

**NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
CLINICAL LABORATORY EVALUATION PROGRAM
P.O. BOX 509
ALBANY, NY 12201-0509
Telephone: (518) 402-4253 Fax: (518) 485-5414
E-mail: clepltd@wadsworth.org
Web: www.wadsworth.org/labcert**

**LIMITED SERVICE LABORATORY
REGISTRATION INSTRUCTIONS**

A. BACKGROUND AND GENERAL INFORMATION

The New York State Public Health Law requires that “no person shall own or operate a clinical laboratory located in or accepting specimens from New York State . . . unless a valid permit has been issued as provided in section five hundred seventy-five of this title.” The only exception to the permit requirement is for clinical laboratories operated by a licensed physician (**as described in Section B**).

The New York State Department of Health’s Clinical Laboratory Evaluation Program has been authorized under the federal Clinical Laboratory Improvement Amendments (CLIA) to provide oversight to laboratories operating in or accepting specimens from New York State, even if only one or a few basic tests are performed, and even if you are not charging for testing. **NOTE: WAIVED TESTS ARE NOT EXEMPT. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST REGISTER AS A LIMITED SERVICE LABORATORY.**

B. HOW TO DETERMINE IF YOUR FACILITY QUALIFIES FOR THE PHYSICIAN OFFICE EXCEPTION

The only facilities that are exempt from the laboratory permit requirements or Limited Service Laboratory Registration are private physician office laboratories (POLs) operated by individual practitioners or as part of a legally constituted, independently owned and managed partnership or group practice. The tests performed must be conducted by the providers or by their own employees, utilizing their own reagents and instrumentation, solely as an adjunct to the practice of medicine for their patients. POLs must apply to the Physicians Office Laboratory Evaluation Program (POLEP) in order to receive a CLIA number. Information and applications may be obtained by calling POLEP at 518-485-5352.

Laboratories which are set up as a joint venture of several practitioners, partnerships or practices and practices which are owned, managed and/or operated by managed care organizations, hospitals or consulting firms are not included within the POL exemption and must obtain a permit. If you have any question about whether a permit is required, contact the program at 518-402-4253 (voice), 518-485-5414 (fax), or via e-mail at clepltd@wadsworth.org.

C. ADDITIONAL RESOURCES

This Program provides educational materials and technical support to staff from Limited Service Laboratories to assist in implementing a quality testing program within these facilities. An additional resource available to Limited Service Laboratory staff is a document published by the Centers for Disease Control and Prevention (CDC) in November 2005 entitled “Good Laboratory Practices for Waived Testing Sites”. This publication is available on the CDC website at <http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf>.

COMPLETING THE REGISTRATION APPLICATION

These instructions should be read carefully, as submission of incomplete or incorrectly completed applications will result in a delay in processing your application. The completed application should be returned to the address above along with the application fee of \$100.00. Please make checks payable to the New York State Department of Health-Clinical Laboratory Evaluation Program.

The authority for the New York State Department of Health, Wadsworth Center, Clinical Laboratory Evaluation Program to request personal information from you, including identifying numbers such as federal Employer Identification Number (EIN) and Social Security Number, and the authority to maintain such information, is found in Section 5 of the New York State Tax Law. Disclosure of this information by you is mandatory. These numbers are routinely used only as identifiers within our Program. They may only be released for tax administration purposes and other purposes authorized by the Tax Law. The Administrator of the Clinical Laboratory Evaluation Program is responsible for maintaining the records of such information. The administrator can be reached by writing to the Clinical Laboratory Evaluation Program at the address indicated at the top of this page.

1. GENERAL LABORATORY INFORMATION

CLIA Number: If you have already obtained a CLIA certification number, please indicate “yes” and enter the number in this section. If you have not obtained a CLIA certification number, indicate “no” in this section. A CLIA number will then be assigned to your facility.

Laboratory Name: Please indicate the legal name and address exactly as you wish it to appear on your Registration confirmation.

Federal Employer ID Number: Under the New York State Tax Law, you are required to provide your federal Employer Identification Number. If you are a sole proprietor, you must provide your Social Security Number. Disclosure of this information by you is mandatory. A CLIA registration number cannot be issued without this information.

County: Please indicate the New York State county that the laboratory is physically located in.

Laboratory Address: Facility street address must be the actual physical location where testing is performed, including floor, suite and/or room, if applicable.

Mailing Address: Please indicate if the laboratory has a separate mailing address. Our office will use this alternate mailing address for all correspondence with your facility (*SEE: Contact Person designee information below).

Contact Person Name, Telephone Number and E-Mail Address: The contact person is the individual designated by the Laboratory Director as their liaison with our Program. This is the individual that you would like us to direct correspondence to and/or follow-up with should questions arise regarding any of the answers provided in your registration materials.

Laboratory Telephone and Fax Numbers, E-mail Address: These sections are self-explanatory.

Days & Hours of Testing: Please indicate the days and hours when laboratory testing will be performed.

2. LABORATORY TYPE

This information is needed to assign and maintain your CLIA certification. Indicate your laboratory type from the list provided. Please check the type that is most descriptive of your facility.

3. OWNERSHIP INFORMATION

All applications **must** list the name and address of the individual, partnership or corporation that owns the laboratory. “Address of Principal Office” refers to the address of the principal office of the corporation, partnership or government entity, which owns the laboratory. Government operated facilities should identify the sponsoring county, city or municipality and provide the name, title, and address of the administrator responsible for the operation of the laboratory. **An Ownership and Controlling Interest Disclosure Statement, form DOH-3486 must also be completed.** This form is enclosed or is available from our website.

Small Business: A small business is defined as one, which is located in New York State, independently owned and operated, and employs 100 or fewer individuals. This includes all employees, both technical and non-technical.

4. AFFILIATION

If your facility is affiliated with a laboratory, please provide the name, address, and NYS laboratory permit PFI Number (if known). Affiliation refers to actual involvement in the technical performance of the testing performed at your facility, or common staff, supplies, etc. **Do not report the name of your reference laboratory.**

5. MANAGEMENT

If the laboratory testing performed on-site in your facility is performed by an agency other than your own, and is provided under a management or consulting contract, please indicate the name and address of the company that you contract with to perform this testing. **Do not report the name of your reference laboratory.**

6. LABORATORY FACILITIES

Please include all locations at which testing is performed, including community screenings. In the case of community screenings, you must also supply this office with a list of locations that you intend to visit, and a calendar of events (as well as a protocol for all laboratory testing to be performed). You are to give this office advance notice of any additions/deletions to the list of sites. Advance notice of locations at which testing will be offered will enable CLEP to respond to inquiries or concerns.

7. TESTING PERSONNEL

Provide the total number of individuals performing *Waived* and/or *Provider-performed Microscopy Procedures*.

8. DIRECTORSHIP

Please supply information concerning the individual who provides technical and clinical direction of your laboratory testing (i.e. the medical director). ***The laboratory director designee must be a licensed health care practitioner (physician, dentist, PA, NP, or CNM only).*** Please indicate if this person holds a New York State Certificate of Qualification as a laboratory director. If this person does not hold a certificate, check "no" in this section.

9A. TESTING CATEGORIES REQUESTED: **WAIVED TESTING**

Indicate the *Waived* Tests that you wish to perform. **Waived* testing includes tests performed using a kit, device or procedure, which has been designated by the Food and Drug Administration as *Waived* for the purposes of CLIA '88. Sites performing these tests shall maintain a copy of the documentation that the tests in use have been so designated. Listings of waived tests are available at the following websites:

By Test System: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/testswaived.cfm

By Analyte: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/analyteswaived.cfm

To Search a Particular Kit/Mfr.: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

IMPORTANT NOTE: Limited Service Laboratories seeking to offer the *Trinity Biotech Uni-Gold Recombigen HIV-1 Antibody* and/or the *OraQuick ADVANCE Rapid HIV-1/2 Antibody Test(s)* must provide CLEP with a written protocol that addresses such issues as temperature monitoring and maintenance, adequate lighting, level testing surface, kit and reagent (controls) storage, confidentiality, proper disposal of regulated medical waste, arrangements and tracking of confirmatory testing, and follow-up to ensure that individuals who test positive are linked to medical care. In addition, the Limited Service Laboratory must provide documentation of governmental or not-for-profit status.

9B. TESTING CATEGORIES REQUESTED: **PROVIDER-PERFORMED MICROSCOPY PROCEDURES**

Indicate the *Provider-performed Microscopy Procedures* that you wish to perform. **Provider-performed Microscopy Procedures (PPMP)* includes tests personally performed as part of physical examinations by health care providers, licensed and currently registered in New York State, including physicians, dentists, podiatrists, physician assistants, nurse practitioners and certified midwives operating within the scope of practice for their profession and which have been designated as *PPMP* by the Centers for Disease Control. Sites performing these tests shall maintain a copy of the documentation that the tests in use have been so designated.

9C. OTHER TESTS PERFORMED

Please list any other tests that you intend to perform (on-site and/or community screenings). Be sure to include these tests in Sections 10A & 10B where applicable.

10A. TECHNICAL INFORMATION: **WAIVED TESTING**

For each *Waived* test indicated in the Testing Categories Requested (Section 9a), complete the appropriate Technical Information section(s) on page 4.

- Indicate the test procedure (i.e. blood glucose, dipstick urinalysis, fecal occult blood, etc.);
- Indicate the name of the kit, instrument, and manufacturer;
- Indicate the number of tests performed annually (i.e. How many tests do you do per year?). If you do not have an actual figure, please provide an estimate;
- Indicate if a package insert available?
- Indicate if quality control performed?
- Indicate if quality control documented?
- Refer to package insert and describe the manufacturer's recommendations for quality control, which includes the use of external control solutions (hi/low/normal, +/-, etc.) and how often you perform quality control (daily, weekly, monthly, etc.).

10B. TECHNICAL INFORMATION: PROVIDER-PERFORMED MICROSCOPY PROCEDURES

For each Provider-performed Microscopy Procedure indicated in the Testing Categories Requested (Section 9b), complete the appropriate Technical Information section(s) on page 5.

- Indicate the test procedure (i.e. Wet Mounts, KOH Preps, etc.);
- Indicate the number of tests done annually (i.e. How many tests do you do per year?). If you do not have an actual figure, please provide an estimate;
- Indicate the type of personnel performing the test (i.e. M.D., N.P.);
- Describe how personnel performing the test are evaluated for competency and any other quality control performed. Testing personnel should perform either proficiency testing or quality assurance (i.e. split sampling or an external QA program) at least two times per year for documentation of accuracy of the procedures. Perform and document microscope and centrifuge maintenance (i.e. daily, or when tests are performed).

11. CERTIFICATION

This section must be signed by the individual indicated in Section 4 as responsible for the technical and clinical direction of your laboratory testing and the individual completing the application, if different.

CLIA REGISTRATION

Once your application is approved, we will issue an initial CLIA certification number, if you do not already hold one. You will be sent an acknowledgment of your application acceptance, which will serve to verify your enrollment with this program and will also provide documentation of your CLIA certification number.

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FOR OFFICE USE ONLY: I _____ R _____	
Rec'd.	_____
Fee No.	_____
PFI: _____	Code No: _____
CLIA No:	_____

LIMITED SERVICE LABORATORY REGISTRATION

Does your laboratory already have a CLIA number? Yes If yes, please indicate: _____
 No

If this is a new facility, indicate the projected opening date: _____

1. GENERAL INFORMATION			
Laboratory Name (limited to 70 characters):		Federal Employer ID Number:	
		County:	
Laboratory Address (Physical Location of Laboratory):		Mailing Address (if Different From Physical Location):	
City	State	ZIP Code	
Telephone Number:	FAX Number:	Contact Person Name:	
() -	() -	Telephone Number: () -	
Laboratory E-mail Address:		E-mail Address:	
Indicate the Days & Hours when testing will be performed:			
MO _____ to _____	TU _____ to _____	WE _____ to _____	TH _____ to _____
FR _____ to _____	SA _____ to _____	SU _____ to _____	
2. LABORATORY TYPE			
<input type="checkbox"/> 01-3B Ambulatory Surgery Center <input type="checkbox"/> 02-3A Community Clinic <input type="checkbox"/> 03-04 Comprehensive Outpatient Rehabilitation Facility <input type="checkbox"/> 04-02 Ancillary Testing Site in Health Care Facility/Hospital Extension Clinic <input type="checkbox"/> 05-3C End Stage Renal Disease Dialysis Facility <input type="checkbox"/> 06 Health Fair <input type="checkbox"/> 07 Health Maintenance Organization <input type="checkbox"/> 08 Home Health Agency <input type="checkbox"/> 09 Hospice <input type="checkbox"/> 10-01 Hospital <input type="checkbox"/> 11 Independent		<input type="checkbox"/> 12 Industrial <input type="checkbox"/> 13 Insurance <input type="checkbox"/> 14 Intermediate Care Facility for the Mentally Retarded <input type="checkbox"/> 15 Mobile Laboratory <input type="checkbox"/> 16 Pharmacy <input type="checkbox"/> 17 School/Student Health Service <input type="checkbox"/> 18 Skilled Nursing Facility or Nursing Facility <input type="checkbox"/> 23 Rural Health Clinic <input type="checkbox"/> 24-3D Federally Qualified Health Center <input type="checkbox"/> 25 Ambulance <input type="checkbox"/> 26 Public Health Laboratory <input type="checkbox"/> 27-99 Other (Indicate): _____	

3. OWNERSHIP INFORMATION

A. Type of control/ownership. NOTE: A Disclosure of Ownership and Controlling Interest Statement, form DOH-3486 must also be completed and submitted.

Proprietary (indicate): Individual Partnership Corporation

Not-For-Profit (indicate): Religious Affiliation Private

Government (indicate): City County State Federal

B. Name of owner (if sole proprietorship) or corporation:

D. This Facility:

Is a small business

Is not a small business

C. Address of principal office of owner (if sole proprietorship) or corporation:

4. AFFILIATION: If your laboratory is owned by a hospital, please provide the name, address, and NYS laboratory permit PFI Number (if known). Please do not provide the name and PFI Number of your reference laboratory.

Name and Address of Affiliated Hospital Laboratory:

PFI Number: _____

5. MANAGEMENT: If the laboratory testing performed on-site in your facility is performed by an agency other than your own, and is provided under a management or consulting contract, please indicate the name, and address of the company you contract with to perform this testing. Please do not provide the name and PFI Number of your reference laboratory.

Name and Address of Management/Consulting Company:

6. LABORATORY FACILITIES

A. Indicate all locations at which testing is performed, including community screenings. If testing is to be performed at off-site Community Screening events, you must provide a protocol for all tests to be offered, as well as a list of specific locations, and a calendar of events:

B. Laboratory Equipment. List and briefly describe the laboratory equipment and instruments used, (e.g., microscopes, incubators, water baths, sterilizers, centrifuges, glucometers). If needed, use a separate sheet of paper:

7. TESTING PERSONNEL

Indicate the total number of individuals performing waived and PPM procedures:

8. DIRECTORSHIP - Please indicate the individual providing technical and clinical direction of your laboratory testing:

First Name:	M.I.:	Last Name:
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Home Address (Number and Street, City, State & ZIP Code):

Degree(s) and/or License(s) Held:

M.D.
 D. O.
 D.D.S.
 Ph.D.
 D.Sc.
 NP
 PA
 CNM

Social Security Number:	Do you currently hold a New York State Certificate of Qualification (CQ) as a laboratory director? <input type="checkbox"/> Yes CQ Code: _____ <input type="checkbox"/> No
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Director Status:

Full-Time Part-Time

Provide the Laboratory Director's Days and Hours On-Site in the Laboratory:

MO _____ to _____ TU _____ to _____ WE _____ to _____ TH _____ to _____
 FR _____ to _____ SA _____ to _____ SU _____ to _____

9A. WAIVED TESTS: Check off all waived tests that you intend to perform. Complete Technical Update Section-10A on page four for each test checked in this section. NOTE: This is not a complete list of waived tests. For a more comprehensive list, please refer to the attached registration instructions (Section 9-Testing Categories Requested) for links to several FDA websites.

<input type="checkbox"/> Alanine Aminotransferase (<i>ALT</i>) <input type="checkbox"/> Bladder Tumor Associated Antigen <input type="checkbox"/> Cholesterol <input type="checkbox"/> Creatinine <input type="checkbox"/> Drugs of Abuse <input type="checkbox"/> Ethanol <input type="checkbox"/> Follicle Stimulating Hormone (<i>FSH</i>) <input type="checkbox"/> Fructosamine <input type="checkbox"/> Glucose (<i>Fingerstick</i>) <input type="checkbox"/> Glycosolated HGB <input type="checkbox"/> HDL Cholesterol <input type="checkbox"/> Helicobacter Pylori <input type="checkbox"/> Hematocrit <input type="checkbox"/> Hemoglobin <input type="checkbox"/> HIV Antibody (***NOTE: Must Submit Protocol with Registration) <input type="checkbox"/> Influenza	<input type="checkbox"/> Lead <input type="checkbox"/> Lithium <input type="checkbox"/> Microalbumin <input type="checkbox"/> Mononucleosis <input type="checkbox"/> Nicotine (or its metabolites) <input type="checkbox"/> Occult Blood <input type="checkbox"/> Ovulation Tests <input type="checkbox"/> Pregnancy Test (<i>Urine</i>) <input type="checkbox"/> Protime <input type="checkbox"/> Strep Antigen Test (<i>Rapid</i>) <input type="checkbox"/> Triglycerides <input type="checkbox"/> Urinalysis (<i>Dipstick</i>) <input type="checkbox"/> Other (Please Indicate): _____ _____ _____
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9B. PROVIDER-PERFORMED MICROSCOPIC PROCEDURES (PPMP): Check off all PPMP tests that you intend to perform. Complete Technical Update Section – 10B on page five for each test checked in this section.

Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
 Fecal Leukocyte examinations
 Fern tests
 Nasal smears for granulocytes
 Pinworm examinations
 Post-coital direct, qualitative examinations of vaginal or cervical mucous
 Potassium hydroxide (KOH) preparations
 Qualitative semen analysis (limited to the presence/absence of sperm and detection of motility)
 Urine sediment examinations

10A. TECHNICAL INFORMATION: WAIVED TESTS. The following questions should be answered for *each* waived test indicated in Section 9A. Make additional copies of table as needed.

Indicate Test Procedure (Ex: glucose, dipstick urinalysis, etc.).	Indicate the Name of Kit, Instrument, and Manufacturer.	Indicate # of Tests Performed Annually.	Is a Package Insert Available?	Is Quality Control Performed?	Is Quality Control Documented?	Refer to package insert and describe the manufacturer's recommendations for quality control, which includes the use of external control solutions (hi/low/normal, +/-) and how often you perform quality control (daily, weekly, monthly).
			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
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			<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	

11. CERTIFICATION

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 made by them in connection with my request for this laboratory permit. 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 is true and correct.

Print Name of Director	Signature of Director	Date
Print Name of Person Completing this Form	Signature of Person Completing this Form	Date

**The \$100 application fee must be enclosed with your application. Make checks payable to:
New York State Department of Health-Clinical Laboratory Evaluation Program**