CLINICAL LABORATORY PERMIT APPLICATION

COVID-19 Response

NEW YORK STATE DEPARTMENT OF HEALTH
Clinical Laboratory Evaluation Program
Wadsworth Center
Empire State Plaza
Albany, NY 12237
Email: clep@health.ny.gov
Web: www.wadsworth/org/regulatory/clep

FOR OFFICE USE ONLY
Recd: _____
Fee No: _____
PFI: _____
CLIA No: _____

This form should be used only to apply for a Temporary Permit in Virology for the detection of SARS-CoV-2 pursuant to Executive Order 11.1 and its continuing orders.

Please review all application materials for completeness prior to submission. Incomplete or incorrect applications, or failure to submit all required forms and application fees will result in delayed processing.

This completed application and the Disclosure of Ownership, Controlling Interest and Corporate Membership statement should be returned, together with the required fees of $100.00, to the appropriate address below. Checks should be made payable to the New York State Department ofHealth.

Regular Mail
CLINICAL LABORATORY EVALUATION PROGRAM
WADSWORTH CENTER
NEW YORK STATE DEPARTMENT OF HEALTH
EMPIRE STATE PLAZA
ALBANY, NEW YORK 12237

Courier Mail Address
CLINICAL LABORATORY EVALUATION PROGRAM
NEW YORK STATE DEPARTMENT OF HEALTH
EMPIRE STATE PLAZA
P1 SOUTH, LOADING DOCK J
ALBANY, NEW YORK 12237

Section 1: GENERAL LABORATORY INFORMATION			
CLIA Number:			
Name of Laboratory: (Please limit number of characters to 70)			
Address: (Number and Street)			
City, Town or Village:	State:	Zip Code:	
Telephone Number:		Fax Number:	
Email Address:			

Testing Hours (Please clarify hours as AM or PM)							
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Start							
End							

LABORATORY POINT OF CONTACT

It is in the best interest of the laboratory to include a contact person other than the laboratory director.

Contact Person Name: (first name, last name)

Contact Person Telephone Number:

LABORATORY DIRECTORSHIP

There must be a doctoral-level individual named as the laboratory director. The laboratory director must hold a New York State Certificate of Qualification (CQ) in Virology to perform testing for detection of SARS-CoV-2. If the proposed laboratory director does not already hold a CQ Virology, the CQ application can be found on our website at: https://www.wadsworth.org/regulatory/clep/certificate-requirements.

CQ Code:	***Last 4 digits of Social Security Number:***

Degree(s) Held: ◯ ***M.D.*** ◯ ***D.O.*** ◯ ***D.D.S*** ◯ ***D.V.M*** ◯ ***Ph.D.*** ◯ ***Sc.D.***

Director's First Name:	***Middle Initial:***	***Last Name:***

Home Address (number and street):

City, Town or Village:	***State:***	***Zip:***

OTHER EMPLOYMENT OF THE DIRECTOR

If the director of this laboratory serves as director for additional laboratories, please provide the following information**:**

CLIA Number	*Lab Name*	*Lab Address*

ASSISTANT DIRECTORS

Excluding the director, list personnel serving the laboratory as assistant directors who hold or can qualify for Certificate(s) of Qualification and who will be designated to assume responsibility for tests performed.

CQ Code:		Last 4 digits of Social Security Number:
If you do not have a CQ, have you applied? ◯ Yes ◯ No		
Degree(s) Held: ◯ M.D. ◯ D.O. ◯ D.D.S. ◯ D.V.M. ◯ Ph.D. ◯ Sc.D.		
Assistant Director's First Name:	Middle Initial:	Last Name:
Home Address: (Number and Street)		
City, Town or Village:	State:	Zip Code:

ASSISTANT DIRECTORS

CQ Code:		Last 4 digits of Social Security Number:
If you do not have a CQ, have you applied? ◯ Yes ◯ No		
Degree(s) Held: ◯ M.D. ◯ D.O. ◯ D.D.S. ◯ D.V.M. ◯ Ph.D. ◯ Sc.D.		
Assistant Director's First Name:	Middle Initial:	Last Name:
Home Address: (Number and Street)		
City, Town or Village:	State:	Zip Code:

CERTIFICATION

Laboratories are required to review the FOLLOWING DOCUMENTS available on our "Laws & Regulations" website at www.wadsworth.org/regulatory/clep/laws**:**

Public Health Law:

Title I - Communicable Disease, Laboratory Reports and Records
Article 5, Title V of the Public Health Law - Clinical Laboratory and Blood Banking Services
Article 5, Title VI of the Public Health Law - Laboratory Business Practices
Article 2, Title II-D of the Public Health Law - Health Care Practitioner Referrals

New York Code of Rules and Regulations (10 NYCRR):

Part 2 - Communicable Diseases
Part 19 - Duties and Qualifications of Clinical Laboratory Directors
Part 22 - Environmental Diseases
Subpart 34-1 Health Care Practitioner Referrals
Subpart 34-2 Laboratory Busines Practices
Subpart 58-1 - Clinical Laboratories
Subpart 58-3 - Clinical Laboratory Inspection and Reference Fees
Part 70 - Regulated Medical Waste

Laboratory Standards,
available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-standards

In signing this application, I hereby certify that the information I have given the Department of Health as a basis for obtaining a laboratory permit is true and correct. I also certify that I have reviewed all the documents listed above.

I understand that the permit of this laboratory may be revoked, suspended, limited, or annulled if any fact is misrepresented in this application. I acknowledge that that Public Health Law stipulates that a laboratory permit is automatically void upon a change of director, owner or location. **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 laboratory permit.

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 in connection with my laboratory permit, or a complaint received by the Department. If additional information is requested, it will be provided in a timely manner by the appropriate staff under the direction of the laboratory director and owner. Further, I understand that, should this application or my status be investigated at any time, I agree to cooperate in such an investigation.

Finally, I understand that all records pertaining to the laboratory in the department's possession will be subject to disclosure to the federal CLIA program.

Print Name of Director	Signature of Director	Date
Print Name of Owner	Signature of Owner/Representative	Date
Print Name of Assistant Director	Signature of Assistant Director	Date