Clinical Laboratory Evaluation Program
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LIMITED SERVICE LABORATORY REGISTRATION NOTIFICATION TO ADD PERMANENT TESTING LOCATION TO A MULTI-SITE NETWORK APPLICATION INSTRUCTIONS

This application is intended for use by not-for-profit and/or government Limited Service Laboratories in order to take advantage of a multi-site Limited Service Laboratory Registration option, whereby you may link multiple permanent locations performing waived and/or provider-performed microscopy procedures under a single CLIA registration number. Read and follow the instructions carefully since submission of incomplete or incorrect applications will delay processing.

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 non-physician office laboratories 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.

B. HOW TO DETERMINE IF YOUR FACILITY QUALIFIES FOR THE 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, sharing a common director and CLIA number. Only one application and reapplication fee would be required for all the laboratories sharing the common CLIA number. Use this form to add a secondary location to a new or existing multi-site network. **All sites in the multi-site network must be operated by the same non-for-profit corporation or government entity.**

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.

SECTION 1 - PRIMARY LABORATORY INFORMATION. Information provided is to be that of the laboratory designated as the Primary Limited Service Laboratory registrant under the CLIA & PFI Numbers referenced.

- **Primary Laboratory Name:** Indicate the legal name and address of the Primary Limited Service Laboratory registrant.
- **Primary CLIA & PFI Numbers:** If the Primary Limited Service Laboratory registrant has already been issued CLIA & PFI Numbers, please indicate them in the areas provided in this section. If no numbers have been issued previously, they will be assigned upon the submission of a Limited Service Laboratory Registration Application, form DOH-4081.
- **Primary Laboratory Telephone & Fax Numbers, and E-mail Address:** These sections are self-explanatory.

SECTION 2 – ADDITIONAL TESTING SITE INFORMATION. Information provided in this section should be that of the NEW permanent testing location to be added to the Primary Limited Service Laboratory Registration (CLIA Number) referenced in Section 1–Primary Laboratory Information.

- **Testing Site Name:** Indicate the legal name of the NEW permanent testing site to be covered under the Primary Limited Service Laboratory registration.
- **County/Borough:** Indicate the New York State county or borough that the NEW permanent testing site is physically located in.
- **Testing Site Address:** The testing site address must be the actual physical location of the NEW permanent testing site, including floor, suite and/or room, if applicable.
- **Testing Site Telephone and Fax Numbers, E-mail Address:** Indicate contact information for the new permanent testing site.
- **Testing Site Contact Person Name, Telephone Number and E-Mail Address:** Indicate contact information for the new permanent testing site.
- **Testing Site Days & Hours of Testing:** Indicate the days and hours when laboratory testing will be performed at the NEW permanent testing site.
- **Laboratory Type:** Select one from the list below that best describes your laboratory and enter in appropriate area on application:

01-*24* Ambulance	14-*01* Hospital
02-*3B* Ambulatory Surgery Center	15-*11* Independent
03-*02* Ancillary Testing Site in Health Care Facility/Hospital Extension Clinic	16-*12* Industrial* **(Include Bureau Lic. Number with application)**
04-*25* Assisted Living Facility	17-*13* Insurance
05- *26* Blood Bank	18-*14* Intermediate Care Facility for the Mentally Retarded
06-*3A* Community Clinic	19-*15* Mobile Laboratory
07-*04* Comprehensive Outpatient Rehabilitation Facility	20-*16* Pharmacy
23-*06* Correctional Facility	21-*19* Physician Office
08-*3C* End Stage Renal Disease Dialysis Facility	22-*20* Practitioner Other
09-*3D* Federally Qualified Health Center	24-*27* Public Health Laboratory
10-*08* Health Fair	25-*3D* Rural Health Clinic
11-*07* Health Maintenance Organization	26-*17* School/Student Health Service
12-*08* Home Health Agency	27-*18* Skilled Nursing Facility or Nursing Facility
13-*09* Hospice	28-*28* Tissue Bank/Repositories
	29-*99* Other* **(Specify Laboratory Type)**

SECTION 2 – ADDITIONAL TESTING SITE INFORMATION (continued). Information provided in this section should be that of the NEW permanent testing location to be added to the Primary Limited Service Laboratory Registration (CLIA Number) referenced in Section 1–Primary Laboratory Information.

- **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.

SECTION 3A – WAIVED TEST PROCEDURES REQUESTED. For each *Waived* test that you wish to perform at the NEW permanent testing site, you must provide the following information:

Indicate the *Waived* test procedure (i.e. blood glucose, dipstick urinalysis, fecal occult blood, etc.) that you wish to perform and provide the combined estimated annual test volume for all *Waived* test procedures indicated. ***Waived* testing includes tests performed using a kit, device or procedure, which has been designated by the Food and Drug Administration (FDA) as *Waived* for the purposes of CLIA '88. Non-DOT breath alcohol testing must be performed using an FDA approved IVD Over-The-Counter device. Sites performing these tests shall maintain 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
To Search FDA's IVD Over-The-Counter Lab Test Database: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm

IMPORTANT NOTE: Limited Service Laboratories seeking approval to perform lead screening must provide CLEP with a written protocol detailing how testing is performed in accordance with the manufacturer's requirements.

Additional guidance with protocol development for lead, and/or rapid HIV testing is available at the following websites:

For Lead Testing: www.wadsworth.org/regulatory/clep/limited-service-lab-certs
For HIV Testing: www.health.state.ny.us/diseases/aids/testing/rapid/index.htm

SECTION 3B – PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES REQUESTED. For each Provider-performed Microscopy (PPM) Procedure that you wish to perform at the NEW permanent testing site, you must provide the following information:

Indicate the Provider-performed Microscopy (PPM) Procedures (i.e. Wet Mounts, KOH Preps, etc.) that you wish to perform and provide the combined estimated annual test volume for all PPM procedures indicated. ***Provider-performed Microscopy (PPM) Procedures* 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 *PPM Procedures* by the Centers for Disease Control. Sites performing these tests shall maintain documentation that the tests in use have been so designated.

SECTION 4 - CERTIFICATION

This section must be completed & signed by the Laboratory Director responsible for the technical and clinical direction of laboratory testing at the Primary Limited Service Laboratory under the CLIA & PFI numbers indicated in Section 1–Primary Laboratory Information and the individual completing the application (if different). This individual assumes responsibility as the laboratory director for testing performed at all sites within the network. **Please Note: All signatures must be original. SIGNATURE STAMPS WILL NOT BE ACCEPTED.**

OUR MAILING ADDRESS

Application documents must be returned to our office at the address below:

Regular Mail
Clinical Laboratory Evaluation Program
Wadsworth Center
New York State Department of Health
Empire State Plaza
Albany, NY 12237

Express Mail
Clinical Laboratory Evaluation Program
Wadsworth Center
New York State Department of Health
Empire State Plaza
P1 South - Loading Dock J
Albany, NY 12237

LIMITED SERVICE LABORATORY MULTI-SITE NETWORK REGISTRATION

Once your application is approved, the Primary Site will be sent registration documents, which will serve to verify your enrollment with this program and will also provide documentation of your CLIA registration number. Registrations will be valid for two years from the date issued. Approximately three months before it expires, the Primary Site will receive an application to renew the registration for the entire network. Multi-site network registrants may only perform the tests listed on the registration certificate issued to the Primary Site.

CHANGES IN STATUS

Once approved, the Primary Site 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, and you must inform our Program of any change in location or laboratory director within 30 days of the change. The Limited Service Laboratory Change forms may be downloaded from our website at:

www.wadsworth.org/regulatory/clep/limited-service-lab-certs

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FOR OFFICE USE ONLY: ***I***____ ***R*** ____

Rec'd._____

PFI:_____SITE:_____Gaz Code: _____

LIMITED SERVICE LABORATORY REGISTRATION NOTIFICATION TO ADD PERMANENT TESTING LOCATION TO A MULTI-SITE NETWORK APPLICATION

This application is intended for use by not-for-profit and/or government Limited Service Laboratories in order to take advantage of a multi-site Limited Service Laboratory Registration option, whereby you may link multiple permanent locations performing waived and/or provider-performed microscopy procedures under a single CLIA registration number. **All sites in the multi-site network must be operated by the same non-for-profit corporation or government entity.**

Are you adding an additional site to an existing CLIA registration number?

☐ **Yes (Complete this document in its entirety)**

☐ **No (Complete a *Limited Service Laboratory Registration, form DOH-4081* to create an initial Limited Service Laboratory Registration)**

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

1. PRIMARY LABORATORY INFORMATION: This section is to be completed in it's entirety by the laboratory designated as the Primary Limited Service Laboratory registrant under the CLIA & PFI Numbers indicated below.

Laboratory Name (Limited to 70 Characters):	CLIA Number:
	PFI Number:

Laboratory Address (Physical Location of Laboratory):

City	State	ZIP Code

Telephone Number:	FAX Number:	Laboratory E-Mail Address:

2. ADDITIONAL TESTING SITE INFORMATION: Complete this section for the NEW permanent Limited Service Laboratory testing location to be added to the Multi-Site Limited Service Laboratory Registration (CLIA Number) referenced in *Section 1-Primary Laboratory Information*.

Site Name (Limited to 70 Characters):	County/Borough:

Site Address (Physical Location of Site):

City:	State:	ZIP Code:

Telephone Number:	Fax Number:	Site Contact Person Name:

Site 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 Laboratory Type Code From List Located in Instructions (form DOH-4081MSi):	Indicate whether your laboratory or laboratory network will perform community screening events: ☐ Yes ☐ No

3. WAIVED TEST PROCEDURES REQUESTED: Check off all Waived tests that you intend to perform and indicate the combined estimated annual test volume.

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

	Indicate the combined estimated annual test volume for all Waived Test Procedures indicated above:

4. PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES REQUESTED. Check 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	☐ Post-coital direct, qualitative examinations of vaginal or cervical mucous
☐ Fecal Leukocyte examinations	☐ Potassium hydroxide (KOH) preparations
☐ Fern tests	☐ Qualitative semen analysis (limited to the presence/absence of sperm and detection of motility)
☐ Nasal smears for granulocytes	
☐ Pinworm examinations	☐ Urine sediment examinations

	Indicate the combined estimated annual test volume for all PPM Procedures indicated above:

5. 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) 3. Waived Test Procedures Requested and/or 4. Provider-Performed Microscopy (PPM) Procedures Requested of this application.

Print Name of Multi-Site Network Laboratory Director	Signature of Multi-Site Network Laboratory Director	Date
Print Name of Person Completing this Form	Signature of Person Completing this Form	Date