



Maryland Department of Health
Office of Health Care Quality
Laboratory Licensing Programs
7120 Samuel Morse Drive
Second Floor
Columbia, Maryland 21046
Phone: 410.402.8025 Fax: 410.402.8213

Instructions for Completion of State Compliance Application

*****Changes to your current State laboratory license must be submitted on the Laboratory Licensing Change Form. Forms can be downloaded on our website: https://health.maryland.gov/ohcq/Labs/docs/LabsApps/Laboratory_Licensing_Change_Form.pdf**

It is important that you fill out this application completely, including signatures where required. Original (ink) signatures are required on all initial applications and must be mailed or hand delivered to our office (address listed above). If the application is incomplete, it will delay the licensing process. Initial applications are not accepted by fax or email.

Please allow 3-4 weeks for permit processing and mailing

There is no fee for this licensure.

If you have any questions, please call the Laboratory Licensing Division at (410) 402-8025.

*****Important*****

*****Before submitting your application, please review the checklist on the last page.*****

Maryland Department of Health Laboratory Licensing Programs Office of Health Care Quality	Date/Amount Paid Office use only
	Invoice # Office use only
	Check # Office use only
	State Permit # Applicant, if known please enter
	CLIA # Applicant, if known please enter

State Compliance Application

Initial Application Reinstatement

I. Laboratory Information			
Type of Laboratory <input type="checkbox"/> Physician Office <input type="checkbox"/> Point of Care <input type="checkbox"/> Independent/Reference <input type="checkbox"/> Hospital			
Laboratory Practice/ Entity Name		Contact Person Name/Phone Number	
Address, City, State and Zip Code	Email Address	Fax	
Mailing address if different from above			
II. Director Information			
Laboratory Director Name	Degree	Full Time	Part Time (hours/week)
Certification by American Specialty Board (Name, Date, Number)		State Medical License Number	
III. Laboratory Supervisor/Consulting Supervisor/Manager Information			
Name	Degree	Full Time	Part Time (hours/week)
Certification by American Specialty Board (Name, Date, Number)			

VI. Mandatory, You Must List Testing Instrumentation and Test Kits Used in the Laboratory

Please also include test discipline/subdiscipline (e.g. Chemistry-Routine) if using Schedule A

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

VII. Proficiency Testing

I am not enrolled

I am enrolled (complete below)

Name of Company

Discipline

_____	_____
_____	_____
_____	_____

VIII. Ownership Information

A. Type of Entity

- Sole Proprietorship
 Partnership
 Corporation
 Unincorporated Association
 Other (Specify) _____

B. This section is MANDATORY, application will be returned if left blank. Social Security Number is unacceptable. Attention- Laboratories not located in Maryland, the EIN must match what you have on file in the CMS CLIA database. Only include one EIN Number below, not several please.

Name	Address	EIN Federal Tax ID

IX. Attestation

I certify that the information provided in this application is true and complete, understanding that any knowing and willful false statement or representation, or failure to fully and accurately disclose the requested information in this application, may be prosecuted under applicable federal or State laws, may lead to a denial, suspension or revocation of the medical laboratory license for this entity, or could result in termination of participation in State or federal reimbursement programs. I further understand that compliance with State laws may not assure compliance with federal laws.

Signature of Laboratory Director

Date

For Informational Purposes Only
Examples of Testing for Schedule A- General Permit (Do Not Circle)

Chemistry

Alkaline Phosphatase
Amylase
B-HCG (quantitative)
Blood Lead
CK-MB
Digoxin
Iron
Lipase
Phenytoin
T4-Free
Troponin
TSH
Vitamin D

Genetics

Chromosome Analysis
FISH Studies (Neoplastic and Congenital)
Fragile X Screen
Gaucher Disease (*GBA*) 8 Mutations
Tay-Sachs (*HEXA*) 7 Mutations
Y Chromosome Deletions

Forensic Toxicology

Job Related Alcohol
Job Related Drugs of Abuse

Microbiology

AFB Smear
Bacterial Culture
Blood Culture
CSF Bacterial Antigen
Fungus/Yeast Culture
Ova and Parasite
Sensitivity Testing
Viral Culture

Hematology

APTT
CBC
Differential
Fetal Hemoglobin
Fibrinogen
INR
Prothrombin Time
Reticulocyte Count
Sedimentation Rate

Molecular Biology

Adenovirus PCR
BD Affirm Probe Test
Chlamydia PCR
EBV PCR
HCV Genotyping
HIV Drug Resistance Genotyping
HIV Viral Load

Pathology

Dermatopathology
Fine Needle Aspirations
Grossing
Histopathology
Oral Pathology
Other Cytology
Pap Smear Interpretations

Immunology

Anti-Nuclear Antibody
Epstein Barr Antibodies
GM1 Antibody
Hepatitis B Surface Antibody
Hepatitis B Surface Antigen
Herpes Antibody
HIV Antibody
Lyme Antibody
Non Transplant Related Histocompatibility

To prevent a delay in processing your application please check to make sure all of the following are included:

- Completed application with each section completely filled out
- Signature of Laboratory Director must match the name in section II of application
- If the status of your CLIA certificate is changing, a completed CMS 116 form must be submitted
- Director Qualifications
 - Copy of CV, Diploma (highest degree), ECFMG (if applicable), board certification for MD or PhD (if applicable)
- Technical Supervisor Qualifications (for the discipline of HISTOLOGY)
 - Copy of American Pathology Board certification in Anatomical Pathology
 - Copy of Maryland (Board of Physicians) license to practice medicine
- Genetics Testing
 - Copy of Technical Supervisor's diploma (must be MD, DO or PhD), board certification from the American Board of Medical Genetics or 4 years of verified (not self-generated) experience in clinical genetics and CV
 - Copy of Test Menu
 - Copy of a Validation Study of one test (includes a summary and raw data)
 - Letter from Director documenting that the lab does not perform "Direct to Consumer" testing
- Certificate of Accreditation Laboratories
 - Copy of enrollment verification from the designated accrediting organization

Applicants Located in Maryland

- Completed CLIA application in agreement with State application
- Copy of Director's Maryland (Board of Physicians) license to practice medicine
- For High Complexity Laboratories: Documentation of training, education and previous experience that meets CLIA Sec. 493.1443: Standard: Laboratory Director Qualifications
- For Moderate Complexity Laboratories: Board Certification or Documentation of 20 CME from approved programs for Medical Director that meets CLIA Sec. 493.1405
- Documentation of licensure as a practitioner seeking a Letter of Exception (midwife, nurse practitioner, etc.)

Applicants Located Out of State

- Copy of CLIA certificate and State Laboratory License, if applicable
- Copy of most recent survey, which includes cited deficiencies and corrective actions
- Copy of Director's State license to practice medicine from the State where the laboratory is located
- Documentation of training, education and previous experience that meets CLIA Sec. 493.1443: Standard: Laboratory Director Qualifications
- Proof of most recent participation in annual GYN cytology proficiency testing