



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

Office Use Only
Date Received:
Date Completed:

Laboratory Licensing Change Form

Please provide us with the changes in the fields below along with the effective date of the change.
For a change of Director, a copy of the Director’s medical license, medical diploma and board certification must be submitted. Please send diploma, board certification and CV for a PhD Director.
CLIA certificate of compliance and PPM labs must submit a CLIA 116 application as well to update director.
CLIA certificate of accreditation labs must contact their accreditation agency to update director.

*****THIS FORM MUST BE SIGNED BY THE DIRECTOR FOR ALL CHANGES TO BE VALID*****

Please return this form by fax:
410-402-8213

Current Name of Lab: _____

State Lab ID # _____ Federal CLIA #: _____ Is this CLIA a multisite? Y N

Laboratory Name: _____ Date of Change: _____

Owner: _____ Date of Change: _____

Tax ID #: _____ Date of Change: _____

Director: _____ Date of Change: _____

Physical Address: _____ Date of Change: _____

Mailing/Billing Address: _____ Date of Change: _____

Telephone #: _____ Date of Change: _____

Fax #: _____ Date of Change: _____

Please list specific tests you are adding or deleting, indicate for each test the instrument/kit and manufacturer used as well as the effective date of change. Please also use the test menu page, Schedule A and B to list the testing discipline that will appear on the license

Changes/Additions/Deletions to Tests

Test Name	Kit/Instrument Used	Add	Delete	Date of Change
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____

Change State License Status to:

Letter of Exception General Permit Date of Change: _____

Change my CLIA Certification Status to: (must submit with a CMS-116, both forms must then be mailed to our address)

Waiver Compliance Provider Performed Microscopic Procedures (PPMP)

Accreditation with which program? _____

Date of Change: _____

Our office has closed and/or discontinued all clinical testing. Date of Change: _____

Print Laboratory Director's Name: _____

Laboratory Director's Signature: _____ Date: _____

IV. Schedule A - General Permit

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

<p>Chemistry</p> <ul style="list-style-type: none"> <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 	<p>Genetics</p> <ul style="list-style-type: none"> <input type="checkbox"/> Routine <input type="checkbox"/> Molecular <input type="checkbox"/> Cytogenetics 	<p>Forensic Toxicology</p> <ul style="list-style-type: none"> <input type="checkbox"/> Toxicology: Job Related 	<p>Microbiology</p> <ul style="list-style-type: none"> <input type="checkbox"/> Bacteriology <input type="checkbox"/> Parasitology <input type="checkbox"/> Mycology <input type="checkbox"/> Mycobacteriology <input type="checkbox"/> Virology 	<p>Health Awareness *</p> <ul style="list-style-type: none"> <input type="checkbox"/> Cholesterol/Lipids <input type="checkbox"/> Glucose Finger Stick <input type="checkbox"/> Hemoglobin A1c <p>* performed at health fairs not routine chemistry lab *must be CLIA waived</p>
<p>Immunoematology/ Blood Bank</p> <ul style="list-style-type: none"> <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 	<p>Hematology</p> <ul style="list-style-type: none"> <input type="checkbox"/> Routine <input type="checkbox"/> Coagulation <input type="checkbox"/> CLIA Waived CBC (Sysmex) 	<p>Molecular Biology</p> <ul style="list-style-type: none"> <input type="checkbox"/> Nucleic Acid Probes <input type="checkbox"/> PCR Amplifications <input type="checkbox"/> Recombinant Nucleic Acid Techniques 	<p>Pathology</p> <ul style="list-style-type: none"> <input type="checkbox"/> Histopathology <input type="checkbox"/> Dermatopathology <input type="checkbox"/> Oral Pathology <input type="checkbox"/> Cytology-GYN <input type="checkbox"/> Cytology-Non- GYN 	<p>Immunology</p> <ul style="list-style-type: none"> <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>

<p>Chemistry</p> <ul style="list-style-type: none"> <input type="checkbox"/> CLIA waived blood lipid analysis for cholesterol, HDL, LDL, and triglycerides. <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"/> Waived Whole Blood Lead Testing <input type="checkbox"/> CLIA Waived Urine Drug Screen <p style="text-align: right;">BNP <input type="checkbox"/></p> <p style="text-align: right;">Microscopic Urinalysis <input type="checkbox"/></p>	<p>Hematology</p> <ul style="list-style-type: none"> <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
<p>Immunology</p> <ul style="list-style-type: none"> <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 	<p>Microbiology</p> <ul style="list-style-type: none"> <input type="checkbox"/> Dermatophyte Screen <input type="checkbox"/> Bacterial Sialidase <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 <p style="text-align: right;">Trichomonas vaginalis antigen <input type="checkbox"/></p> <p style="text-align: right;">Adenovirus antigen eye fluid <input type="checkbox"/></p>