

**NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
CLINICAL LABORATORY EVALUATION PROGRAM
P.O. BOX 509
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E-mail: clepltd@wadsworth.org
Web: www.wadsworth.org/labcert**

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"/> 02-3B Ambulatory Surgery Center <input type="checkbox"/> 03-02 Ancillary Testing Site in Health Care Facility/ Hospital Extension Clinic <input type="checkbox"/> 04-25 Assisted Living Facility <input type="checkbox"/> 06-3A Community Clinic <input type="checkbox"/> 07-04 Comprehensive Outpatient Rehabilitation Facility <input type="checkbox"/> 23-06 Correctional Facilities <input type="checkbox"/> 07-3C End Stage Renal Disease Dialysis Facility <input type="checkbox"/> 09-3D Federally Qualified Health Center <input type="checkbox"/> 10-08 Health Fair <input type="checkbox"/> 11-07 Health Maintenance Organization <input type="checkbox"/> 12-08 Home Health Agency	<input type="checkbox"/> 13-09 Hospice <input type="checkbox"/> 14-01 Hospital <input type="checkbox"/> 15-11 Independent <input type="checkbox"/> 16-12 Industrial* (Indicate Bureau License No.: _____) <input type="checkbox"/> 17-13 Insurance <input type="checkbox"/> 18-14 Intermediate Care Facility for the Mentally Retarded <input type="checkbox"/> 19-15 Mobile Laboratory <input type="checkbox"/> 20-16 Pharmacy <input type="checkbox"/> 24-27 Public Health Laboratory <input type="checkbox"/> 25-3D Rural Health Clinic <input type="checkbox"/> 26-17 School/Student Health Service <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 <u>One</u> 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:
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.		
<input type="checkbox"/> Is a small business <input type="checkbox"/> Is <u>not</u> 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 <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:
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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"/> Protine <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 <i>Section 8A-Waived Test Procedures Requested</i> . 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 <i>each</i> Provider-performed Microscopy test indicated in <i>Section 8B-Provider Performed Microscopy Procedures Requested</i> . 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.		
<p>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.</p>		
<p>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.</p>		
Print Name of Laboratory Director	Signature of Laboratory Director	Date
Print Name of Person Completing this Form	Signature of Person Completing this Form	Date

