



CHANGE OF STATUS FORM

FOR DEPARTMENT USE ONLY

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 please 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. A copy of the actual medical license must be included. Printouts from the PA Department of State website will not be accepted. Additional documents, such as board certifications and/or Continuing Educational Units (CEUs), will be required for laboratories performing moderate and/or high complexity testing.

State Lab ID # _____ (Required) Federal CLIA # _____ (Required)

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
 Pharmacy
 Mobile Lab
 Screening Site

Effective Date: _____

State Lab ID # _____(Required)

Federal CLIA # _____(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 kit/instrument, 510(k) Number and PT provider, if applicable. Additional documents may be required if your laboratory is adding moderate and/or high complexity testing.

Changes/Additions/Deletions to Test

Test Name	Kit/Instrument/510(k) Number/PT Provider	Add/Delete/Current	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: (If changing from Certificate of Waiver to another certificate type, a revised CMS-116 form must also be submitted)

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 New Owner/Corporation Name Authorized Signature Date

Print Previous 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.

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 Owner/Tax ID Number

Provide the name of the person(s) or corporation that owns the laboratory and the federal tax ID number. The previous owner and the new owner must sign the form.

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. A copy of the actual medical license must be included. Printouts from the PA Department of State website will not be accepted. Additional documents may be required for laboratories performing moderate and/or high complexity testing.

Medical License Number

Indicate the medical license number for an M.D. or a D.O.

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 a separate address. Both physical and mailing/billing addresses must be exactly as it appears on your CLIA certificate.

Telephone/Fax Number

Provide telephone and fax numbers for the physical location.

Contact Person

Provide the name of the person to contact in the event that there are questions about the changes. Include the contact person's phone number and email address.

Change My State Clinical Laboratory Permit To

Indicate the laboratory type (if it will be changing).

Adding/Deleting Tests

Provide a list of all tests being added and/or deleted. Also list tests on the laboratory's current test menu. The following documents must be available upon request: procedure manual, list of testing personnel, validation studies, training documentation and/or proof of proficiency testing enrollment. List all equipment used to perform each test. Indicate the PT provider for regulated analytes.

Change My CLIA Certificate To

Check the appropriate type of certificate if the addition or deletion of tests will change your certificate type. For a change from a Certificate of Waiver to any other certificate type, and updated CLIA application (CMS-116) must also be submitted. If changing to a Certificate of Accreditation or to a different Accreditation Organization (AO), you must also submit a letter from the AO confirming accreditation.

Office is Closing/Discontinuing Testing

Check this box if the laboratory is closing and/or has discontinued all laboratory testing.

ALLOW 4-6 WEEKS FOR INITIAL REVIEW*

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

Return the form with all required documentation to:

Bureau of Laboratories
P.O. Box 500
Exton, PA 19341

For overnight delivery services, our physical location is:

110 Pickering Way
Exton, PA 19341

The form may also be faxed to (610) 450-1932