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
Web: www.wadsworth.org/regulatory/clep

INITIAL LABORATORY PERMIT APPLICATION

Contact Person:

Title: 1 Dr. 2 Mr. 3 Ms. 4 Miss 5 Mrs.

Contact Person Telephone Number:

Contact Person Email:

Date ready for on-site survey:

FOR OFFICE USE ONLY

Rec'd: ______________________________

Fee No: ______________________________

PFI: ____________

CLIA No: __________________________

1. GENERAL LABORATORY INFORMATION

NAME OF LABORATORY: (Please limit number of characters to 70)

ADDRESS (NUMBER AND STREET)	EMAIL ADDRESS	COUNTY

CITY, TOWN OR VILLAGE	STATE	ZIP CODE	THIS LABORATORY [ ] IS [ ] IS NOT A SMALL BUSINESS

TELEPHONE NUMBER	FAX NUMBER

	Mo	Tu	We	Th	Fr	Sa	Su
Testing Hours	to	to	to	to	to	to	to

2. OWNERSHIP INFORMATION

A. Type of ownership: 1 Individual 2 Partnership 3 Corporation 4 Government Unknown 5 Non-Profit Corporation 6 Government – Local 7 Government – County 8 Government – State 9 Government – Federal

B. Name of owner(s) or corporation:	FEDERAL EMPLOYER ID NO.

C. Owner/corporation address (principal office):

D. List all individuals having direct or indirect ownership or a controlling interest on the Disclosure of Ownership and Controlling Interest Statement (DOH-3486) available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit.

3. FACILITY TYPE

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)

4. OTHER APPROVALS

CLIA NO. Approved Pending Requested (New York State Laboratories Only)

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

NYS MEDICAID NO. Approved Pending Not Requested

5. OTHER INFORMATION

5. OTHER INFORMATION	YES	NO
Is the laboratory operating Patient Service Centers (Collecting Stations) or Limited Service Laboratories? If yes, you must complete a separate application for each (see instructions).		
Is the laboratory operating a mobile courier service?		
Is the laboratory operated under a management contract? If yes, give name of management company and attach a copy of the contract (dollar amounts may be redacted).		
Is the laboratory located within space occupied by any other health service provider? If yes, please explain on separate sheet.		
Is the laboratory accredited by other agencies (i.e. JC, CAP, AOA, AABB, COLA, ASHI, other)? If yes, please identify agency(s):		

6. LABORATORY TESTING

A. Description of the laboratory facility

1. Is all laboratory space contiguous?
   If no, please indicate other location(s).

2. What is the total approximate square footage of the laboratory workspace in square feet?

B. All applications must be accompanied by a list of your test offerings to New York State clients. Please complete and submit a Test Menu form, available on our website at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit. Please refer to our website at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval for information on the process of notification to offer tests after the application has been submitted.

7. LABORATORY DIRECTORSHIP

There must be a doctoral-level individual named as the laboratory director who holds, or can qualify for, a New York State Certificate of Qualification (CQ) as a laboratory director in each permit category. Please specify the hours the director will be available ***on-site*** in the laboratory.

A. Laboratory Director

Degree(s) Held: 1 M.D 2 D. O. 3 D.D.S. 4 D.V.M. 5 Ph.D. 6 D.SC. 7 Sc.D.	CQ Code: Or applied for CQ? Yes No	Last 4 digits of Social Security Number:

First Name:	Middle Name:

Last Name:

Home Address - Number and Street:

City, Town or Village:	State:	Zip Code:

Hours: M to W to F to Su to
Tu to Th to Sa to

Director Status: 1 Full-time 2 Part-time

B. Other Employment of Director

List **ALL** other employers of the director, including private practice, service to other laboratories, and non-health related facilities (e.g., teaching). Provide days of the week and hours per day **on-site** at each location, title and a brief description of duties.

Name and Address of Institution/Employer	Hours: From - To	Title/Duties
	M Tu W Th F Sa Su	
	M Tu W Th F Sa Su	
	M Tu W Th F Sa Su	
	M Tu W Th F Sa Su	

C. Assistant Directors

Excluding the director, list below those 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. Please specify the hours the assistant director(s) will be available **on-site** in the laboratory. All assistant director(s) must sign and date the attestation on page 6. Attach additional sheets if necessary. Responsibility for categories must be indicated on page 5. 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.

Assistant Director

Degree(s) Held: 1 M.D. 2 D. O. 3 D.D.S. 4 D.V.M. 5 Ph.D. 6 D.SC. 7 Sc.D.

CQ Code:

Or applied for CQ? Yes No

Last 4 digits of Social Security Number:

First Name:

Middle Initial:

Last Name:

Home Address - Number and Street:

City, Town or Village:

State:

Zip Code:

Hours: M to W to F to Su to
Tu to Th to Sa to

Assistant Director Status: 1 Full-time 2 Part-time

Assistant Director

Degree(s) Held: 1 M.D. 2 D. O. 3 D.D.S. 4 D.V.M. 5 Ph.D. 6 D.SC. 7 Sc.D.

CQ Code:

Or applied for CQ? Yes No

Last 4 digits of Social Security Number:

First Name:

Middle Initial:

Last Name:

Home Address - Number and Street:

City, Town or Village:

State:

Zip Code:

Hours: M to W to F to Su to
Tu to Th to Sa to

Assistant Director Status: 1 Full-time 2 Part-time

Assistant Director

Degree(s) Held: 1 M.D. 2 D. O. 3 D.D.S. 4 D.V.M. 5 Ph.D. 6 D.SC. 7 Sc.D.

CQ Code:

Or applied for CQ? Yes No

Last 4 digits of Social Security Number:

First Name:

Middle Initial:

Last Name:

Home Address - Number and Street:

City, Town or Village:

State:

Zip Code:

Hours: M to W to F to Su to
Tu to Th to Sa to

Assistant Director Status: 1 Full-time 2 Part-time

8. CATEGORIES OR SUBCATEGORIES FOR WHICH YOU SEEK A LABORATORY PERMIT

Indicate the CQ Code or last name for all individuals (director/assistant director) responsible for each category requested. Attach additional sheets if necessary.

Category	CQ CODE OF 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	
Non-Malignant Leukocyte Immunophenotyping	
Malignant Leukocyte Immunophenotyping	
Clinical Chemistry	
Cytogenetics	....
Cytokines	
Cytopathology	
Gynecological Testing Not Including HPV	....
Non-gynecological Testing	....
Diagnostic Immunology	
Diagnostic Services Serology	....
Donor Services Serology	....
Endocrinology	....
Fetal Defect Markers	....
Forensic Identity	....
Genetic Testing	
Molecular	....
Biochemistry	....
Hematology	....

Category	CQ CODE OF DIR/ASST.DIR
Histocompatibility	....
Histopathology	
General	....
Dermatopathology	....
Oral Pathology	....
Immunohematology	....
Mycobacteriology	....
Mycology	....
Oncology	
Soluble Tumor Markers	....
Molecular and Cellular Tumor Markers	....
Parasitology	....
Parentage/Identity Testing	....
Ther. Sub. Mon./Quant. Toxicology	....
Toxicology	
Blood Lead - Comprehensive	....
Blood Lead - ASV Using Screen-Printed Sensors	....
Forensic Toxicology – Comprehensive	....
Forensic Toxicology – Initial Testing Only	....
Clinical Toxicology - Comprehensive	....
Clinical Toxicology – QualitativeTesting	....
Trace Elements	....
Transplant Monitoring	....
Virology	....
Wet Mounts	....

9. CERTIFICATION	YES	NO
I HAVE REVIEWED COPIES OF THE FOLLOWING DOCUMENTS available on our "Laws & Regulations" website at www.wadsworth.org/regulatory/clep/laws**:**		
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, - 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		

I understand that under section 577.1(a) of the Public Health Law the permit of this laboratory may be revoked, suspended, limited, or annulled if any fact is misrepresented in this application. I acknowledge that 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. **Changes in any of the information in this application must be reported to the Clinical Laboratory Evaluation Program immediately by the laboratory director(s) 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. Further, I understand that offering a false instrument constitutes a crime under the penal law of the State of New York.

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, I will provide it. Further, I understand that, should this application or my status be investigated at any time, I agree to cooperate in such an investigation.

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. Article V, Title 5 of the NYS Public Health Law Section 577 stipulates that misrepresentation in obtaining a laboratory permit or in the operation of a laboratory may be used as grounds to revoke, suspend, or limit the permit as grounds to censure, reprimand, or otherwise discipline the holder. Such misrepresentation may also violate NYS Penal Law Article 175 and subject parties who file a false instrument to criminal prosecution.

THE $1,100.00 REGISTRATION AND INSPECTION AND REFERENCE FEE MUST BE INCLUDED WITH THIS APPLICATION. PLEASE ENCLOSE A CHECK MADE PAYABLE TO THE NEW YORK STATE DEPARTMENT OF HEALTH.

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