NEW YORK STATE DEPARTMENT OF HEALTH
Wadsworth Center
Clinical Laboratory Evaluation Program
Empire State Plaza
Albany, NY 12237
E-mail: CLEPLtd@health.ny.gov
Web: www.wadsworth.org/regulatory/clep/limited-service-lab-certs

INITIAL LIMITED SERVICE LABORATORY REGISTRATION APPLICATION INSTRUCTIONS

COVID-19 Response For Pharmacists

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 with your application. 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. This fee is non-refundable.

A. BACKGROUND AND GENERAL INFORMATION

Executive Order 202.24, issued April 25, 2020, authorizes pharmacies to perform COVID-19 testing. Testing is limited to COVID-19 tests that have Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) and have been deemed to be a "waived" test by the FDA. COVID-19 tests that have been granted EUA approval and manufacturer package inserts (abbreviated as IFU) can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov.

Note that tests with the designation of "W" in the Authorized Setting(s) column are COVID-19 tests considered to be waived by the FDA.

In order to perform waived COVID-19 testing, a pharmacy must register as a Limited Service Laboratory and be issued a Clinical Laboratory Improvement Amendments (CLIA) certification number by the New York State Department of Health, Clinical Laboratory Evaluation Program. In addition, the pharmacy needs to identify an individual who will act as the laboratory director of the Limited Service Laboratory. Executive Order 202.24 designates pharmacists as qualified healthcare professionals who can act as laboratory directors of a Limited Service Laboratories for COVID-19 testing.

To become registered as a Limited Service Laboratory, you must complete this application. Instructions on how to complete and submit this application are provided below.

- **Approval of Limited Service Laboratory registrations with pharmacists as laboratory directors is TEMPORARY and will expire when the applicable Executive Orders expire.**
- **Testing at sites where pharmacists are laboratory directors is limited to COVID-19 tests ONLY.**

B. REGISTRATION TYPES

Limited Service Laboratory registrations are issued to individual locations based on address. A $200.00 registration application fee must be paid for each location, unless your pharmacy qualifies for the not-for-profit (NFP) exception below.

If you wish to register multiple individual locations under the same ownership and directorship, and do not qualify for the NFP exception, please complete the DOH-4081 Cov19Ph form and the DOH-4081 Cov19Ph(WS) form listing all locations to be registered. The $200.00 registration fee is required for all locations being registered.

NFP Exception: New York State Public Health Law allows for limited service laboratories that are operated under the same not-for-profit corporation or owned by the same state or local government to apply for a multi-site registration under a single CLIA number. One registration fee of $200.00 would be required for all laboratories sharing a common CLIA number. One location must be designated as the Primary Site; this application must be completed for that site. Applicants must indicate that they meet the NFP exception in Section 1 of the application. To verify eligibility please provide legal documentation denoting the corporation's not-for-profit designation. To include secondary locations, complete and include with this application a DOH-4081 Cov19Ph(WS) listing all locations to be registered.

C. ADDITIONAL RESOURCES

Technical support is available to assist Limited Service Laboratory staff with implementing a quality testing program within these facilities. **Questions can be sent to CLEPLtd@health.ny.gov.**

D. COMPLETING THE REGISTRATION APPLICATION

1. CLIA STATUS AND APPLICATION TYPE

CLIA Number: In order to perform testing, a CLIA certification number needs to be issued. 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.

2. GENERAL LABORATORY INFORMATION

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

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 where the laboratory is physically located.

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 under the NFP exception, 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 anticipated days and hours when laboratory testing will be performed.

3. LABORATORY TYPE

This information is needed to assign and maintain your CLIA certification.

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.

Small Business: A small business is defined as one, 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. LABORATORY DIRECTORSHIP

Provide requested information about the individual responsible for the technical and clinical direction of the laboratory testing within your facility and/or laboratory network.

The laboratory director designee must be a licensed pharmacist. A copy of their current New York State Professional License is required with this application.

Indicate whether the individual is available to the facility and/or laboratory network on a full-time or part-time basis during the days & hours when laboratory testing will be performed.

6. COVID-19 TESTING REQUESTED

List the *Waived* COVID-19 test(s) that will be used under a Limited Service Laboratory Registration and provide the combined estimated annual test volume for COVID-19 testing.

For a current list of tests approved under the FDA Emergency Use Authorization, please visit https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations. Note that tests with the designation of "W" in the Authorized Setting(s) column are COVID-19 tests considered to be waived by the FDA.

In the event additional COVID-19 tests receive Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) and are deemed to be a "waived" test by the FDA, the laboratory may update the registration to include these tests by completing and submitting the Notification to Add and/or Delete Test Procedures form (DOH-4236(e)) available on our website at https://www.wadsworth.org/regulatory/clep/limited-service-lab-certs.

7. CERTIFICATION

This section must be completed & signed by the individual indicated in Section 5 - 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).

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 REGISTRATION

Once the Limited Service Laboratory Registration application is approved, an initial registration certificate will be issued. The certificate 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 network registration, registration certificates for all locations in the network will be sent to the primary location. **Certificates are valid for the period defined in Executive Order 202.24 or as extended under a subsequent Executive Order.**

Registrants may only perform the tests listed on the registration certificate issued by the Department. Sites operating under a Not-for-profit Exception may only perform the tests listed on the registration certificate issued to the Primary Site.

CHANGES IN STATUS

Once approved, you must keep the program informed of any changes which may affect registration status (i.e. laboratory name, address, director, owner, additional testing sites, etc.). Be advised that Limited Service Laboratory registrations are void upon change in the laboratory location or the owner. In addition, registrants must inform the 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 www.wadsworth.org/regulatory/clep/limited-service-lab-certs.

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FOR OFFICE USE ONLY:

Rec'd._____

Fee No._____

PFI:_____Gaz Code: _____

CLIA No: _____

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COVID-19 Response For Pharmacists

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1. CLIA STATUS AND APPLICATION TYPE:

If your laboratory already has a CLIA number, please indicate here: _____

Is more than one site being registered under this application? ☐ Yes ☐ No

If Yes, the completed DOH-4081 Cov19Ph(WS) form must also be submitted.

Please indicate if the laboratory qualifies for the Not-for-Profit Exception: ☐ Yes ☐ No

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/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:	Laboratory E-mail Address:

LABORATORY CONTACT PERSON INFORMATION:

First Name:	Telephone Number:
Last Name:	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 _____

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

☐ Pharmacy (20-16)	☐ 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 One 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 not a small business

5. LABORATORY DIRECTORSHIP: Complete this section in its entirety for the individual providing technical and clinical direction of your laboratory testing.

First Name:	Last Name:

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

☐ PharmD ☐ RPh Indicate New York State Professional License Number:

Director Status: Will the Laboratory Director be available to the laboratory and/or laboratory network on a full-time, or part-time basis?

(Select One): ☐ Full-Time ☐ Part-Time

Phone:	Email:
Mobile Phone:	

6. COVID-19 TESTING REQUESTED: List the waived COVID-19 test(s) that will be used under this Limited Service Laboratory registration and indicate the estimated annual test volume. Enter the name of the test(s) exactly as stated on the FDA EUA webpage to avoid a delay in processing resulting from the necessity for additional clarification: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

	COVID-19 Waived Test(s):	
	Indicate your estimated annual test volume for COVID-19 testing:	

7. CERTIFICATION: I understand that by signing this application form, I agree to cooperate with 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. I understand this registration may be denied, limited, suspended, revoked, or annulled by the Department in accordance with Section 579 of New York State Public Health Law.

I further understand that registrants shall: (i) provide only the tests and services listed on the registration issued by the Department; (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) designate a qualified health care professional, as defined in Section 571 of the Public Health Law, or qualified individual holding a certificate of qualification pursuant to Section 573 of Public Health Law; (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) provide the Department with immediate access to all facilities, equipment, records, and personnel necessary to determine compliance with the requirements of limited service laboratory registrants.

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 performed at this limited service laboratory.

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

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

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