

**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/labcert/clep/clep.html**

**INITIAL LABORATORY  
 PERMIT  
 APPLICATION**

Contact Person: \_\_\_\_\_  
 (If not the laboratory director)  
 Title: 1 Dr. 2 Mr. 3 Ms. 4 Miss 5 Mrs. 6 Sr.  
 Contact Person Telephone Number: \_\_\_\_\_  
 Contact Person Email: \_\_\_\_\_  
 Ready for on-site survey on or after: \_\_\_\_\_  
 (Date)  
 Ready to receive proficiency testing samples on or after: \_\_\_\_\_  
 (Date)

**FOR OFFICE USE ONLY**

Rec'd. \_\_\_\_\_  
 Fee No. \_\_\_\_\_  
 PFI: \_\_\_\_\_ Code No.: \_\_\_\_\_  
 CLIA No.: \_\_\_\_\_

**1. GENERAL LABORATORY INFORMATION**

NAME OF LABORATORY: (Please limit number of characters to 70)		FEDERAL EMPLOYER ID NO.
ADDRESS (NUMBER AND STREET)		COUNTY
CITY, TOWN OR VILLAGE		
STATE	ZIP CODE	
LABORATORY TELEPHONE NUMBER	FAX NUMBER	THIS LABORATORY IS IS NOT A SMALL BUSINESS
DAYS AND HOURS WHEN TESTS ARE PERFORMED		
Hours M _____ to _____ Tu _____ to _____ W _____ to _____ Th _____ to _____ F _____ to _____ Sa _____ to _____ Su _____ 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:

C. Owner/corporation address (principal office):

D. List all individuals having direct or indirect ownership or a controlling interest on the enclosed Ownership and Controlling Interest Disclosure Statement form (DOH-3486).

**3. FACILITY TYPE**

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

	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. Applications can be obtained by contacting our office (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.		
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?

B. Laboratory tests performed

List your New York State test menu and indicate the methods used. Please indicate if any of these are in-house developed or "home-brew" methods, and if so, please provide a brief description of the method. For commercially distributed kits, indicate the FDA status of the kit, e.g., approved for In-Vitro Diagnostic use (IVD), Research Use Only (RUO), Investigational Use Only (IUO) or as an Analyte-Specific Reagent (ASR).

**7. TECHNICAL PERSONNEL**

List on the enclosed Facility Personnel Sheet (DOH-709) the technical personnel working in the laboratory. You may attach employee personnel rosters or listings on a disk provided they are set up in the same format. This form may be downloaded from our website at [www.wadsworth.org/labcert/clep/clep.html](http://www.wadsworth.org/labcert/clep/clep.html).

**8. 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:**

	CQ Code:      Or applied for CQ? Yes      No	Social Security Number:
First Name:	Middle Name:	
Last Name:		
Home Address - Number and Street:		
City, Town or Village:	State:	Zip Code:
Hours M _____ to _____ Tu _____ to _____ W _____ to _____ Th _____ to _____ F _____ to _____ Sa _____ to _____ Su _____ to _____		
Director Status: 1      Full-time 2      Part-time	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.	

**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, your 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 read the certification and sign and date this application on page 6. Attach additional sheets if necessary. Responsibility for categories must be indicated on page 5. **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.**

**ASSISTANT DIRECTOR**

Title: 1 Dr. 2 Mr. 3 Ms. 4 Miss 5 Mrs.	CQ Code: _____ Or applied for CQ? Yes No	Social Security Number: _____
First Name: _____		Middle Initial: _____
Last Name: _____		
Home Address - Number and Street: _____		
City, Town or Village: _____		State: _____ Zip Code: _____
Hours M _____ to _____ Tu _____ to _____ W _____ to _____ Th _____ to _____ F _____ to _____ Sa _____ to _____ Su _____ to _____		
Assistant Director Status: 1 Full-time 2 Part-time	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.	

**ASSISTANT DIRECTOR**

Title: 1 Dr. 2 Mr. 3 Ms. 4 Miss 5 Mrs.	CQ Code: _____ Or applied for CQ? Yes No	Social Security Number: _____
First Name: _____		Middle Initial: _____
Last Name: _____		
Home Address - Number and Street: _____		
City, Town or Village: _____		State: _____ Zip Code: _____
Hours M _____ to _____ Tu _____ to _____ W _____ to _____ Th _____ to _____ F _____ to _____ Sa _____ to _____ Su _____ to _____		
Assistant Director Status: 1 Full-time 2 Part-time	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.	

**ASSISTANT DIRECTOR**

Title: 1 Dr. 2 Mr. 3 Ms. 4 Miss 5 Mrs.	CQ Code: _____ Or applied for CQ? Yes No	Social Security Number: _____
First Name: _____		Middle Initial: _____
Last Name: _____		
Home Address - Number and Street: _____		
City, Town or Village: _____		State: _____ Zip Code: _____
Hours M _____ to _____ Tu _____ to _____ W _____ to _____ Th _____ to _____ F _____ to _____ Sa _____ to _____ Su _____ to _____		
Assistant Director Status: 1 Full-time 2 Part-time	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.	

**9. CATEGORIES OR SUBCATEGORIES FOR WHICH YOU SEEK A LABORATORY PERMIT**

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

**CQ CODE OF  
DIR/ASST.DIR**

**CQ CODE OF  
DIR/ASST.DIR**

- Andrology**
- \* Bacteriology**
  - General
  - Gram Stains
  - Other
  - Restricted
- Blood pH and Gases**
- \* Blood Services**
  - Collection
  - Collection-Autogeneic Only
  - Transfusion
  - Transfusion Storage Only
  - Plasma Processing
- \* Cellular Immunology**
  - Lymphoid Function
  - Lymphoid Immunophenotyping
  - T-Lymphoid Immunophenotyping
  - Non-Lymphoid Function
  - Non-Lymphoid Immunophenotyping
  - Malignant Leukocyte Immunophenotyping
- \*Clinical Chemistry**
  - Restricted
- \* Cytogenetics**
  - Cancer
  - Prenatal
  - Restricted
- 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**
  - Cellular Hematology
  - Coagulation
  - Cytohematology Diagnostic
- \* Histocompatibility**
  - General
  - HLA Typing Only
- Histopathology**
  - General
  - Dermatopathology
  - Oral Pathology
- \* Human Immunodeficiency Virus**
  - General
  - Viral Identification
  - Screening Tests Only
- \*Immunochemistry**
- Mycobacteriology**
  - General
  - General-S
  - Smears Only
- Mycology**
  - General
  - Yeast Only
  - \* Antifungal Testing – Yeast Only
  - Direct Detection
  - Restricted
- \* Oncology**
  - Soluble Tumor Markers
  - Molecular and Cellular Tumor Markers
  - Human papillomavirus (HPV) Testing
- \* Parasitology**
  - General
  - Blood – Borne Parasites Only
  - Restricted
- \* Parentage/Identity Testing**
  - \*Ther. Sub. Mon./Quant. Toxicology**
- \*Toxicology**
  - Blood Lead
  - Erythrocyte Protoporphyrin
  - Forensic Toxicology – Comprehensive
  - Forensic Toxicology – Initial Testing Only
  - Clinical Toxicology - Comprehensive
  - Clinical Toxicology – Initial Testing Only
- \*Trace Elements**
- Transplant Monitoring**
- \*Urinalysis**
- Urine Pregnancy Testing**
- \* Virology**
  - General
  - Direct Detection
- Wet Mounts**

Refer to the enclosed "New York State Laboratory Permit Category Descriptions" for the definition of these categories, and complete the enclosed questionnaire(s) for any categories indicated with an (\*) asterisk. If you are using the electronic version of this application, the category descriptions may be downloaded from our website, however category questionnaires must be obtained by contacting the program.

10. CERTIFICATION	YES	NO
<b>I HAVE REVIEWED COPIES OF THE FOLLOWING DOCUMENTS available on our Regulatory Affairs website at <a href="http://www.wadsworth.org/labcert/regaffairs">www.wadsworth.org/labcert/regaffairs</a>:</b>		
<u>Public Health Law:</u> 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		
<u>New York Code of Rules and Regulations (10 NYCRR):</u> 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		
<u>Laboratory Standards</u>		
<p>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. 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.</p> <p>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 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.</p> <p>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.</p>		
<p><b>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.</b></p>		

\_\_\_\_\_  
 Print Name of Director

\_\_\_\_\_  
 Signature of Director

\_\_\_\_\_  
 Date

\_\_\_\_\_  
 Print Name of Owner

\_\_\_\_\_  
 Signature of Owner

\_\_\_\_\_  
 Date

\_\_\_\_\_  
 Print Name of Assistant Director

\_\_\_\_\_  
 Signature of Assistant Director

\_\_\_\_\_  
 Date

\_\_\_\_\_  
 Print Name of Assistant Director

\_\_\_\_\_  
 Signature of Assistant Director

\_\_\_\_\_  
 Date