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) 402-4253 Fax: (518) 449-6902
E-mail: CLEPLtd@health.ny.gov
Web: www.wadsworth.org/regulatory/clep/limited-service-lab-certs

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. **This fee is non-refundable.**

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 One):

- ☐ Single-Site Registration
- ☐ 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: (Note: If applying for a multi-site registration, complete this information for the primary 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 Not 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 off-site community screening events:

☐ No ☐ Yes

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

- ☐ 01-*24* Ambulance
- ☐ 02-*3B* Ambulatory Surgery Center
- ☐ 03-*02* Ancillary Testing Site in Health Care Facility/ Hospital Extension Clinic
- ☐ 04-*25* Assisted Living Facility
- ☐ 05-*26* Blood Bank
- ☐ 06-*3A* Community Clinic
- ☐ 07-*04* Comprehensive Outpatient Rehabilitation Facility
- ☐ 23-*06* Correctional Facilities
- ☐ 08-*3C* End Stage Renal Disease Dialysis Facility
- ☐ 09-*3D* Federally Qualified Health Center
- ☐ 10-*08* Health Fair
- ☐ 11-*07* Health Maintenance Organization
- ☐ 12-*08* Home Health Agency
- ☐ 13-*09* Hospice
- ☐ 14-*01* Hospital
- ☐ 15-*11* Independent
- ☐ 16-*12* Industrial* (Indicate Bureau License Number: _____)
- ☐ 17-*13* Insurance
- ☐ 18-*14* Intermediate Care Facility for the Mentally Retarded
- ☐ 19-*15* Mobile Laboratory
- ☐ 20-*16* Pharmacy
- ☐ 21-*19* Physician Office
- ☐ 22-*20* Practitioner Other
- ☐ 24-*27* Public Health Laboratory
- ☐ 25-*3D* Rural Health Clinic
- ☐ 26-*17* School/Student Health Service
- ☐ 27-*18* Skilled Nursing Facility or Nursing Facility
- ☐ 28-*28* Tissue Bank/Repositories
- ☐ 29-*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 (Check Only <u>One</u> Box From the List Below):

For-Profit (indicate):	☐ Individual	☐ Partnership	☐ Corporation	
Not-For-Profit (indicate):	☐ Religious Affiliation	☐ Private		
Government (indicate):	☐ City	☐ County	☐ State	☐ 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:

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 <u>not</u> a small business

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

PFI Number:	Name of Affiliated Laboratory:

Street Address:

City:	State:	ZIP Code:

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 <u>not</u> provide the name and PFI Number of your reference laboratory.

Name of Management/Consulting Company:

Street Address:

City:	State:	ZIP Code:

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:

Do you currently hold a NYS Laboratory Director Certificate of Qualification?

☐ Yes (Indicate CQ Code): _____ ☐ No

Check Degree(s) and License(s) Held (Include a Copy of Current New York State Professional License):

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

Indicate New York State Professional 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

8. WAIVED TEST PROCEDURES REQUESTED: Check off all waived tests that you intend to perform and indicate the estimated annual test volume for all waived tests to be performed.

☐ Adenovirus	☐ Erythrocyte Sedimentation Rate *(ESR)*	☐ Occult Blood
☐ Aerobic/Anaerobic Organisms-Vaginal	☐ Ethanol	☐ Ovulation Tests
☐ Alanine Aminotransferase *(ALT)*	☐ Follicle Stimulating Hormone (*FSH*)	☐ pH
☐ Albumin	☐ Fructosamine	☐ Phosphorous
☐ Alkaline Phoshatase *(ALP)*	☐ Gamma Glutamyl Transferace *(GGT)*	☐ Platelet Aggregation
☐ Amylase	☐ Glucose	☐ Potassium
☐ Aspartate Aminotransferase *(AST)*	☐ Glycosylated Hemoglobin	☐ Pregnancy Test (*Urine*)
☐ B-Type Natriuretic Peptide *(BNP)*	☐ HDL Cholesterol	☐ Protime
☐ Bacterial Vaginosis, Rapid	☐ Helicobacter Pylori	☐ RSV *(Respiratory Syncytial Virus)*
☐ Bladder Tumor Associated Antigen	☐ Hematocrit	☐ Saliva Alcohol
☐ Blood Urea Nitrogen *(BUN)*	☐ Hemoglobin	☐ Sodium
☐ Breath Alcohol *(FDA OTC Devices Only)*	☐ HCV, Rapid	☐ Strep Antigen Test (*Rapid*)
☐ Calcium	☐ HIV, Rapid	☐ Thyroid-Stimulating Hormone *(TSH)*
☐ Calcium, Ionized	☐ Influenza	☐ Total Bilirubin
☐ Carbon Dioxide	☐ Ketones	☐ Total Protein
☐ Catalase *(Urine)*	☐ Lactic Acid *(Lactate)*	☐ Trichomonas, Rapid
☐ Chloride	☐ LDL Cholesterol	☐ Triglycerides
☐ Cholesterol	☐ Lead *(*Submit Protocol w/App.)*	☐ Urinalysis
☐ Creatine Kinase *(CK)*	☐ Microalbumin	☐ Other: _____
☐ Creatinine	☐ Mononucleosis	
☐ Drugs of Abuse	☐ Nicotine	

	Indicate the combined estimated annual test volume for <u>all</u> Waived Test Procedures indicated above:

9. PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES 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.

- ☐ 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

	Indicate the combined estimated annual test volume for <u>all</u> PPM Procedures indicated above:

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. Registration under this subdivision may be denied, limited, suspended, revoked or annulled by the Department upon a determination that a laboratory services registrant: (i) failed to comply with the requirements of this subdivision; (ii) provided services that constitute an unwarranted risk to human health; (iii) intentionally provided any false or misleading information to the Department relating to registration or performing laboratory services; or (iv) has demonstrated incompetence or shown consistent errors in the performance of examinations or procedures. 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.

Laboratory test registrants shall: (i) provide only the tests and services listed on the registration issued by the Department hereunder; (ii) advise the Department of any change in the registrant's name, ownership, location or qualified health care professional or laboratory director designated to supervise testing within thirty days of such change; (iii) provide the department with immediate access to all facilities, equipment, records, and personnel as required by the Department to determine compliance with this subdivision; (iv) comply with all public health law and federal requirements for reporting reportable diseases and conditions to the same extent and in the same manner as a clinical laboratory; (v) perform one or more tests as required by the department to determine the proficiency of the persons performing such tests; and (vi) designate a qualified health care professional or qualified individual holding a certificate of qualification pursuant to section five hundred seventy-three of this title, who shall be jointly and severally responsible for the testing performed.

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 tests indicated in Section(s) 8. Waived Test Procedures Requested and/or 9. Provider-Performed Microscopy (PPM) 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

SPECIAL NOTICE

The submission of incomplete and/or incorrect application materials will delay processing. Required information includes, but is not limited to the following:

- $200.00 Application Fee (*Volunteer Ambulances Services Refer to Page - 1 of the Instructions*);
- A Working E-Mail Address;
- A Copy of Laboratory Director's Current New York State Professional License;
- Estimated Annual Test Volumes for Waived and/or PPM Procedures;
- Name & Original Signature of Laboratory Director and Individual Completing Application. Signature stamps will <u>not</u> be accepted.