Maryland Department of Health	Office Use Only
Office of Health Care Quality – Laboratory Licensing	Date Received:
7120 Samuel Morse Drive	
Second Floor	
Columbia, Maryland 21046	Date Completed:
Phone: 410.402.8025 Fax: 410.402.8213	

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
Fax: 410-402-8213
Email: ohcq.fax@maryland.gov

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:**_____

Email: _____ **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
_____	_____	☐	☐	_____
_____	_____	☐	☐	_____
_____	_____	☐	☐	_____
_____	_____	☐	☐	_____
_____	_____	☐	☐	_____
_____	_____	☐	☐	_____
_____	_____	☐	☐	_____
_____	_____	☐	☐	_____

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:** _____

☐ **Check to request an updated CLIA certificate. CMS fees may be applied for this request.**

IV. Schedule A – General Permit

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

Chemistry	Genetics	Forensic Toxicology	Microbiology	Health Awareness *
☐ Routine ☐ Blood Gas ☐ Endocrinology ☐ Toxicology: Drugs of Abuse ☐ Toxicology: Therapeutic ☐ Toxicology: Heavy Metals ☐ Radioimmunoassay	☐ Routine ☐ Molecular ☐ Cytogenetics	☐ Toxicology: Job Related	☐ Bacteriology ☐ Parasitology ☐ Mycology ☐ Mycobacteriology ☐ Virology	☐ Cholesterol/Lipids ☐ Glucose Finger Stick ☐ Hemoglobin A1c * performed at health fairs not routine chemistry lab *must be CLIA waived

Immunohematology/ Blood Bank	Hematology	Molecular Biology	Pathology	Immunology
☐ ABO/Rh/Non Trans-fusion/Transplant ☐ ABO/Rh ☐ Antibody Detection ☐ Antibody Identification ☐ Compatibility Testing	☐ Routine ☐ Coagulation ☐ CLIA Waived CBC (Sysmex)	☐ Nucleic Acid Probes ☐ PCR Amplifications ☐ Recombinant Nucleic Acid Techniques	☐ Histopathology ☐ Dermatopathology ☐ Oral Pathology ☐ Cytology-GYN ☐ Cytology-Non- GYN	☐ 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   Microscopic Urinalysis ☐
☐ Dipstick Microalbumin & creatinine, urine
☐ Fructosamine (whole blood)
☐ Glucose (FDA Home Device)
☐ Hemoglobin A1c (Glycohemoglobin)
☐ Waived Whole Blood Lead Testing
☐ CLIA Waived Urine Drug Screen

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