

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**

FOR OFFICE USE ONLY

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)

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) _____ EMAIL ADDRESS _____ COUNTY _____

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

LABORATORY TELEPHONE NUMBER _____ FAX NUMBER _____ DAYS AND HOURS WHEN TESTS ARE
 PERFORMED
 M _____ to _____ F _____ to _____
 Tu _____ to _____ Sa _____ to _____
 W _____ to _____ Su _____ to _____
 Th _____ to _____

2. OWNERSHIP INFORMATION

A. Type of ownership: 1 [] Individual 2 [] Partnership 3 [] Corporation [] Non-Profit 4 [] Government – Local
 5 [] Government – County 6 [] Government – State 7 [] 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*
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*
Dialysis Facility | [] 15-19 Mobile Laboratory |
| [] 3D-09 D/T Center-Rural Health Clinic/Federally*
Qualified Health Center | [] 16-20 Pharmacy |
| [] 3E-29 D/T Center-Other* | [] 17-26 School/Student Health Service |
| [] 4-03 Comprehensive Rehabilitation Facility*
(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) _____ |

* enclose copy of NYS operating certificate

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.

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. JCAHO, 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? Square Feet _____

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.

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:

Title: 1[<input type="checkbox"/>] Dr. 2[<input type="checkbox"/>] Mr. 3[<input type="checkbox"/>] Ms. 4[<input type="checkbox"/>] Miss 5[<input type="checkbox"/>] Mrs.	CQ Code: Or applied for CQ? Yes [<input type="checkbox"/>] No [<input type="checkbox"/>]	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[<input type="checkbox"/>] Full-time 2[<input type="checkbox"/>] Part-time	Degree(s) Held: 1[<input type="checkbox"/>] M.D. 2[<input type="checkbox"/>] D. O. 3[<input type="checkbox"/>] D.D.S. 4[<input type="checkbox"/>] D.V.M. 5[<input type="checkbox"/>] Ph.D. 6[<input type="checkbox"/>] D.SC. 7[<input type="checkbox"/>] 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. Provide days of the week and hours per day on-site at each location, and give a 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.

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
<input type="checkbox"/> Andrology	* Histocompatibility	
* Bacteriology		<input type="checkbox"/> General
<input type="checkbox"/> General	<input type="checkbox"/> HLA Typing Only
<input type="checkbox"/> Gram Stains	Histopathology	
<input type="checkbox"/> Other	<input type="checkbox"/> General
<input type="checkbox"/> Restricted	<input type="checkbox"/> Dermatopathology
<input type="checkbox"/> Blood pH and Gases	<input type="checkbox"/> Oral Pathology
* Blood Services		* Human Immunodeficiency Virus	
<input type="checkbox"/> Collection	<input type="checkbox"/> General
<input type="checkbox"/> Collection-Autogeneic Only	<input type="checkbox"/> Viral Identification
<input type="checkbox"/> Transfusion	<input type="checkbox"/> Screening Tests Only
<input type="checkbox"/> Transfusion Storage Only	<input type="checkbox"/> *Immunoematology
<input type="checkbox"/> Plasma Processing	Mycobacteriology	
* Cellular Immunology		<input type="checkbox"/> General
<input type="checkbox"/> Lymphoid Function	<input type="checkbox"/> General-S
<input type="checkbox"/> Lymphoid Immunophenotyping	<input type="checkbox"/> Restricted
<input type="checkbox"/> T-Lymphoid Immunophenotyping	<input type="checkbox"/> Restricted -S
<input type="checkbox"/> Non-Lymphoid Function	<input type="checkbox"/> Smears Only
<input type="checkbox"/> Non-Lymphoid Immunophenotyping	Mycology	
<input type="checkbox"/> Malignant Leukocyte Immunophenotyping	<input type="checkbox"/> General
<input type="checkbox"/> *Clinical Chemistry	<input type="checkbox"/> Yeast Only
<input type="checkbox"/> Restricted	<input type="checkbox"/> * Antifungal Testing – Yeast Only
* Cytogenetics		<input type="checkbox"/> Direct Detection
<input type="checkbox"/> Cancer	<input type="checkbox"/> Restricted
<input type="checkbox"/> Prenatal	* Oncology	
<input type="checkbox"/> Restricted	<input type="checkbox"/> Soluble Tumor Markers
<input type="checkbox"/> Cytokines	<input type="checkbox"/> Molecular and Cellular Tumor Markers
Cytopathology		* Parasitology	
<input type="checkbox"/> Gynecological Testing Not Including HPV	<input type="checkbox"/> General
<input type="checkbox"/> Non-gynecological Testing	<input type="checkbox"/> Blood – Borne Parasites Only
<input type="checkbox"/> Human papillomavirus (HPV) Testing	<input type="checkbox"/> Restricted
* Diagnostic Immunology		* Parentage/Identity Testing
<input type="checkbox"/> Diagnostic Services Serology	<input type="checkbox"/> *Ther. Sub. Mon./Quant. Toxicology
<input type="checkbox"/> Donor Services Serology	*Toxicology	
<input type="checkbox"/> *Endocrinology	<input type="checkbox"/> Blood Lead
<input type="checkbox"/> *Fetal Defect Markers	<input type="checkbox"/> Erythrocyte Protoporphyrin
<input type="checkbox"/> Forensic Identity	<input type="checkbox"/> Forensic Toxicology – Comprehensive
* Genetic Testing		<input type="checkbox"/> Forensic Toxicology – Initial Testing Only
<input type="checkbox"/> Molecular	<input type="checkbox"/> Clinical Toxicology - Comprehensive
<input type="checkbox"/> Biochemistry	<input type="checkbox"/> Clinical Toxicology – Initial Testing Only
* Hematology		<input type="checkbox"/> *Trace Elements
<input type="checkbox"/> Cellular Hematology	<input type="checkbox"/> Transplant Monitoring
<input type="checkbox"/> Coagulation	<input type="checkbox"/> *Urinalysis
<input type="checkbox"/> Cytohematology Diagnostic	<input type="checkbox"/> Urine Pregnancy Testing
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.		* Virology	
		<input type="checkbox"/> General
		<input type="checkbox"/> Direct Detection
		<input type="checkbox"/> Herpes Group Viruses Only
		<input type="checkbox"/> Wet Mounts

10. CERTIFICATION	YES	NO
<p>I HAVE RECEIVED AND READ COPIES OF THE FOLLOWING DOCUMENTS (available on the disk enclosed with this application. If you are using the electronic version of this form, these documents are available on our Regulatory Affairs website at www.wadsworth.org/labcert/regaffairs:</p>		
<p><u>Statutes-Public Health Law:</u></p> <p>Title I of the Public Health Law - 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 Section 79-I, New York State Civil Rights Law – Confidentiality of Records of Genetics Tests</p>		
<p><u>New York Code of Rules and Regulations (NYCRR):</u></p> <p>Part 2 of 10NYCRR - Communicable Diseases Part 19 of 10 NYCRR -Duties and Qualifications of Clinical Laboratory Directors Subpart 34 of 10 NYCRR - Health Care Practitioner Referrals Subpart 58-1 of 10 NYCRR - Clinical Laboratories Subpart 58-2 of 10 NYCRR - Blood Banks Subpart 58-3 of 10 NYCRR - Clinical Laboratory Inspection and Reference Fees Subpart 58-8 of 10 NYCRR – Human Immunodeficiency Virus (HIV) Testing Part 63 of 10 NYCRR -AIDS Testing and The Confidentiality of HIV-Related Information Part 67-3 of 10NYCRR –Reporting of Blood Lead Levels Part 70 of 10 NYCRR - Regulated Medical Waste</p>		
<p>Laboratory Standards</p>		
<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 filed with 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.</p> <p>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>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.</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