



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**

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 Number:
Mailing Address (if different from above):

II. Director Information

Laboratory Director Name:
Contact Person Name and Phone Number:
Certification by American Specialty Board (Name, Date, Number):
Email Address:
Fax Number:

III. Laboratory Supervisor/Consulting Supervisor/Manager Information

Name:
Certification by American Specialty Board (Name, Date, Number):
Degree:
Full Time:
Part Time (Hours/weeks):

IV. Schedule A - General Permit

*** If you are only performing tests that are CLIA Waived, MD Excepted, use Schedule B, do not use this section***

Chemistry

- Routine
- Blood Gas
- Endocrinology
- Toxicology: Drugs of Abuse
- Toxicology: Therapeutic
- Toxicology: Heavy Metals
- Radioimmunoassay

Genetics

- Routine
- Molecular
- Cytogenetics

Forensic Toxicology

- Toxicology: Job Related

Microbiology

- Bacteriology
- Parasitology
- Mycology
- Mycobacteriology
- Virology

Health Awareness* (*performed at health fairs not routine chemistry lab)

- Cholesterol/Lipids
 - Glucose Finger Stick
 - Hemoglobin A1c
- (*must be CLIA waived)

Immunohematology/ Blood Bank

- ABO/Rh/Non Trans-fusion/Transplant
- ABO/Rh
- Antibody Detection
- Antibody Identification
- Compatibility Testing

Hematology

- Routine
- Coagulation

Molecular Biology

- Nucleic Acid Probes
- PCR Amplifications
- Recombinant Nucleic Acid Techniques

Pathology

- Histopathology
- Dermatopathology
- Oral Pathology
- Cytology-GYN
- Cytology-Non-GYN

Immunology

- General Immunology
- Syphilis Serology
- Histocompatibility

V. Schedule B - Excepted Tests *

* Note: All tests that are Waived by CLIA are Excepted by Maryland regulations. You can check the test categories for CLIA: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/search.cfm>
List below CLIA Waived test name and then its manufacturer. A separate page may be added if additional space is required.

ANALYTE / TEST	TEST NAME	MANUFACTURER
Example: Streptococcus group A	Ace Rapid Strep Test	Acme Corporation

VI. If Nonwaived or PPM Testing Is Performed, You Must List Testing Instrumentation and Test Kits Used in the Laboratory

Please also include test discipline/subdiscipline (e.g. Chemistry-Routine) using Schedule A
 If the laboratory performs any Provider-Performed Microscopy Procedures (PPM), list each PPM test performed and classify it under the applicable Schedule A discipline/subdiscipline.(see page 6)

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

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):

A. 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	Lipase
Amylase	Phenytoin
B-HCG (quantitative)	T4-Free
Blood Lead	Troponin
CK-MB	TSH
Digoxin	Vitamin D
Iron	
Forensic Toxicology	
Job Related Alcohol	
Job Related Drugs of Abuse	
Genetics	
Chromosome Analysis	Gaucher Disease (GBA) 8 Mutations
FISH Studies (Neoplastic and Congenital)	Tay-Sachs (HEXA) 7 Mutations
Fragile X Screen	Y Chromosome Deletions
Hematology	
APTT	
CBC	
Differential	
Fetal Hemoglobin	
Fibrinogen	
INR	
Prothrombin Time	
Reticulocyte Count	
Sedimentation Rate	
Immunology	
Anti-Nuclear Antibody	Herpes Antibody
Epstein Barr Antibodies	HIV Antibody
GM1 Antibody	Lyme Antibody
Hepatitis B Surface Antibody	Non-Transplant Related Histocompatibility
Hepatitis B Surface Antigen	
Microbiology	
AFB Smear	Fungus/Yeast Culture
Bacterial Culture	Ova and Parasite
Blood Culture	Sensitivity Testing
CSF Bacterial Antigen	Viral Culture
Molecular Biology	
Adenovirus PCR	HCV Genotyping
BD Affirm Probe Test	HIV Drug Resistance Genotyping
Chlamydia PCR	HIV Viral Load
EBV PCR	
Pathology	
Dermatopathology	
Fine Needle Aspirations	
Grossing	
Oral Pathology	
Other Cytology	
Pap Smear Interpretation	

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 of GYN cytology PT