



Maryland Department of Health and Mental Hygiene  
Office of Health Care Quality – Laboratory Licensing Programs  
Spring Grove Center – Bland Bryant Building  
55 Wade Avenue, Catonsville, MD 21228  
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. The form can be downloaded on our website at [www.dhmf.state.md.us/ohcq](http://www.dhmf.state.md.us/ohcq) \*\*\*

It is important that you fill out this application completely, including signatures where required. If the application is incomplete it will delay the licensing process.

Please submit no money at this time. Once your application is reviewed for completeness and compliance with the applicable regulations, you will be issued an invoice for the application fee as well as other fees as outlined in COMAR 10.10.04.02.

Please allow 6-8 weeks for permit processing and invoicing.

Once your payment is received, the appropriate license will be issued.


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.\*\*\***



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State of Maryland Department of Health and Mental Hygiene 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  Physician Office  Point of Care  Independent/Reference  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

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)			

## IV. Schedule A - General Permit

\*\*\* If you are only performing tests on Excepted list, Schedule B, do not use this section\*\*\*

<b>Chemistry</b> <input type="checkbox"/> Routine <input type="checkbox"/> Blood Gas <input type="checkbox"/> Endocrinology <input type="checkbox"/> Toxicology: Drugs of Abuse <input type="checkbox"/> Toxicology: Therapeutic <input type="checkbox"/> Toxicology: Heavy Metals <input type="checkbox"/> Radioimmunoassay	<b>Genetics</b> <input type="checkbox"/> Routine <input type="checkbox"/> Molecular <input type="checkbox"/> Cytogenetics	<b>Forensic Toxicology</b> <input type="checkbox"/> Toxicology: Job Related	<b>Microbiology</b> <input type="checkbox"/> Bacteriology <input type="checkbox"/> Parasitology <input type="checkbox"/> Mycology <input type="checkbox"/> Mycobacteriology <input type="checkbox"/> Virology	<b>Health Awareness</b> <input type="checkbox"/> Cholesterol/HDL <input type="checkbox"/> Other Excepted Tests *  * Excepted tests under Health Awareness require a General Permit.
<b>Immunohematology</b> <input type="checkbox"/> ABO/Rh/Non Transfusion/Transplant <input type="checkbox"/> ABO/Rh <input type="checkbox"/> Antibody Detection <input type="checkbox"/> Antibody Identification <input type="checkbox"/> Compatibility Testing	<b>Hematology</b> <input type="checkbox"/> Routine <input type="checkbox"/> Coagulation	<b>Molecular Biology</b> <input type="checkbox"/> Nucleic Acid Probes <input type="checkbox"/> PCR Amplifications <input type="checkbox"/> Recombinant Nucleic Acid Techniques	<b>Pathology</b> <input type="checkbox"/> Histopathology <input type="checkbox"/> Dermatopathology <input type="checkbox"/> Oral Pathology <input type="checkbox"/> Cytology-GYN <input type="checkbox"/> Cytology-Non- GYN	<b>Immunology</b> <input type="checkbox"/> General Immunology <input type="checkbox"/> Syphilis Serology <input type="checkbox"/> Histocompatibility

## V. Schedule B - Excepted Tests \*

\* Note: Not all tests excepted by Maryland regulations are waived by CLIA. You can check the test categories for CLIA at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/search.cfm>

<b>Chemistry</b> <input type="checkbox"/> BNP <input type="checkbox"/> Dipstick Glucose <input type="checkbox"/> Dipstick Urinalysis <input type="checkbox"/> Dipstick Microalbumin & creatinine, urine <input type="checkbox"/> Fructosamine (whole blood) <input type="checkbox"/> Glucose (FDA Home Device) <input type="checkbox"/> Hemoglobin A1c (Glycohemoglobin) <input type="checkbox"/> Microscopic Urinalysis <input type="checkbox"/> Urine or saliva drug or alcohol for approved counselors	<b>Hematology</b> <input type="checkbox"/> Fern Test <input type="checkbox"/> Hematocrit <input type="checkbox"/> Hemoglobin <input type="checkbox"/> Nitrazine Test <input type="checkbox"/> Semen analysis, qualitative <input type="checkbox"/> Sickle Cell Testing <input type="checkbox"/> CLIA Waived PT/INR
<b>Immunology</b> <input type="checkbox"/> Bladder marker, H-related protein, qualitative <input type="checkbox"/> H.Pylori (whole blood) <input type="checkbox"/> Heterophyle AG (whole blood) <input type="checkbox"/> Mono Slide Test <input type="checkbox"/> NMP Bladder Marker, qualitative <input type="checkbox"/> Rheumatoid Factor <input type="checkbox"/> Urine Pregnancy Test	<b>Microbiology</b> <input type="checkbox"/> Dermatophyte Screen <input type="checkbox"/> Fecal Fat <input type="checkbox"/> Gram Stain <input type="checkbox"/> Group A Strep Screen (non-culture) <input type="checkbox"/> Influenza Antigen (nasal or throat swab) <input type="checkbox"/> KOH Preparation <input type="checkbox"/> Occult Blood <input type="checkbox"/> Occult Blood, gastric <input type="checkbox"/> Pinworm Prep <input type="checkbox"/> Urine Colony Count (no ID) <input type="checkbox"/> Wet Mount  <input type="checkbox"/> Trichomonas vaginalis antigen <input type="checkbox"/> Bacterial Sialidase <input type="checkbox"/> Adenovirus antigen eye fluid

**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

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 Medical Director must match Director 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, PA, chiropractor, podiatrist, dentist)

### 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