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 OFF | FICE 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

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

| GENERA | L LABORATO | RY INFORMA | TION | | | | | | |
|---|---|-----------------|-----------------|----------------|-------|-------------|---------------|----------------|---|
| Name of L | _aboratory: (70 | character limi | t) | | | | | | |
| Address: (| (Number and S | treet) | | | | | | | |
| City, Town or Village: | | | | State: | | Zip Code: | | County: | |
| Telephone Number: | | | | | | Fax Number: | | | |
| Email Add | lress: | | | | | | | | |
| Testing H | ours: (Please c | larify hours as | : AM o | r PM) | | | | | |
| l esting in | Monday | Tuesday | | nesday | Th | ursday | Friday | Saturday | Sunday |
| From: | | | | | | _ | | | _ |
| То: | | | | | | | | | |
| - | nber: rrently operate 's CLIA numbe | | Appro ervice | | Pend | Ü | | | aboratories Only) se <i>provid</i> e |
| - | npleted by labo | | ing a N | NYS Med | icaid | Provider | r ID Number f | or New York S | tate ONLY: |
| NYS Medicaid Number: Approved Pending Not Requested | | | | | | i | | | |
| LABORA | TORY POINT | OF CONTACT | - | | | | | | |
| It is in the | e best interest | of the labora | tory to | o includ | e a c | ontact p | erson other t | than the labor | atory director. |
| Contact P | erson Name: (f | irst name, last | t name | ;) | | | | | |
| Contact P | erson Telephor | ne Number: | | | | | | | |
| Contact P | erson 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):

| mu res ho at | ere must be a ust hold a New sponsibility of ld a CQ in on thttps://www.v | v York S n pages e or all p wadswo | State Cells 6 & 7 or propose rth.org/re | rtificate f this app d catego egulatory | of Qualificolication. Ories of testion of the control of the cont | cation (C If the pro sting, the icate-req | Q) in opos e CQ uiren | n all catego sed laborat applicatio nents. Sub | ories f ory di on can mittin | for which th irector does n be found o ng your CQ | ney indicate s not alread on our web application | dy site at |
|-----------------------|---|---|---|--|--|--|--------------------------------|---|---------------------------------------|--|---|------------------|
| | e same time a plication proc | | | | | applicat | ion, | can delay | the C | linical Labo | oratory Per | mit |
| | Code: | | | | | | La | ast 4 digits o | of Soc | ial Security | Number: | |
| lf y | ou do not have | e a CQ, | have you | ı applied | ? Yes | No | | | | | | |
| | gree(s) Held: ector's First N | M.D. ame: | D.O. | D.D.S. | D.V.M. Middle II | Ph.D. | Sc | .D. st Name: | | | | |
| | | | | | | | | | | | | |
| Но | me Address: (| Number | and Stre | eet) | | | | | | | | |
| City | y, Town or Vill | age: | | | | | | State: | Zi | ip Code: | | |
| Lak | poratory Direct | or Emai | l: | | | | | | | | | |
| If o | erefore, do non-site presented in the proval by the urs Note: | nce is le Hours | ess freq Note fie | uent tha Id below | n every o | ther wee at all rep | ek, p orte | lease choo | ose "(| Other" and | describe y | our |
| 0 | THER EMPLO | YMENT | OF THE | DIREC | TOR | | | | | | | |
| | he director of lowing inforn | | boratory | serves | as directo | r for add | lition | al laborato | ories, | please pro | vide the | |
| - - - | PFI | CL | _IA Numl | per | | | N | Name of La | borato | ory | | |
| - | | | | | | | | | | | | |
| | | | | | | | | | | | | |

LABORATORY DIRECTORSHIP

| ASSISTANT DIRECTORS | | | | | |
|---|--------------------------------------|--|---|---|--|
| Excluding the director, list personnel ser qualify for Certificate(s) of Qualification a performed. Note that the responsibilities *A person should not be designated as a category indicated on pages 6 & 7. | and who v s of assist | vill be desig tant director | nated to assurs must be sp | ıme responsibility for tests ecified in writing. | |
| CQ Code: | | | Last 4 digits o | of Social Security Number: | |
| | | | | | |
| If you do not have a CQ, have you applied? | | No So | L | | |
| Degree(s) Held: M.D. D.O. D.D.S. Assistant Director's First Name: | D.V.M. Middle Ir | | Last Name: | | |
| Assistant Director's First Name. | Ivildale II | IIIIaI. | Last Maille. | | |
| Home Address: (Number and Street) | | | | | |
| City, Town or Village: | | | State: | Zip Code: | |
| City, 10wil of Village. | | | State. | Zip Gode. | |
| Assistant Laboratory Director Email: | | | | 1 | |
| If on-site presence is less frequent than eschedule in the Hours Note field below. It by the Department. Hours Note: | | | | | |
| ASSISTANT DIRECTORS | | | | | |
| CQ Code: | | | Last 4 digits o | 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. | | :.D. | | |
| Assistant Director's First Name: | itial: | Last Name: | | | |
| Llarge Address (Newsberg and Office 4) | | | | | |
| Home Address: (Number and Street) | | | | | |
| City, Town or Village: | | | State: | Zip Code: | |
| Assistant Laboratory Director Email: | | | | <u>I</u> | |
| Please enter the average number of hou We assume that the laboratory assistant Therefore, do not include remote access If on-site presence is less frequent than eschedule in the Hours Note field below. | t director hours in every othe | may be ren the reported er week, ple | notely access d hours of on ease choose " | ible to the laboratory 24/7. -site presence. Other" and describe your | |
| approval by the Department. | a a lab : | F | 4la a 10 \ 0 / - | Othern | |
| | eekly | ∟very O | ther Week | Other | |
| Hours Note: | | | | | |
| Attach | additional | sheets if ne | cessary. | | |

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/requlatory/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.

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

Director Asst. Dir Asst. Dir

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

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 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.

Director Asst. Dir. Asst. Dir

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

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 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:

Public Health Law:

YES

NO

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 |