



**DEPARTMENT OF PUBLIC HEALTH  
CLINICAL LABORATORY PROGRAM  
BOSTON, MA 02111  
(617)753-8439 (617)753-8240 - Fax**



**CLINICAL LABORATORY LICENSE APPLICATION FORM**

In Accordance with the "Rules and Regulations Relating to the Operation, Approval and Licensing of Clinical Laboratories" (105 CMR 180.000) the undersigned hereby applies for a license to establish and/or maintain a clinical laboratory at the premises set forth below under the provisions of the General Laws, Chapter 111D.

**COMPLETE EACH SECTION**

**CLINICAL LABORATORY**

NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_  
Street City/Town Zip

TELEPHONE: \_\_\_\_\_

**APPLICANT/LICENSEE (Proprietor, Corporation, Partnership, or Group)**

NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_  
Street City/Town Zip

TELEPHONE: \_\_\_\_\_

- Initial (New Laboratories or Change of Ownership)-** check one of the following:
- New Laboratory: Projected opening date: \_\_\_\_\_
  - Transfer of Ownership: From: \_\_\_\_\_  
 Date of Transfer: \_\_\_\_\_
- Renewal** Are you applying for a licensure type that is different from the license you currently have (i.e. from a limited license to a full license or vice versa) ?  No  
 Yes (specify) \_\_\_\_\_

**TYPE OF LABORATORY:**     Independent         Physician Office    # of Physicians: \_\_\_\_\_

Satellite of Main Laboratory

Other    (Specify) \_\_\_\_\_

**TYPE OF LICENSE APPLYING FOR OR RENEWING:**

**IF RENEWING YOUR LABORATORY LICENSE, CHECK YOUR CURRENT LICENSE BEFORE COMPLETING THIS SECTION AS THIS WILL AFFECT THE APPLICATION FEE PAID (Refer to page 5)**

**Full** (High complexity testing)                       **Limited** (Moderate complexity testing)

**CLIA CERTIFICATE:**

**Type of certificate that the Laboratory has or has applied for:**

- Certificate of Waiver         Certificate for Provider Performed Microscopy Procedures
- Certificate of Accreditation: Accrediting agency:  CAP    COLA    JCAHO    Other: \_\_\_\_\_
- Certificate (Regular)    **CLIA NUMBER:** \_\_\_\_\_

**LABORATORY DIRECTOR:** \_\_\_\_\_

If this is an application for an original license, submit documentation ( transcripts, diplomas, board certifications, and letters of experience to qualify the Laboratory Director under State licensure and CLIA regulations.)

**DAYS AND HOURS OF OPERATION:**

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Hours							

**PROFICIENCY TESTING PROGRAMS:**

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

\_\_\_\_\_  
\_\_\_\_\_

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

**TYPE OF OWNERSHIP (\*\* Include a copy of the approved Articles of Incorporation or Partnership AND complete Section I or II below, as appropriate).**

Sole Proprietor    \*\*\*  Partnership    \*\*\*  Corporation    Date Incorporated: \_\_\_\_\_

Other (Specify)

**Complete if ownership is a corporation or partnership**

**\*\*SECTION I:**

If the **Applicant** under **TYPE OF LABORATORY** is a **CORPORATION** list:

Name and title of officers: Attach an addendum if necessary.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Name and business address of all directors and holders of 5% or more of the corporation's stock:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**\*\* CORI forms must be completed on all of the persons listed in Sections I and II. Refer to fact sheet regarding who else must complete CORI forms.**

**\*\*SECTION II**

If the **Applicant** under Item 2 is a **PARTNERSHIP** list:

Name and business address of all general and limited partners with 5% or greater ownership in the partnership.

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**\*\* CORI forms must be completed on all of the persons listed in Sections I and II. Refer to fact sheet regarding who else must complete CORI forms.**

**COLLECTION STATIONS:**

List contact name, address and telephone number of all collection stations maintained under the license (refer to 180.017 for definition). Attach an additional sheet if necessary.  NONE

<u>Contact Name</u>	<u>Address</u>	<u>Telephone number</u>	<u>Days &amp; Hours of Operation</u>
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**SATELLITE LABORATORIES (PHYSICIAN OFFICE LABORATORIES ONLY):**

List contact name, address and telephone number of all PHYSICIAN OFFICE satellite laboratories maintained under the license (refer to 180.042 for definition). Attach an additional sheet if necessary.  NONE

<u>Contact Name</u>	<u>Address</u>	<u>Telephone number</u>	<u>Days &amp; Hours of Operation</u>
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## SPECIALTIES / SUBSPECIALTIES

Check each specialty and subspecialty in which tests are performed:

**LICENSURE RENEWALS - Unless there have been changes to your laboratory services please check off the same specialty and subspecialty areas on this section of the application that are on your current license. If you have added new tests and are unsure of what specialty area the test falls under you may either check the FDA CLIA searchable database**

**([www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm)) or call our office.**

**MICROBIOLOGY-SPECIALTY**

- Bacteriology
- Mycology
- Parasitology
- Virology
- Other Microbiology

**IMMUNOLOGY-SPECIALTY**

- Syphilis
- Viral Serology [HIV Testing]
- Non-Syphilis

**CLINICAL CHEMISTRY-SPECIALTY**

- Routine Chemistry
- Endocrinology
- Toxicology
- Urinalysis
- Other Chemistry

**IMMUNOHEMATOLOGY-SPECIALTY**

- Blood Group / Rh Type
- Rh Titers
- Other Immunohematology [Antibody Work-ups]

**HEMATOLOGY-SPECIALTY**

- Routine Hematology
- Cellular Studies
- Coagulation
- Other Hematology

**PATHOLOGY-SPECIALTY**

- Diagnostic Cytology
- Histopathology
- Oral Pathology

**RADIO BIOASSAY (in-vivo)-SPECIALTY**

**CYTOGENETICS-SPECIALTY**

**HISTOCOMPATIBILITY TESTING-SPECIALTY**

**TAX CERTIFICATION STATEMENT AND SIGNATURE**

\*(A) Pursuant to M.G.L.c.62C,S.49A I certify under the penalties of perjury that I, to the best of my knowledge and belief, have filed all State Tax returns and paid all State taxes required by law.

\_\_\_\_\_  
\*\*Social Security Number or Federal Identification Number (voluntary)

(B) I, the undersigned, attest that I am duly authorized to complete and sign this application, that I have read this application in its entirety and that the information contained therein is accurate. I understand that additional information may be required by the Massachusetts Department of Public Health to complete the application process and agree to provide such information as requested. I understand that an unannounced on-site inspection may be made to confirm the information contained herein. Signed under the pains and penalties of perjury on

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Authorized Representative

\_\_\_\_\_  
Title

**\* A license will not be issued unless this certification clause is signed by the applicant.**

**\*\* Your Social Security Number/Federal Identification Number will be furnished to the Massachusetts Department of Revenue to determine whether you have met tax filing or payment obligations. Licensees who fail to correct their non-filing delinquency will be subject to license suspension or revocation. This request is made under the authority of Massachusetts General Law**

**APPLICATION FEE**

**Check the category of license applying for, or which the laboratory currently holds, as indicated on page 1 of the application:**

**Full License:** remit a fee of **\$300** for each Specialty area checked on page 4 of the application payable to the COMMONWEALTH OF MASSACHUSETTS.

**Limited License:** remit a fee of **\$300** payable to the COMMONWEALTH OF MASSACHUSETTS.

**REMINDERS**

**Ensure that the entire application is completed and the correct specialty /subspecialty areas on page 4 are checked.**

**Ensure that the correct fee is enclosed**

**Name and E-mail contact in order to expedite and resolve issues or problems with licensure documentation:**

\_\_\_\_\_  
Name (Please Print)

\_\_\_\_\_  
E-mail