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 http://dhmh.maryland.gov/ohcq/Labs/docs/LabsApps/md_compliance_app.pdf

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 3-4 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.

MARYLAND	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

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

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)			

IV. Schedule A – General Permit

*** If you are only performing tests on Excepted list, 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 *

- ☐ Cholesterol/Lipids
- ☐ Glucose Finger Stick
- ☐ Hemoglobin A1c

* performed at health fairs not routine chemistry lab
*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
- ☐ Histocompatability

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

Chemistry

- ☐ CLIA waived blood lipid analysis for cholesterol, HDL, LDL, and triglycerides.
- ☐ Dipstick Glucose BNP ☐
- ☐ Dipstick Urinalysis
- ☐ Dipstick Microalbumin & creatinine, urine
- ☐ Fructosamine (whole blood)
- ☐ Glucose (FDA Home Device)
- ☐ Hemoglobin A1c (Glycohemoglobin)
- ☐ Microscopic Urinalysis
- ☐ Urine or saliva drug or alcohol for approved counselors

Hematology

- ☐ Fern Test
- ☐ Hematocrit
- ☐ Hemoglobin
- ☐ Nitrazine Test
- ☐ Semen analysis, qualitative
- ☐ Sickle Cell Testing
- ☐ CLIA Waived PT/INR

Immunology

- ☐ Bladder marker, H-related protein, qualitative
- ☐ H.Pylori (whole blood)
- ☐ Heterophyle AG (whole blood)
- ☐ Mono Slide Test
- ☐ NMP Bladder Marker, qualitative
- ☐ Rheumatoid Factor
- ☐ Urine Pregnancy Test

Microbiology

- ☐ Dermatophyte Screen Trichomonas vaginalis antigen ☐
- ☐ Bacterial Sialidase
- ☐ Gram Stain Adenovirus antigen eye fluid ☐
- ☐ Group A Strep Screen (non-culture)
- ☐ Influenza Antigen (nasal or throat swab)
- ☐ KOH Preparation
- ☐ Occult Blood
- ☐ Occult Blood, gastric
- ☐ Pinworm Prep
- ☐ Urine Colony Count (no ID)
- ☐ Wet Mount

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, 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**