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.

Subpart 58-3 of Title 10 of the New York Codes, Rules and Regulations requires collection of a first year accreditation fee of $1,000. This fee is in addition to the 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 for $1,100.00 payable to the New York State Department of Health**
- ☐ **Completed Disclosure of Ownership Interest, Controlling Interest, and Corporate Membership Statement, available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit**

Required only if it applies to your laboratory:

- ☐ **Copy of Management Contract** (if a third party runs the laboratory for the owner)
- ☐ **Copy of Article 28 Operating Certificate** (for NYS health facilities like a hospital or diagnostic center)

GENERAL LABORATORY INFORMATION

Name of Laboratory: (70 character limit)

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 your laboratory already holds an active CLIA number for the applying location, please provide it above. For laboratories located in NY, this could be a CLIA number issued by the Physician Office Laboratory Evaluation Program (POLEP) or a Limited Service Laboratory (LSL) registration.

*****Note a laboratory may not operate under two different CLIA numbers at the same physical location.***

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 LAYOUT

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 DIRECTOR

The laboratory director must hold a Laboratory Director Certificate of Qualification (LDCQ). The application can be found on our website at: www.wadsworth.org/regulatory/clep/certificate-requirements. ***Submitting your LDCQ application at the same time as your Clinical Laboratory Permit application may delay the Clinical Laboratory Permit application process.***

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 will 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.

# of Hours ☐ Weekly ☐ Every Other Week ☐ Other

Hours Note:

OTHER EMPLOYMENT OF THE LABORATORY DIRECTOR

If the laboratory director serves as laboratory director or technical director for additional laboratories, please provide the following information.

PFI	CLIA Number	Name of Laboratory

TECHNICAL DIRECTOR

Staff assuming responsibility for the technical oversight of one or more permit categories listed on pages 6 & 7 must hold a Technical Director Certificate of Qualification. The application can be found on our website at: www.wadsworth.org/regulatory/clep/certificate-requirements. Note that the responsibilities of technical directors must be specified in writing.
*****If the Laboratory Director will also serve as a Technical Director, they do not need to be listed again here.***

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.

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

Home Address: (Number and Street)

City, Town or Village:	State:	Zip Code:

Technical Director Email:

Please enter the average number of hours and frequency of your on-site presence at the laboratory. We assume that the technical director will 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.

# of Hours ☐ Weekly ☐ Every Other Week ☐ Other

Hours Note:

OTHER EMPLOYMENT OF THE TECHNICAL DIRECTOR

If this technical director serves as laboratory director or technical director at additional laboratories, please provide the following information.

PFI	CLIA Number	Name of Laboratory

Attach additional pages for technical directors if necessary.

PERMIT CATEGORIES REQUESTED

A description of the permit categories offered is available on our website at: 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 Technical Director(s) by checking the box under their column:	***Enter the CQ Code(s) of the Technical Director(s) below.*** **Tech. Dir**	**Tech. Dir**	**Tech. Dir**
☐ **Andrology**	☐	☐	☐
☐ **Bacteriology**	☐	☐	☐
☐ **Blood pH and Gases**	☐	☐	☐
Blood Services			
☐ Collection	☐	☐	☐
☐ Collection-Autogeneic Only	☐	☐	☐
☐ Transfusion	☐	☐	☐
☐ Transfusion Storage Only	☐	☐	☐
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			
☐ Biochemistry	☐	☐	☐
☐ Molecular	☐	☐	☐

Attach additional pages for technical directors if necessary.

PERMIT CATEGORIES REQUESTED (continued)

Enter the CQ Code(s) of the Technical Director(s) below.

Check all requested Permit Categories and indicate the responsible Technical Director(s) by checking the box under their column:	**Tech. Dir**	**Tech. Dir**	**Tech. Dir**
☐ **Hematology**	☐	☐	☐
☐ **Histocompatibility**	☐	☐	☐
Histopathology			
☐ General	☐	☐	☐
☐ Dermatopathology	☐	☐	☐
☐ Oral Pathology	☐	☐	☐
☐ **Immunohematology**	☐	☐	☐
☐ **Mycobacteriology**	☐	☐	☐
☐ **Mycology**	☐	☐	☐
☐ **Oncology-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**	☐	☐	☐
☐ **Urinalysis**	☐	☐	☐
☐ **Virology**	☐	☐	☐
☐ **Wet Mounts**	☐	☐	☐

Attach additional pages for technical 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 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 Fee		
Subpart 58-6		
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	☐	☐

By signing this application, the undersigned hereby certifies, acknowledges, and agrees to the following terms and conditions:

1. **Accuracy of Information and Penalties for Misrepresentation:** I certify that all information provided to the Department of Health in support of this laboratory permit application is true, accurate, and complete. I understand that any misrepresentation, concealment, or failure to disclose material facts regarding initial or continuing eligibility may result in the suspension, limitation, revocation, or annulment of the laboratory permit, in addition to any other penalties prescribed by law.
2. **Mandatory Notification of Operational Changes:** Pursuant to the Public Health Law, I acknowledge that a laboratory permit shall become automatically void upon any change in the laboratory's director, owner, or physical location. The laboratory director or owner must immediately report any such changes, or any other modifications to the information contained in this application, to the Clinical Laboratory Evaluation Program.
3. **Consent to Investigation and Cooperation:** I consent to any investigation conducted by the Department of Health to verify the information submitted herein, to review permit eligibility, or to investigate complaints. I agree to cooperate fully with all such investigations and ensure that appropriate staff, under the direction of the laboratory director and owner, provide all requested information in a timely manner.
4. **Federal Disclosure and Inspection Authority:** I acknowledge that all records pertaining to the laboratory in the possession of the Department of Health are subject to disclosure to the federal Clinical Laboratory Improvement Amendments (CLIA) program. Furthermore, if the laboratory is located within New York State, it is subject to federal validation inspections, and I agree to permit federal CLIA personnel entry to the facility for such purposes.

Note: Handwritten signatures are required. Electronic signatures or stamped signatures will result in your application being rejected.

Print Name of Laboratory Director	Signature of Laboratory Director	Date
Print Name of Owner	Signature of Owner/Representative	Date
Print Name of Technical Director	Signature of Technical Director	Date
Print Name of Techincal Director	Signature of Technical Director	Date