NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM
WADSWORTH CENTER P.O. BOX 509
ALBANY, NEW YORK 12201-0509

LIMITED TESTING 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)**.

Additionally, the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), requires that all facilities performing clinical laboratory procedures register with the federal Centers for Medicare and Medicaid (CMS), formerly known as the Health Care Financing Administration. One of the requirements for such registration is compliance with state law. The Department of Health Clinical Laboratory Evaluation Program (CLEP) was granted exempt status under CLIA '88. All facilities required to obtain a clinical laboratory permit must obtain their CLIA registration numbers from CLEP. **CLIA registration numbers will not be issued or reissued unless the facility has applied for a New York State clinical laboratory permit.**

However, in an effort to enhance patient management, a limited testing registration process was established for facilities that perform only *Waived* and/or *Provider-performed Microscopy Procedures (PPMP).* *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 the CLIA'88. Sites performing these tests shall maintain a copy of the documentation that the tests in use have been so designated. *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.

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 testing 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 submit a CMS-116 to CMS in order to receive a CLIA number. Information and applications may be obtained by calling the Physician Office Laboratory Evaluation Program at 518-485-5352.

However, 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 518-485-5391(voice), 518-485-5414 (fax), or via e-mail at CLEP@health.state.ny.us.

DOH-4081(i) (04/03)

COMPLETING THE 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. 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: Clinical Laboratory Evaluation Program, Wadsworth Center, New York State Department of Health, Empire State Plaza, PO Box 509, Albany, NY 12201-0509.

1. GENERAL FACILITY INFORMATION

Name and Address of Facility: Please indicate the legal name and address exactly as you wish it to appear on your permit and include any specific mailing information such as room or suite numbers.

Federal Employer ID Number: Under the New York State Tax Law, you are required to provide your federal Employer Identification Number, Social Security Number, or both if available. Disclosure of this information by you is mandatory. The principle purpose for which the information is collected is to enable the Department of Taxation and Finance to identify individuals, businesses and others who have been delinquent in filing tax returns or may have understated their tax liabilities and to generally identify persons affected by the taxes administered by the Commissioner of Taxation and Finance. The information will be used for tax administration purposes and for any other purposes authorized by the Tax Law. A CLIA registration number cannot be issued without this information.

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.

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

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

2. FACILITY TYPE

This information is needed to assign and maintain the CLIA certificate. Indicate facility 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 Disclosure Statement" (DOH-3486) **must** also be completed. This form is enclosed or is available from our website.

4. MANAGEMENT
If your facility is affiliated through ownership or management contract with any laboratory under permit to this department or another organization which provides technical support, supervision or direction, please indicate the name and the laboratory permit PFI number, if applicable. 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. LABORATORY FACILITIES
Please include all locations at which testing is performed including community screenings. Additions and deletions to the list must be submitted to the Department.

6. TESTING PERSONNEL
This section is self-explanatory.

7. DIRECTORSHIP
Please provide information concerning the individual who provides technical and clinical direction of your laboratory testing. The director must be a licensed health care practitioner (physician, dentist, PA, NP, or CNW). 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.

8. TESTING CATEGORIES REQUESTED
Indicate the tests you are performing and annual test volumes. If you do not have an actual figure for your annual test volumes, please provide an estimate. Performance of tests not categorized as waived or PPMP will require that your laboratory obtain a full laboratory permit. A listing of all waived tests is available at the following websites:

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

9. CERTIFICATION
This section must be signed by the individual indicated in Section 7 as responsible for the direction of the testing performed and the individual completing the application, if different. If the facility is affiliated with another laboratory which holds a permit, the director of the permitted lab must also sign the application.

CLIA REGISTRATION

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

NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM
WADSWORTH CENTER
EMPIRE STATE PLAZA, P.O. BOX 509
ALBANY, NEW YORK 12201-0509

LIMITED TESTING REGISTRATION

FOR OFFICE USE ONLY

Rec'd._____

Fee No._____

PFI: _____ Code No: _____

CLIA No: _____

Contact Person:
_____

Telephone Number:_____ Email:_____

If New Facility, Projected Opening Date:_____

1. GENERAL INFORMATION

NAME OF FACILITY (Please limit number of characters to 70):			FEDERAL EMPLOYER ID NO.:
ADDRESS (NUMBER AND STREET):			COUNTY:
CITY, TOWN OR VILLAGE:	STATE:	ZIP CODE:	THIS FACILITY [ ] IS [ ] IS NOT A SMALL BUSINESS

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 _____

CLIA NUMBER: Does your facility already have a CLIA number? [ ] Yes [ ] No If yes, please indicate: _____	E-MAIL ADDRESS: If you can be reached by e-mail, please provide your e-mail address: _____

2. FACILITY TYPE

01 [ ] Ambulatory Surgery Center	16 [ ] Pharmacy
02 [ ] Community Clinic	17 [ ] School/Student Health Service
03 [ ] Comprehensive Outpatient Rehabilitation Facility	18 [ ] Skilled Nursing Facility or Nursing Facility
04 [ ] Ancillary Testing Site in Health Care Facility / Hospital Extension Clinic	20 [ ] Other Practitioner (Indicate): _____
05 [ ] End Stage Renal Disease Dialysis Facility	21 [ ] Tissue Banks/Repositories
06 [ ] Health Fair	23 [ ] Rural Health Clinic/Federally Qualified Health Center
07 [ ] Health Maintenance Organization	24 [ ] Ambulance
08 [ ] Home Health Agency	25 [ ] Other (Indicate): _____
09 [ ] Hospice	
10 [ ] Hospital	
11 [ ] Independent	
12 [ ] Industrial	
13 [ ] Insurance	
14 [ ] Intermediate Care Facility for the Mentally Retarded	
15 [ ] Mobile Laboratory	

3. OWNERSHIP INFORMATION

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

[ ] Proprietary
[ ] Not-For-Profit Corporation (indicate):
[ ] Religious Affiliation [ ] Private
[ ] Government (indicate):
[ ] City [ ] County [ ] State [ ] Federal
[ ] Other (indicate): _____

B. Name of owner(s) or corporation:

C. Address of principal office of owner/corporation:

4. MANAGEMENT

If your laboratory is affiliated with another laboratory, which holds a permit from this program, please indicate the name and PFI Number of the laboratory (if known). Do <u>not</u> provide the name and PFI Number of your reference laboratory:

NAME OF LABORATORY:

PFI Number: _____

5. LABORATORY FACILITIES

A. Indicate ALL locations at which testing is performed, including community screenings:

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:

6. TESTING PERSONNEL

Total Number of individuals performing waived and PPM procedures:

7. DIRECTORSHIP

A. Please indicate the individual providing technical and clinical direction of your laboratory testing:

First Name:	M.I.:	Last Name:

Home Address:

Number and Street:

City, Town or Village, Zip Code:

Social Security Number:	Do you currently hold a New York State Certificate of Qualification (CQ) as a laboratory director? Yes [ ] CQ Code: _____ No [ ]

Hours On-site in the Laboratory:

M _____ to _____ W _____ to _____ F _____ to _____ Su _____ to _____

Tu _____ to _____ Th _____ to _____ Sa _____ to _____

Director Status: [ ] Full-time [ ] Part-time

Degree(s) and/or Licenses Held: 1[ ] M.D. 2[ ] D. O. 3[ ] D.D.S. 4[ ] D.V.M.

5[ ] Ph.D. 6[ ] D.SC. 7[ ] PNP 8[ ] PA 9[ ] CNM

10[ ] Other (Please specify): _____

B. Other Employment of Director. List all other directorships held by the director, including the CLIA number of each facility. If needed, use a separate sheet of paper:

Name and Address of Institution/Employer:	CLIA Number:

8. TESTING CATEGORIES REQUESTED: Please check off the testing category you are requesting and indicate the tests you are performing, or intend to perform.

MICROBIOLOGY: BACTERIOLOGY AND VIROLOGY Annual Test Volume: _____

[ ] Rapid strep antigen Name of kit: _____ Name of manufacturer: _____
[ ] Influenza A Name of kit: _____ Name of manufacturer: _____
[ ] H. pylori (presumptive identification) Name of kit: _____ Name of manufacturer: _____

CHEMISTRY Annual Test Volume: _____

[ ] Blood glucose, by glucose monitoring devices approved by the FDA for home use
Name of instrument: _____ Name of manufacturer: _____
[ ] Blood cholesterol, by cholesterol monitoring device approved by the FDA for home use
Name of instrument: _____ Name of manufacturer: _____
[ ] Cholestech LDX system for total cholesterol, HDL cholesterol, triglycerides, glucose
[ ] Glycosylated Hemoglobin (HgbA1C)
Name of instrument: _____ Name of manufacturer: _____
[ ] LXN Fructosamine Test System

DIAGNOSTIC IMMUNOLOGY Annual Test Volume: _____

[ ] Rapid Mono (whole blood) Name of kit: _____ Name of manufacturer: _____
[ ] Bladder tumor antigen Name of kit: _____ Name of manufacturer: _____
[ ] H. pylori (whole blood antigen detection) Name of kit: _____ Name of manufacturer: _____

ENDOCRINOLOGY Annual Test Volume: _____

[ ] Ovulation tests-visual color for human luteinizing hormone Name of kit: _____ Name of manufacturer: _____
[ ] Urine pregnancy test-visual color comparison Name of kit: _____ Name of manufacturer: _____

HEMATOLOGY AND MISCELLANEOUS TESTS Annual Test Volume: _____

[ ] Hemoglobin-copper sulfate method or other non-automated method (indicate method) : _____ [ ] Spun microhematocrit [ ] Wampole STAT-CRIT
[ ] Hemoglobin by copper sulfate or by single analyte instruments
Name of instrument: _____ Name of manufacturer: _____
[ ] Erythrocyte sedimentation rate (non-automated)
[ ] Prothrombin time Name of instrument: _____ Name of manufacturer: _____

TOXICOLOGY Annual Test Volume: _____

[ ] Saliva Alcohol Test Name of kit: _____ Name of manufacturer: _____
[ ] Urine Drug Test Name of kit: _____ Name of manufacturer: _____

URINALYSIS AND MISCELLANEOUS TESTS Annual Test Volume: _____

[ ] Dipstick or tablet reagent urinalysis (non-automated) [ ] Bayer Clinitek 50 Analyzer
[ ] SmithKline Gastroccult-gastric occult blood [ ] Fecal occult blood
[ ] Body fluid pH (other than blood)-all qualitative color comparison pH testing

PROVIDER PERFORMED MICROSCOPIC PROCEDURES Annual Test Volume: _____

[ ] Potassium hydroxide (KOH) preparations [ ] Pinworm examinations
[ ] Wet Mounts [ ] Fern tests
[ ] Nasal smears for eosinophils [ ] Fecal leukocyte examinations
[ ] Urinalysis, microscopic only
[ ] Qualitative semen analysis (limited to the presence or absence of sperm and/or detection of motility)
[ ] Post-coital direct, qualitative examination of vaginal or cerival mucus

OTHER TESTS Annual Test Volume: _____

List Test, Method or Instrument Used. If needed, use a separate sheet of paper.

9. 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**
********* FOR AFFILIATED LABORATORIES ONLY ********* **(Complete Area Below Only If You Answered Section 4. Management on Page 2 of This Document)**		
Print Name of Director of Affiliated Laboratory	**Signature of Director of Affiliated Laboratory**	**Date**

The $100.00 application fee must be enclosed with your application. Make checks payable to: New York State Department of Health.