

CLINICAL LABORATORY APPLICATION

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

ALL SECTIONS MUST BE COMPLETED
(Please allow a minimum of 4 weeks for initial review*)

NO PATIENT TESTING MAY BE PERFORMED UNTIL A PERMIT HAS BEEN ISSUED

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:			OWNER NAME:	
CITY:	STATE:	ZIP CODE:	FEDERAL TAX ID #:	NAME OF CONTACT PERSON:
LABORATORY BILLING ADDRESS:			CONTACT PERSON TELEPHONE NUMBER:	CONTACT PERSON EMAIL ADDRESS:
CITY:	STATE:	ZIP CODE:	CLIA # (IF PREVIOUSLY ASSIGNED):	
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
 Pharmacy

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

List all laboratory kits/instruments that will be used for testing
(e.g., Name/Manufacturer of glucose meter, strep kit, FDA 510(K) number, etc.)

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

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
- Chlamydia Screen
- Throat Screen (rapid strep)
- Throat Screen (culture)
- Urine Culture (including colony counts)
- Bacterial Susceptibility

MYCOLOGY

- Dermatophyte Screening
- KOH Prep

PARASITOLOGY

- Wet Mounts
- Pinworms
- Scabies
- Trichomonas Screen

VIROLOGY

- COVID-19
- Influenza A/B
- RSV

SYPHILIS SEROLOGY

NON-SYPHILIS SEROLOGY

- Allergy Testing
- Chlamydia Antibody
- COVID-19 Antibody
- Hepatitis C
- HIV
- Histocompatibility
- Infectious Mononucleosis
- Lyme Disease

HEMATOLOGY

- Bleeding Time
- CBC
- Differential Smear

- FERN Testing
- Hematocrit
- Hemoglobin
- Manual Differential of Atypical Cells
- Prothrombin Time
- PTT
- Sedimentation Rate
- Semen Analysis
- Sickle Cell Screening

IMMUNOHEMATOLOGY

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

TISSUE PATHOLOGY

- Cytogenetics
- Dermatopathology
- Pathology Frozen Section
- Histopathology
- Oral Pathology

EXFOLIATIVE CYTOLOGY

- Histocompatibility
- Gynecological
- Non-Gynecological

URINALYSIS

- Dipstick Urinalysis
- Automated Urinalysis
- Microscopic Urinalysis

CLINICAL CHEMISTRY

- Routine Chemistry
- Basic Metabolic Panel
- Comprehensive Metabolic Panel
- Blood Gases
- Electrolytes

- Fecal Occult Blood
- Lipid Panel
- Cholesterol
- HDL Cholesterol
- LDL Cholesterol
- Triglycerides
- Glucose (including whole blood)
- Glycohemoglobin (A1C)
- Inflammadry
- TearLab Osmolarity
- pH of Body Fluids
- pH of Vaginal Fluids
- Pregnancy Testing
- Synovial Fluid
- Therapeutic Drug Monitoring
- TSH Screen

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 (CLIA-waived)
- Blood Lead
- Erythrocyte Protoporphyrin

Other Please list:

PROFICIENCY TESTING

All facilities performing tests on CLIA regulated analytes are **required** to participate in a proficiency testing program. You must instruct the program to release results to 'The State Agency'. **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. Listed below are the programs approved under the regulations of the Commonwealth and CLIA. Please check below the agency with which you have enrolled, if applicable, 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 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 the 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.

Director

This must be a person who holds a doctorate level degree 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. Please note, a copy of the license with expiration date must be submitted. A print-out from the PA Department of State's website is not acceptable. 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 numbers for the physical location.

Laboratory Owner/Federal Tax ID Number

Provide the name of the person(s) or corporation that owns the laboratory and the federal tax ID number.

Contact Person

Provide the name of the person to contact in the event that there are questions about the application. Please provide the contact person's full name, phone number and email address.

CLIA Number

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

Type of CLIA Certificate Requested

If applying for a CLIA certificate, indicate the type of CLIA certificate being requested.

Application Type

Check the appropriate type of laboratory.

Laboratory Instruments/Kits Used for Testing

List all instruments/kits used to perform laboratory tests including glucose meters, strep test kits, etc. Please include the FDA 510(K) numbers for all kits.

Testing Performed

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

Proficiency Testing Program

If applicable, choose a proficiency testing program 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.

A CHECK OR MONEY ORDER FOR \$100.00, PAYABLE TO THE "PENNSYLVANIA DEPARTMENT OF HEALTH", MUST ACCOMPANY THIS APPLICATION.

ALLOW 4 WEEKS FOR INITIAL REVIEW*

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

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