

# Clinical Laboratory Permit and Proficiency Testing Fees

This document explains the various fees related to operating a clinical laboratory in Pennsylvania. Additional information on obtaining a Pennsylvania clinical laboratory permit or participating in the Bureau of Laboratories' proficiency testing programs can be found on the Bureau's website at [www.health.state.pa.us/labs](http://www.health.state.pa.us/labs). Clicking on the Lab Licensure and Proficiency Testing links in the blue navigation bar on the left side of the page will take you to information on those topics.

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## FEDERAL CLINICAL LABORATORY CERTIFICATE FEES

The United States Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) charges fees for federal Clinical Laboratory Improvement Amendments (CLIA) certificates. Laboratories must pay an initial fee prior to receipt of their first certificate and a biannual renewal fee.

**CMS handles all activities related to CLIA certificate fees.** The Bureau does not issue invoices or collect payments. However, the Bureau can assist in resolving problems related to CLIA fees. Please do not contact the Bureau with routine inquiries regarding the status of your invoice or payment.

Laboratories **MUST** have both a federal CLIA certificate and a Pennsylvania Clinical Laboratory Permit in order to perform patient testing. **Patient testing cannot begin until the CLIA invoice is paid and the certificate is received. Laboratories with an expired CLIA certificate that have not recently submitted a payment to CMS should contact the Bureau immediately. Laboratories with an expired CLIA certificate that have recently submitted a payment to CMS should allow a minimum of two weeks for their new certificate to arrive.** CMS billing for CLIA fees is an automated process that is not controlled by the Bureau. Consequently, **the Bureau cannot expedite the generation of invoices or processing of payments.** Once CMS has processed a laboratory's payment, a CLIA certificate will be mailed. **The Bureau cannot generate CLIA certificates.**

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## PENNSYLVANIA CLINICAL LABORATORY PERMIT FEES

### Initial Permit Fee

All laboratories are required to pay a one-time fee of \$100 upon receipt of their first Pennsylvania clinical laboratory permit. Payment is due with the submission of the new laboratory application. If payment is not submitted along with the application the laboratory will be invoiced for the fee and payment must be made by the date specified on the invoice. The licensure process will not be complete until the fee is paid.

### Permit Renewal Fee

Pennsylvania clinical laboratory permits are valid from their issue date until the following August 15<sup>th</sup>. In order to renew a permit for the following year, a laboratory must pay an annual permit renewal fee. Invoices for renewal fees are automatically sent out to all laboratories prior to August 15<sup>th</sup>. Payment is due by the date specified on the invoice.

The permit renewal fee amount is dependent upon the types of testing a laboratory performs. Tests are placed into the five categories listed below. Laboratories are charged \$100 for each category in which they perform one or more tests. Therefore, a renewal fee may be \$100, \$200, \$300, \$400, or \$500 depending upon the type of tests a laboratory performs.

# Clinical Laboratory Permit and Proficiency Testing Fees

- Clinical Chemistry (including urinalysis)
- Hematology (including immunohematology)
- Microbiology (including bacteriology, virology, mycology, parasitology, syphilis serology, and non-syphilis serology)
- Radioisotope Techniques
- Tissue Pathology (including exfoliative cytology)

The number of different tests a laboratory performs within a category does not affect the renewal fee, nor is the fee affected by the laboratory's annual test volume.

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## BUREAU OF LABORATORIES PROFICIENCY TESTING FEES

Laboratories participating in the Bureau's proficiency testing programs are required to pay an annual enrollment fee. The annual fee for each program is listed below. Laboratories enrolling in proficiency testing programs will receive an invoice following review of submitted documents by the bureau's program coordinator. Payment is due by the date on the invoice.

In September/October of each year, all laboratories enrolled in the Bureau's proficiency testing programs will automatically receive an invoice for the following year's enrollment fee. Payment is due by the date specified on the invoice.

Laboratories that wish to discontinue their enrollment in a program should complete a change of status form or submit a letter with the laboratory director's signature, attach the invoice and mail the documents to the Bureau of Laboratories.

- Blood and/or Serum Alcohol - \$350
- Blood and/or Serum Drugs of Abuse - \$700
- Blood Lead - \$350
- Erythrocyte Protoporphyrin - \$350
- Urine Drugs of Abuse - \$600
- Urine Drugs of Abuse – Limited Service - \$200

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## SUBMITTING PAYMENT

Payment must be made using a check made payable to "Pennsylvania Department of Health". Please include the laboratory's state identification number and the invoice number on the check to ensure payment is credited to the proper account. Please return the bottom portion of the invoice with your payment. Payment should be mailed to the following address.

**Bureau of Laboratories  
Division of Laboratory Improvement  
P.O. Box 500  
Exton, PA 19341**

# Clinical Laboratory Permit and Proficiency Testing Fees

## CONTACTING THE BUREAU

When contacting the Bureau regarding fees please be prepared to provide the following information. If you reach voicemail, or contact the Bureau by fax or e-mail, please include this information in your message.

- Laboratory Name
- Pennsylvania Laboratory Identification Number
- Clinical Laboratory Improvement Amendments (CLIA) Identification Number
- Contact Person's Name
- Telephone Number
- Fax Number
- E-mail Address

## Billing Contacts

Questions related to invoices and payments for both Pennsylvania clinical laboratory permits and proficiency testing should be directed to the individuals listed below.

Name	Phone	Fax	E-mail
Pam Groff	(484) 870-6425	(610) 450-1932	pgroff@pa.gov
Deb Kern	(484) 870-6396	(610) 450-1932	debkern@pa.gov

## Proficiency Testing Contacts

Technical questions related to participating in the Bureau's proficiency testing programs should be directed to the individuals listed below.

Program	Coordinator	Phone	Fax	E-mail
Blood and/or Serum Alcohol	Jennifer Okraska	(484) 870-6405	(610) 450-6608	jokraska@pa.gov
Blood and/or Serum Drugs of Abuse	Chris Andrychowski	(484) 870-6377	(610) 450-6608	candrychow@pa.gov
Urine Drugs of Abuse				
Urine Drugs of Abuse – Limited Service				
Blood Lead	Peter Lambert	(484) 870-6426	(610) 280-3461	plambert@pa.gov
Erythrocyte Protoporphyrin				