



FOR DEPARTMENT USE ONLY
STATE ID # _____
LEVEL _____
CHECK REC'D Y OR N

## CLINICAL LABORATORY APPLICATION

**ALL SECTIONS MUST BE COMPLETED, please allow a minimum of 4-6 weeks for initial review\***  
**NO PATIENT TESTING MAY BE PERFORMED UNTIL A PERMIT HAS BEEN GRANTED**

LABORATORY NAME:			DIRECTOR:		
LABORATORY PHYSICAL ADDRESS:			IF M.D. OR D.O. GIVE MEDICAL LICENSE NUMBER:		
CITY:	STATE:	ZIP CODE:	TELEPHONE NUMBER:	FAX NUMBER:	
LABORATORY MAILING ADDRESS:			FEDERAL TAX ID #	E-MAIL ADDRESS:	
CITY:	STATE:	ZIP CODE:	OWNER NAME:		
LABORATORY BILLING ADDRESS:			CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) #: (IF PREVIOUSLY ASSIGNED OTHERWISE FOR DEPT USE ONLY): 39D		
CITY:	STATE:	ZIP CODE:	NAME OF CONTACT PERSON:	CONTACT PERSON TELEPHONE NUMBER:	
TYPE OF CLIA CERTIFICATE REQUESTED (CHECK ONE)					
<input type="checkbox"/> CERTIFICATE OF WAIVER		<input type="checkbox"/> PROVIDER-PERFORMED MICROSCOPY PROCEDURES (PPMP)		<input type="checkbox"/> COMPLIANCE	
<input type="checkbox"/> ACCREDITATION					

Application is for (Check only one):

- Hospital Laboratory     
  Independent Laboratory     
  Physician Office/Clinic     
  Nursing Home

**Before submitting the application, choose the kits/instruments your lab will use for testing. For Toxicology testing these kits/instruments must be available for pre-licensure testing.**

List All Laboratory Equipment/Kits Used for Testing (e.g., 510(k) Number, name of glucose meter, strep test kit, etc.):


**A check or money order for \$100.00, payable to the "Pennsylvania Department of Health", must accompany this application.**

-OVER-

Check all lab tests that are being performed by your facility. Also, check the proficiency testing program (if applicable) in which you have enrolled. If the testing you perform is not on this list, please describe those tests on a separate sheet.

**BACTERIOLOGY**

- Gram Stain
- GC Screen
- Throat Screen (rapid strep)
- Throat Screen (culture)
- Urine Culture Screen (including colony counts)
- Bacterial Susceptibility
- Chlamydia Antigen
- H. pylori* (urease)

**MYCOLOGY**

- Dermatophyte Screening
- KOH Prep

**PARASITOLOGY**

- Wet Mounts
- Pinworms
- Scabies

**VIROLOGY**

- Tzanck Smears

**SYPHILIS SEROLOGY**

**NON-SYPHILIS SEROLOGY**

- Pregnancy Testing
- Infectious Mononucleosis
- Rheumatoid Factor
- HIV
- Allergy Testing
- Histocompatibility
- Chlamydia Antibody
- ANA
- H. pylori* Antibody
- Influenza A and/or B Screen
- HIV (Rapid)

**HEMATOLOGY**

- Hemoglobin
- Differential Smears
- Prothrombin Time

- Hematocrit
- CBC
- ACT
- Centrifugal Hematology
- Semen Analysis
- Nasal Smears
- Sedimentation Rate
- Sickle Cell Screening
- Manual Differential of Atypical Cells
- Bleeding Time

**IMMUNOHEMATOLOGY**

- Non Transfusion
- Immuno-Group & RH Typing
- RH Titers
- Cross Matching
- Transfusion Service

**TISSUE PATHOLOGY**

- Pathology Frozen Section
- Oral Pathology
- Cytogenetics
- Dermatopathology

**EXFOLIATIVE CYTOLOGY**

- Histocompatibility
- Gynecological
- Non-Gynecological

**RADIOISOTOPE TECHNIQUES**

**URINALYSIS**

- Dipstick Urinalysis
- Microscopic Urinalysis
- Automated Urinalysis

**CLINICAL CHEMISTRY**

- Routine Chemistry
- Endocrinology
- Cholesterol
- Fecal Occult Blood
- Fecal Occult Blood Instrument

- Blood Glucose (incl. Whole Blood)
- Blood Gases
- Therapeutic Drug Monitoring
- PSA Testing
- Synovial Fluid
- Glycohemoglobin (A1C)
- Theophylline
- Electrolytes
- Fructosamine
- pH of Body Fluids
- HDL Cholesterol
- LDL Cholesterol
- Triglycerides
- TSH Rapid
- BNP
- Bladder Tumor Antigen

**TOXICOLOGY**

- Alcohol Analysis
  - Serum/Plasma
  - Blood
- Drugs Blood and/or Serum
  - Drugs Blood Screening
  - Drugs Blood Confirmatory
  - Drugs Serum Screening
  - Drugs Serum Confirmatory
- Drugs Urine
  - Drugs Urine Screening
  - Drugs Urine Confirmatory
- Limited Urine Drugs Survey
- Blood Lead
- Erythrocyte Protoporphyrin

Other Please list:

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\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**PROFICIENCY TESTING**

All facilities performing tests on CLIA regulated analytes are **required** to participate in a proficiency testing program. **Enrollment into the Pennsylvania Toxicology Proficiency Testing Program is a requirement for state licensure for Toxicology analytes.\*** Unregulated analytes (those not regulated by CLIA or CLIA-waived) require the laboratory to take steps to assure the accuracy of testing in lieu of testing PT samples. CLIA requires that, at least twice annually, you verify the accuracy of any test or procedure that you perform. You must instruct the program to release results to 'The State Agency'. Listed below are the programs approved under the regulations of the Commonwealth and CLIA. Please check below the agency with which you have enrolled and send in proof of enrollment with this application.

- College of American Pathologists (800) 323-4040
- American Proficiency Institute (800) 333-0958
- American Academy of Family Physicians (800) 274-2237
- American Thoracic Society (Blood Gas Only) (212) 315-8808
- American College of Physicians/Medical Laboratory Evaluation (MLE) (800) 523-1546
- American Association of Bioanalysts (800) 234-5315
- American Society of Internal Medicine (800) 338-2746
- AccuTest (800) 665-2575
- Pennsylvania Toxicology Program\***

I hereby certify that the information stated herein is true and complete to the best of my knowledge and belief.

Print Laboratory Director Name

Signature of Director

Date

Print Owner/Corporation Name

Authorized Signature

Date

## INSTRUCTIONS FOR COMPLETING THE CLINICAL LABORATORY APPLICATION

### 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 application.

### 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).

### Medical License Number

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

### Telephone/Fax Number

Provide telephone and fax number for the physical location.

### CLIA Number

Fill in only if a number has been assigned by the Centers for Medicare and Medicaid Services (CMS) otherwise leave blank.

### Application Type

Check the appropriate type of laboratory.

### Laboratory Equipment/Kits Used for Testing

Check all tests that are being performed in your laboratory. Please do not include tests that are sent to reference laboratories.

List all equipment used to perform laboratory tests including glucose meters, strep test kits, etc. Please include 510(k) Number on all kits.

### Proficiency Testing Program

Chose a proficiency testing program if applicable and send in proof of enrollment with this application (invoice or order confirmation).

**APPLICATIONS MUST BE SIGNED BY DIRECTOR/OWNER. THE STATE AND CLIA APPLICATIONS MUST BE SENT IN TOGETHER WITH ALL SECTIONS COMPLETED.**

ALLOW 4-6 WEEKS FOR INITIAL REVIEW\*

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

Return both CLIA and Clinical Laboratory Application 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