code:

Please enter the average number of hours and frequency of your on-site presence at the laboratory. We assume that the laboratory assistant director may be remotely accessible to the laboratory 24/7. Therefore, do not include remote access hours in the reported hours of on-site presence.

If on-site presence is less frequent than every other week, please choose "Other" and describe your schedule in the Hours Note field below. Note that all reported hours are subject to review and approval by the Department.

Hours ☐Weekly ☐Every Other Week ☐Other

Hours Note:

Attach additional sheets if necessary.

CATEGORIES OR SUBCATEGORIES FOR WHICH YOU SEEK A LABORATORY PERMIT

A description of the permit categories offered is available on our website at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit. Please note the difference between categories and apply for only those categories covering the tests you intend to perform on specimens from New York.

Check all requested Permit Categories and indicate the responsible person by checking the box under their column:	***Enter the CQ Code or last name for the director and assistant director(s), if any.*** **Director**	**Asst. Dir**	**Asst. Dir**
☐ **Andrology**	☐	☐	☐
☐ **Bacteriology**	☐	☐	☐
☐ **Blood pH and Gases**	☐	☐	☐
Blood Services			
☐ Collection	☐	☐	☐
☐ Collection-Autogeneic Only	☐	☐	☐
☐ Transfusion	☐	☐	☐
☐ Transfusion Storage Only	☐	☐	☐
☐ Plasma Processing	☐	☐	☐
Cellular Immunology			
☐ Leukocyte Function	☐	☐	☐
☐ Malignant Leukocyte Immunophenotyping	☐	☐	☐
☐ Non-Malignant Leukocyte Immunophenotyping	☐	☐	☐
☐ **Clinical Chemistry**	☐	☐	☐
☐ **Cytogenetics**	☐	☐	☐
☐ **Cytokines**	☐	☐	☐
Cytopathology			
☐ Gynecological Testing	☐	☐	☐
☐ Non-gynecological Testing	☐	☐	☐
Diagnostic Immunology			
☐ Diagnostic Services Serology	☐	☐	☐
☐ Donor Services Serology	☐	☐	☐
☐ **Endocrinology**	☐	☐	☐
☐ **Fetal Defect Markers**	☐	☐	☐
☐ **Forensic Identity**	☐	☐	☐
Genetic Testing			
☐ Molecular	☐	☐	☐
☐ Biochemistry	☐	☐	☐

Attach additional sheets for assistant directors if necessary.

CATEGORIES OR SUBCATEGORIES FOR WHICH YOU SEEK A LABORATORY PERMIT (continued)

Enter the CQ Code or last name for the director and assistant director(s), if any.

Check all requested Permit Categories and indicate the responsible person by checking the box under their column:

	Director	Asst. Dir.	Asst. Dir
☐ **Hematology**	☐	☐	☐
☐ **Histocompatibility**	☐	☐	☐
Histopathology			
☐ General	☐	☐	☐
☐ Dermatopathology	☐	☐	☐
☐ Oral Pathology	☐	☐	☐
☐ **Immunohematology**	☐	☐	☐
☐ **Mycobacteriology**	☐	☐	☐
☐ **Mycology**	☐	☐	☐
Oncology			
☐ Soluble Tumor Markers	☐	☐	☐
☐ Molecular and Cellular Tumor Markers	☐	☐	☐
☐ **Parasitology**	☐	☐	☐
☐ **Parentage/Identity Testing**	☐	☐	☐
☐ **Therapeutic Substance Monitoring/ Quantitative Toxicology**	☐	☐	☐
Toxicology			
☐ Blood Lead - Comprehensive	☐	☐	☐
☐ Blood Lead - ASV Using Screen- Printed Sensors	☐	☐	☐
☐ Forensic Toxicology - Initial Testing Only	☐	☐	☐
☐ Forensic Toxicology - Comprehensive	☐	☐	☐
☐ Clinical Toxicology - Qualitative Testing	☐	☐	☐
☐ Clinical Toxicology - Comprehensive	☐	☐	☐
☐ **Trace Elements**	☐	☐	☐
☐ **Transplant Monitoring**	☐	☐	☐
☐ **Virology**	☐	☐	☐
☐ **Wet Mounts**	☐	☐	☐

Attach additional sheets for assistant directors if necessary.

CERTIFICATION

I HAVE REVIEWED COPIES OF THE FOLLOWING DOCUMENTS available on our "Laws & Regulations" website at www.wadsworth.org/regulatory/clep/laws:

	YES	NO
Public Health Law:		
Title I - Communicable Disease, Laboratory Reports and Records		
Article 5, Title V of the Public Health Law - Clinical Laboratory and Blood Banking Services	☐	☐
Article 5, Title VI of the Public Health Law - Laboratory Business Practices		
Article 2, Title II-D of the Public Health Law - Health Care Practitioner Referrals		
Article 27-F, of the Public Health Law - HIV and AIDS Related Information		
Civil Rights Law, Section 79-I - Confidentiality of Records of Genetics Tests		
New York Code of Rules and Regulations (10 NYCRR):		
Part 2 - Communicable Diseases		
Part 19 - Duties and Qualifications of Clinical Laboratory Directors		
Part 22 - Environmental Diseases		
Subpart 34 - Health Care Practitioner Referrals		
Subpart 58-1 - Clinical Laboratories	☐	☐
Subpart 58-2 - Blood Banks		
Subpart 58-3 - Clinical Laboratory Inspection and Reference Fees		
Subpart 58-8 - Human Immunodeficiency Virus (HIV) Testing		
Part 63 - AIDS Testing and The Confidentiality of HIV-Related Information		
Part 67 - Reporting of Blood Lead Levels		
Part 70 - Regulated Medical Waste		
Laboratory Standards, available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-standards	☐	☐

In signing this application, I hereby certify that the information I have given the Department of Health as a basis for obtaining a laboratory permit is true and correct.

I understand that the permit of this laboratory may be revoked, suspended, limited, or annulled if any fact is misrepresented in this application. I acknowledge that that Public Health Law stipulates that a laboratory permit is automatically void upon a change of director, owner or location. **Changes in any of the information in this application must be reported to the Clinical Laboratory Evaluation Program immediately by the laboratory director or owner.** I also understand that additional penalties may apply if I misrepresent, conceal, or fail to disclose facts or information regarding my initial and continuing eligibility for said laboratory permit.

I understand that by signing this application form I agree to any investigation made by the Department of Health to verify or confirm the information I have given or any other investigation in connection with my laboratory permit, or a complaint received by the Department. If additional information is requested, it will be provided in a timely manner by the appropriate staff under the direction of the laboratory director and owner. Further, I understand that, should this application or my status be investigated at any time, I agree to cooperate in such an investigation.

Finally, I understand that all records pertaining to the laboratory in the department's possession will be subject to disclosure to the federal CLIA program.

Print Name of Director	Signature of Director	Date
Print Name of Owner	Signature of Owner/Representative	Date
Print Name of Assistant Director	Signature of Assistant Director	Date
Print Name of Assistant Director	Signature of Assistant Director	Date