CONNECTICUT DEPARTMENT OF PUBLIC HEALTH
BUREAU OF REGULATORY SERVICES, DIVISION OF HEALTH SYSTEMS REGULATION
410 CAPITOL AVE., MS#12HSR, P.O. BOX 340308, HARTFORD, CT 06134-0308, TEL: 860 509-7400

APPLICATION FOR CLINICAL LABORATORY LICENSURE, REGISTRATION & APPROVAL

REV. 01-26-2010

Office Use Only: License / Registration No.: ; Date Received: Fee Paid : ☐ *Price List:* ☐

1. **NAME OF LABORATORY:**

2. **ADDRESS**:
   Street City State Zip Code

3. **TELEPHONE #:** **FAX #:** **CLIA #**

   E-mail ID of Director, Lab Manager, or Supervisor:

4. **NAME OF DIRECTOR**:

5. **NAME OF LICENSEE / REGISTRANT:**

6. **Type of Laboratory**: ☐ Hospital ☐ Clinical Laboratory (CL).
   ☐ Government / Municipal ☐ (Other specify):

7. **OWNERSHIP:**
   ☐ Sole Proprietorship ☐ Partnership ☐ Other (Specify):
   ☐ Corporation (profit) ☐ Corporation (nonprofit)
   If sole proprietorship, partnership or other, **list name and address of owner below**. **If a corporation, list name of corporation, address, directors and officers. Corporation or other Ownership entity:**

   Name **Address**

   Directors / Officers:
   Name Title

8. **LABORATORY DIRECTOR QUALIFICATIONS**:
   For **High Complexity** Testing, the director is: (Check One):
   - ☐ Licensed Physician, Certified in Anatomic Pathology by the American Board of Pathology or American Osteopathic Board of Pathology; or is a
   - ☐ Licensed Physician, Certified in Clinical Pathology; or is a
   - ☐ Licensed Physician & 1 Yr. Training or 2 Yrs. Directing / Supervising Experience; or earned a
   - ☐ Ph.D. and is Board Certified by: (specify board: _____).
     An acceptable doctoral degree is a Doctor of Philosophy (Ph.D.) or Doctor of Science (D.Sc.)
   - ☐ Previously qualified as director of a high complexity laboratory.

9. LABORATORY DIRECTOR QUALIFICATIONS:

For **Moderate Complexity** Testing, the director qualifies as above, or has earned a: (Check One):

- ☐ Doctoral degree in medicine, dentistry, or in a chemical, physical, biological or clinical laboratory science and has at least 1 year experience directing or supervising non-waived testing.
- ☐ Master's degree in chemical, physical, biological or clinical laboratory science and has at least 1 year experience supervising non-waived testing.
- ☐ Bachelor's degree in a chemical, physical, or biological science, or medical technology and at least 2 years of laboratory training or experience or both in non-waived testing and at least 2 years of supervisory laboratory experience in non-waived testing.

10. Name of Clinical Consultant: _____

Clinical Consultant Qualifications: The clinical consultant is a: (Check One)

- ☐ Licensed Physician Certified in Anatomic or Clinical Pathology; or has earned a:
- ☐ Ph.D. and is certified by: the ☐ American Board of Medical Microbiology *(ABMM),*
  - ☐ American Board of Clinical Chemistry *(ABCC),* ☐ American Board of Medical Genetics *(ABMG),*
  - ☐ American Board of Bioanalysis *(ABB),* ☐ American Board of Forensic Toxicology *(ABFT),*
  - ☐ American Board of Histocompatibility and Immunogenetics *(ABHI),* or the
  - ☐ American Board of Medical Laboratory Immunology *(ABMLI);* or is a
- ☐ Physician licensed to practice medicine, osteopathy or podiatry in Connecticut.

11. DAYS AND HOURS OF OPERATION:

☐ M. ☐ Tues. ☐ Wed. ☐ Th. ☐ Fri. ☐ Sat. ☐ Sun.

From: AM

To: PM

12. HOURS OF SUPERVISOR(S):

☐ Day Shift ☐ Evening Shift ☐ Night Shift ☐ Coverage 24 Hrs./Day, 7 Days/Wk.

13. Supervisor: **Title / Degree:**

(Person who, in the absence of the director, assumes the duties and responsibilities of the laboratory director.)

14. If this is a **renewal** application for an existing license/registration, application is made: (check all that apply)

☐ prior to expiration of current license/registration ☐ before any change in ownership or director;
☐ prior to major expansion or alteration in quarters ☐ prior to relocating the laboratory to new quarters.

Connecticut License #: CL- _____ **Registration #**: HP- _____ or PH#: _____

GUIDELINES FOR COUNTING TESTS

- For chemistry profiles, each individual test is counted separately.
- For complete blood counts, each measured individual analyte is counted separately.
- Differential leukocyte counts are counted as one test.
- Do not count calculations, i.e. A/G ratio, MCH, MCHC, HCT, and T7.
- Do not count quality control, quality assurance and proficiency test results.
- Urinalysis by dipstick and/or tablet reagent is counted as one test. Urine microscopic is counted as one test.
- Microbiology susceptibility: count one test per group of antibiotics used to determine sensitivity for one organism.
- Microbiology cultures are counted as one test per specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.
- Testing for allergens should be counted as one test per individual allergen.
- For cytology, each slide (not case) is counted as one test for both Pap smears and non-gynecologic cytology.
- For histopathology, each block (not slide) is counted as one test
- For histocompatibility, each HLA typing (including disease associated antigens), HLA antibody screen, and HLA crossmatch is counted as one test.

15. ***LIST OF TESTS PERFORMED ON-SITE & ANNUAL TEST VOLUME REPORT.*** Laboratory Name:
Laboratory Address: Date:
For each test performed in your laboratory, list the **test** performed, **instrument** or method used, the **estimated annual test volume,** and (if applicable).the **proficiency testing program** (CAP, AAB, EXCEL, MLE, API, AAP, etc), that you are enrolled in. Continue on next page if necessary.

Test	Instrument Method or Test Kit	Proficiency Test Program	Annual Test Volume	*State Use Complexity*	*State Use Specialty*

Make additional copies of this page if necessary. Complexity column is for State use only.

16. Laboratory Specialties:
Check the laboratory specialties and subspecialties performed in your laboratory.

Specialties / Subspecialties	**Specialties** / Subspecialties	**Specialties** / Subspecialties
☐ **Histocompatibility**	☐ **Chemistry**	☐ **Immunohematology**
☐ **Microbiology**	☐ Routine	☐ ABO Group & Rh Type
☐ Bacteriology	☐ Urinalysis	☐ Antibody Detection (transfusion)
☐ Mycobacteriology	☐ Endocrinology	☐ Antibody Detection (non-transfusion)
☐ Mycology	☐ Toxicology & TDM	☐ Antibody Identification
☐ Parasitology	☐ Other - Chemistry	☐ Compatibility Testing
☐ Virology	☐ **Hematology**	☐ Other – Immunohem.
☐ Other - Micro		☐ **Pathology**
☐ **Diagnostic Immunology**	☐ **Radiobioassay**	☐ Histopathology
☐ Syphilis Serology	☐ **Clinical Cytogenetics**	☐ Oral Pathology
☐ General Immunology		☐ Cytology

17. Annual volume of tests referred to out-of-state laboratories:

Reference Laboratories outside Connecticut:
(Provide Name, Address & CLIA Number or attach a list).

18. Laboratory Report of Significant Findings: Form OL-15C. To order forms call (860) 519-7994.

Tests of public health significance are reported within 48 hours to the local director of health of the town in which the affected person normally resides, or, in the absence of such information, of the town from which the specimen originated, and to the CT Dept. of Public Health on form OL-15C.

☐ Yes ☐ No ☐ N/A

See: Public Health Code, Section 19a-36-A3(b); and Updated List of Reportable Diseases at:
www.state.ct.us/dph

19. A Current Itemized Price List for laboratory tests is included with this application ☐ Yes ☐ No

20. Contractual relationships, written or oral, with any physician(s) are included with this application.

☐ Yes ☐ No ☐ N/A

21. Licensee or Registrant: Enter the name of the individual designated by the owner(s) or corporation to be the agent for service of process and the agent's address. **"Licensee" means** the person in whose name licensure of a laboratory is sought and granted; **this shall be the owner** if an individual, the owners if a partnership of two, or a responsible officer of any other group, firm or corporation owning the laboratory. (19a-36-D20). **"Registrant" means any person, firm or corporation**, or the duly authorized agent thereof, operating or maintaining a laboratory in which there is made any examination, determination or test specified in section 19a-36-A26. (19a-36-A25).

*For registered hospital laboratories, if the director of the laboratory requests to also be the registrant, the director must attach a letter from the hospital verifying that he or she is the duly authorized agent for the hospital laboratory.

Name:

Address:

22. A list of all additional blood collection facilities in permanent locations is attached?

☐ Yes ☐ No ☐ NA

23. For clinical laboratory licensure, a non-refundable fee of **$200.00,** made payable to: Treasurer, State of Connecticut is included with this application. ☐ Yes ☐ No ☐ NA (Not applicable to Municipality/State or Federal laboratories).

We, the undersigned, individually and jointly certify that the information provided in this application is to the best of our knowledge and belief accurate and correct.

If licensure or registration is granted to this laboratory by the Commissioner of Health, we agree to comply fully with all statutes and regulations by the State of Connecticut and directives pursuant thereto that may be issued by the Commissioner of Health or his/her representatives.

We fully understand that the Commissioner of Health may at any time revoke or suspend the license / registration of this laboratory if in his / her opinion, the laboratory has violated any statutes, regulations, or directives pursuant thereto, or if the continued operation of the laboratory is not in the best interest of the health and safety of the citizens of the state of Connecticut.

In witness whereof, we have hereunto set our hands and seal this _____ day of _____, 20 _____

Name of Director (print)

_____

Signature of Director

Name of Licensee / Registrant (print)

_____

Signature of Licensee / Registrant

State of: County of: .

Personally appeared before me duly qualified to administer oaths and subscribed and made oath to the truth of the foregoing affidavit.

_____ _____

Signature of Notary Public **Notary Public Name (Print)** Date My Commission Expires.