

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@health.state.ny.us
Web: www.wadsworth.org/labcert

INITIAL LIMITED SERVICE LABORATORY
REGISTRATION APPLICATION
INSTRUCTIONS

Please follow the instructions carefully since submission of incomplete applications will delay processing and issuance of the registration. **NOTE: You must enclose a \$200.00 application fee payment. Your check or money order should be made payable to:** New York State Department of Health. The check or check stub should indicate the laboratory's name.

A. BACKGROUND AND GENERAL INFORMATION

The New York State Department of Health's Clinical Laboratory Evaluation Program has been authorized under Section 579 of Article 5, Title V of the Public Health Law to provide oversight to facilities performing waived and/or provider-performed microscopy procedures in New York State. These facilities are considered Limited Service Laboratories and must register with the Department as described in this registration package in order to obtain a federal CLIA number and authorization to perform patient testing. **Not-for-profit, state or local government laboratories or programs engaged in limited public health testing not exceeding fifteen types of test per registration may be eligible to apply for a multi-site CLIA number.**

B. PHYSICIAN OFFICE EXCEPTION

The only facilities that are exempt from 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, or the independent practice of a nurse practitioner operating under a practice agreement with a licensed physician. 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. Laboratories that meet the criteria above for a POL 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 do not qualify for the POL exemption and must obtain a Limited Service Laboratory Registration. If you have any question about whether a permit is required, contact our program at 518-402-4253 (voice), 518-485-5414 (fax), or via e-mail at clepltd@wadsworth.org

C. ADDITIONAL RESOURCES

Technical support is available from our program to assist Limited Service Laboratory staff 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

Please note that 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 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. CLIA STATUS AND APPLICATION TYPE

CLIA Number: If you have already obtained a CLIA certification number, please indicate the number in the area provided. If you do not already have a CLIA certification number, one will be assigned to your facility.

Multi-Site Registration: Not-for-profit, state or local government laboratories or programs engaged in limited public health testing not exceeding fifteen types of tests per registration may be eligible to apply for a multi-site CLIA number. One location must be designated as the primary location; this application should be completed for that site. To include secondary locations, complete and include with this application a Limited Service Laboratory Registration Notification to Add Permanent Testing Location to Multi-Site Registration (form, DOH-4081MS). Note that the laboratory director listed on this application will be responsible for all sites operating under a multi-site CLIA number.

2. GENERAL LABORATORY INFORMATION (Note: If you are completing this application for the primary site in a multi-site network, provide the information for that site).

Laboratory Name: Indicate the legal name exactly as you wish it to appear on the Limited Service Laboratory Registration.

Federal Employer ID Number: Under the New York State Tax Law, you are required to provide your federal Employer Identification Number. A CLIA registration number cannot be issued without this information.

County/Borough: Indicate the New York State county or borough that the laboratory is physically located in.

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

Mailing Address: Indicate if the laboratory has a separate mailing address. Our office will use the mailing address for all correspondence with your facility.

Contact Person Name, Telephone Number and E-Mail Address: The contact person is the individual designated by the Laboratory Director as the 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. If you are applying for a multi-site registration, this individual will be the point of contact for all sites within the network.

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

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

Community Screening: Indicate whether your laboratory or laboratory network will perform community screening events. Laboratories seeking approval to operate community screening events must maintain a protocol describing in detail how laboratory testing will be performed.

Permanent off-site locations performing testing should be registered under a multi-site CLIA number using form DOH-4081MS.

3. 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.

4. OWNERSHIP INFORMATION

All applications **must** list the name and address of the individual, partnership or corporation that owns or operates the laboratory or laboratory network. "Address of Principal Office" refers to the address of the principal office of the corporation, partnership or government entity, which owns or operates the laboratory. Government-operated facilities should identify the sponsoring county, city or municipality and provide the name, title, and address of the administrator.

Laboratories indicating not-for-profit status must provide proof by submitting a copy of the organization's IRS letter of determination for nonprofit status or a copy of the organization's NYS Charities Registration Filing. Please note that the form used for making a tax-exempt purchase is not acceptable proof of not-for-profit status.

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.

5. AFFILIATION

If your facility is affiliated with a laboratory holding a New York State permit, 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.**

6. MANAGEMENT

If the laboratory testing performed under this registration is provided under a management or consulting contract, 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.**

7. LABORATORY DIRECTORSHIP

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) or an individual holding a New York State Certificate of Qualification as a laboratory director.** Indicate if the individual holds a Certificate of Qualification. If the director is a health care practitioner, a license number must be provided. Indicate whether the individual is employed at the laboratory on a full-time or part-time basis.

8A. WAIVED TEST PROCEDURES REQUESTED

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:

To Search By Test System: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/testswaived.cfm
To Search 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 approval to perform lead and/or rapid HIV screening(s) **must** provide CLEP with a written protocol detailing how testing is performed in accordance with the manufacturer's requirements. Guidance with protocol development for lead and/or rapid HIV testing is available at the following websites:

For HIV Testing: www.health.state.ny.us/diseases/aids/testing/rapid/index.htm
For Lead Testing: www.wadsworth.org/labcert/clep/Administrative/ChangeForms.htm

8B. PROVIDER-PERFORMED MICROSCOPY PROCEDURES REQUESTED

Indicate the *Provider-performed Microscopy Procedure(s)* 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.

9A. TECHNICAL INFORMATION: WAIVED TEST PROCEDURES

For each *Waived* test indicated in Section 8A-Waived Test Procedures Requested, 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 and/or instrument, and manufacturer;
- Provide an estimate of the total number of tests performed annually (i.e. How many tests do you do per year?).

9B. TECHNICAL INFORMATION: PROVIDER-PERFORMED MICROSCOPY PROCEDURES

For each Provider-performed Microscopy Procedure indicated in Section 8B-Provider Performed Microscopy Procedures Requested, complete the appropriate Technical Information section(s) on page 4.

- Indicate the test procedure (i.e. Wet Mounts, KOH Preps, etc.);
- Provide an estimate of the total number of tests performed annually (i.e. How many tests do you do per year?).

10. CERTIFICATION

This section must be completed & signed by the individual indicated in Section 7–Laboratory Directorship as responsible for the technical and clinical direction of your laboratory testing and the individual completing the application (if different from the Laboratory Director).

CLIA REGISTRATION

Once your application is approved, we will issue an initial CLIA registration number. You will be sent a registration document, which will serve to verify your enrollment with this program and will also provide documentation of your CLIA registration number. If you are applying for a multi-site registration, registration documents for all locations in the network will be sent to the primary location. Registrations are valid for two years from the date issued. Approximately three months before the registration expires, you will receive an application to renew your registration or multi-site registration.

Registrants may only perform the tests listed on the registration document issued by the Department. Multi-site registrants may only perform the tests listed on the registration document issued to the Primary Site.

CHANGES IN STATUS

Once approved, you must keep our Program informed of any changes which may affect your registration status (i.e. laboratory name, address, director, test menu, owner, additional testing sites, etc.). Please be advised that Limited Service Laboratory registrations are void upon change in the laboratory location or the owner. In addition, registrants must inform our Program of any change in location or laboratory director within 30 days of the change. Limited Service Laboratory Change forms may be downloaded from our website at:

<http://www.wadsworth.org/labcert/lep/Administrative/ChangeForms.htm>

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

**INITIAL LIMITED SERVICE LABORATORY
 REGISTRATION APPLICATION**

Please follow the instructions carefully since the submission of incomplete applications will delay the processing and issuance of the registration. **NOTE: You must enclose a \$200.00 application fee payment with your application. Your check or money order should be made payable to: New York State Department of Health.**

1. CLIA STATUS AND APPLICATION TYPE:		
If your laboratory already has a CLIA number, please indicate here: _____		
Type of Limited Service Laboratory Registration Requested (Select <u>One</u>):		
<input type="checkbox"/> Single-Site Registration		
<input type="checkbox"/> Multi-Site Registration (if you wish to add secondary testing sites, please complete form, DOH-4081MS)		
If this is a new facility, indicate the projected opening date: _____		
2. GENERAL INFORMATION: If applying for a multi-site registration, complete this information for the main site.		
Laboratory Name (Limited to 70 Characters):		Federal Employer ID Number:
		County/Borough:
Laboratory Address (Physical Location of Laboratory):		
City:	State:	ZIP Code:
Mailing Address (If Different From Physical Location):		
City:	State:	ZIP Code:
Telephone Number:	FAX Number:	Contact Person Name (If <u>Not</u> the Laboratory Director):
Laboratory E-mail Address:		Telephone Number:
		E-mail Address:
Indicate the Days & Hours when testing will be performed (Please clarify hours as AM and/or PM):		
MO _____ to _____	TU _____ to _____	WE _____ to _____ TH _____ to _____
FR _____ to _____	SA _____ to _____	SU _____ to _____
Indicate whether your laboratory or laboratory network will perform community screening events: <input type="checkbox"/> No <input type="checkbox"/> Yes		

3. LABORATORY TYPE: Select one from the list below that best describes your laboratory.

- | | |
|---|---|
| <input type="checkbox"/> 01-24 Ambulance | <input type="checkbox"/> 13-09 Hospice |
| <input type="checkbox"/> 02-3B Ambulatory Surgery Center | <input type="checkbox"/> 14-01 Hospital |
| <input type="checkbox"/> 03-02 Ancillary Testing Site in Health Care Facility/
Hospital Extension Clinic | <input type="checkbox"/> 15-11 Independent |
| <input type="checkbox"/> 04-25 Assisted Living Facility | <input type="checkbox"/> 16-12 Industrial* (Indicate Bureau License No.: _____) |
| <input type="checkbox"/> 06-3A Community Clinic | <input type="checkbox"/> 17-13 Insurance |
| <input type="checkbox"/> 07-04 Comprehensive Outpatient Rehabilitation Facility | <input type="checkbox"/> 18-14 Intermediate Care Facility for the Mentally Retarded |
| <input type="checkbox"/> 23-06 Correctional Facilities | <input type="checkbox"/> 19-15 Mobile Laboratory |
| <input type="checkbox"/> 07-3C End Stage Renal Disease Dialysis Facility | <input type="checkbox"/> 20-16 Pharmacy |
| <input type="checkbox"/> 09-3D Federally Qualified Health Center | <input type="checkbox"/> 24-27 Public Health Laboratory |
| <input type="checkbox"/> 10-08 Health Fair | <input type="checkbox"/> 25-3D Rural Health Clinic |
| <input type="checkbox"/> 11-07 Health Maintenance Organization | <input type="checkbox"/> 26-17 School/Student Health Service |
| <input type="checkbox"/> 12-08 Home Health Agency | <input type="checkbox"/> 27-18 Skilled Nursing Facility or Nursing Facility |
| | <input type="checkbox"/> 28-99 Other (Indicate): _____ |

4. OWNERSHIP INFORMATION: List the name and address of the individual, partnership or corporation owning or operating the laboratory or laboratory network. "Address of Principal Office" refers to the address of the principal office of the corporation, partnership or government entity, which owns or operates the laboratory or laboratory network.

Type of Control/Ownership (Select Only One From the List Below):

- | | | | |
|----------------------------|--|--------------------------------------|---|
| For-Profit (indicate): | <input type="checkbox"/> Individual | <input type="checkbox"/> Partnership | <input type="checkbox"/> Corporation |
| Not-For-Profit (indicate): | <input type="checkbox"/> Religious Affiliation | <input type="checkbox"/> Private | |
| Government (indicate): | <input type="checkbox"/> City | <input type="checkbox"/> County | <input type="checkbox"/> State <input type="checkbox"/> Federal |

Name of Owner (if Sole Proprietorship) or Corporation:

Street Address of Principal Office of Owner (if Sole Proprietorship) or Corporation:

City:	State:	ZIP Code:
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This Facility: 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.

- Is a small business Is not a small business

5. AFFILIATION: If your laboratory is affiliated with a laboratory holding a NYS permit, provide the name, address, and NYS laboratory permit PFI Number (if known). Do not provide the name and PFI Number of your reference laboratory.

PFI Number:	Name of Affiliated Laboratory:
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Street Address:

City:	State:	ZIP Code:
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6. MANAGEMENT: If the laboratory testing performed on-site in your facility is provided under a management or consulting contract, indicate the name, and address of the company you contract with to perform this testing. Do not provide the name and PFI Number of your reference laboratory.

Name of Management/Consulting Company:

Street Address:

City:	State:	ZIP Code:
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7. LABORATORY DIRECTORSHIP: Complete this section in its entirety for the individual providing technical and clinical direction of your laboratory testing.

First Name:	M.I.:	Last Name:
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Do you currently hold a NYS Laboratory Director Certificate of Qualification?

Yes CQ Code: _____ No

Check Degree(s) and License(s) Held & Indicate License Number Below:

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

Provide License Number: _____

Indicate whether the Laboratory Director is employed at the laboratory on a full-time or part-time basis (Select One):

Director Status: Full-Time Part-Time

8A. WAIVED TEST PROCEDURES REQUESTED: Check off all waived tests that you intend to perform. *NOTE: This is not a complete list of waived tests. For a more comprehensive list, refer to the attached registration instructions Section 8A – Waived Test Procedures Requested for links to several FDA websites. Complete Section 9A-Technical Information: Waived Test Procedures for each test checked in this section.

<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: Submit Testing Protocol w/Registration) <input type="checkbox"/> Influenza	<input type="checkbox"/> LDL Cholesterol <input type="checkbox"/> Lead (*Note: Submit Testing Protocol w/Registration) <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"/> Thyroid-Stimulating Hormone (<i>TSH</i>) <input type="checkbox"/> Triglycerides <input type="checkbox"/> Urinalysis (<i>Dipstick</i>) <input type="checkbox"/> Other (Please Indicate): _____
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8B. PROVIDER-PERFORMED MICROSCOPY PROCEDURES (PPMP) REQUESTED: Check off all PPM Procedures that you intend to perform. NOTE: Only providers (physicians, nurse practitioners, nurse midwives and physician assistants) may perform testing. Complete Section 9B - Technical Information: Provider-performed Microscopy Procedures 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

9A. TECHNICAL INFORMATION: WAIVED TEST PROCEDURES. The following information <u>must</u> be provided for each waived test indicated in Section 8A-Waived Test Procedures Requested. Make additional copies of table as needed and attach to the application.		
Indicate Test Procedure (Ex: fingerstick glucose, dipstick urinalysis, etc.).	Indicate the Name of the Kit and/or Instrument, <u>and</u> the Name of the Manufacturer of the Device.	Estimate the Total Number of Tests Performed Annually.

9B. TECHNICAL INFORMATION: PROVIDER-PERFORMED MICROSCOPY PROCEDURES. The following information <u>must</u> be provided for each Provider-performed Microscopy test indicated in Section 8B-Provider Performed Microscopy Procedures Requested. Make additional copies of table as needed and attach to the application.	
Indicate Test Procedure.	Estimate the Total Number of Tests Performed Annually.

10. 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 provided herein or adjunctive to this application, and any investigation in connection with my laboratory registration, a complaint or incident report made known to 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.

I understand that under Section 579 of the Public Health Law the registration of this limited service 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 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 limited service laboratory registration. Further, I understand that misrepresentation may constitute offering a false instrument, which is a crime under New York State Penal Law.

By signing this application, I hereby attest that the information I have given the Department of Health as a basis for obtaining a limited service laboratory registration is true and correct, that I have read the relevant rules and regulations, and that I accept responsibility for the categories indicated in Section(s) 8A- Waived Test Procedures Requested and/or 8B- Provider Performed Microscopy Procedures Requested of this application.

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