



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 medical license must be enclosed. Additional documents, such as board certifications, evidence of clinical laboratory experience, and/or Continuing Educational Units (CEUs), will also be required.

**State Lab ID #:** \_\_\_\_\_ **Federal CLIA #:** \_\_\_\_\_ **Is this CLIA a multisite?**  Yes  No

**Laboratory Name:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

**Owner:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

**Tax ID #:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

**Director:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

**Dr.'s Medical License:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

**Physical Address:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

\_\_\_\_\_ **Effective Date:** \_\_\_\_\_

**Mailing Address:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

\_\_\_\_\_ **Effective Date:** \_\_\_\_\_

**Billing Address:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

\_\_\_\_\_ **Effective Date:** \_\_\_\_\_

**Telephone Number:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

**Fax Number:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

**Contact Name:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

**Contact Phone #:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

**Contact Email Address:** \_\_\_\_\_ **Effective Date:** \_\_\_\_\_

**VIN #:** \_\_\_\_\_ **Plate #:** \_\_\_\_\_ **State:** \_\_\_\_\_ **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: (A revised CMS-116 form must also be submitted when changing from a Certificate of Waiver)**

- 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.**

**SIGN IN INK OR USE A SECURE ELECTRONIC SIGNATURE**

**For director changes, the new director MUST sign the Lab Director Attestation.**

## 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 for a director, a copy of any board certifications and or a copy of the director's medical license must be enclosed. The Director's attestation form must be submitted. 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 are 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. Laboratories are advised to use a generic contact email.

### 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, an 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