pennsylvania
DEPARTMENT OF HEALTH

Bureau of Laboratories
PO Box 500
Exton PA 19341-0500
Phone: 610-280-3464

Change of Status Form

This form is for **changes and updates only**. Please only provide the Bureau with information that is changing in the fields below along with the effective date of the change. Note that the name of the laboratory cannot exceed 32 characters including spaces so make any necessary abbreviations.

Changes will be made to both state permit and CLIA certificates (if applicable).

In order for the Department to qualify a director a copy of the curriculum vitae (CV) and medical license must be enclosed. For the Department to qualify a director as a moderate or high complexity director under CLIA, additional documents are required. Please include a copy of any board certifications and a copy of any CEUs (continuing educational units).

State Lab ID # _____ (required) **Federal CLIA # 39D _____(required)**

Is this Clinical Laboratory Improvement Amendments number (CLIA) a multisite laboratory? Y N

Are you reopening a laboratory that was previously closed less than 6 months? Y N ***

Laboratory Name: _____ _____ **Effective Date:** _____

Owner: _____ **Effective Date:** _____

Tax ID #: _____ **Effective Date:** _____

Director: _____ _____ **Effective Date:** _____

Dr.'s Medical License: _____ **Effective Date:** _____

Physical Address: _____ **Effective Date:** _____

_____

Mailing Address: _____ **Effective Date:** _____

_____

Billing Address: _____ **Effective Date:** _____

_____

Telephone Number: _____ **Effective Date:** _____

Fax Number: _____ **Effective Date:** _____

Contact Name: _____ **Effective Date:** _____

Contact Phone #: _____ **Effective Date:** _____

Contact Email Address: _____ **Effective Date:** _____

Change my state Clinical Laboratory Permit to:

☐ **Physician's Office or Clinic** ☐ **Hospital** ☐ **Independent** ☐ **Nursing Home** ☐ **Mobile Lab** ☐ **Screening Site**

Effective Date: _____

State Lab ID # _____(required) **Federal CLIA # 39D _____(required)**

Please use the chart below and list the tests you are **adding or deleting** from your current test menu **as well as the laboratories' current test menu**. List the effective date of the change for the addition or deletion. For each test, indicate the instrument/kit and 510(k) Number. If your laboratory is adding moderate and/or high complexity testing, include the following documents: procedure, validation studies, training documentation and proof of proficiency testing enrollment.

Changes/Additions/Deletions to Test

Test Name	Kit/Instrument/510(k) Number	Add/Delete	Effective Date

If your laboratory is adding alcohol, drug, lead or EP testing, enrollment into the Pennsylvania Toxicology Proficiency Testing Program is a requirement for state licensure. Your lab will be contacted with details concerning this program.

Change my CLIA Certificate to:

☐ Waiver ☐ Compliance ☐ Provider-Performed Microscopic Procedures (PPMP)

☐ Accreditation-with which program? _____

Effective Date: _____

☐ **Our office has closed and/or discontinued all clinical testing.** **Effective Date:** _____

Print Laboratory Director Name Signature of Director Date

Print Owner/Corporation Name Authorized Signature Date

THIS FORM MUST BE SIGNED BY THE DIRECTOR/OWNER FOR ALL CHANGES TO BE VALID -

for director changes, the new director MUST sign this form.

Revised MAM 3/10/2014

INSTRUCTIONS FOR COMPLETING THE CHANGE OF STATUS FORM

Please provide only the information that is changing along with the current test menu.

Laboratory Name

This is the name that will be used for all aspects of the facility (billing, etc.). This name must be exactly the same as it appears on your CLIA certificate. Name may only be 32 characters including spaces.

Laboratory Address

This is the physical location of the laboratory where testing and treatment is performed. Use the mailing/billing address only if facility wants bills and other correspondence sent to separate address. Both physical and mailing/billing address(es) must be exactly as it appears on your CLIA certificate.

Laboratory Owner

Provide the name of the person(s) or corporation that owns the laboratory.

Contact Person

Provide the name of the person to contact in the event that there are questions about the changes.

Director

This must be a person who holds a doctorate and who qualifies under Section 5.21 of the Clinical Laboratory Regulations. The director must be the same for both State and CLIA purposes. Neither the state nor the federal government recognizes co-directors. In order for the Department to qualify a director, a copy of the curriculum vitae (CV), a copy of any board certifications and a copy of the director's medical license must be enclosed. For the Department to qualify a director as a moderate or high complexity director under CLIA, additional documents are required. Please include a copy of any board certifications and a copy of any CEUs (continuing educational units).

Adding Tests

The following documents must be enclosed for the addition of all moderate, high complexity tests and lab-developed tests: procedure manual, validation studies, training documentation and proof of proficiency testing enrollment. The following documents must be enclosed for PPMP tests: list of testing personnel for PPMP tests and documentation of Quality Assurance plan two times per year (example: proficiency testing or split samples).

Change My Certificate To

Check the appropriate type of certificate if the addition or deletion of tests will change your certificate.

Laboratory Equipment/Kits Used for Testing

List all equipment used to perform laboratory tests including glucose meters, strep test kits, etc.

ALLOW 4-6 WEEKS FOR INITIAL REVIEW

*Initial review is defined as the time the application is first reviewed for completion of required documents.

****Laboratories closed 6 months or longer must submit a completed PA Dept. of Health Clinical Laboratory Application and Clinical Laboratory Improvement Amendments (CLIA) application. Indicate your existing State Laboratory identification number and Federal CLIA number on the appropriate application.