RI Department of Health

Application
and instructions for

Clinical Laboratory

RI General Law Chapter 23-16.2

Licensee Name: _____

Licensee Number: _____

Reason for application (Please check all that apply):

☐ In State ☐ Out of State

1. ☐ Initial Licensure
2. ☐ Change of Ownership (New FEIN/Tax ID)
3. ☐ Change of Facility Address

Fees are applicable for applications submitted for any of the above reasons

(Complete the following for either 2 or 3)

Current Licensee name:_____ License #:_____

Current address:_____

State of Rhode Island and Providence Plantations
Department of Health

INSTRUCTIONS

- Please answer all questions. Do not leave blanks. Incomplete forms will be returned to you and your license/permit will not be issued. Please use a ballpoint pen.
- Please use the fee calculation section to determine your fee. Licenses are non-transferrable. A new fee is applicable for: initial applications, changes of physical location and changes of ownership that involve a change in Tax ID/FEIN. Please contact us if you need to make any other changes to your license.
- Make your check/money order payable to "General Treasurer, State of Rhode Island." Do not send cash.
- Please sign the completed application, return it with the required fee and mail to:

  Rhode Island Department of Health
  3 Capitol Hill, Room 306
  Providence, RI 02908-5097

- If you have any questions concerning this application, call the office of **Facilities Regulations** at (401) 222-2566.
- Licensure application materials are public records as mandated by Rhode Island law and may be made available to the public, unless otherwise prohibited by State or Federal law.

ATTACHMENTS: please label and staple each separate attachment and securely affix any and all attachments to this application.

1. **You must attach a current printed list of all direct and indirect owners whether individual partnership, limited partnership, limited liability company, or corporation with percent of ownership. If a corporation, this list must also include all officers, directors and other persons of any subsidiary corporation owning stock**.
2. **Director**: Provide documentation of qualifications of the individual designated as Laboratory Director and a copy of that individual's resume. If the director is not full time the name and qualifications of the director's designee must be also submitted.
3. **Laboratory Staff:** Provide a list of technical personnel, which includes qualification designations (e.g. MT, MLT etc.). Designate the individual's primary specialty area, if this application is for more than one specialty area.
4. **Hours of Operation:** Describe the laboratory hours of operation.
5. **Laboratory Facility:** Provide, floor plans, or a description of the facility, which support the statement that, the facility is adequate for the scope of services for which licensure is desired.
6. **Equipment:** Provide a current equipment list representing all the testing equipment for the specialty areas for which licensure is desired.
7. **Summary of Tests Performed**: Provide a list of all the tests for which licensure is desired.
8. **Proficiency Testing Program**: Identify the proficiency testing program(s) for each specialty, subspecialty or analyte for which licensure is desired.
9. **Quality Control Program**: Provide information regarding how your daily quality control program is achieved and used to assure accurate testing.
10. **Quality Assurance**: Provide a copy of your **current** quality assurance plan.
11. **Evidence of good standing in your state:** Out-of-state laboratories provide a copy of your state license and/or your CLIA certificate.

Postage: The amount of postage required for mail delivery will vary depending upon the total weight of your attachment(s) and application. Please be careful to include the appropriate postage necessary to mail your completed application.

Please complete the following:

Lab Director Information: Please provide the name and mailing address for the laboratory director for whom you are submitting the required documentation.	Name: _____ Address Line 1: _____ Address Line 2: _____ Address Line 3: _____ City, State, Zip Code: _____
Federal CLIA Provider Number	Federal CLIA Provider Number: _____

Fee Calculation:

If you are uncertain about any aspect of fee calculation, please call the office of Facilities Regulations at 222-2566.

A. Please check the **specialties and sub-specialties** in which licensure is desired. Requested specialties must match your CLIA certificate.

1. _____ **HISTOCOMPATABILITY**
2. _____ **MICROBIOLOGY**
   - _____ Bacteriology
   - _____ Mycobacteriology
   - _____ Mycology
   - _____ Parasitology
   - _____ Virology
3. _____ **DIAGNOSTIC IMMUNOLOGY**
   - _____ Syphilis Serology
   - _____ General Immunology
4. _____ **CHEMISTRY**
   - _____ Routine Chemistry
   - _____ Urinalysis
   - _____ Endocrinology
   - _____ Toxicology
5. _____ **HEMATOLOGY**
6. _____ **IMMUNO-HEMATOLOGY**
   - _____ ABO Group & Rh Type
   - _____ Antibody Transfusion
   - _____ Antibody Non-Transfusion
   - _____ Antibody Identification
   - _____ Compatibility Testing
7. _____ **PATHOLOGY**
   - _____ Histopathology
   - _____ Oral Pathology
   - _____ Cytology
8. _____ **RADIOBIOASSAY**
9. _____ **CLINICAL CYTOGENETICS**

	B. Calculate the Fee: The renewal fee is based on the number of SPECIALTIES in which licensure is desired. Currently, there are nine (9) possible SPECIALTIES. They are indicated in **capital bold letters**. Whenever you check one or more subspecialties within a SPECIALTY, you will need to submit the fee for the SPECIALTY. For example, if your laboratory tests for Bacteriology and Mycobacteriology in the **MICROBIOLOGY** specialty, your fee will be $650 for one SPECIALTY. If you are uncertain about any aspect of fee calculation, please contact Facilities Regulation at 401-222-2566. Number of Specialties checked in **A.** _____ X $650.00= _____ **Total Fee**: _____
Facility Name: Please provide the name of the facility (as known to the public).	Name: _____
Facility Contact Person: Please provide the name and telephone number of a person we can contact concerning this facility.	Name: _____ Phone Number: _(_____)_____
Facility Mailing Information: Please provide the mailing information for all communication regarding this license. (**Not published on HEALTH website**).	Address Line 1 _____ Address Line 2 _____ Address Line 3 _____ Address City, State, Zip Code _____ Address Country _____ Phone: _____ Fax: _____ Email Address:_____
Facility Location Information: Please provide the location information for this facility. (**Published on HEALTH website**).	Address Line 1 _____ Address Line 2 _____ Address Line 3 _____ Address City, State, Zip Code _____ Address Country _____ Phone: _____ Fax: _____ Email Address:_____
Ownership Type: Please check ONE	☐ Corporation ☐ Limited Liability Company ☐ Governmental Entity ☐ Sole Proprietorship ☐ Partnership ☐ Limited Partnership ☐ Partner

State of Rhode Island and Providence Plantations
Department of Health

Ownership Information: Please provide the ownership information for the Sole Proprietorship, Partnership, Limited Partnership, Corporation, Limited Liability Company or Governmental Entity per page 2 instructions	Name: _____ DBA: _____
Ownership Address Information: Please provide the address and telephone number(s) of the Sole Proprietorship, Partnership, Limited Partnership, Corporation, Limited Liability Company or Governmental Entity.	Address Line 1 _____ Address Line 2 _____ Address Line 3 _____ Address City, State, Zip code _____ Phone: _____ Fax: _____ Email Address: _____
Parent Organization, Group Affiliation: Please complete this section if there is any parent organization, group affiliation or other entity that is on the top of the Facility/agency control	Corporation Type _____ Name of Organization _____ Address Line 1 _____ Address Line 2 _____ Address Line 3 _____ Address City, State, Zip Code _____ Phone: _____ Fax: _____ Email Address: _____
Land/Building Info: If the owner of the land and building is other than the operator of this agency/facility, please complete the following:	Name: _____ Address Line 1 _____ Address Line 2 _____ Address Line 3 _____ Address City, State, Zip Code _____ Phone _____
Compliance with Conditions of Approval Please check yes or no.	This facility/agency is in compliance with all conditions of approval (i.e. relative to Certificate of Need, Change of Effective Control, Initial Licensure and/or Licensure renewal). ☐ Yes ☐ No

Acknowledgements

I am aware of Chapter 23-16.2 of the General Laws of Rhode Island, 1956, as amended, and the standards, rules and regulations prescribed thereunder, which regulate the operation of this facility.

I acknowledge that authorized representative of the Licensing Agency shall, in conformity with the authority continued under Chapter 23-16.2 of the General Laws of Rhode Island, as amended, have the right to enter without prior notice to inspect the entire premises and services, including all records of any facility/residence.

FEIN Number:

(Federal Employer Identification Number)

Note: If you are a sole proprietor this number may be your Social Security Number.

Pursuant to Chapter 76 of Title 5 of the Rhode Island General Laws, as amended, any person applying for or renewing any license, permit, or other authority to conduct a business or occupation within Rhode Island must have filed all required state tax returns and paid all taxes due the state or must have entered into a written installment agreement to pay delinquent state taxes that is satisfactory to the Tax Administrator.

Please provide below SSN/FEIN for this license:

SSN/F.E.I.N. Number: _____

Affidavit of Applicant

Read, sign, and date this affidavit.

AFFIDAVIT AND SIGNATURE

This Application Must be Signed

I have read carefully the questions in the foregoing application and have answered them completely, without reservations of any kind, and I declare under penalty of perjury that my answers and all statements made by me herein are true and correct. Should I furnish any false information in this application, I hereby agree that such act shall constitute cause for denial, suspension or revocation of this License in the State of Rhode Island.

I understand that this is a continuing application and that I have an affirmative duty to inform the Rhode Island Department of Health of any change in the answers to these questions after this application and this Affidavit is signed.

I hereby declare, under penalty of perjury, that I have filed all required state tax returns and have either paid all taxes due the state or have entered into a written installment agreement with the Rhode Island Division of Taxation.

_____ _____

Signature of Authorized Person **Date of Signature (MM/DD/YY)**

_____

Printed Name of Authorized Person

_____

Title of Authorized Person

Furnishing the SSN and/or FEIN is mandatory. The SSN and/or FEIN will be transmitted to the Rhode Island Division of Taxation pursuant to Chapter 76 of Title 5 of the Rhode Island General Laws, as amended.