



DEPARTMENT OF PUBLIC HEALTH
 DIVISION OF HEALTH CARE FACILITY
 LICENSURE & CERTIFICATION
 67 Forest Street
 Marlborough, MA 01752

**CLINICAL LABORATORY
 CLIA-WAIVED COVID-19
 TEMPORARY LICENSE APPLICATION**

Submit your completed application with documentation of laboratory director qualifications and fee payment to: Clinical Laboratory Program, Mass. Department of Public Health, 67 Forest St., Marlborough, MA 01752

CLINICAL LABORATORY CLIA-WAIVED COVID-19 LICENSE APPLICATION FORM

In accordance with M.G.L. c. 111D and the rules and regulations governing clinical laboratories (105 CMR 180.000), the undersigned hereby applies for a license to maintain a clinical laboratory for COVID-19 testing purposes only at the premises set forth below.

1. CLINICAL LABORATORY

NAME: _____

ADDRESS: _____
Street City/Town Zip

TELEPHONE: _____ Fax: _____

Check if the laboratory will be providing mobile services or will be testing at temporary locations. Please provide a description of mobile services and/or temporary locations:

CLIA # (if a CLIA number has been assigned):

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2. APPLICANT/LICENSEE (Name of legal name of company¹)

NAME: _____
Name listed under the Secretary of the Commonwealth of Massachusetts Corporations Division

ADDRESS: _____
Street City/Town Zip

TELEPHONE: _____ Fax: _____

APPLICATION CONTACT:

 Name (Please Print)

 Email

3. CLIA-WAIVED COVID-19 TESTS TO BE PERFORMED UNDER FDA EMERGENCY USE AUTHORIZATION (EUA):

- Molecular Test(s) Microbiology/(Virology) Test System(s): _____
- Antigen Test(s) Microbiology/(Virology) Test System(s): _____
- Antibody Test(s) (Immunology/Viral Serology) Test System(s): _____

¹ “Company” is defined as a corporation, partnership, limited liability company, limited liability partnership, an association, a trust or an organized group of persons, whether incorporated or not. M.G.L. c. 111D, § 1(3).

4. **CLINICAL LABORATORY DIRECTOR:** _____

Is documentation of qualifications attached? Yes No (not required if already submitted with CLIA application)

5. **PROFICIENCY TESTING PROGRAMS:**

List Proficiency Testing Program(s) in which the clinical laboratory is enrolled

Has the proficiency testing service(s) been authorized to make proficiency testing results available to the State Agency (Department of Public Health, Clinical Laboratory Program)? Yes No

6. Application fee: **Attach check, payable to “Commonwealth of Massachusetts” for the appropriate fee.** (For more information see <http://www.mass.gov/eohhs/docs/dph/quality/healthcare/table-fee.pdf>)

Check number: _____ in the amount of: _____ attached.

7. **ACKNOWLEDGMENT:**

I certify, under the pains and penalties of perjury, that I am the proposed licensee, or authorized agent of the proposed licensee, and that the information provided in and submitted with this document is accurate and correct to the best of my knowledge.

I understand that the failure to file a complete and accurate application for a CLIA-Waived COVID-19 license may constitute grounds for denial or revocation of a license; and that the Department may not accept an incomplete application.

I understand that ownership and control information must be kept current, and that it is the responsibility of licensees to file changes within 30 days of execution with the Department of Public Health, Division of Health Care Facility Licensure and Certification through its Licensure Coordinator.

I certify that I have read and understand the statutory and regulatory requirements applicable to licensure and operation, including M.G.L. c. 111D and 105 CMR 180.000, and understand that the failure to meet these requirements may be grounds for the denial, revocation or refusal to renew a license, and that any legal or administrative action or claim arising from or related to this application or any resulting license shall be interpreted in accordance with and subject to the judicial and administrative laws, regulations and procedures of the Commonwealth of Massachusetts.

I certify pursuant to M.G.L. c. 62C, §49A that all applicants have complied with all laws of the Commonwealth relating to taxes, the reporting of employees and contractors, and the withholding and remitting of child support; and that no applicant who owns or leases a motor vehicle or trailer that is required to be registered in the Commonwealth under M.G.L. c. 90 has improperly registered the motor vehicle or trailer in another state or misrepresents the place of garaging of the motor vehicle or trailer in another city or town.

I understand that the Department may, at its discretion, request additional information concerning ownership and control to reach its determination of the applicant’s suitability for licensure, and that this application shall not be deemed complete until such information has been submitted, received and reviewed by the Department, and that failure to submit such information may result in the return or denial of this application.

I understand that the Department or its agents may visit and inspect this facility or program at any time, without prior notice, in order to determine compliance with state law and applicable regulations, and that all parts of the facility or program, all staff and activities, and all records covered by this application are subject to such visit and inspection.

Date

Signature of Applicant’s Authorized Representative

Print Name

Title

