

eCLEP Manual

Permit Materials Module

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eCLEP MANUAL

Introduction

The purpose of this manual is to provide clinical laboratories with the information needed to begin using the web-based, electronic clinical laboratory information management tool, eCLEP. It includes the following major sections:

- **Getting Started: An Overview** introduces a laboratory to eCLEP.
- **Requirements for Use** provides hardware and software specifications and configuration settings required to access eCLEP.
- **Navigating in eCLEP** provides detailed directions for accessing eCLEP and entering data.
- **Reapplication Submissions** provides detailed instructions for submitting the clinical laboratory permit reapplication.
- **Open Mode Submissions** provides detailed instructions for submitting changes in facility information outside of the permit reapplication period.

Getting Started: An Overview

The New York State Department of Health (NYSDOH) has developed eCLEP to enable clinical laboratories to exchange information electronically in place of mailing paper forms. This web-based application supports the inquiry, maintenance, and reporting requirements as defined by the Wadsworth Center Clinical Laboratory Evaluation Program (CLEP) and acts as a single repository for the data. eCLEP has evolved to support the submission of permit reapplications and notification of laboratory changes, as well as provide each clinical laboratory the ability to check their laboratory licensure status 24/7.

Note: *the eCLEP application does not service Limited Service Laboratories. Please see our website at <https://www.wadsworth.org/regulatory/clep/limited-service-lab-certs> for information on Limited Service Laboratories.*

eCLEP offers many advantages over existing paper-based processes, including:

Persistent Data – The system displays general laboratory information as found in the Clinical Laboratory Evaluation Program's licensure database. The most current information is displayed, eliminating redundant data entry.

Data Validation – User entries are validated for incorrectly formatted and incomplete submissions at every step, eliminating submission failures and reducing the need for follow-up communications to correct minor errors such as missing entries.

Delegating Submission – The Laboratory Director may delegate the electronic submission of Laboratory information.

Documented Delivery – Permit reapplications and changes to laboratory information are electronically transmitted; the time of the submission and username submitting the data is recorded.

eCLEP MANUAL**Requirements for Use**

To enter information into the eCLEP system, your laboratory must have a personal computer that is minimally configured as follows:

- Pentium processor or higher
- DSL or a broadband Internet connection (The laboratory is responsible for obtaining Internet access with an Internet Service Provider (ISP)).
- Printer (optional)

Browser Requirements and Configuration

Access to the Health Commerce System and eCLEP requires 256-bit encryption, browser setting to accept cookies and enabling of Javascript.

Supported browsers on desktop computers include: Microsoft Internet Explorer, Google Chrome and Safari (Mac OS only). Support browsers on mobile devices include: Google Chrome (iOS5.1/Android 4.0 or later) and Safari (iOS5.1 or later). The Health Commerce System supports the current and two previous versions supported browsers.

Limited support is available for the following browsers: Mozilla Firefox (desktop/mobile) and WebKit-based browsers. Microsoft Internet Explorer Mobile and Safari for Windows are not supported.

ECLIP MANUAL**Roles and Responsibilities**

This section describes the different levels of eCLIP users and their access and data submission privileges in the system. It also gives instructions on how to request access to the system.

eCLIP users at the laboratory will belong to one of two roles. Below is a description of the roles, followed by the user qualifications:

A **Laboratory Director** is an individual who is responsible for the administration of the technical and scientific operation of a clinical laboratory or blood bank, including the supervision of procedures, reporting of results and responsibilities specified in Section 19.3 of 10 NYCRR (New York Codes, Rules and Regulations) and Article 5 Title V Section 571 of the Public Health Law. Such person shall possess a Certificate of Qualification issued pursuant to Part 19 of 10 NYCRR. A Director is authorized to **view, enter, attest, and submit** laboratory information electronically using the eCLIP system.

An **Assistant Director** is a person who has been designated by the Laboratory Director to serve as an Assistant Director in one or multiple categories or subcategories of testing. Such person shall possess a Certificate of Qualification issued pursuant to Part 19 of 10 NYCRR. A responsible Assistant Director holding a Certificate of Qualification is authorized to **view, enter, attest, and submit** laboratory information electronically using the eCLIP system.

A **Delegated Submitter** is a person who has been given written authorization by the Laboratory Director to electronically submit laboratory information on behalf of the Laboratory Director. A Delegated Submitter is authorized to **view, enter, attest, and submit** laboratory information electronically using the eCLIP system.

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HCS Access Permissions

Before logging on to eCLEP to submit data, you will need access to the New York State Health Commerce System (HCS) at <https://commerce.health.state.ny.us>.

The New York State Department of Health assigns a NYSDOH HCS Account ID (User ID) and password to each individual who has been granted access to the HCS.

As the HCS contains confidential information, safeguard your HCS User ID and password by not revealing them to other users. Violation of the security and use agreement (e.g. sharing your User ID and password with someone else) will result in the temporary suspension of your account privileges and repeat offenses may result in the permanent removal of the account. Also, do not leave your computer logged on to the HCS unattended. For security purposes, there are **session timeouts after one hour of inactivity** and **system timeouts after eight hours of total connectivity**.

Clinical Laboratory Directors and HCS Coordinators without HCS accounts

Clinical Laboratory Directors without HCS accounts may begin the HCS account application process with the HCS Affiliation Request form available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce. After completing the form, scan and email to CLEPHCS@health.ny.gov or fax it to 518-449-6901. The Laboratory Director will receive an e-mail from camu@its.ny.gov which will include a bar-coded PDF document to sign and have notarized. This form must be returned to the Commerce Account Management Unit (CAMU) to complete the affiliation process. Laboratory directors are expected to complete and submit this form promptly. An amended permit reflecting the change in directorship will not be issued until the laboratory director's HCS account has been verified.

The HCS Affiliation Request form is also used to establish HCS Coordinators at your laboratory.

Requesting HCS Accounts for Other Individuals

The Laboratory Director or HCS Coordinator for the laboratory can electronically request an account for additional laboratory staff. The Laboratory Director or HCS Coordinator needs to log into the Health Commerce System at <https://commerce.health.state.ny.us>, select the Coordinator's Account Tools (left side under My Applications), then click on the appropriate 'Request an Account for...' link.

Delegated Submitter

The Laboratory Director may delegate data submission privileges to a staff member who already has an HCS account by signing and completing a Delegated Submitter Request form. The form is available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce.

eCLEP MANUAL

Accessing eCLEP and the Permit Materials Module

1. To access the eCLEP Home Page enter the following web address into an Internet browser:
<https://commerce.health.state.ny.us>
2. Enter your User ID and Password into the **HCS Login screen** and click **Sign In**:

PLEASE LOGIN TO BEGIN USING THE HEALTH COMMERCE SYSTEM (HCS)



User ID

Password

Forgot Your [User ID](#) or [Password](#)
 Remember User ID

LOGIN

[Don't Have An Account? Sign Up Here](#)

3. The **HCS Homepage** displays. Look for **eCLEP** in the left frame under **My Applications**:

The screenshot shows the HCS homepage with a purple header. On the left, a 'My Applications' menu is open, listing 'Acronyms & Abbreviations', 'eCLEP' (highlighted with a red box), 'Emergency Contacts', 'Secure File Transfer 2.0', and 'ServNY'. Below the menu is a 'Refresh My Applications List' button. The main content area features 'Important Health Events' with 'Donate Life' and 'NYS PMP' buttons, 'Important Health Notifications' with a table of recent notifications, 'Newsroom Highlights...', and 'New Items' and 'Newslett' sections.

Posted	Priority	Keyword	Source	Audience	Description
04/01/2022	Advisory	Influenza	NYSDOH	All Users	Influenza Surveillance R
03/30/2022	Advisory	Commissioner's Letter	NYSDOH	All Users	Happy Doctor's Day
03/25/2022	Advisory	Influenza	NYSDOH	All Users	Influenza Surveillance R
03/18/2022	Advisory	Influenza	NYSDOH	All Users	Influenza Surveillance R
03/11/2022	Advisory	Influenza	NYSDOH	All Users	Influenza Surveillance R

eCLEP MANUAL

- Click on **eCLEP** in the left frame and the eCLEP Home Page will display. Click on **Permit Materials, Laboratory Reapplication / Laboratory Changes** area at the upper right

home

Welcome to e-CLEP

This site contains a collection of tools and resources to assist you in meeting the requirements of the New York State Clinical Laboratory Reference System.

For general information and guidance, please refer to the [Wadsworth Center Public Website](#).

Date	Priority	Message
------	----------	---------

Permit Materials
Laboratory Reapplication
Laboratory Changes

Proficiency Testing
PT Designations
PT Documents

Gross Annual Receipts
Reporting

LDT Approval
Test approval materials for permitted and non-permitted laboratories

Survey
Tools and information related to laboratory surveys

Blood Resources
BSAR

Tools
Extension Date Request

- HCS account holders affiliated with more than one laboratory will be required to enter an appropriate 4-digit numeric Permanent Facility Identifier (**PFI**).
(An alphanumeric PFI denotes a Limited Service Laboratory (LSL). LSLs are not serviced by the eCLEP application.)

home > facility

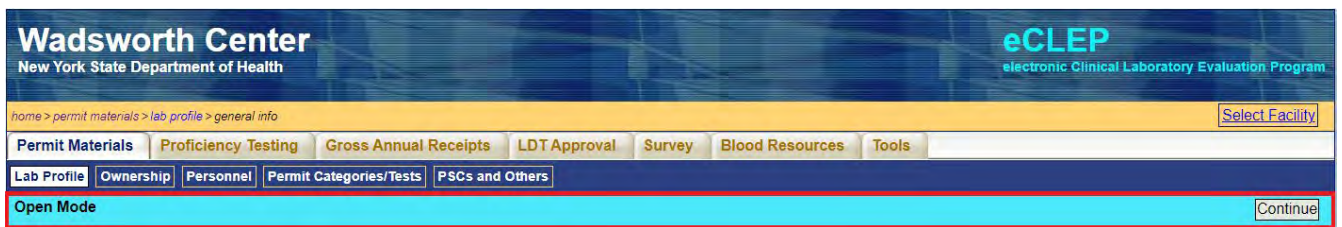
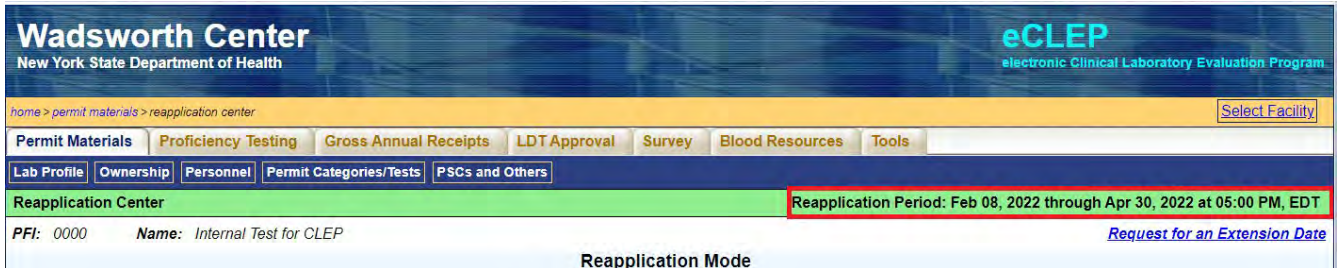
You have access to all facilities. Please enter a facility ID :

[Contact Us](#) [Help](#) [FAQ](#) [Accessibility](#) [Message Center](#)

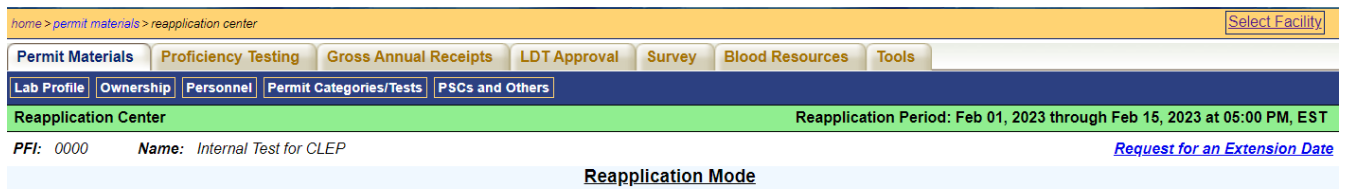
eCLEP MANUAL

- Most users, however, will be brought directly to the **Reapplication Mode** or **Open Mode** page. The reapplication period occurs in April, actual dates will vary year to year. Open Mode is available the rest of the year, provided there are no laboratory information changes submissions pending.

Note: Reapplication mode is denoted by the presence of green bar at the top of the screen with the dates of the reapplication period; Open mode is denoted by the presence of teal bar at the top of the screen.

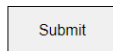


- On the **Reapplication Mode** or **Open Mode** page, you may want to review the Current Data on File (without pending changes) using the “**View Summary**” link and print it out to use as a worksheet. Reapplication Mode Screenshot:



It's time to reapply for your facility's permit.

Click the 'Submit' button below to complete the reapplication process and ensure you receive your new permit by July 1.



If you would like to view the data currently on file for your facility, or view submissions your facility has made, use the links below.

Current Data on File (without pending changes)

[View Summary](#)

Electronic Submissions

- [Reapplication Submission dated Mar 28, 2019 7:57:08 AM EDT \(PDF\)](#)
- [Reapplication Submission dated Jan 19, 2018 1:46:23 PM EST \(PDF\)](#)
- [Reapplication Submission dated Jan 19, 2018 1:22:48 PM EST \(PDF\)](#)
- [Reapplication Submission dated Jun 29, 2017 11:39:24 AM EDT \(PDF\)](#)
- [Reapplication Submission dated Apr 12, 2017 7:20:42 AM EDT \(PDF\)](#)

[view all...](#)

eCLEP MANUAL

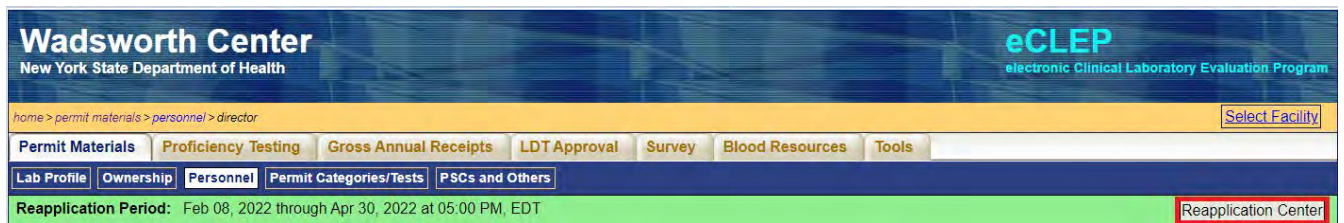
Open Mode Screenshot:

8. Make changes to laboratory information as required using the links on the dark blue menu bar (Lab Profile, Ownership, Personnel, Permit Categories/Tests, and PSCs and Others).

eCLEP MANUAL**Reapplication Mode Submissions**

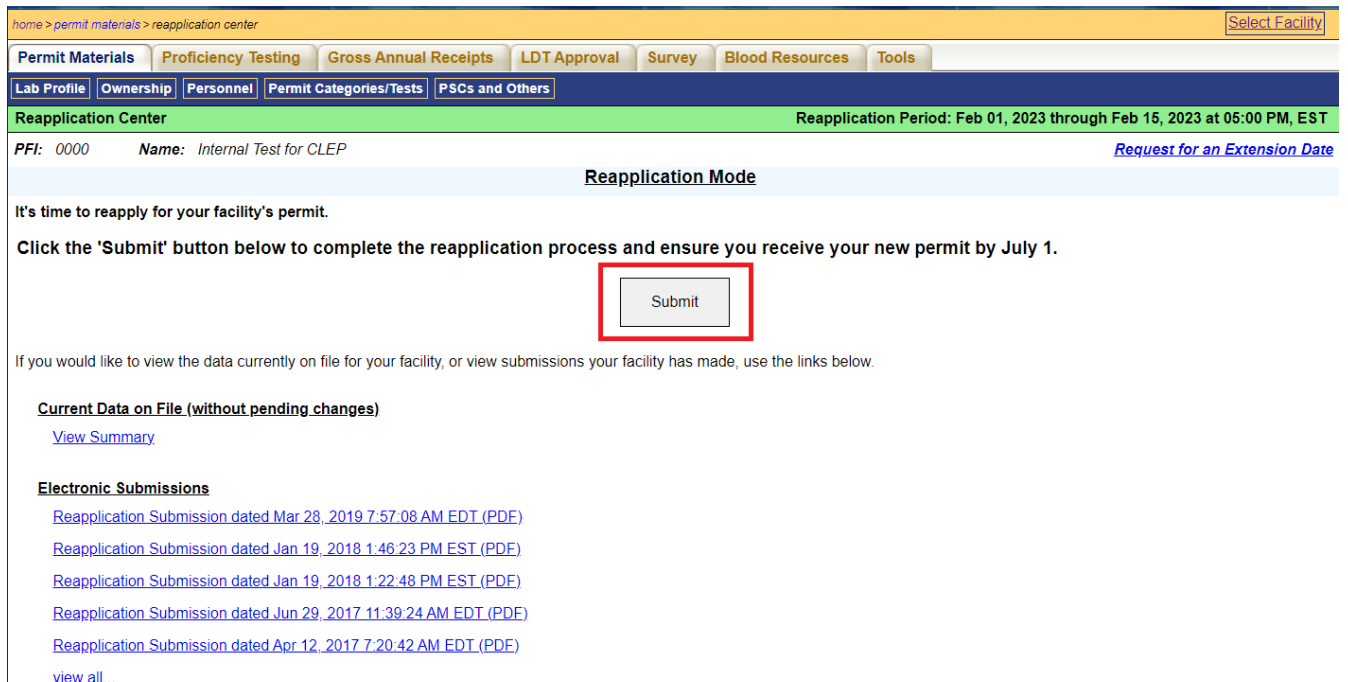
NOTE: All eCLEP submissions are reviewed by the Clinical Laboratory Evaluation Program prior to acceptance. The Program reserves the right to request additional information, request re-submission to obtain missing information, or to reject the request in total if the eCLEP submission is not acceptable. eCLEP submission does not constitute approval by the Program.

We suggest that you first review the information on file for your laboratory and make any necessary revisions prior to beginning the reapplication submission. If you have already been navigating through the sections on the blue menu bar, click on the **Reapplication Center** button on the green menu bar to return to the main Reapplication Mode page.



Alternatively, you may start the reapplication submission process before revising facility information, however; once you begin navigating through the sections indicated on the blue bar to provide required information, you must return to the main Reapplication Mode page to continue with the submission process.

Click **Submit** to begin the reapplication submission process.



E/CLEP MANUAL

The **Step 1: Review and Update** page displays the data on file in the Laboratory Licensure database (and any pending changes already entered via eCLEP) for your facility. Review and click **Next**. A printable version of this information is available by clicking the “**Printable Summary in PDF Format**” link.

home > permit materials > reapplication center > reapplication wizard [Select Facility](#)

Permit Materials | Proficiency Testing | Gross Annual Receipts | LDT Approval | Survey | Blood Resources | Tools

Lab Profile | Ownership | Personnel | Permit Categories/Tests | PSCs and Others

Reapplication Center Reapplication Period: Apr 05, 2022 through Apr 28, 2022 at 05:00 PM, EDT

PFI: 0000 Name: Internal Test for CLEP 1

[Review and Update >>](#) [Provide Required Data >>](#) [Attest and Submit >>](#) [Print For Your Records](#)

Step 1: Review and Update

Please review the summary below for accuracy and completeness. If you need to make changes, click the appropriate link in the blue menu bar above (for example, facility address data is found in the Lab Profile area). Once in an area, you'll be able to save changes to the data.

Once you are satisfied that the information in the summary below is complete and accurate, click 'Next' to continue.

[Next](#) [Cancel](#)

[Printable Summary in PDF format](#)

SUMMARY OF DATA ON FILE PLUS PENDING CHANGES FOR JULY 1, 2022

Submitted On not submitted	Submitter's HCS ID not submitted	Generated On Apr 5, 2022 10:06:38 AM EDT
--------------------------------------	--	--

SECTION I -- GENERAL LABORATORY INFORMATION

Field Name	Current Data	Changes
Laboratory PFI:	0000	

The **Step 2: Provide Required Data** page will list sections/subsections that you will have to visit in order to complete the reapplication. Required information that must be completed before you will be able to submit include:

- laboratory contact person
- owner declaration and Disclosure of Ownership and Controlling Interest Statement upload
- facility e-mail
- test volume, if applicable
- POC testing, if applicable
- PSCs and Others tab, if applicable

You may proceed to the areas with outstanding data requirements by either method below, or a combination of these two methods.

- a) Navigate to each section by clicking the links in the blue menu bar near the top, e.g. **Lab Profile, Ownership, Personnel, Permit Categories/Tests, PSCs and Others**.
- b) If there are no, or few, owner/personnel/testing changes during this reapplication, you may navigate directly to the sections with outstanding data requirements by clicking the underlined links in the **How to Resolve** column.

eCLEP MANUAL

[Permit Materials](#) | [Proficiency Testing](#) | [Gross Annual Receipts](#) | [LDT Approval](#) | [Survey](#) | [Blood Resources](#) | [Tools](#)
[Lab Profile](#) | [Ownership](#) | [Personnel](#) | [Permit Categories/Tests](#) | [PSCs and Others](#)
Reapplication Center Reapplication Period: Apr 05, 2022 through Apr 28, 2022 at 05:00 PM, EDT
 PFI: 0000 Name: Internal Test for CLEP 1
Review and Update >> **Provide Required Data >>** Attest and Submit >> Print For Your Records

Step 2: Provide Required Data

In order to complete your renewal, there are certain areas for which your facility must provide data. You may have completed some or all of these areas in the normal course of updating your facility's information.

The table below lists areas in which required data has not yet been provided; you will not be able to proceed to the next step until each requirement listed below is resolved.

Once you have provided all required information, click 'Next' to continue.

Required Data

Area	Data Requirement	How to Resolve
Ownership / Declaration Upload	Identify the laboratories in which the owner(s) has a controlling interest on a separate sheet.	Visit the Ownership / Declaration Upload area, and upload the required Owner Other Lab document(s). Then click the Save button.
Test Volume	For labs located in New York State, test volume data must be entered, or the lab must indicate that no tests were performed.	Visit the Test Volume area, and either enter test volume data, or click the "No tests performed this year" checkbox and provide an explanation. Then click the Save button.
PSC Self Assessment	Your facility has indicated that it has added a new PSC or changed address of an existing PSC,(PSC 0000 - W3403), but has not completed the self assessment questions.	Visit the PSC Self Assessment page, provide the information requested and click the Save button.
PSC Home	Your facility ,0000, must attest to having reviewed the appropriate regulations and submitted data to ensure your lab is in compliance with the appropriate regulations.	Visit the PSC Home page, provide the information requested and click the Save button.

To return to the **Step 2: Provide Required Data** page to resolve further outstanding data requirements, or to verify that all data requirements have been resolved, click the button on the green bar at the top of the screen from any page to get back to the main Reapplication Mode page.

Wadsworth Center **eCLEP**
electronic Clinical Laboratory Evaluation Program
 New York State Department of Health
 home > permit materials > personnel > director [Select Facility](#)
[Permit Materials](#) | [Proficiency Testing](#) | [Gross Annual Receipts](#) | [LDT Approval](#) | [Survey](#) | [Blood Resources](#) | [Tools](#)
[Lab Profile](#) | [Ownership](#) | [Personnel](#) | [Permit Categories/Tests](#) | [PSCs and Others](#)
Reapplication Period: Apr 05, 2022 through Apr 28, 2022 at 05:00 PM, EDT **Reapplication Center**

ECLEP MANUAL

Click **Submit**, and then click **Next** on the **Step One: Review and Update** page. The **Step 2: Provide Required Data** page will list any outstanding data entry requirements. If there are no outstanding data entry requirements, the Required Data table will read "All required data has been provided." Only after all data requirements have been resolved will you be able to proceed to **Step 3: Attest and Submit** by clicking **Next**.

Lab Profile | Ownership | Personnel | Permit Categories/Tests | PSCs and Others | Tools

Reapplication Center Reapplication Period: Feb 09, 2017 through Feb 24, 2017 at 05:00 PM, EST

PFI: 8888 Name: Internal Test for EPTRS

Review and Update >> Provide Required Data >> Attest and Submit >> Print For Your Records

Step 2: Provide Required Data

In order to complete your renewal, there are certain areas for which your facility must provide data. You may have completed some or all of these areas in the normal course of updating your facility's information.

The table below lists areas in which required data has not yet been provided; you will not be able to proceed to the next step until each requirement listed below is resolved.

Once you have provided all required information, click 'Next' to continue.

Next Cancel

Required Data

Area	Data Requirement	How to Resolve
All required data has been provided.		

Please read the **Step 3: Attest and Submit** page in its entirety and click the checkbox to signify that you have read, and agree with, the attestation; then click **Next**.

Lab Profile | Ownership | Personnel | Permit Categories/Tests | PSCs and Others | Tools

Reapplication Center Reapplication Period: Feb 09, 2017 through Feb 24, 2017 at 05:00 PM, EST

PFI: 8888 Name: Internal Test for EPTRS

Review and Update >> Provide Required Data >> Attest and Submit >> Print For Your Records

Step 3: Attest and Submit

Please read the following attestation carefully. If you agree, signify by clicking the checkbox below (* required), then click 'Next'.

I understand that signing and submitting this record in this fashion is the legal equivalent of having placed my handwritten signature on the submitted record and this affirmation. I understand and agree that by electronically signing and submitting this record in this fashion I am affirming to the truth of the information contained therein.

I, the laboratory director or delegated submitter, as a representative of the owner and laboratory director, understand that under section 577.1(a) of the Public Health Law the permit of this laboratory may be revoked, suspended, limited or annulled if any fact is misrepresented in this application. I acknowledge that Article 5, Title V, Section 575 of New York State Public Health Law stipulates that a laboratory permit is automatically void upon a change of director, owner or location. Any changes of the information in this application must be reported to the Clinical Laboratory Evaluation Program immediately by the laboratory director(s) or owner. I also understand that additional penalties may apply if facts or information regarding the initial and continuing eligibility for said laboratory permit are misrepresented, concealed, or undisclosed. Further, I understand that offering a false instrument constitutes a crime under the penal law of the State of New York (NYS Penal Law Article 175). Such misrepresentation may subject parties who file a false instrument to criminal prosecution.

I, the laboratory director or delegated submitter, as a representative of the owner and laboratory director, understand that by signing this attestation I have agreed, on the behalf of the laboratory, to any investigation made by the Department of Health to verify or confirm the information provided in this application, any other investigation in connection with the laboratory permit or any complaint filed with the Department. If additional information is requested, it will be provided in a timely manner by the appropriate staff under the direction of the laboratory director and owner. Further, I understand that should the laboratory permit status be investigated at any time, cooperation in such an investigation will be provided by all staff under the direction of the laboratory director and owner.

In signing this attestation I, the laboratory director or the delegated submitter, as a representative of the owner and laboratory director, certify that the information provided to the Department of Health as a basis for obtaining a laboratory permit is true and correct, that the laboratory director has received and read the rules and regulations pertaining to the clinical laboratories, and that the laboratory director and/or applicable assistant directors accept responsibility for the oversight of the laboratory permit categories listed in this application. Please note that as described in the Clinical Laboratory Standards of Practice, Director Standard of Practice 3: Responsibilities, the responsibilities of assistant directors must be delegated in writing by the laboratory director. If an assistant director is attesting to responsibility for a category, it is expected that documentation is available to demonstrate that the individual is actively engaged in tasks specific to the category or categories. Compliance with this requirement will be monitored during on-site survey.

I have read, and agree with, the above attestation

Next Cancel

eCLEP MANUAL

The **Step 4: Print for Your Records** page allows access to the eCLEP summary in PDF format. Click on the **Submission dated [date, time] (PDF)** and print or save this document for your records, if desired. Then click **Finished**. You will be directed to the main Read-Only mode page.

Reapplication CenterReapplication Period: Feb 09, 2017 through Feb 24, 2017 at 05:00 PM, EST

PFI: 8888 Name: Internal Test for EPTRS

[Review and Update >>](#) [Provide Required Data >>](#) [Attest and Submit >>](#) [Print For Your Records](#)

Step 4: Print For Your Records

You may print the application submission for your records using the link below.

Most Recent Submission for 2017

[Submission dated Feb 13, 2017 1:32:18 PM EST \(PDF\)](#)

Finished

[Contact Us](#) [Help](#) [FAQ](#) [Accessibility](#) [Message Center](#)

eCLEP MANUAL

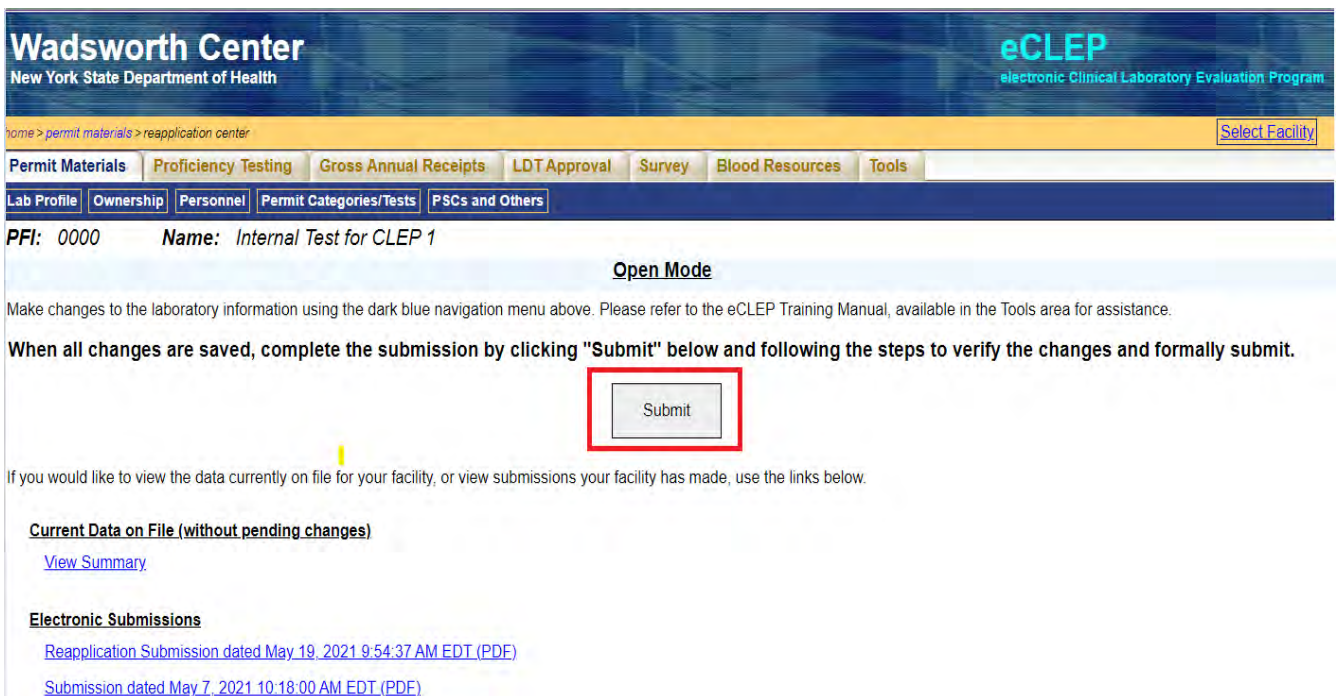
Open Mode Submissions

NOTE: All eCLEP submissions are reviewed by the Clinical Laboratory Evaluation Program prior to acceptance. The Program reserves the right to request additional information, request re-submission to obtain missing information, or to reject the request in total if the eCLEP submission is not acceptable. eCLEP submission does not constitute approval by the Program.

Enter laboratory changes as necessary by navigating the blue menu bar. Click on the **Continue** button to begin the Open Mode submission process.



Click **Submit** to begin the Open Mode submission process.



eCLEP MANUAL

The **Step 1: Review and Update** page displays the data on file in Laboratory Licensure database (and any pending changes already entered via eCLEP) for your facility. Review and click **Next**. A printable version of this information is available by clicking the **“Printable Summary in PDF Format”** link.

Wadsworth Center
New York State Department of Health

eCLEP
electronic Clinical Laboratory Evaluation Program

home > permit materials > reapplication center > submit changes Select Facility

Permit Materials | Proficiency Testing | Gross Annual Receipts | LDT Approval | Survey | Blood Resources | Tools

Lab Profile | Ownership | Personnel | Permit Categories/Tests | PSCs and Others

PFI: 0000 Name: Internal Test for CLEP 1

Review and Update >> Attest and Submit >> Print For Your Records

Step 1: Review and Update

Please review the summary below for accuracy and completeness. If you need to make changes, click the appropriate link in the blue menu bar above (for example, facility address data is found in the Lab Profile area). Once in an area, you'll be able to save changes to the data.

Once you are satisfied that the information in the summary below is complete and accurate, click 'Next' to continue.

Next Cancel

[Printable Summary in PDF format](#)

SUMMARY OF PENDING CHANGES

Submitted On not submitted	Submitter's HCS ID not submitted	Generated On Apr 5, 2022 3:22:03 PM EDT
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SECTION I -- GENERAL LABORATORY INFORMATION

Field Name	Current Data	Changes
Laboratory PFI:	0000	

eCLEP MANUAL

Please read the **Step 2: Attest and Submit** page in its entirety and click the checkbox to signify that you have read, and agree with, the attestation; then click **Next**.

Permit Materials | Proficiency Testing | LDT Approval | Survey | Limited Labs

Lab Profile | Ownership | Personnel | Permit Categories/Tests | PSCs and Others | Tools

PFI: 0000 Name: Internal Test for CLEP TEST 1

Review and Update >>
Attest and Submit >>
Print For Your Records

Area	Data Requirement	How to Resolve
PSC Self Assessment	Your facility has indicated that it has added a new PSC or changed address of an existing PSC (PSC 0000 - W0423), but has not completed the self assessment questions.	Visit the PSC Self Assessment page, provide the information requested and click the Save button.

Step 2: Attest and Submit

Please read the following attestation carefully. If you agree, signify by clicking the checkbox below (* required), then click 'Next'.

I understand that signing and submitting this record in this fashion is the legal equivalent of having placed my handwritten signature on the submitted record and this affirmation. I understand and agree that by electronically signing and submitting this record in this fashion I am affirming to the truth of the information contained therein.

I, the laboratory director or delegated submitter, as a representative of the owner and laboratory director, understand that under section 577.1(a) of the Public Health Law the permit of this laboratory may be revoked, suspended, limited or annulled if any fact is misrepresented in this application. I acknowledge that Article 5, Title V, Section 575 of New York State Public Health Law stipulates that a laboratory permit is automatically void upon a change of director, owner or location. Any changes of the information in this application must be reported to the Clinical Laboratory Evaluation Program immediately by the laboratory director(s) or owner. I also understand that additional penalties may apply if facts or information regarding the initial and continuing eligibility for said laboratory permit are misrepresented, concealed, or undisclosed. Further, I understand that offering a false instrument constitutes a crime under the penal law of the State of New York (NYS Penal Law Article 175). Such misrepresentation may subject parties who file a false instrument to criminal prosecution.

I, the laboratory director or delegated submitter, as a representative of the owner and laboratory director, understand that by signing this attestation I have agreed, on the behalf of the laboratory, to any investigation made by the Department of Health to verify or confirm the information provided in this application, any other investigation in connection with the laboratory permit or any complaint filed with the Department. If additional information is requested, it will be provided in a timely manner by the appropriate staff under the direction of the laboratory director and owner. Further, I understand that should the laboratory permit status be investigated at any time, cooperation in such an investigation will be provided by all staff under the direction of the laboratory director and owner.

In signing this attestation I, the laboratory director or the delegated submitter, as a representative of the owner and laboratory director, certify that the information provided to the Department of Health as a basis for obtaining a laboratory permit is true and correct, that the laboratory director has received and read the rules and regulations pertaining to the clinical laboratories, and that the laboratory director and/or applicable assistant directors accept responsibility for the oversight of the laboratory permit categories listed in this application. Please note that as described in the Clinical Laboratory Standards of Practice, Director Standard of Practice 3: Responsibilities, the responsibilities of assistant directors must be delegated in writing by the laboratory director. If an assistant director is attesting to responsibility for a category, it is expected that documentation is available to demonstrate that the individual is actively engaged in tasks specific to the category or categories. Compliance with this requirement will be monitored during on-site survey.

I have read, and agree with, the above attestation

Next
Cancel

The **Step 3: Print For Your Records** page allows access to the eCLEP summary in PDF format. **NOTE: The eCLEP Summary is no longer required to be signed and returned to CLEP.** Click on the **Submission dated [date, time] (PDF)** and print or save this document for your records, if desired. Then click **Finished**. You will be directed to the main Read-Only mode page.

home > permit materials > reapplication center > submit changes

Permit Materials | Proficiency Testing | Gross Annual Receipts | LDT Approval | Survey | Blood Resources | Tools

Lab Profile | Ownership | Personnel | Permit Categories/Tests | PSCs and Others

PFI: 0000 Name: Internal Test for CLEP 1

Review and Update >>
Attest and Submit >>
Print For Your Records

Step 3: Print For Your Records

You may print the submission for your records using the link below.

Be sure to review the electronic submission document and furnish all additional supporting information as required, using one of the following methods:

Email:
clep@health.ny.gov

Fax:
 518-449-6901

Mail:
 CLEP
 Wadsworth Center
 PO Box 509
 Albany, NY 12201-0509

Most Recent Submission for 2022

[Submission dated Apr 5, 2022 3:24:59 PM EDT \(PDF\)](#)

Finished

ECLEP MANUAL

Navigating in the Permit Materials Module

Lab Profile

General Information

The **General Information** webpage allows you to make changes to the laboratory name and address, facility type and lab contact information. Note an effective date for any laboratory name and address changes is required. Enter the required information and click **Save**.

Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey Tools	
Lab Profile Ownership Personnel Permit Categories/Tests PSCs and Others	
Reapplication Period: Feb 02, 2021 through Feb 28, 2021 at 05:00 PM, EST Reapplication Center	
<ul style="list-style-type: none"> ▪ General Information Regulatory Information Hours Alternate Address Contact Person Accounting Information 	<p>PFI: 0000 Name: Internal Test for CLEP</p> <p>Name and Address Information</p> <p>Name: <input type="text" value="Internal Test for CLEP"/></p> <p>Address: <input type="text" value="PO Box 509"/></p> <p>City: <input type="text" value="Albany"/></p> <p>Country: <input type="text" value="United States"/> ▼</p> <p>State/Province: <input type="text" value="New York"/> ▼ <input type="button" value="Refresh List"/></p> <p>NY County: <input type="text" value="Albany"/> ▼ <input type="button" value="Refresh List"/></p> <p>Zip Code: <input type="text" value="12203"/></p> <p>All name/address changes effective: <input type="text" value="11/18/2016"/> <input type="button" value="Calendar"/></p> <p><small>* Effective Date is required for any name/address change</small></p> <hr/> <p>General Information</p> <p>Facility Type: <input type="text" value="Hospital"/> ▼ Fac Status: Open</p> <hr/> <p>Lab Contact Information</p> <p>Telephone (###-###-####): <input type="text" value="123-456-7890"/> Ext: <input type="text" value="1234"/></p> <p>Fax (###-###-####): <input type="text" value="098-765-4321"/></p> <p>Email: <input type="text" value="Shalini.Banka@its.ny.gov"/></p> <p><input type="button" value="Clear"/> <input type="button" value="Save"/></p>

ECLIP MANUAL

Regulatory Information

The **Regulatory Information** webpage allows you to revise the CLIA registration and Medicaid number for the laboratory. Enter the required information and click **Save**. Laboratories in New York should not revise the CLIA number without first contacting CLEPCERT@health.ny.gov.

Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey Tools	
Lab Profile Ownership Personnel Permit Categories/Tests PSCs and Others	
Reapplication Period: Feb 02, 2021 through Feb 28, 2021 at 05:00 PM, EST Reapplication Center	
<ul style="list-style-type: none"> General Information <li style="border: 1px solid red; padding: 2px;">Regulatory Information Hours Alternate Address Contact Person Accounting Information 	<p>Pending Changes:</p> <p><input type="checkbox"/> CLIA No. : 0000000001 Old CLIA No. : 0000000000</p> <p><input type="checkbox"/> Medicaid No : NA Old Medicaid No. : none</p> <p style="text-align: right;">Cancel Selected Changes</p> <hr/> <p>PFI: 0000 Name: Internal Test for CLEP</p> <p>Regulatory Information:</p> <p>CLIA Registration No: <input type="text" value="0000000001"/></p> <p>Medicaid No: <input type="text" value="NA"/></p> <p><input type="button" value="Save"/> <input type="button" value="Clear"/></p>

Hours

The **Hours** section allows you to change laboratory testing hours. Enter the required information and click **Save**. Note: The Clinical Laboratory Evaluation Program may seek clarification of information entered in the “Hours Note” field before accepting the proposed change.

NEW: Hours are now collected in military (24-hour) format.

ECLP MANUAL

Permit Materials	Proficiency Testing	Gross Annual Receipts	LDT Approval	Survey	Blood Resources	Tools																																										
Lab Profile	Ownership	Personnel	Permit Categories/Tests	PSCs and Others																																												
Reapplication Period: Mar 10, 2023 through Mar 31, 2023 at 05:00 PM, EDT						Reapplication Center																																										
General Information Regulatory Information Hours Contact Person Accounting Information	Pending Changes: <input type="checkbox"/> Thursday: 07:00 - 19:00 was: 00:00 - 19:00 <input type="checkbox"/> Friday: 08:00 - 23:45 was: 00:00 - 23:45 <input type="button" value="Cancel Selected Changes"/>																																															
	PFI: 0000 Name: Internal Test for CLEP Lab Hours: <table border="1"> <tr> <td>Monday</td> <td>00:00</td> <td>24:00</td> <td><input checked="" type="radio"/> 24 Hours</td> <td><input type="radio"/> Closed</td> <td><input type="radio"/> Select Hours</td> </tr> <tr> <td>Tuesday</td> <td>00:00</td> <td>24:00</td> <td><input checked="" type="radio"/> 24 Hours</td> <td><input type="radio"/> Closed</td> <td><input type="radio"/> Select Hours</td> </tr> <tr> <td>Wednesday</td> <td>00:00</td> <td>23:30</td> <td><input type="radio"/> 24 Hours</td> <td><input type="radio"/> Closed</td> <td><input checked="" type="radio"/> Select Hours</td> </tr> <tr> <td>Thursday</td> <td>07:00</td> <td>19:00</td> <td><input type="radio"/> 24 Hours</td> <td><input type="radio"/> Closed</td> <td><input checked="" type="radio"/> Select Hours</td> </tr> <tr> <td>Friday</td> <td>08:00</td> <td>23:45</td> <td><input type="radio"/> 24 Hours</td> <td><input type="radio"/> Closed</td> <td><input checked="" type="radio"/> Select Hours</td> </tr> <tr> <td>Saturday</td> <td>00:00</td> <td>17:00</td> <td><input type="radio"/> 24 Hours</td> <td><input type="radio"/> Closed</td> <td><input checked="" type="radio"/> Select Hours</td> </tr> <tr> <td>Sunday</td> <td>00:00</td> <td>15:30</td> <td><input type="radio"/> 24 Hours</td> <td><input type="radio"/> Closed</td> <td><input checked="" type="radio"/> Select Hours</td> </tr> </table> Hours Note: Open as needed NEW <input type="button" value="Clear"/> <input type="button" value="Save"/>						Monday	00:00	24:00	<input checked="" type="radio"/> 24 Hours	<input type="radio"/> Closed	<input type="radio"/> Select Hours	Tuesday	00:00	24:00	<input checked="" type="radio"/> 24 Hours	<input type="radio"/> Closed	<input type="radio"/> Select Hours	Wednesday	00:00	23:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours	Thursday	07:00	19:00	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours	Friday	08:00	23:45	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours	Saturday	00:00	17:00	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours	Sunday	00:00	15:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours
Monday	00:00	24:00	<input checked="" type="radio"/> 24 Hours	<input type="radio"/> Closed	<input type="radio"/> Select Hours																																											
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Sunday	00:00	15:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours																																											

E/CLEP MANUAL

Contact Person

The **Contact Person** section allows you to change/update the contact person for the laboratory and their contact information (e-mail and phone number).

- The laboratory contact person is the individual who is designated by the laboratory director and owner(s) to communicate with the Department on matters relating to the clinical laboratory permit.
- You are required to verify/update the **Contact Person** in Reapplication mode.

USER TIP: More than one email address may be entered in the Contact Person Email field by separating each address with a comma.

Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey Blood Resources Tools									
Lab Profile Ownership Personnel Permit Categories/Tests PSCs and Others									
Reapplication Period: Mar 10, 2023 through Mar 31, 2023 at 05:00 PM, EDT Reapplication Center									
General Information Regulatory Information Hours Alternate Address <div style="border: 1px solid red; padding: 2px;">• Contact Person</div> Accounting Information	<div style="background-color: #fff9c4; padding: 5px;"> <p>Pending Changes:</p> <table border="0"> <tr> <td><input type="checkbox"/> First Name : Janette</td> <td>Old First Name : Cindy</td> </tr> <tr> <td><input type="checkbox"/> Last Name : Doe</td> <td>Old Last Name : Stevens</td> </tr> <tr> <td><input type="checkbox"/> Telephone : 5183309999</td> <td>Old Telephone : none</td> </tr> <tr> <td><input type="checkbox"/> Email : dummyemail@test.com, hello@test.com</td> <td>Old Email : cindy.stevens@health.ny.gov</td> </tr> </table> <p style="text-align: right;">Cancel Selected Changes</p> </div> <p>PFI: 0000 Name: Internal Test for CLEP</p> <p style="text-align: center;">Contact Person</p> <p>First Name: <input type="text" value="Janette"/></p> <p>Middle Name: <input type="text"/></p> <p>Last Name: <input type="text" value="Doe"/></p> <p>Telephone (###-###-####): <input type="text" value="518-330-9999"/> Ext: <input type="text"/></p> <p>Email: <input type="text" value="dummyemail@test.com, hello@test.co"/></p> <p>Save Clear</p>	<input type="checkbox"/> First Name : Janette	Old First Name : Cindy	<input type="checkbox"/> Last Name : Doe	Old Last Name : Stevens	<input type="checkbox"/> Telephone : 5183309999	Old Telephone : none	<input type="checkbox"/> Email : dummyemail@test.com, hello@test.com	Old Email : cindy.stevens@health.ny.gov
<input type="checkbox"/> First Name : Janette	Old First Name : Cindy								
<input type="checkbox"/> Last Name : Doe	Old Last Name : Stevens								
<input type="checkbox"/> Telephone : 5183309999	Old Telephone : none								
<input type="checkbox"/> Email : dummyemail@test.com, hello@test.com	Old Email : cindy.stevens@health.ny.gov								

ECLP MANUAL

Accounting Information

The **Accounting Information** section allows you to add/update the accountant information for the laboratory and their contact information (e-mail, phone number and address). Enter the required information and click **Save**.

****NOTE: This section is optional. Data entered here will be used for emailing the permit and reference fees invoices. If no data is entered here, the invoice will be emailed to the laboratory director.**

As of permit year 2020-2021, invoices are emailed to the laboratory and are not mailed in hard copy.

Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey Tools	
Lab Profile Ownership Personnel Permit Categories/Tests PSCs and Others	
Reapplication Period: Feb 02, 2021 through Feb 28, 2021 at 05:00 PM, EST Reapplication Center	
General Information Regulatory Information Hours Contact Person Accounting Information	<p>PFI: 0000 Name: Internal Test for CLEP</p> <p style="text-align: center;">Accounting Information</p> <p>Contact</p> <p>Entity Name: <input type="text"/></p> <p>First Name: <input type="text"/></p> <p>Last Name: <input type="text"/></p> <p>Telephone : <input type="text" value="###-###-####"/></p> <p>Email: <input type="text"/></p> <hr/> <p>Address</p> <p>Street Address: <input type="text"/></p> <p>Suite/Room/Building Number: <input type="text"/></p> <p>City: <input type="text"/></p> <p>Country: <input type="text" value="United States"/></p> <p>State/Province: <input type="text" value="Alabama"/></p> <p>Zip Code: <input type="text"/></p> <p>Save <input type="button" value="Clear"/></p>

ECLP MANUAL**Ownership**

The Ownership section is divided into three subsections, **Owner, Declaration, and Upload**.

Laboratories will be required to upload a list of direct and indirect owners using the Upload Feature as part of the permit reapplication.

- **Direct ownership** means an individual or entity with an ownership interest or controlling interest in the applying facility.
- **Indirect ownership** means an individual or entity with an ownership interest, controlling interest, or corporate membership, in an entity with direct or indirect ownership in the applying clinical facility. Indirect owners who hold a ten (10) percent or greater ownership interest, controlling interest, or corporate membership, are required to be disclosed by the applying clinical facility

Examples of ownership structures:

Example 1 (Business Corporation): ABC Lab is owned by ABC Lab, Inc. ABC Lab Inc. has two major stockholders, Mr. Smith and Mr. Hernandez. ABC Lab, Inc. is the direct owner. Mr. Smith and Mr. Hernandez are indirect owners.

Example 2 (Business Corporation): ABC Lab, Inc. dba ABC Lab is owned by ABC Lab, Inc. ABC Lab, Inc has two primary investors; Umbrella Corp, Inc. and Ms. Smirnov. ABC Lab, Inc., is the direct owner. Umbrella Corp, Inc. and Ms. Smirnov are indirect owners.

Example 3 (Partnership): Acme Lab is owned by Zhang Brothers, LLP. The partners of Zhang Brothers, LLP are Zhang Industries and Mr. Lee. Zhang Industries is owned by A. Zhang and B. Zhang. Zhang Brothers, LLP is the direct owner. Zhang Industries, Mr. Lee, A. Zhang, and B. Zhang are all indirect owners.

Example 4 (Not-for-Profit Corporation): Healthy Hospital Laboratory is owned by Healthy Hospital, Inc., a not-for-profit corporation. Healthy Hospital, Inc. has two corporate members, Biggie Health Systems, Inc. and Bigger Health Systems, Inc. Biggie Health Systems, Inc. and Bigger Health Systems, Inc. are considered indirect owners in Healthy Hospital Laboratory.

Example 5: (Professional Corporation): Neighborhood Physicians, PLLC operates a clinical laboratory. Neighborhood Physicians, PLLC is owned by Hospital Physicians, PC and Dr. Patel. Hospital Physicians, PC and Dr. Patel are indirect owners.

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- **Ownership Interest** means the possession of stock, equity in the capital, or any interest in revenue of an entity.
- **Controlling interest** means the ability to direct or control the operation or management of an entity. Members on the Board of Directors or Board of Trustees for not-for-profit corporations are considered to have controlling interests. Any individual or entity with a ten (10) percent or greater controlling interest is required to be disclosed by the applying clinical facility. Licensed physicians who are included on the Board of Directors/Board of Trustees for a not-for-profit corporation are required to disclose their authority to order laboratory tests if they have greater than 10% controlling interest in the applying clinical facility.
- **Corporate membership** means an individual or entity with a voting interest in a not-for-profit corporation that directly owns the applying facility. Corporate membership includes, but is not limited to, the right to vote in the election for directors of the clinical laboratory or on fundamental corporate transactions such as closing the business or amending the bylaws.
- **Management company** means any organization that operates and manages a clinical laboratory on behalf of the owner, with the owner retaining ultimate legal responsibility for the operation of the business.
- During the **Reapplication** period, you will be required to enter any missing data and/or update information. **The reapplication cannot be submitted without providing this information.** You will receive error messages when you try to continue without addressing these fields. When this happens, please enter the missing data, select a dropdown option and/or click the radio button; then click **Save** again.
- During the **Open Mode**, update information as necessary to accurately reflect a laboratory change.

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Owner

This section captures information such as the owner type, Federal Employer Identification Number (EIN, aka TIN), owner name, etc. If the response to question 1 is “Yes”, you will be prompted to upload a list of all laboratories in which any of the direct or indirect owners have ownership, controlling interest, or corporate membership.

PLEASE NOTE: All laboratories that share a common Federal Employer Identification Number (EIN) are considered to be owned by the same entity and disclosure of the other laboratories owned by the direct owner is required. Note that to complete this section, the applying facility should consult their administration and/or legal department. It is not necessary to include Limited Service Laboratories in this list.

Lab Profile	Ownership	Personnel	Permit Categories/Tests	PSCs and Others
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Reapplication Period: Mar 10, 2023 through Mar 31, 2023 at 05:00 PM, EDT Reapplication Center

[Instructions](#)

- Owner
- [Declaration](#)
- [Upload](#)

PFI: 0000 Name: Internal Test for CLEP

1. Do any of the direct or indirect owners of this facility have a direct or indirect ownership interest, controlling interest, or corporate membership in any other clinical laboratory permitted by New York State? Refer to the Ownership section of the eCLEP Permit Materials User Manual for definitions and examples of interests that need to be disclosed. (Limited Service Laboratory registrations are not required to be disclosed.)

Yes No

On a separate sheet, identify each direct or indirect owner and the laboratory(ies) for which the person or entity has an ownership interest, controlling interest or corporate membership. The PFI and name of the laboratory(ies) must be indicated. This sheet must be uploaded in the field labeled "List of Other Labs Owned" on the Upload page.

Owner Information

Owner Type: ▼

EIN: (Employer Identification No.)

Name:

*EIN/Name Change effective: * Effective Date is required for EIN/Name Change

Address:

City:

Country: ▼

State/Province: ▼ Zip:

At a minimum, the laboratory is required to annually submit a listing of all direct owners of the laboratory and all indirect owners of the laboratory who hold a 10% or greater ownership interest, controlling interest or corporate membership. This listing must be uploaded in the "List of Owners" field on the Upload page. Refer to the Ownership section of the eCLEP Permit Materials User Manual for definitions of direct owner and indirect owner, including examples.

Additionally, the laboratory may be required to submit additional supplemental material in response to various ownership questions on this Owner page and the Declaration page. These supplemental materials must be uploaded in the appropriate field on the Upload page as directed.

Owner Contact Information

Title:

First Name:

Middle Name:

Last Name:

Telephone (### ### ####): Ext:

Fax (### ### ####):

Email:

ECLP MANUAL**During Reapplication, all laboratories are required to upload a list of direct and indirect owners of the laboratory.**

The list of direct owners must include (based on ownership type):

- **Individuals:** Names, addresses, percentage of ownership, and social security numbers of individual owners.
- **Partnership:** Names, addresses, percentage of ownership, and social security numbers of all partners.
- **Government:** The governmental entity and name of the representative official (i.e., Commissioner of Health, Chancellor, etc.) who can be contacted regarding ownership issues.
- **For-Profit Corporation:** Names, addresses, percentage of ownership, and social security numbers (or EIN) for corporate officers, and/or shareholders.
- **Not-for-Profit Corporation (NFPC):** A list of the Board of Directors/Trustees/Governors of the NFPC.
- **Other:** Names, addresses, percentage of ownership and SSN or EIN, as appropriate.

The list of indirect owners must include those individuals or entities that 1) possess ten (10) percent or more of the voting shares of an entity that directly owns/operates a clinical laboratory; 2) maintain a controlling interest of ten (10) percent or more in an entity that directly owns/operates a clinical laboratory; or 3) maintain corporate membership in a not-for-profit corporation that directly owns/operates a clinical laboratory.

The list must include (based on ownership type):

- **Individuals:** Names, addresses, percentage of ownership, and social security numbers of individual owners
- **Partnership:** Names, addresses, percentage of ownership, and social security numbers the partners
- **For-Profit Corporation:** Names, addresses, percentage of ownership, and social security numbers (or EIN) for corporate officers, and/or shareholders
- **Not-for-Profit Corporation:** A list of the Board of Directors/Trustees/Governors of the NFPC.

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Declaration section

Respond to the questions presented in this section. For each “Yes” response, the laboratory will be prompted to upload supplemental documentation. These documents will be uploaded in the Upload screen described below.

Permit Materials	Proficiency Testing	Gross Annual Receipts	LDT Approval	Survey	Blood Resources	Tools
Lab Profile	Ownership	Personnel	Permit Categories/Tests	PSCs and Others		
Reapplication Period: Mar 10, 2023 through Mar 31, 2023 at 05:00 PM, EDT						Reapplication Center

[Instructions](#)
[Owner](#)

[Declaration](#)

[Upload](#)

PFI: 0000 **Name:** Internal Test for CLEP

1. Has the director, any assistant director(s), or those having direct or indirect ownership, controlling interest, or corporate membership in the applying facility ever been charged with violations of local, state, or federal laws or regulations including, but not limited to, the Public Health Law or related statutes concerning the provision of health care services or the reimbursement for such services? To the extent that such charges are currently pending, respond "Yes".

Yes No

On a separate sheet, list the name and address of the individual(s) or entity(ies), a description of the charge(s) and dispositions of the charge(s), including dates. The PFI of the laboratory must be included on this sheet. This sheet must be uploaded in the field labeled "Director/Owner Violation or Charges" on the Upload page.

2. Has the director, any assistant director(s), or those having direct or indirect ownership, controlling interest, or corporate membership in the applying clinical facility ever been charged with any crime, including but not limited to any offense related to the furnishing of, or billing for, clinical laboratory services, medical care, services, or supplies, or which is considered an offense involving theft or fraud? To the extent that such charges are currently pending, respond "Yes".

Yes No

On a separate sheet, list the name and address of the individual(s) or entity(ies), a description of the charge(s) and dispositions of the charge(s), including dates. The PFI of the laboratory must be included on this sheet. This sheet must be uploaded in the field labeled "Director/Owner Crime Conviction" on the Upload page.

3. Is any individual with a direct or indirect ownership or controlling interest in the applying clinical facility a licensed health professional authorized by law to order clinical laboratory tests and receive results? Note that a "Yes" response is expected if any direct or indirect owners are licensed physicians with 10% or greater ownership or controlling interest.

Yes No

On a separate sheet, identify all individuals with greater than 10% ownership interest or controlling interest who are authorized by law to order clinical laboratory tests. The PFI of the laboratory must be included on this sheet. This sheet must be uploaded in the field labeled "List of Authorized Individuals" on the Upload page.

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If a laboratory declares it has entered into a new management contract, a follow-up request to submit a copy of the contract to CLEP will be made, there is currently no upload feature for management contract submission.

4. Is the applying clinical facility operated by a management company, or leased in whole or in part by any other organization?

Yes No

Management Company

Name:

Address:

City:

Country: ▼

State/Province: ▼ Zip:

Management Contact Information

First Name:

Middle Name:

Last Name:

Telephone (### ### ####): Ext:

Email:

ECLEP MANUAL

Upload section

Depending on the laboratory's responses to the questions on the Declaration page, users will see one or more fields requesting specific documents to be uploaded. **During Reapplication, all laboratories are required to upload a list of direct and indirect owners of the laboratory. Refer to page 24 for definitions of direct and indirect owners and page 27 for specific instruction on reporting the ownership.**

To upload a document, verify the document type you wish to upload matches the document type on the screen (List of Owners, List of Other Labs Owned, Director/Owner Violation or Charges, Director/Owner Crime Conviction, List of Authorized Individuals) then click **Browse** button to the right of the File Name space. Navigate to the electronic file on your computer, then click **Open** to upload.

If you accidentally upload the wrong document, you may click on **Browse** button again and choose another document, the original uploaded document will be overwritten.

Once all documents have been uploaded, click **Save**.

[Owner](#)

[Declaration](#)

Upload

Ownership / Declaration Upload

Please upload the requested documents in the fields below. File formats accepted are Microsoft Word, Microsoft Excel or PDF. **Each document should have the PFI of the applying facility prominently indicated at the top of the page.** If more than one upload field is displayed, be certain to upload the correct document in the relevant field. For example, use the upload field labeled, "List of Owners", for the list of direct/indirect owners for the annual reapplication or the Disclosure of Ownership, Controlling Interest and Corporate Membership Statement for a direct owner change.

Note that only one document may be uploaded in a given upload field. Each time you upload a document into the field, it overwrites the previous document uploaded. Only the most recent document uploaded is submitted to CLEP when you Submit Changes.

The file name can contain only numbers, letters and a period. Spaces and special characters are not allowed.

File	Name	Uploaded By	Time
List of Owners	3.pdf	-	03-Nov-2021 9:51 AM

Each file uploaded represents the latest file of that type to be uploaded. The previous version of the file has been overwritten.

Items with an asterisk (*) are required.

List of Owners

* **File Name:** No file chosen
 Use this upload field to list the direct and indirect owners of the laboratory.

List of Other Labs Owned

* **File Name:** No file chosen
 Use this upload field to identify each direct or indirect owner and the laboratory(ies) for which the owner has an ownership interest, controlling interest or corporate membership, in response to Question 1 on the Owner page. The PFI and name of the laboratory(ies) must be indicated.

Director/Owner Violation or Charges

* **File Name:** No file chosen
 Use this upload field to provide additional information in response to Question 1 on the Declaration page.

Director/Owner Crime Conviction

* **File Name:** No file chosen
 Use this upload field to provide additional information in response to Question 2 on the Declaration page.

List of Authorized Individuals

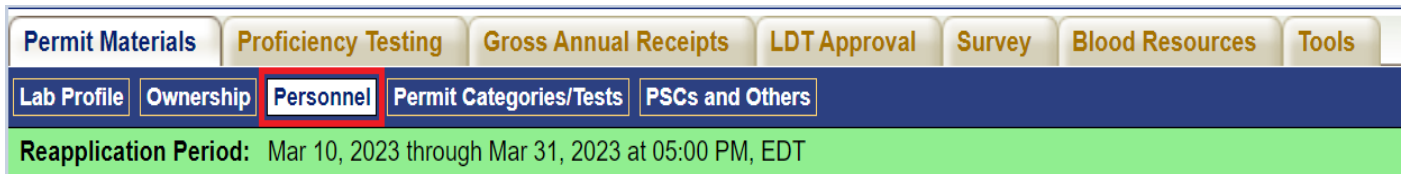
* **File Name:** No file chosen
 Use this upload field to provide additional information in response to Question 3 on the Declaration page.

ECLP MANUAL

Personnel

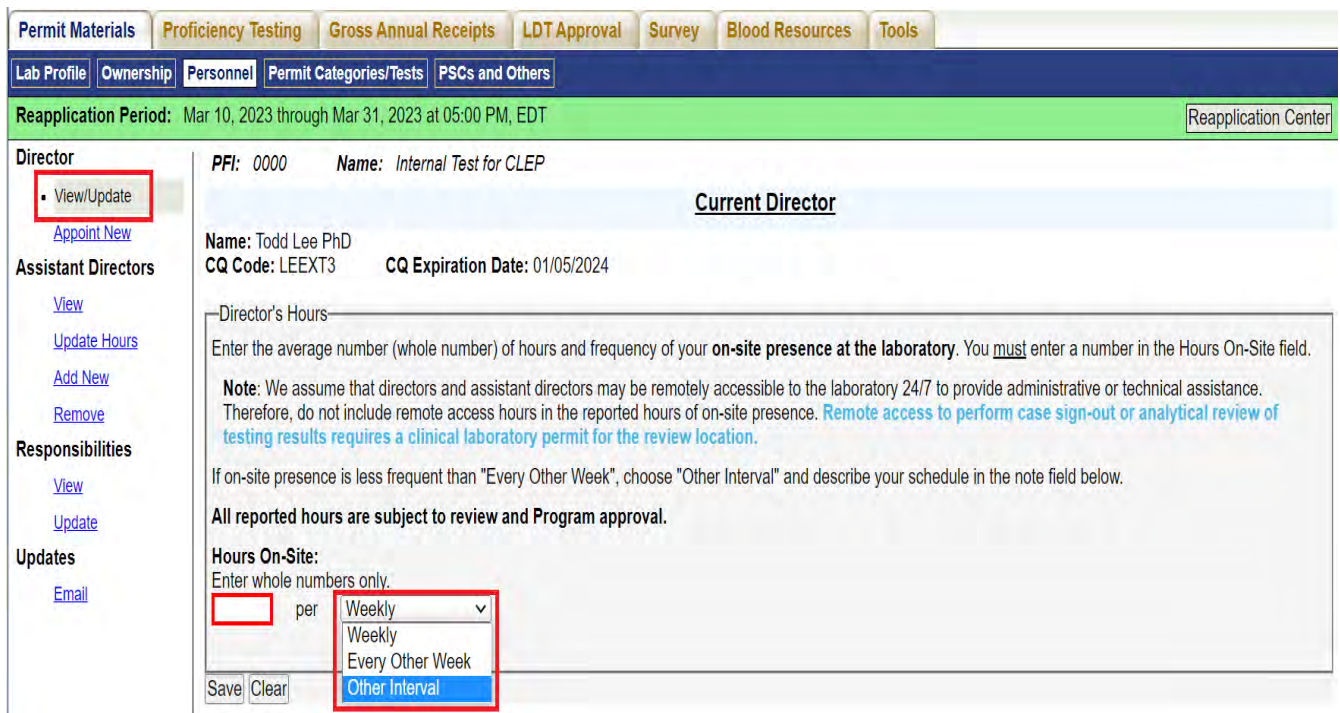
The **Personnel** section has many subsections, including Director, Assistant Director, and Responsibilities. Note that any **yellow highlighted** areas are required. You will need to know the Certificate of Qualification (**CQ**) code of any new directors or assistant directors. The CQ code (five letters followed by a number) can be found on the individual's certificate. If you are unable to locate this document for the individual, e-mail CLEP@health.ny.gov for help in looking up CQ codes.

- During the Reapplication mode, please review each subsection for accuracy.



Director section

The **Director** section allows you to view and update current on-site hours for the Laboratory Director as well as appoint a new Laboratory Director. Update hours (whole numbers ONLY) and frequency as needed and click **Save**.



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If the frequency "Other interval" is selected from the drop-down menu, then it is mandatory to provide the proposed frequency in the note field provided. Click **Save**.

Permit Materials	Proficiency Testing	Gross Annual Receipts	LDT Approval	Survey	Blood Resources	Tools
Lab Profile	Ownership	Personnel	Permit Categories/Tests	PSCs and Others		
Reapplication Period: Mar 10, 2023 through Mar 31, 2023 at 05:00 PM, EDT						Reapplication Center
Director	PFI: 0000 Name: Internal Test for CLEP					
<input type="checkbox"/> View/Update	Current Director					
Appoint New	Name: Todd Lee PhD					
Assistant Directors	CQ Code: LEEXT3 CQ Expiration Date: 01/05/2024					
View	Director's Hours					
Update Hours	Enter the average number (whole number) of hours and frequency of your on-site presence at the laboratory . You <u>must</u> enter a number in the Hours On-Site field.					
Add New	Note: We assume that directors and assistant directors may be remotely accessible to the laboratory 24/7 to provide administrative or technical assistance. Therefore, do not include remote access hours in the reported hours of on-site presence. Remote access to perform case sign-out or analytical review of testing results requires a clinical laboratory permit for the review location.					
Remove	If on-site presence is less frequent than "Every Other Week", choose "Other Interval" and describe your schedule in the note field below.					
Responsibilities	All reported hours are subject to review and Program approval.					
View	Hours On-Site:					
Update	Enter whole numbers only.					
Email	20 per <input type="text" value="Other Interval"/>					
	Describe On-Site Frequency if "Other Interval" is chosen:					
	"As needed" or "on-call" will not be accepted.					
	<input type="text"/>					
	<input type="button" value="Save"/> <input type="button" value="Clear"/>					

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To appoint a new Director, enter the CQ Code of the new director, the effective dates of the change and the work email address at this facility. Click **Next**.

Note: In order to indicate a replacement for the outgoing laboratory director in eCLEP, the incoming director must hold a valid Certificate of Qualification and his/her CQ code must be entered. If the incoming director does not currently hold or has not applied for a Certificate of Qualification, please contact clepcert@health.ny.gov for alternate instructions.

Permit Materials	Proficiency Testing	Gross Annual Receipts	LDT Approval	Survey	Blood Resources	Tools
Lab Profile	Ownership	Personnel	Permit Categories/Tests	PSCs and Others		
Reapplication Period: Mar 14, 2023 through Mar 31, 2023 at 05:00 PM, EDT						Reapplication Center

Director PFI: 0000 Name: Internal Test for CLEP Dev

[View/Update](#)

- Appoint New

Assistant Directors

[View](#)

[Update Hours](#)

[Add New](#)

[Remove](#)

Responsibilities

[View](#)

[Update](#)

Updates

[Email](#)

In order to indicate a replacement for the outgoing laboratory director in eCLEP, the incoming director must hold a valid Certificate of Qualification and his/her CQ code must be entered. If the incoming director does not currently hold a Certificate of Qualification, please contact clepcert@health.ny.gov for alternate instructions.

When assigning a current Assistant Director to Director, do not submit a request to delete the Assistant Director. This process will be handled automatically when the Director's appointment is accepted.

A new Director must also complete and submit an [HCS Affiliation Request](#) form to establish / affiliate an existing Health Commerce System account with this laboratory. Failure to submit this form will delay the issuance of an amended permit.

Appoint A New Director

To begin, please fill in the data requested below; items with an asterisk (*) are required.

Outgoing Director

Name: Todd Lee

* Ending Date:

This outgoing director will continue at this facility as an assistant director

New Director

* CQ Code of New Director: [Help with CQ Codes](#)

* Starting Date:

* Email:

- Note, when a new Laboratory Director is appointed, s/he must also complete and submit an HCS Affiliation Request form available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce.
- Note, a current Laboratory Director cannot be removed from the laboratory without identifying a replacement. **If the incoming director does not currently hold a Certificate of Qualification, please contact CLEP at clepcert@health.ny.gov for alternate instruction.**

Article 5 Title V of the New York State Public Health Law at Section 575 states that a permit shall become void by a change in the director, owner, or location. Therefore, timely transition to a new qualified director is essential. Please contact CLEP at clepcert@health.ny.gov for assistance.

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On the following screen, enter the new director's on-site hours (whole number ONLY) and select the frequency from the drop-down menu, click **Save**.

<p>Director</p> <p>View/Update</p> <p>▪ Appoint New</p> <p>Assistant Directors</p> <p>View</p> <p>Update Hours</p> <p>Add New</p> <p>Remove</p> <p>Responsibilities</p> <p>View</p> <p>Update</p>	<p>PFI: 0000 Name: Internal Test for CLEP</p> <p style="text-align: right;">Appoint A New Director</p> <p>Please specify the new Director's hours at this facility (required):</p> <p>Outgoing Director</p> <p>Name: Todd Lee (LEEXT3) Ending Date: 11/01/2019 Continuing as Assistant Director: false</p> <hr/> <p>New Director</p> <p>Name: Michael P Ryan (RYANM1) CQ Expiration Date: 08/10/2020 Starting Date: 11/01/2019</p> <p>Enter the average number (whole number) of hours and frequency of your on-site presence at the laboratory. You <u>must</u> enter a number in the Hours On-Site field.</p> <p>Note: We assume that directors and assistant directors may be remotely accessible to the laboratory 24/7 to provide administrative or technical assistance. Therefore, do not include remote access hours in the reported hours of on-site presence. Remote access to perform case sign-out or analytical review of testing results requires a clinical laboratory permit for the review location.</p> <p>If on-site presence is less frequent than "Every Other Week", choose "Other Interval" and describe your schedule in the note field below.</p> <p>All reported hours are subject to review and Program approval.</p> <p>Hours On-Site: Enter whole numbers only.</p> <p><input type="text" value=""/> per <input type="text" value="Weekly"/></p> <p><input type="button" value="Next"/> <input type="button" value="Cancel"/></p>
--	--

If the frequency "Other interval" is selected from the drop-down menu, then it is mandatory to provide the proposed frequency in the note field provided.

<p>Director</p> <p>View/Update</p> <p>▪ Appoint New</p> <p>Assistant Directors</p> <p>View</p> <p>Update Hours</p> <p>Add New</p> <p>Remove</p> <p>Responsibilities</p> <p>View</p> <p>Update</p>	<p>PFI: 0000 Name: Internal Test for CLEP</p> <p style="text-align: right;">Appoint A New Director</p> <p>Please specify the new Director's hours at this facility (required):</p> <p>Outgoing Director</p> <p>Name: Todd Lee (LEEXT3) Ending Date: 11/01/2019 Continuing as Assistant Director: false</p> <hr/> <p>New Director</p> <p>Name: Michael P Ryan (RYANM1) CQ Expiration Date: 08/10/2020 Starting Date: 11/01/2019</p> <p>Enter the average number (whole number) of hours and frequency of your on-site presence at the laboratory. You <u>must</u> enter a number in the Hours On-Site field.</p> <p>Note: We assume that directors and assistant directors may be remotely accessible to the laboratory 24/7 to provide administrative or technical assistance. Therefore, do not include remote access hours in the reported hours of on-site presence. Remote access to perform case sign-out or analytical review of testing results requires a clinical laboratory permit for the review location.</p> <p>If on-site presence is less frequent than "Every Other Week", choose "Other Interval" and describe your schedule in the note field below.</p> <p>All reported hours are subject to review and Program approval.</p> <p>Hours On-Site: Enter whole numbers only.</p> <p>20 per <input type="text" value="Other Interval"/></p> <p>Describe On-Site Frequency if "Other Interval" is chosen: "As needed" or "on-call" will not be accepted.</p> <p><input type="text" value=""/></p> <p><input type="button" value="Next"/> <input type="button" value="Cancel"/></p>
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ECLP MANUAL

Review the additional places of employment for the new director; add additional facilities as needed; click **Next**.

According to our records, the new Director is affiliated with the following facilities:

1. (PFI 1899) Albany Medical Center Hospital Clinical Laboratories -- Asst. Director

Does this Director work at any facility not listed above? If so, please describe below:

Indicate the permit categories in which the new director will have responsibilities, click **Finish**. The check box list includes all categories either held or in applied status for the laboratory.

Note: The new director must hold a Certificate of Qualification in the corresponding category to allow assignment of responsibility for a permit category. If the laboratory director does not hold the appropriate corresponding category on his/her Certification of Qualification, the request for assignment of responsibility for the permit category will be rejected. An individual may not serve as laboratory director unless s/he is assigned responsibility for at least one permit category.

This page also allows the laboratory to request one additional category by choosing a category from the New Category dropdown below the check box list, then click **Finish**.

New Director's Responsibilities (select all that apply):

- Andrology
- Bacteriology -- Comprehensive
- Blood pH and Gases
- Blood Services -- Transfusion
- Clinical Chemistry
- Cytopathology -- Non-gynecological Testing
- Diagnostic Immunology -- Diagnostic Services Serology
- Endocrinology
- Hematology -- Cellular Hematology
- Hematology -- Coagulation
- Hematology -- Cytohematology Diagnostic
- Histopathology -- General
- Immunohematology
- Mycobacteriology -- Restricted
- Mycology -- Restricted
- Oncology -- Soluble Tumor Markers
- Parasitology -- Comprehensive
- Toxicology -- Clinical Toxicology-Initial Testing Only
- Ther. Sub. Mon./Quant. Tox.
- Urinalysis
- Urine Pregnancy Testing
- Virology

NOTE: If this Director is to be responsible for a category not yet held by this facility, you may select the new category below:

New Category:

eCLEP MANUAL

The next page will display the new director change. Review the information for accuracy and click **Save**.

Reapplication Period: Mar 14, 2023 through Mar 31, 2023 at 05:00 PM, EDT Reapplication Center

Director

- View/Update
- Appoint New

Assistant Directors

- View
- Update Hours
- Add New
- Remove

Responsibilities

- View
- Update

Updates

- Email

Pending Changes:

Director: Michael P Ryan (RYANM1) was: Todd Lee (LEEXT3) Cancel Selected Changes

PFI: 0000 Name: Internal Test for CLEP Dev

Warnings:

- The CQ for this director has expired.

In order to indicate a replacement for the outgoing laboratory director in eCLEP, the incoming director must hold a valid Certificate of Qualification and his/her CQ code must be entered. If the incoming director does not currently hold a Certificate of Qualification, please contact clepcert@health.ny.gov for alternate instructions.

A new Director must also complete and submit an [HCS Affiliation Request](#) form to establish / affiliate an existing Health Commerce System account with this laboratory. Failure to submit this form will delay the issuance of an amended permit.

Current Director

Name: Michael P Ryan PhD
 CQ Code: RYANM1 CQ Expiration Date: 08/10/2022

Director's Hours

Enter the average number (whole number) of hours and frequency of your **on-site presence at the laboratory**. You must enter a number in the Hours On-Site field.

Note: We assume that directors and assistant directors may be remotely accessible to the laboratory 24/7 to provide administrative or technical assistance. Therefore, do not include remote access hours in the reported hours of on-site presence. [Remote access to perform case sign-out or analytical review of testing results requires a clinical laboratory permit for the review location.](#)

If on-site presence is less frequent than "Every Other Week", choose "Other Interval" and describe your schedule in the note field below.

All reported hours are subject to review and Program approval.

Hours On-Site:
 Enter whole numbers only.
 4 per Weekly

Save Clear

Assistant Director section

The **Assistant Director** section allows you to view the current assistant directors, update assistant director on-site hours, add a new assistant director(s), and remove an assistant director(s).

Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey Blood Resources Tools

Lab Profile Ownership Personnel Permit Categories/Tests PSCs and Others

Reapplication Period: Mar 14, 2023 through Mar 31, 2023 at 05:00 PM, EDT Reapplication Center

Director

- View/Update
- Appoint New

Assistant Directors

- View
- Update Hours
- Add New
- Remove

Responsibilities

- View
- Update

Updates

- Email

PFI: 0000 Name: Internal Test for CLEP Dev

Assistant Directors

ABRAM1	Mark E Abrahamson	remove
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To add an Assistant Director, please follow the steps as presented above for appointing a new Laboratory Director.

- To update the on-site hours for an Assistant Director, either click on the individual’s name in the **View** page (see above) or choose the individual from the drop-down list presented on the **Update Hours** page, click **Next**.

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- On the next screen, update the hours as needed, click **Save**. **Note:** The Clinical Laboratory Evaluation Program may seek clarification of the Assistant Director’s work schedule before accepting the proposed change.

[Permit Materials](#)
[Proficiency Testing](#)
[Gross Annual Receipts](#)
[LDT Approval](#)
[Survey](#)
[Blood Resources](#)
[Tools](#)

[Lab Profile](#)
[Ownership](#)
[Personnel](#)
[Permit Categories/Tests](#)
[PSCs and Others](#)

Reapplication Period: Mar 14, 2023 through Mar 31, 2023 at 05:00 PM, EDT Reapplication Center

Director
[View/Update](#)
[Appoint New](#)

Assistant Directors
[View](#)
Update Hours
[Add New](#)
[Remove](#)

Responsibilities
[View](#)
[Update](#)

Updates
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PFI: 0000 Name: Internal Test for CLEP Dev

Assistant Director

Name: Mark E Abrahamson OD, PhD
 CQ Code: ABRAM1 CQ Expiration Date:

Assistant Director's Hours

Enter the average number (whole number) of hours and frequency of your **on-site presence at the laboratory**. You must enter a number in the Hours On-Site field.

Note: We assume that directors and assistant directors may be remotely accessible to the laboratory 24/7 to provide administrative or technical assistance. Therefore, do not include remote access hours in the reported hours of on-site presence. [Remote access to perform case sign-out or analytical review of testing results requires a clinical laboratory permit for the review location.](#)

If on-site presence is less frequent than "Every Other Week", choose "Other Interval" and describe your schedule in the note field below.

All reported hours are subject to review and Program approval.

Hours On-Site:
 Enter whole numbers only.
 per

Save Clear

- If the frequency “Other interval” is selected from the drop-down menu, then it is mandatory to provide the proposed frequency in the note field provided.

Assistant Director's Hours

Enter the average number (whole number) of hours and frequency of your **on-site presence at the laboratory**. You must enter a number in the Hours On-Site field.

Note: We assume that directors and assistant directors may be remotely accessible to the laboratory 24/7 to provide administrative or technical assistance. Therefore, do not include remote access hours in the reported hours of on-site presence. [Remote access to perform case sign-out or analytical review of testing results requires a clinical laboratory permit for the review location.](#)

If on-site presence is less frequent than "Every Other Week", choose "Other Interval" and describe your schedule in the note field below.

All reported hours are subject to review and Program approval.

Hours On-Site:
 Enter whole numbers only.
 per

Describe On-Site Frequency if "Other Interval" is chosen:
 "As needed" or "on-call" will not be accepted.

Save Clear

ECLEP MANUAL

- To remove an Assistant Director, either click the remove link next to the individual's name on the **View** page; or choose the individual from the list presented on the **Remove** page, click **Next**.

Permit Materials | Proficiency Testing | Gross Annual Receipts | LDT Approval | Survey | Blood Resources | Tools

Lab Profile | Ownership | Personnel | Permit Categories/Tests | PSCs and Others

Reapplication Period: Mar 14, 2023 through Mar 31, 2023 at 05:00 PM, EDT Reapplication Center

Director
[View/Update](#)
[Appoint New](#)

Assistant Directors
View

Update Hours
[Add New](#)
[Remove](#)

Responsibilities
[View](#)
[Update](#)

Updates
[Email](#)

PFI: 0000 Name: Internal Test for CLEP Dev

Assistant Directors

ABRAM1	Mark E Abrahamson	remove
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- On the following page, enter the effective date of the Assistant Director's departure, click **Remove**.

Permit Materials | Proficiency Testing | Gross Annual Receipts | LDT Approval | Survey | Blood Resources | Tools

Lab Profile | Ownership | Personnel | Permit Categories/Tests | PSCs and Others

Reapplication Period: Mar 14, 2023 through Mar 31, 2023 at 05:00 PM, EDT Reapplication Center

Director
[View/Update](#)
[Appoint New](#)

Assistant Directors
[View](#)
[Update Hours](#)
[Add New](#)
Remove

Responsibilities
[View](#)
[Update](#)

Updates
[Email](#)

PFI: 0000 Name: Internal Test for CLEP Dev

Warnings:

- This director is the SOLE DIRECTOR for the following permit categories:
 - Clinical Chemistry

Remove Assistant Director

To remove this director, please fill in the data requested below; items with an asterisk (*) are required.

When assigning a current Assistant Director to Director, do not submit a request to delete the Assistant Director. This process will be handled automatically when the Director's appointment is accepted.

Name: Mark E Abrahamson
CQ Code: ABRAM1 CQ Expiration Date:

* Ending Date:

Remove

Note: If the departing assistant director is the sole individual responsible for a permit category(ies), the Clinical Laboratory Evaluation Program will notify the director that the laboratory is in jeopardy

ECLP MANUAL

of losing an approved (or pending) permit category unless a timely arrangement is made for assigning a qualified person (current or new) to be responsible for the permit category.

Article 5 Title V of the New York State Public Health Law at Section 575 states that a permit shall become void by a change in the director, owner, or location. Therefore, timely transition to a new qualified director is essential. Please contact CLEP at clepcert@health.ny.gov for assistance.

NEW

- To update a personnel's email address, on the Email webpage choose the individual from the drop-down list presented. Update the email address. Click **Save**.

The screenshot shows the ECLP web application interface. At the top, there are navigation tabs: Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, Blood Resources, and Tools. Below these are sub-tabs: Lab Profile, Ownership, Personnel, Permit Categories/Tests, and PSCs and Others. A green banner indicates the Reapplication Period: Mar 14, 2023 through Mar 31, 2023 at 05:00 PM, EDT, with a Reapplication Center button. The main content area is titled 'Update Email Address' and shows details for a Director with PFI: 0000 and Name: Internal Test for CLEP Dev. A dropdown menu labeled 'Select Person' is visible. A red dashed box highlights the '* Email:' field. Below the field are 'Save' and 'Cancel' buttons. On the left sidebar, under 'Updates', the 'Email' option is highlighted with a red box.

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Responsibilities Section

This section allows the laboratory to view all the permit categories and the corresponding CQ holders with responsibility. On the “**View**” page, clicking on a Director’s name will allow you to edit the responsibilities for that individual.

Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey Blood Resources Tools

Lab Profile Ownership Personnel Permit Categories/Tests PSCs and Others

Reapplication Period: Mar 14, 2023 through Mar 31, 2023 at 05:00 PM, EDT Reapplication Center

Director
[View/Update](#)
[Appoint New](#)

Assistant Directors
[View](#)
[Update Hours](#)
[Add New](#)
[Remove](#)

Responsibilities
View
[Update](#)

Updates
[Email](#)

Pending Changes:
 Add to Mark E Abrahamson: Endocrinology was: N/A
[Cancel Selected Changes](#)

PFI: 0000 Name: Internal Test for CLEP Dev

Responsible Directors

RYANM1	Michael P Ryan	pending	Andrology Bacteriology Blood Services -- Transfusion Service Blood Services -- Transfusion Storage Only Cellular Immunology -- Leukocyte Function Cellular Immunology -- Malignant Leukocyte Immunophenotyping Cellular Immunology -- Non-Malignant Leukocyte Immunophenotyping Clinical Chemistry Cytopathology -- Gynecological Testing
ABRAM1	Mark E Abrahamson		Clinical Chemistry Endocrinology

From the **Update** page, choose a Director from the dropdown to make edits to responsibilities.

Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey Blood Resources Tools

Lab Profile Ownership Personnel Permit Categories/Tests PSCs and Others

Reapplication Period: Mar 14, 2023 through Mar 31, 2023 at 05:00 PM, EDT Reapplication Center

Director
[View/Update](#)
[Appoint New](#)

Assistant Directors
[View](#)
[Update Hours](#)
[Add New](#)
[Remove](#)

Responsibilities
[View](#)
Update

Updates
[Email](#)

PFI: 0000 Name: Internal Test for CLEP Dev

Choose Director to Update

To begin, choose a director from the list and click 'Next':

RYANM1 Michael P Ryan

Next Cancel

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Existing permit category responsibilities are indicated by a check mark. Additional permit categories can be requested by adding a check mark next to the desired category and clicking 'Save'.

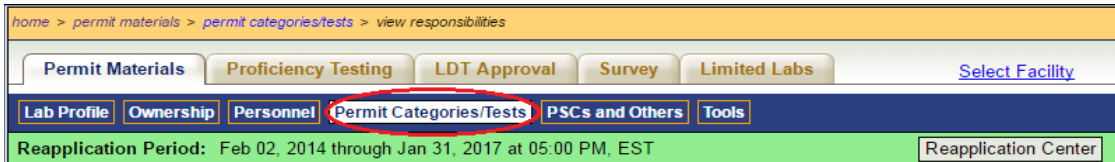
<p>View/Update</p> <p>Appoint New</p> <p>Assistant Directors</p> <p>View</p> <p>Update Hours</p> <p>Add New</p> <p>Remove</p> <p>Responsibilities</p> <p>View</p> <p>Update</p> <p>Updates</p> <p>Email</p>	<p>Update Responsibilities</p>
	<p>Name: Michael P Ryan PhD CQ Code: RYANM1 CQ Expiration Date: 08/10/2022</p> <p>Please select all categories this Director is responsible for (at least 1 must be specified); items with an asterisk (*) are required.</p> <p>Effective Date of Changes</p> <p>* Effective Date: <input type="text" value="mm/dd/yyyy"/> <input type="button" value="📅"/></p> <hr/> <p>Director's Responsibilities (select all that apply):</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Andrology <input checked="" type="checkbox"/> Bacteriology <input type="checkbox"/> Blood pH and Gases <input type="checkbox"/> Blood Services -- Collection <input checked="" type="checkbox"/> Blood Services -- Transfusion Service <input checked="" type="checkbox"/> Blood Services -- Transfusion Storage Only <input checked="" type="checkbox"/> Cellular Immunology -- Leukocyte Function <input checked="" type="checkbox"/> Cellular Immunology -- Malignant Leukocyte Immunophenotyping <input checked="" type="checkbox"/> Cellular Immunology -- Non-Malignant Leukocyte Immunophenotyping <input checked="" type="checkbox"/> Clinical Chemistry <input checked="" type="checkbox"/> Cytopathology -- Gynecological Testing <input type="checkbox"/> Cytopathology -- Non-gynecological Testing <input type="checkbox"/> Cytogenetics <input type="checkbox"/> Diagnostic Immunology -- Diagnostic Services Serology <input type="checkbox"/> Diagnostic Immunology -- Donor Services Serology <input type="checkbox"/> Endocrinology <input type="checkbox"/> Fetal Defect Markers <input type="checkbox"/> Forensic Identity <input type="checkbox"/> Hematology <input type="checkbox"/> Histocompatibility <input type="checkbox"/> Immunohematology <input type="checkbox"/> Mycobacteriology <input type="checkbox"/> Mycology <input type="checkbox"/> Oncology -- Molecular and Cellular Tumor Markers <input type="checkbox"/> Oncology -- Soluble Tumor Markers <input type="checkbox"/> Parentage/Identity Testing <input type="checkbox"/> Parasitology <input type="checkbox"/> Toxicology -- Blood Lead-Comprehensive <input type="checkbox"/> Toxicology -- Blood Lead-ASV Using Screen Printed Sensors <input type="checkbox"/> Toxicology -- Clinical Toxicology-Comprehensive <input type="checkbox"/> Toxicology -- Clinical Toxicology-Qualitative Testing Only <input type="checkbox"/> Toxicology -- Forensic Toxicology-Comprehensive <input type="checkbox"/> Toxicology -- Forensic Toxicology-Initial Testing Only <input type="checkbox"/> Trace Elements <input type="checkbox"/> Transplant Monitoring <input type="checkbox"/> Ther. Sub. Mon./Quant. Tox. <input type="checkbox"/> Virology <input type="checkbox"/> Wet Mounts

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Permit Categories/Tests

The **Permit Categories/Tests** sections allows you to:

- add permit categories to the laboratory permit;
- change permit category responsibilities for the laboratory director and/or assistant director(s);
- remove permit categories from the laboratory permit;
- enter test volumes (required for laboratories located in NYS during permit reapplication).



Responsibilities section

Under the **Responsibilities** section, you may view the laboratory’s current permit categories, the status of each category, and the laboratory director (DI) /assistant director (AD) responsible for each permit category.

- Click on the permit category name to view the current DI/ AD responsible for the category and to add or remove individuals as responsible.

Category status	Permit Categories	Responsibilities Status	Responsible Directors
Pending Add	Andrology	Pending	Kathleen Curran
Pending	Bacteriology	Pending	Kathleen Curran
Pending	Blood pH and Gases	Pending	Monica M. Parker
Pending	Cellular Immunology Leukocyte Function		No responsible AD/DI for this Category
Pending	Cellular Immunology Malignant Leukocyte Immunophenotyping		No responsible AD/DI for this Category
Pending	Cellular Immunology Non-Malignant Leukocyte Immunophenotyping		No responsible AD/DI for this Category
Pending	Clinical Chemistry	Pending	Monica M. Parker

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PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY

Add/Remove Responsibilities

Category Name: Clinical Chemistry

Responsible AD/DI

- Monica M. Parker
- Jill Taylor

Available AD/DI

Person Id	Person Name	Add/Remove Responsibility
LEEXT3	Todd Lee	Add
PARKM1	Monica M. Parker	Pending
TAYLJ1	Jill Taylor	Pending

("Person Id" is the Certificate of Qualification code)

Alternatively, choose the category to update from the Responsibilities Update page, click **Next**. This dropdown menu will include all categories that the laboratory has applied for (pending) and those already held (approved). This will take you to the same page as above.

Note: Personnel changes still pending review by the Department will not appear as available for responsibility assignment (e.g., changes entered but not yet submitted in eCLEP). Only Certificate of Qualification holders already associated with the laboratory will be listed. A new Assistant Director must be added through the Personnel section.

Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey Limited Labs

Lab Profile Ownership Personnel Permit Categories/Tests PSCs and Others Tools

Reapplication Period: Apr 01, 2018 through Dec 15, 2018 at 05:00 PM, EST [Reapplication Center](#)

Responsibilities

[View](#)

Update

Category

[Pending Changes](#)

[Add New](#)

[Upload](#)

[Remove](#)

PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY

Update Responsibility

Permit Category :

[Next](#) [Clear](#)

On the following page, indicate the effective date of the individual's new responsibility, click Add.

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Permit Materials | Proficiency Testing | Gross Annual Receipts | LDT Approval | Survey | Limited Labs

Lab Profile | Ownership | Personnel | Permit Categories/Tests | PSCs and Others | Tools

Reapplication Period: Apr 01, 2018 through Dec 15, 2018 at 05:00 PM, EST Reapplication Center

Responsibilities PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY

[View](#)

Update

Category **Add/Remove Responsibilities**

[Pending Changes](#)

[Add New](#)

[Upload](#)

[Remove](#)

Items with an asterisk (*) are required.

Effective Date of Changes

Category Name: Bacteriology

Person Name: Todd Lee

Person Id: LEEXT3

* Effective Date (mm/dd/yyyy):

Category Upload – Cytopathology Proficiency Testing Enrollment

During permit reapplication, laboratories holding the category of **Cytopathology – Gynecological Testing** are required to upload proof of enrollment in a CMS-approved proficiency testing (PT) program. **Acceptable documentation is an enrollment confirmation from the PT program.** Purchase orders and order forms are not acceptable.

- The enrollment confirmation must reference the laboratory name and address.
- The PFI number of the laboratory must be handwritten on the paper if the PFI or CLIA number is not already included.
- If the laboratory personnel participate in PT at another site, the order confirmation for “paper enrollment” must be provided.

Permit Materials | Proficiency Testing | Gross Annual Receipts | LDT Approval | Survey | Tools

Lab Profile | Ownership | Personnel | Permit Categories/Tests | PSCs and Others

Reapplication Period: Feb 02, 2021 through Feb 28, 2021 at 05:00 PM, EST Reapplication Center

Responsibilities PFI: 0000 Name: Internal Test for CLEP

[View](#)

[Update](#)

Category **Cytopathology Gynecological Proficiency Testing**

[Pending Changes](#)

[Add New](#)

Cytopathology

[Remove](#)

Test Volume Laboratories holding or applying for the category of Cytopathology - Gynecological Testing are required to submit proof of enrollment in a federally-approved proficiency testing program each year.

[View Previous](#)

[Edit Current](#)

The documentation must include the laboratory's PFI number and a date the test was taken or is scheduled to be taken; this would include the PT enrollment confirmation from the PT vendor. The date of the test was taken must fall into the current calendar year.

We will not accept a December PT event from the previous year to satisfy enrollment for the current year.

If all of your laboratory's employees take the test elsewhere, your laboratory must still be enrolled ("paper enrollment" or "laboratory enrollment only") to maintain the category. Please submit proof of paper enrollment with notification that the test is taken elsewhere. Please contact your proficiency test provider about obtaining a proof of enrollment when all employees take a PAP PT elsewhere. PT enrollment confirmations from the site where the PT is taken will not be accepted as confirmation for your laboratory.

Uploaded Files:

File	Name	Uploaded By	Time
Cytopathology	ECLEPSURVEYFILENETFLOWDIAGRAM.pdf -		02-Jan-2019 9:48 AM

Each file uploaded represents the latest file of that type to be uploaded. The previous version of the file has been overwritten.

The file name can contain only numbers, letters and a period. Spaces and special characters are not allowed.

Items with an asterisk (*) are required.

Cytopathology

* File Name: No file chosen

ECLEP MANUAL**Add a Category**

To request to add a permit category, click on the **Add New** hyperlink from the left panel under Category.

Lab Profile	Ownership	Personnel	Permit Categories/Tests	PSCs and Others
Reapplication Period: Feb 02, 2021 through Feb 28, 2021 at 05:00 PM, EST				Reapplication Center
Responsibilities View Update		PFI: 0000 Name: Internal Test for CLEP		
Category Pending Changes Add New Cytopathology Remove		Add New Category		
Test Volume View Previous Edit Current		<p>Please select the category you wish to add to the clinical laboratory permit. If you are unsure of the permit category for the test you wish to offer, please search for the category by entering the test name in the Search field. You may also review the Program Guide for permit category descriptions at our website at www.wadsworth.org/regulatory/clep.</p> <p>Once a permit category is chosen, the Certificate of Qualification code (CQ Code) of the responsible Director or Assistant Director must be entered. Please note the Director and/or Assistant Director assigned to this new category must hold the relevant corresponding category on his/her Certificate of Qualification or be in the process of adding the category to the CQ. If the responsible person for the new permit category is a new Assistant Director, you must add them via the Personnel tab before their CQ code is visible in the dropdown list.</p> <p>If your laboratory is proposing to offer laboratory developed tests (LDT) in the new permit category you must submit the materials specified in the Test Approval section of the Clinical Laboratory Evaluation Program's public website Test Approval for each LDT and receive explicit approval prior to initiating patient testing.</p> <p>Permit Category: <input type="text" value="Blood Services - Collection"/> <input type="button" value="v"/> or <input type="text" value="Search for Category by Test Name"/> <input type="button" value="Search"/></p> <p>CQ Code: <input type="text" value="LEEXT3 Kathleen Currar"/> <input type="button" value="v"/></p> <p>Additional Information If you would like to provide additional information regarding this Add Category request, please enter below. (200 characters max)</p> <div style="border: 1px solid gray; height: 30px; width: 100%;"></div>		
		<p>Note: The Clinical Laboratory Evaluation Program assumes the laboratory is prepared to meet applicable requirements for permit approval on the date the new permit category request is submitted. These requirements may include successful participation in on-site survey, enrollment and successful participation in proficiency testing, and review and approval of validation materials for laboratory-developed tests.</p>		
		<input type="button" value="Next"/>		

Choose the desired permit category from the dropdown menu and choose a responsible director or assistant director for the new category using the individual's CQ code. If you do not see the individual's CQ code in the list, you must add the individual under the Personnel tab before proceeding with the Add Category request. Please note that both **Permit Category** and **CQ Code** fields are mandatory.

Once the Permit Category and CQ code have been chosen, click the Next button. When requesting to add a category that includes analytes/test that are described in CLIA Subpart I (42 CFR 493 Subpart I), you will be required to indicate the CMS-approved proficiency test provider and product that will be used to satisfy proficiency testing requirements.

ECLP MANUAL

Lab Profile	Ownership	Personnel	Permit Categories/Tests	PSCs and Others
Reapplication Period: Feb 02, 2021 through Feb 28, 2021 at 05:00 PM, EST				<input type="button" value="Reapplication Center"/>
Responsibilities View Update	PFI: 0000 Name: Internal Test for CLEP			
Category Pending Changes <input checked="" type="button" value="Add New"/> Cytopathology Remove	Add New Category			
Test Volume View Previous Edit Current	Please select the category you wish to add to the clinical laboratory permit. If you are unsure of the permit category for the test you wish to offer, please search for the category by entering the test name in the Search field. You may also review the Program Guide for permit category descriptions at our website at www.wadsworth.org/regulatory/clep . Once a permit category is chosen, the Certificate of Qualification code (CQ Code) of the responsible Director or Assistant Director must be entered. Please note the Director and/or Assistant Director assigned to this new category must hold the relevant corresponding category on his/her Certificate of Qualification or be in the process of adding the category to the CQ. If the responsible person for the new permit category is a new Assistant Director, you must add them via the Personnel tab before their CQ code is visible in the dropdown list. If your laboratory is proposing to offer laboratory developed tests (LDT) in the new permit category you must submit the materials specified in the Test Approval section of the Clinical Laboratory Evaluation Program's public website Test Approval for each LDT and receive explicit approval prior to initiating patient testing.			
	Permit Category: <input type="text" value="Blood Services - Collection"/>			
	or <input type="text" value="Search for Category by Test Name"/> <input type="button" value="Search"/>			
	CQ Code: <input type="text" value="LEEXT3 Kathleen Currar"/>			
	Additional Information If you would like to provide additional information regarding this Add Category request, please enter below. (200 characters max)			
	<div style="border: 1px solid gray; height: 30px;"></div>			
	Note: The Clinical Laboratory Evaluation Program assumes the laboratory is prepared to meet applicable requirements for permit approval on the date the new permit category request is submitted. These requirements may include successful participation in on-site survey, enrollment and successful participation in proficiency testing, and review and approval of validation materials for laboratory-developed tests.			
	<input type="button" value="Next"/>			

If you are unsure of what category is required for the testing that will be offered by the laboratory, you can use the search engine to search for category by test name. Please make sure the browser you are using is not blocking pop-ups, otherwise your search result will not be displayed.

Responsibilities View Update	PFI: 0000 Name: Internal Test for CLEP			
Category Pending Changes <input checked="" type="button" value="Add New"/> Cytopathology Remove	Add New Category			
Test Volume View Previous Edit Current	Please select the category you wish to add to the clinical laboratory permit. If you are unsure of the permit category for the test you wish to offer, please search for the category by entering the test name in the Search field. You may also review the Program Guide for permit category descriptions at our website at www.wadsworth.org/regulatory/clep . Once a permit category is chosen, the Certificate of Qualification code (CQ Code) of the responsible Director or Assistant Director must be entered. Please note the Director and/or Assistant Director assigned to this new category must hold the relevant corresponding category on his/her Certificate of Qualification or be in the process of adding the category to the CQ. If the responsible person for the new permit category is a new Assistant Director, you must add them via the Personnel tab before their CQ code is visible in the dropdown list. If your laboratory is proposing to offer laboratory developed tests (LDT) in the new permit category you must submit the materials specified in the Test Approval section of the Clinical Laboratory Evaluation Program's public website Test Approval for each LDT and receive explicit approval prior to initiating patient testing.			
	Permit Category: <input type="text" value="----Select a Category----"/>			
	or <input type="text" value="Search for Category by Test Name"/> <input type="button" value="Search"/>			
	CQ Code: <input type="text" value="----Select a CQ Code----"/>			
	Additional Information If you would like to provide additional information regarding this Add Category request, please enter below. (200 characters max)			
	<div style="border: 1px solid gray; height: 30px;"></div>			
	Note: The Clinical Laboratory Evaluation Program assumes the laboratory is prepared to meet applicable requirements for permit approval on the date the new permit category request is submitted. These requirements may include successful participation in on-site survey, enrollment and successful participation in proficiency testing, and review and approval of validation materials for laboratory-developed tests.			
	<input type="button" value="Next"/>			

ECLEP MANUAL

Indicate Tests Offered on NYS Specimens

This page provides a list of NYS-mandated PT analytes that are included under the new category. Please indicate whether you offer these tests or not by selecting an option from the drop-down menu.

More information on NYS-mandated PT Analytes can be found in the Proficiency Testing Guide available at <https://www.wadsworth.org/regulatory/clep/pt>.

The hyperlink **Category Specific Help** provides additional Proficiency Testing guidance by category.

All fields in this page are mandatory. Click Next button to proceed to the next page.

Indicate Tests Offered on NYS Specimens

Laboratories seeking a permit must enroll in an acceptable CMS-approved proficiency testing (PT) program for those tests described in CLIA Subpart I (42 CFR 493 Subpart I). Laboratories offering these tests on NYS specimens must designate which PT provider and product they will use to satisfy these requirements for the upcoming calendar year.

First, please indicate if the laboratory will be offering any of the tests listed below for the category requested.

Category Requiring PT: Bacteriology

Help/Instructions

Bacteriology

- Refer to Category Specific Help for additional information
- Laboratories are required to enroll in a program(s) that includes:
 - a minimum of five samples per testing event
 - three shipments per year
 - samples for bacterial isolation and identification (culture and molecular methods), antigen detection, gram stain, and antimicrobial susceptibility testing
 - Choose a PT module that best defines the laboratory's level of service for identification. These are defined in the Category Specific Help document.

[Category Specific Help](#)

Show 40 entries Search:

Name	Test Status
Identification of bacterial meningitis pathogens by molecular methods	Test Offered
Identification of bacteria by culture	Test Not Offered
Identification of blood pathogens (bacterial) by molecular methods	Test Offered
Identification of gastrointestinal bacterial pathogens by molecular methods	
Identification of genital pathogens (bacterial) by molecular methods	
Identification of respiratory bacterial pathogens by molecular methods	
Chlamydia/Neisseria gonorrhoeae by direct detection	
Clostridium difficile direct detection	
Group A Streptococcus direct detection	
Gram stains	
Susceptibility (bacterial) testing (AST)	

Showing 1 to 11 of 11 entries 1 row selected

[Next](#) [Clear](#) Previous 1 Next

E CLEP MANUAL

Designate PT Provider and Product

This page displays the tests that have been marked as “Test Offered” offered on the previous page.

Please provide the **PT Provider** and **Product** for each test and then click **Save** to proceed.

All fields in this form are mandatory.

USER TIP: If the PT Provider and Product you intend to purchase is not listed, then it has not been deemed acceptable to meet proficiency testing requirements. Contact PTAdmin@health.ny.gov for additional guidance.

home > permit materials > permit categories > add category pt test selection Select Facility

Permit Materials | Proficiency Testing | Gross Annual Receipts | LDT Approval | Survey | Limited Labs

Responsibilities **PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY**

[View](#)
[Update](#)

Category **Designate PT provider and product**

[Pending Changes](#)
[Add New](#)
[Upload](#)
[Remove](#)

Test Volume [View Previous](#)
[Edit Current](#)

Next, please choose a PT provider and PT product. Approved PT products must include at least 5 samples provided 3 times per year (except for Mycobacteriology, which is 2 times per year). This requirement also applies to laboratories offering these tests using waived kits/devices.

Category Requiring PT: Bacteriology

Show 40 entries Search:

Test Name	Provider	Product
Identification of bacterial meningitis pathogens by molecular methods	American Proficiency Inst	Meningitis Panel - 371
Identification of bacteria by culture	AAB Proficiency Testing S	Genital Culture - 2009523
Identification of genital pathogens (bacterial) by molecular methods	College of American Path	Vaginitis Screen - VS
Identification of respiratory bacterial pathogens by molecular methods	College of American Path	Infectious Disease Respir
Group A Streptococcus direct detection	American Academy of Fa	Group A Strep - 783
Gram stains	Medical Laboratory Evalu	Bacteriology 2 - 640
Susceptibility (bacterial) testing (AST)	Accutest Inc	Bacterial Identification - B

Showing 1 to 7 of 7 entries Previous 1 Next

[Save](#) [Clear](#)

ECLEP MANUAL

View Designation page is a summary of the Proficiency Testing information that had been entered. Review and click on **Next** button to complete the process.

Permit Materials	Proficiency Testing	Gross Annual Receipts	LDT Approval	Survey	Limited Labs
----------------------------------	-------------------------------------	---------------------------------------	------------------------------	------------------------	------------------------------

Responsibilities
[View](#)
[Update](#)

Category
[Pending Changes](#)
Add New
[Upload](#)
[Remove](#)

Test Volume
[View Previous](#)
[Edit Current](#)

PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY

View Designations

Please review your choices for PT Provider and product. If corrections are required, please click on "Pending Changes" from the menu on the left. Then click on PT Changes next to the category being added to be returned to the beginning of the PT designation process. If everything is acceptable, click Next.

Tests Offered

Category	Test	Provider	Product
Bacteriology	Gram stains	Medical Laboratory Evaluation	Bacteriology 2 - 640
	Group A Streptococcus direct detection	American Academy of Family Physicians	Group A Strep - 783
	Identification of bacteria by culture	AAB Proficiency Testing Service	Genital Culture - 2009523
	Identification of bacterial meningitis pathogens by molecular methods	American Proficiency Institute	Meningitis Panel - 371
	Identification of genital pathogens (bacterial) by molecular methods	College of American Pathologists	Vaginitis Screen - VS
	Identification of respiratory bacterial pathogens by molecular methods	College of American Pathologists	Infectious Disease Respiratory Panel - IDR
	Susceptibility (bacterial) testing (AST)	Accutest Inc	Bacterial Identification - BACT435
Category	Test	Provider	Product

Tests Not Offered

Category	Test
Bacteriology	
(+)	Chlamydia/Neisseria gonorrhoeae by direct detection
(+)	Clostridium difficile direct detection
Bacteriology	
(+)	Identification of blood pathogens (bacterial) by molecular methods
(+)	Identification of gastrointestinal bacterial pathogens by molecular methods
Category	Test

Next

ECLEP MANUAL

Adding More Than One CQ Holder to a New Category

To add multiple CQ holders to a new category, first add the new Category, then go to **View** under **Responsibilities** and select the newly added Category.

The screenshot shows the ECLEP interface with the 'View' option highlighted under the 'Responsibilities' section. The main content area displays 'All permit categories at this facility:' with a table listing categories like Bacteriology, Blood pH and Gases, Clinical Chemistry, and Virology, all with a 'Pending Add' status and 'Todd Lee' as the responsible director.

Category status	Permit Categories	Responsibilities Status	Responsible Directors
Pending Add	Bacteriology	Pending	Todd Lee
Approved	Blood pH and Gases		Todd Lee
Pending Add	Clinical Chemistry	Pending	Todd Lee
Pending Add	Virology		Todd Lee

Then proceed to add additional CQ holders to the new Category:

The screenshot shows the 'Add/Remove Responsibilities' dialog box for the 'Bacteriology' category. It lists 'Responsible AD/DI' as 'Todd Lee' and 'Available AD/DI' with a table of potential candidates.

Person Id	Person Name	Add/Remove Responsibility
LEEXT3	Todd Lee	Pending
PARKM1	Monica M. Parker	Add
TAYLJ1	Jill Taylor	Add

ECLIP MANUAL

Pending Changes page displays the list of all unsubmitted requests.

To cancel an Add Category request: select a change request by clicking the box to the left of the category name and press the **Cancel Selected Changes** button.

To modify the Add Category request: Click on the hyperlink **PT Changes**. This will allow user to modify ONLY the Proficiency Testing information entered.

Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey Limited Labs	
Lab Profile Ownership Personnel Permit Categories/Tests PSCs and Others Tools	
Reapplication Period: Apr 01, 2018 through Dec 15, 2018 at 05:00 PM, EST Reapplication Center	
Responsibilities View Update	PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY
Category Pending Changes Add New Upload Remove	<div style="background-color: #fff9c4; padding: 5px;"> Pending Changes: <input type="checkbox"/> Bacteriology: PT Changes Add was: ~ <input type="checkbox"/> Clinical Chemistry: PT Changes Add was: ~ <input type="checkbox"/> Virology: PT Changes Add was: ~ <div style="text-align: center; margin-top: 5px;">Cancel Selected Changes</div> </div>
Test Volume View Previous Edit Current	

ECLEP MANUAL

Remove a Category

Under the **Category** subsection, you may remove a permit category from the laboratory's permit. Select the category to remove from the dropdown list, click **Delete**.

The screenshot shows the 'Delete Permit Category' interface. At the top, there are navigation tabs: Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, and Limited Labs. Below these are sub-tabs: Lab Profile, Ownership, Personnel, Permit Categories/Tests, PSCs and Others, and Tools. A green banner displays the 'Reapplication Period: Apr 01, 2018 through Dec 15, 2018 at 05:00 PM, EST' and a 'Reapplication Center' button. The main content area is titled 'Delete Permit Category' and includes 'Category Information' with a dropdown menu for 'Permit Category' and a date field for 'Effective Date'. On the left, a sidebar contains options: View, Update, Pending Changes, Add New, Upload, and Remove (highlighted with a red box). Buttons for 'Delete' and 'Clear' are located at the bottom of the form.

Note: When a permit category is removed, the director's and/or assistant director(s) assigned responsibility for that permit category will also be removed.

On the following page, indicate the effective date of the permit category deletion, and then click **Delete**.

This screenshot is similar to the previous one but shows a calendar pop-up for the 'Effective Date' field. The calendar is for 'December 2018' and has the 4th day highlighted in yellow. The 'Remove' button in the sidebar is now greyed out. The 'Delete' and 'Clear' buttons remain at the bottom of the form.

eCLEP MANUAL

Test Volume

Note: this section is only visible to laboratories located in New York.

Laboratories located in New York are required to report **Test Volume** for each category of testing. The Test Volume section allows you to view the volumes of testing entered during the previous reapplication period and, in the Reapplication mode, enter the previous year's testing volumes for each permit category of testing. A Guidelines for Reporting Test Volume is available in the Tools Section of eCLEP. Please contact CLEP at CLEP@health.ny.gov for questions on reporting test volumes.

- In the Open mode, you can view the current information in the database.

The screenshot displays the eCLEP web application interface. At the top, there are navigation tabs: Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, Blood Resources, and Tools. Below these are sub-tabs: Lab Profile, Ownership, Personnel, Permit Categories/Tests, and PSCs and Others. The main content area is titled 'Open Mode' and shows a 'Continue' button. The left sidebar contains a 'Responsibilities' section with links for View, Update, Pending Changes, Add New, Cytopathology, and Remove. Below this is a 'Test Volume' section with a 'View Previous' link highlighted in a red box. The main content area shows 'PFI: 0000' and 'Name: Internal Test for CLEP 1'. A red box highlights the text 'Test Volume for January 1, 2020 through December 31, 2020'. Below this is a table with the following data:

Test Specialty/SubSpecialty	Total Tests/Specimens per Specialty/SubSpecialty
HISTOCOMPATIBILITY	
Total	0
MICROBIOLOGY	
Bacteriology	0
Mycobacteriology	0
Mycology	0
Parasitology	0
Virology	0
HPV Testing	0
Total	0

- In Reapplication mode, the laboratory is required to report the testing volumes for the previous calendar year. Enter volumes for each permit category held on the laboratory permit. Use the scroll bar to view all categories.
 - If you indicate "No tests performed this year", you must provide a reason.

ECLEP MANUAL

[Permit Materials](#) | [Proficiency Testing](#) | [Gross Annual Receipts](#) | [LDT Approval](#) | [Survey](#) | [Limited Labs](#)

[Lab Profile](#) | [Ownership](#) | [Personnel](#) | [Permit Categories/Tests](#) | [PSCs and Others](#) | [Tools](#)

Reapplication Period: Apr 01, 2018 through Dec 15, 2018 at 05:00 PM, EST Reapplication Center

PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY

Test Volume for January 1, 2017 through December 31, 2017

No Tests

No tests performed this year

Reason for not performing any tests this year:

Specialty/SubSpecialty Total

Test Specialty/SubSpecialty	Total Tests/Specimens per Specialty/SubSpecialty
HISTOCOMPATIBILITY	0
Total Tests/Specimens	0
MICROBIOLOGY	
Bacteriology	86587
Mycobacteriology	392
Mycology	498
Parasitology	1080
Virology	3108
HPV Testing	1997
Total Tests/Specimens	93662
DIAGNOSTIC IMMUNOLOGY	

- o To obtain a pdf version of the previous year's test volume, access the previous year's Reapplication Submission from the Reapplication Center page and print or save as needed.

[Permit Materials](#) | [Proficiency Testing](#) | [Gross Annual Receipts](#) | [LDT Approval](#) | [Survey](#) | [Blood Resources](#) | [Tools](#)

[Lab Profile](#) | [Ownership](#) | [Personnel](#) | [Permit Categories/Tests](#) | [PSCs and Others](#)

Reapplication Center Reapplication Period: Apr 05, 2022 through Apr 28, 2022 at 05:00 PM, EDT

PFI: 0000 Name: Internal Test for CLEP 1 [Request for an Extension Date](#)

Reapplication Mode

It's time to reapply for your facility's permit.

Click the 'Enter' button below to complete the reapplication process and ensure you receive your new permit by July 1.

If you would like to view the data currently on file for your facility, or view submissions your facility has made, use the links below.

Current Data on File (without pending changes)

[View Summary](#)

Electronic Submissions

[Reapplication Submission dated Mar 28, 2019 7:57:08 AM EDT \(PDF\)](#)

[Reapplication Submission dated Jan 19, 2018 1:46:23 PM EST \(PDF\)](#)

[Reapplication Submission dated Jan 19, 2018 1:22:48 PM EST \(PDF\)](#)

[Reapplication Submission dated Jun 29, 2017 11:39:24 AM EDT \(PDF\)](#)

[Reapplication Submission dated Apr 12, 2017 7:20:42 AM EDT \(PDF\)](#)

[view all...](#)

ECLP MANUAL

POC Testing

This section is visible only to laboratories at hospitals, Article 28 facilities, correctional facilities, etc., located in New York.

The **Point-of-Care (POC) Testing** section allows you to manage locations and testing performed at the point of care, rather than the laboratory proper, at the facility.

- o Under **Manage Locations**, you may add or delete Point-of-Care Testing (POCT) locations.

Reapplication Period: Apr 05, 2022 through Apr 28, 2022 at 05:00 PM, EDT Reapplication Center

Responsibilities
[View](#)
[Update](#)

Category
[Pending Changes](#)
[Add New](#)
[Cytopathology](#)
[Remove](#)

Test Volume
[View Previous](#)
[Edit Current](#)

POC Testing
Manage Location
[Add](#)
[Delete/Update](#)
[Contact Person](#)

PFI: 0000 **Name:** Internal Test for CLEP 1

Manage Point-of-Care Testing Locations

Point-Of-Care Testing Questions

Please indicate whether this facility performs point-of-care testing by answering the question below.

Note that in order to answer "No", you must not have any existing point-of-care testing locations defined. If you have existing locations defined, you'll need to delete them before you will be able to save your answer.

1. Does this facility perform point-of-care testing?

Yes **No**

Existing Locations

* Deleting an existing location will delete all the associated data

Location Id	Location Type	Location Desc	Clia No
<input type="checkbox"/> ED01	Emergency Room	Adult ER	33d0123456
<input type="checkbox"/> LAD	Obstetrics	Labor and Delivery	33d1234567

Add New Location

Location ID : (User defined. Examples: OR1, ER1, AMC-OR1)

Location Type : ▼

Location Desc :

CLIA Number : (If separate number for this site)

- o The **Add** page allows you to add a test to a POCT location. Choose a POCT location from the dropdown list, choose the test being performed from the dropdown list, enter the instrument used and finally choose the staff performing the testing by selecting the check box next to the appropriate staff description. Click **Save**.

RELEASE 1.11

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The screenshot shows the ECLEP application interface. At the top, there are navigation tabs: Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, Blood Resources, and Tools. Below these are sub-tabs: Lab Profile, Ownership, Personnel, Permit Categories/Tests, and PSCs and Others. A green banner indicates the 'Reapplication Period: Apr 05, 2022 through Apr 28, 2022 at 05:00 PM, EDT' and a 'Reapplication Center' button. The main content area is titled 'Point-Of-Care-Testing' and includes fields for 'Testing Location', 'Types of tests provided', and 'Instruments/Test systems Used'. A 'Select Staff' section contains a list of roles with radio buttons for selection. In the left-hand navigation menu, the 'Add' option under 'POC Testing' is highlighted with a red box.

- The **Delete/Update** page allows you to update or delete a test from a POCT location.
 - Choose a test by clicking the appropriate radio button, then click **Update** or **Delete**, as appropriate.
 - Clicking **Delete** will automatically remove the test from the list.

This screenshot shows the 'Delete/Update' page in the ECLEP application. It features a table with columns for 'Test Loc', 'Test Type', 'Instrument', and 'Staff'. Each row represents a different test location and includes a radio button for selection. At the bottom of the table, there are buttons for 'Update', 'Delete', and 'Clear', with the 'Delete' button highlighted by a red box. The left-hand navigation menu shows the 'Delete/Update' option under 'POC Testing' highlighted with a red box.

Test Loc	Test Type	Instrument	Staff
<input type="radio"/> ASU	Glucose	Nova Stat Strip	Licensed Practical Nurse, PCA/PCT, Registered Nurse
<input type="radio"/> ASU	Pregnancy Test (Urine)	Cardinal Rapid HCG	Registered Nurse
<input type="radio"/> Angio	Activated Clotting Time	Hemachron Jr.	Registered Nurse
<input type="radio"/> ED	Glucose	Nova Stat Strip	PCA/PCT, Registered Nurse
<input type="radio"/> ED	Pregnancy Test (Urine)	Cardinal Rapid HCG	Registered Nurse
<input type="radio"/> EmployeeHealth	Pregnancy Test (Urine)	Cardinal Rapid HCG	Registered Nurse
<input type="radio"/> Endo	Glucose	Nova Stat Strip	PCA/PCT, Registered Nurse
<input type="radio"/> Endo	Pregnancy Test (Urine)	Cardinal Rapid HCG	Registered Nurse
<input type="radio"/> M-LABCRDEC	Other	Siemens DCA 2000	Other, Tech
<input type="radio"/> OR	Glucose	Nova Stat Strip	PCA/PCT, Registered Nurse
<input type="radio"/> PACU	Glucose	Nova Stat Strip	PCA/PCT, Registered Nurse
<input type="radio"/> Radiology	Glucose	Nova Stat Strip	PCA/PCT, Registered Nurse
<input type="radio"/> WoundCare	Breath Alcohol	Nova Stat Strip	PCA/PCT, Registered Nurse
<input type="radio"/> WoundCare	B-Type Natriuretic Peptide (BNP)	Nova Stat Strip	PCA/PCT, Registered Nurse
<input type="radio"/> WoundCare	Glucose	Nova Stat Strip	PCA/PCT, Registered Nurse

ECLP MANUAL

- Clicking Update will bring you back to the Add page, where you can revise the appropriate information, click **Save**.

Open Mode Continue

Responsibilities
[View](#)
[Update](#)

Category
[Pending Changes](#)
[Add New](#)
[Cytopathology](#)
[Remove](#)

Test Volume
[View Previous](#)

POC Testing
[Manage Locations](#)

- **Add** (highlighted)
- [Delete/Update](#)
- [Contact Person](#)

PFI: 0000 **Name:** Internal Test for CLEP 1

Point-Of-Care-Testing

Enter Test Details

Testing Location : Select a Location

Types of tests provided : Select

Instruments/Test systems Used :

Select Staff

- Other
- Licensed Practical Nurse
- Medical Doctor
- Physician Assistant
- Nurse Practitioner
- Nurse Midwife
- Registered Nurse
- Resp Therapy Tech
- Certified Nurse Midwife
- Certified Nurse Anesthetist
- Registered Cardiovascular Technologist
- Medical Assistants
- Counselor
- Pharmacist
- PCA/PCT
- Social Worker
- Perfusionist
- Nursing Assistant
- Phlebotomist
- Tech
- Aide

Save Clear

The **Point-Of-Care Contact Person** page allows you to indicate a POCT Coordinator for the laboratory. Enter the appropriate contact information and click **Save**.

Permit Materials | **Proficiency Testing** | **Gross Annual Receipts** | **LDT Approval** | **Survey** | **Blood Resources** | **Tools**

Lab Profile | **Ownership** | **Personnel** | **Permit Categories/Tests** | **PSCs and Others**

Open Mode Continue

Responsibilities
[View](#)
[Update](#)

Category
[Pending Changes](#)
[Add New](#)
[Cytopathology](#)
[Remove](#)

Test Volume
[View Previous](#)

POC Testing
[Manage Locations](#)

- **Contact Person** (highlighted)
- [Delete/Update](#)

PFI: 0000 **Name:** Internal Test for CLEP

Point-Of-Care Contact Person

If there is an individual responsible for coordinating the Point-of-Care testing programs within your facility, please indicate the name of that individual below

POC Contact Person Details

Salutation: Dr. v

Title:

First Name:

Middle Name:

Last Name:

Telephone (###-###-####):

Email:

Save Clear

ECLP MANUAL

PSCs and Others

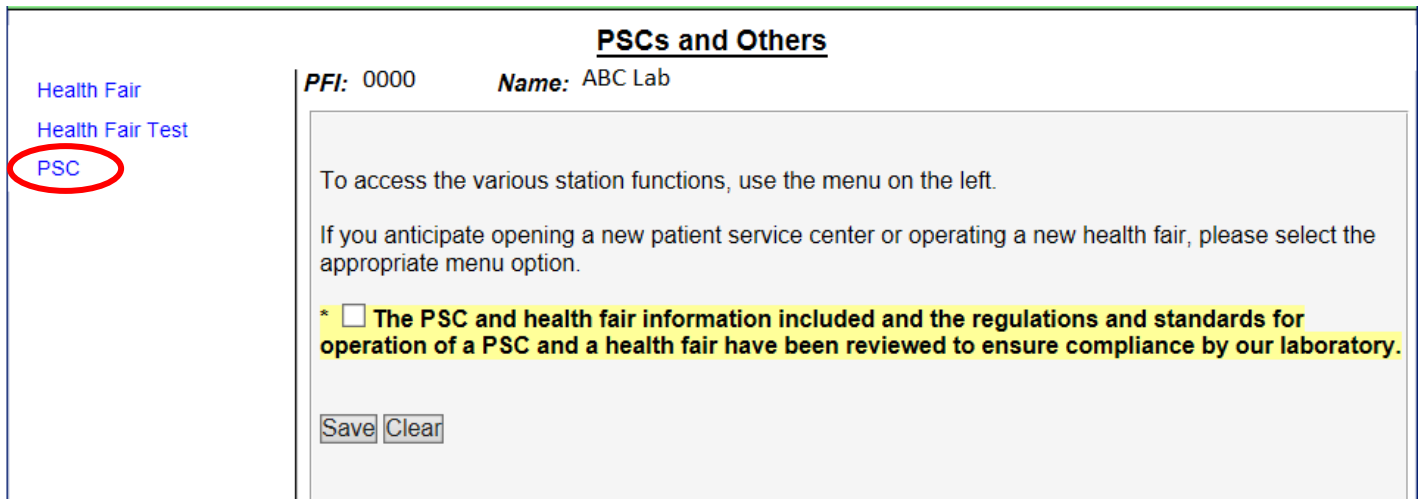
The PSCs and Others tab allows the laboratory to request approval to operate a patient service center (PSC) and/or health fair (HF). This area also allows you to update the PSC and HF information (location, phone number, etc.) and complete the annual reapplication process for both.



Note: This feature was introduced for the 2016 reapplication.

PSC Reapplication

During the reapplication period each Spring, laboratories currently operating an approved patient service center (PSC) should review the current data on file with the Department and update such information as appropriate. To review, click on the **PSC** link on the left of the screen.



ECLIP MANUAL

On the next screen, choose 'Stations on File' from the menu on the left to view all stations associated with the laboratory.

A list of all patient service centers is viewable and printable from a new screen under the PSC section. Click on the **Print PSC Listing** link to print or save the list.

PSCs and Others Home New / Select <input checked="" type="checkbox"/> Stations on File	PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY Patient Service Centers on File Print PSC Listing	
	Station ID: 0000-0001 Status: N/A - Open Station Info POBox 509 Empire State Plaza Albany, NY, 12201-0509 Contact Info	Hours Mon 05:30 AM to 03:30 PM Tue 05:30 AM to 03:30 PM Wed 05:30 AM to 03:30 PM Thu 05:30 AM to 03:30 PM Fri 05:30 AM to 03:30 PM Sat Off/Closed Sun Off/Closed Note
	Station ID: 0000-0002- Test PSC Status: Approved - Open Station Info Test PSC 30 South Broadway in the basement ALBANY, NY, 12208 Contact Info Frodo Khan p@w.com 518-445-8877	Hours Mon Open 24 hours Tue Off/Closed Wed Open 24 hours Thu Open 24 hours Fri Off/Closed Sat Off/Closed Sun Off/Closed Note

To make updates to an existing PSC, click on the 'New/Select' link from the PSC menu on the left. Then Choose the desired PSC from the dropdown box and click 'Next'.

PSCs and Others Home <input checked="" type="checkbox"/> New / Select Stations on File	PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY Station Status: Permit Status: Patient Service Center Application
	Items with an asterisk (*) are required. New PSC <input type="radio"/> *New: <hr/> Select PSC <input type="text" value="0002 - 30 South Broadway in the basement , ALBANY"/>
	<input checked="" type="button" value="Next"/> <input type="button" value="Clear"/>

ECLEP MANUAL

If an existing PSC location has been selected, the menu of links on the left of the screen will now look different and the PSC address screen will be shown. Users can update the Address, Contact and Hours screens. Click **Save** after making changes. Address changes require an effective date.

[PSCs and Others](#)
[Home](#)

[New / Select](#)
[Stations on File](#)

[Manage PSC](#)

- [Address](#)
- [Contact](#)
- [Hours](#)
- [Self Assessment](#)
- [Upload](#)
- [Comment](#)

PFI: 0000 Station: W3403 Name: Internal Test for CLEP 1
Station Status: N/A Permit Status: N/A

Patient Service Center Application

Items with an asterisk (*) are required.

Address

* **Street Address:**

Suite/Room/Building Number:

* **City:**

* **State:**

* **County:**

* **Zip Code:**

Also during the reapplication period each Spring, the laboratory will be requested to attest that the relevant NYS regulations and standards for the operation of a PSC and/or HF have been reviewed to ensure compliance by the laboratory. Click the check box next to the highlighted text to indicate this, then click **Save**.

[Health Fair](#)
[Health Fair Test](#)
[PSC](#)

PSCs and Others

PFI: 0000 Name: ABC Lab

To access the various station functions, use the menu on the left.

If you anticipate opening a new patient service center or operating a new health fair, please select the appropriate menu option.

* **The PSC and health fair information included and the regulations and standards for operation of a PSC and a health fair have been reviewed to ensure compliance by our laboratory.**

ECLEP MANUAL

Request a New PSC

To request approval to operate a patient service center (PSC), click on the PSC link on the left of the screen. On the next screen, click on the New radio button, then click **Next**.

The screenshot shows the 'Patient Service Center Application' form. On the left sidebar, there are links for 'PSCs and Others Home', 'New / Select', and 'Stations on File'. The main content area shows 'PFI: 0000' and 'Name: Internal Test for CLEP 1'. Below this, there are fields for 'Station Status:' and 'Permit Status:'. The title 'Patient Service Center Application' is centered. A note states 'Items with an asterisk (*) are required.' Below this, there are two radio buttons: 'New PSC' and '*New:'. The '*New:' radio button is highlighted with a red rectangular box. Below the radio buttons is a 'Select PSC' dropdown menu with the selected option 'W3403 - 45 Reade Placebo Street test , Poughkeepsie'. At the bottom of the form are 'Next' and 'Clear' buttons.

On the next screen, fill in the requested information and click **Save**. Please allow at least two weeks for processing; enter the expected opening date accordingly. Please be reminded that the PSC cannot operate without explicit approval from the Department.

The screenshot shows the 'Patient Service Center Application' form with various input fields. The title 'Patient Service Center Application' is centered. A note states 'To begin, please fill in the data requested below; items with an asterisk (*) are required.' The form is divided into several sections:

- Date:** A field for '* Expected opening date:' with a date picker icon.
- Contact Person Information:** Fields for '* First Name:', 'Middle Name:', '* Last Name:', 'Telephone:', 'Fax:', and '* Email:'.
- PSC Contact Information:** A field for 'Telephone:'.
- Address:** Fields for 'PSC Station Name:', '* Street Address:', 'Suite/Room/Building Number:', '* City:', '* State:' (pre-filled with 'New York'), '* County:' (dropdown menu with 'Select NY County'), and '* Zip Code:'.
- Hours of Operation:** A table with columns for days of the week (Monday through Sunday) and options for 'Set Start Time', 'Set End Time', '24 Hours', 'Closed', and 'Select Hours'.
- Hours Note:** A text input field.
- Comment:** A text input field with a note: 'If you would like to provide a comment, please do so below: (200 characters max)'.

 At the bottom of the form are 'Save' and 'Clear' buttons.

ECLP MANUAL

Once you click Save, the links on the left will change.

Initial view:

- [PSCs and Others](#)
- [Home](#)
- [New / Select](#)
- [Stations on File](#)

Current view:

- [PSCs and Others](#)
- [Home](#)
- [New / Select](#)
- [Stations on File](#)
- [Manage PSC](#)
- [Address](#)
- [Contact](#)
- [Hours](#)
- [Self Assessment](#)
- [Upload](#)
- [Comment](#)

To complete the application process, a self assessment must be completed and requested documents (i.e., floor plan and lease) must be uploaded. Click on **Self Assessment**. Answer the questions provided.

Station Status: N/A

Permit Status: N/A

Patient Service Center Application

*** Answers to all questions are required.**

Self Assessment	
*	Will or do PSC phlebotomists or other employees of the parent laboratory perform duties for any referring health services purveyor? <input type="radio"/> Yes <input type="radio"/> No *
1	Is the PSC located within the offices of, or otherwise share space with, the practice of a physician or other health services purveyor in a position to make referrals of specimens to the laboratory? ("Referral" implies that the health services purveyor is not under the same ownership as the PSC.) <input type="radio"/> Yes <input type="radio"/> No *
2	Is the PSC located in a building in which a physician or other health services purveyor in a position to make referrals to the laboratory has an ownership or investment interest? (?Referral? implies that the health services purveyor is not under the same ownership as the PSC.) <input type="radio"/> Yes <input type="radio"/> No *

Once all questions have been answered, click **Save**.

ECLEP MANUAL

Patient Service Center Application

*** Answers to all questions are required.**

28.F	Does the PSC dispose of potentially infectious articles that might cause punctures or cuts in leakproof, rigid, puncture-resistant containers that are secured in a manner to preclude content loss?	<input type="radio"/> Yes <input type="radio"/> No *
29	Does the PSC collect specimens requiring chain of custody protocols (i.e. pre-employment, incident/accident related, return-to-work or paternity testing)?	<input type="radio"/> Yes <input type="radio"/> No *
30.A	Has this PSC been inspected by the laboratory prior to opening?	<input type="radio"/> Yes <input type="radio"/> No *
30.B	Is the inspection record available on-site for review by the Department?	<input type="radio"/> Yes <input type="radio"/> No *

After all the questions have been answered and the responses have been saved, click **Upload** on the left of the screen to upload a copy of the PSC floor plan and lease. Click on **Choose File** to navigate to the electronic file on your computer, then click **Open** to upload. Once both documents have been uploaded, click **Save**.

[PSCs and Others](#)
[Home](#)

[New / Select](#)
[Stations on File](#)

[Manage PSC](#)
[Address](#)
[Contact](#)
[Hours](#)
[Self Assessment](#)

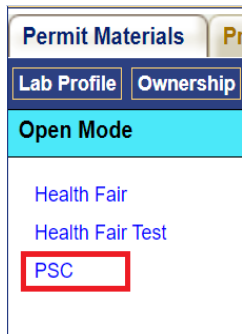
Upload
[Comment](#)

<p>PSCs and Others Home</p> <p>New / Select Stations on File</p> <p>Manage PSC Address Contact Hours Self Assessment</p> <p><input checked="" type="radio"/> Upload Comment</p>	<p><i>PFI: 0000 Station: W3403 Name: Internal Test for CLEP 1</i> <i>Station Status: N/A Permit Status: N/A</i></p> <p style="text-align: center;">Patient Service Center Application Upload</p> <p>Uploaded Files</p> <table border="1"> <thead> <tr> <th>File</th> <th>Name</th> <th>Uploaded By</th> <th>Time</th> </tr> </thead> <tbody> <tr> <td colspan="4">Each file uploaded represents the latest file of that type to be uploaded. The previous version of the file has been overwritten.</td> </tr> <tr> <td colspan="4">The file name can contain only numbers, letters and a period. Spaces and special characters are not allowed.</td> </tr> </tbody> </table> <p>Items with an asterisk (*) are required.</p> <p>Floor Plan</p> <p>Please upload a scale floor plan of the PSC that illustrates the relationship between the PSC and any other health services purveyor(s) on the same floor.</p> <p>* File Name: <input type="button" value="Choose File"/> No file chosen</p> <p>Lease/Ownership</p> <p>* File Name: <input type="button" value="Choose File"/> No file chosen</p> <p><input type="button" value="Save"/> <input type="button" value="Clear"/></p>	File	Name	Uploaded By	Time	Each file uploaded represents the latest file of that type to be uploaded. The previous version of the file has been overwritten.				The file name can contain only numbers, letters and a period. Spaces and special characters are not allowed.			
File	Name	Uploaded By	Time										
Each file uploaded represents the latest file of that type to be uploaded. The previous version of the file has been overwritten.													
The file name can contain only numbers, letters and a period. Spaces and special characters are not allowed.													

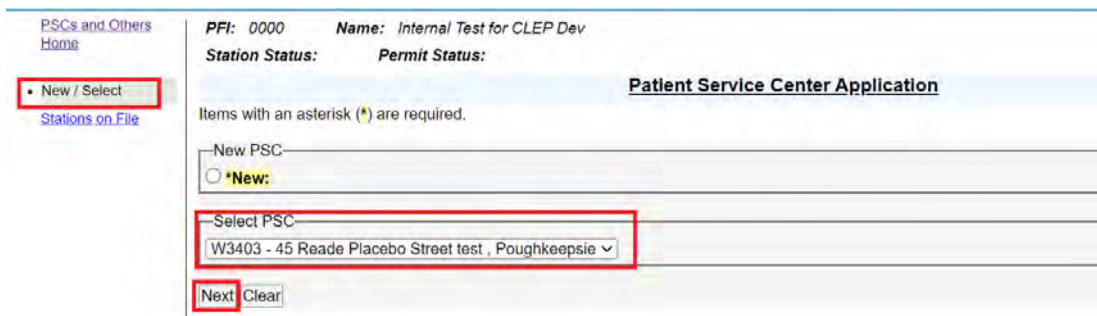
ECLEP MANUAL

Temporary or Permanent Closure of a PSC

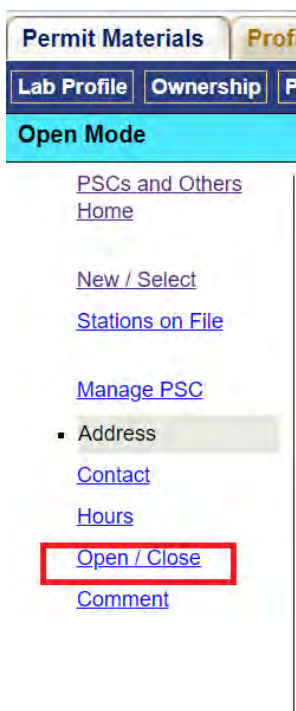
Navigate to the PSC webpage:



On the **New/Select** webpage, select the PSC station from the drop-down menu and click on **Next**:



Click on the Open/Close link on the left panel:



E/CLEP MANUAL

Select the appropriate radio button to either **Close (Temporarily)** or **Close (Permanently)** the station. Enter an effective date and then click on **Save**. Click on the **Continue** button (located to the top right corner of the teal bar) to continue with the submission process. Please note that you need attest and successfully complete the submission process.

The screenshot displays the 'PSCs and Others' section of the E/CLEP application. At the top, there is a navigation bar with tabs for 'Permit Materials', 'Proficiency Testing', 'Gross Annual Receipts', 'LDT Approval', 'Survey', 'Blood Resources', and 'Tools'. Below this is a sub-navigation bar with 'Lab Profile', 'Ownership', 'Personnel', 'Permit Categories/Tests', and 'PSCs and Others'. The 'Open Mode' bar is teal and contains a 'Continue' button. The main content area shows 'PSCs and Others' with a 'Home' link and a list of links: 'New / Select', 'Stations on File', 'Manage PSC', 'Address', 'Contact', 'Hours', 'Open / Close', and 'Comment'. The 'Open / Close' link is selected. The main content area displays 'PFI: 0000 Station: 0001 Name: Internal Test for CLEP Dev' and 'Station Status: Open Permit Status: Approved'. Below this is the 'Patient Service Center Application' section, which includes a note: 'Items with an asterisk (*) are required.' There are three radio buttons: '*Close (Temporarily)', '*Close (Permanently)', and '*Reopen:'. Below the radio buttons is an 'Effective date' field with a calendar icon. At the bottom left, there are 'Save' and 'Clear' buttons. The 'Save' button is highlighted with a red box.

Health Fair Reapplication

During the reapplication period each Spring, laboratories currently holding a health fair permit should review the current data on file with the Department and update such information as appropriate. To review, click on the **Health Fair** link on the left of the screen.

The screenshot shows the 'PSCs and Others' section. On the left, there is a menu with links for 'Health Fair', 'Health Fair Test', and 'PSC'. The 'PFI: 0000' field is circled in red. The main content area displays 'Name: ABC Lab' and instructions: 'To access the various station functions, use the menu on the left. If you anticipate opening a new patient service center or operating a new health fair, please select the appropriate menu option.' Below this is a checkbox with the text: '* The PSC and health fair information included and the regulations and standards for operation of a PSC and a health fair have been reviewed to ensure compliance by our laboratory.' At the bottom, there are 'Save' and 'Clear' buttons.

ECLP MANUAL

The Health Fair screen will appear. Review and update information as required. If changes are made, click **Save**.

Health Fair

Items with an asterisk (*) are required.

Contact Information

* Salutation: ▾

* First Name:

Middle Name:

* Last Name:

* Telephone (###-###-####):

* Email:

Additional Information

Date of First Event (mm/dd/yyyy):

If you would like to provide a comment, please do so below: (200 characters max)

Health Fair Contact Information

Telephone : Ext:

Using the links on the left of the screen, review the tests associated with the health fair. Click on a test name.

PSCs and Others Home Health Fair View/Update Remove Health Fair Tests <input checked="" type="radio"/> View Update Add New Remove	Pending Changes: <input type="checkbox"/> Remove: alpha-1 antitrypsin was: N/A <input type="checkbox"/> Add: HbsAg was: N/A <input type="checkbox"/> Add: Bilirubin Total was: N/A <input type="button" value="Cancel Selected Changes"/>		
	PFI: 0000 Name: Internal Test for CLEP TEST(WCQA)		
	Health Fair Tests		
	LDL Cholesterol		remove
	HbsAg	pending	
	Bilirubin Total	pending	

ECLEP MANUAL

Review and update the test information as needed. If changes are made, click **Save**.

[PSCs and Others Home](#) *PFI:* 0000 *Name:* Internal Test for CLEP TEST(WCQA)

Health Fair Test

Items with an asterisk (*) are required.

Health Fair Test Information

Test: LDL Cholesterol

* Test at Health Fair: Yes No

* Test at Lab: Yes No

* Test Referred to Another Lab: Yes No

If yes, please provide the PFI of the lab referred to, and any comments: (100 characters max)

Please provide any other comments about this test: (200 characters max)

Request a Health Fair Permit

To request approval to operate health fairs, click on the **Health Fair** link on the left of the screen.

PSCs and Others

PFI: 0000 *Name:* ABC Lab

[Health Fair](#)
[Health Fair Test](#)
[PSC](#)

To access the various station functions, use the menu on the left.

If you anticipate opening a new patient service center or operating a new health fair, please select the appropriate menu option.

* The PSC and health fair information included and the regulations and standards for operation of a PSC and a health fair have been reviewed to ensure compliance by our laboratory.

Save Clear

Click on **Add New** on the left of the screen.

Health Fair

▪ View/Update
[Add New](#)

Health Fair

No Health Fair defined.

ECLEP MANUAL

Enter the requested information, click **Next**.

Add Health Fair

To begin, please fill in the data requested below; items with an asterisk (*) are required.

Contact Information

* Salutation:

* First Name:


Middle Name:

* Last Name:

* Telephone (###-###-####):

* Email:

Additional Information

Date of First Event (mm/dd/yyyy): 


If you would like to provide a comment, please do so below: (200 characters max)

Enter the requested information about the tests to be associated with the health fair, click **Save**.

Add Health Fair

Please add a test to the Health Fair by filling in the data requested below; items with an asterisk (*) are required. Additional tests may be added later as needed.

Health Fair Test Information

* Start Date (mm/dd/yyyy): 

* Test:

Contact CLEP via email at clep@health.ny.state.us if the test you are looking for is not listed.

* Test at Health Fair: Yes No

* Test at Lab: Yes No

* Test Referred to Another Lab: Yes No

If yes, please provide the PFI of the lab referred to, and any comments: (100 characters max)

Add additional health fair tests by using the Add New link under Health Fair Tests on the left of the screen.

ECLEP MANUAL

Remove a Health Fair Permit

To remove approval to operate health fairs, click on the **Health Fair** link on the left of the screen.

PSCs and Others

Health Fair
Health Fair Test
PSC

PFI: 0000 **Name:** ABC Lab

To access the various station functions, use the menu on the left.

If you anticipate opening a new patient service center or operating a new health fair, please select the appropriate menu option.

* The PSC and health fair information included and the regulations and standards for operation of a PSC and a health fair have been reviewed to ensure compliance by our laboratory.

Save Clear

Click on **Remove** on the left side of the screen.

Pending Changes:

Add: Health Fair was:

PFI: 0000 **Name:** Internal Test for CLEP TEST 1

Health Fair

Items with an asterisk (*) are required.

Contact Information

* **Salutation:** Mr.
* **First Name:** Test
Middle Name:
* **Last Name:** Pumpkineater
* **Telephone (### ### ####):** 123-456-78901
* **Email:** t@TEsting

Additional Information

Date of First Event (mm/dd/yyyy):

If you would like to provide a comment, please do so below. (200 characters max)

Health Fair Contact Information

Telephone: (### ### ####) **Ext:**

Save Clear

ECLEP MANUAL

Remove a Health Fair Test

To remove a test from an approved Health Fair permit, click **Health Fair** of **Health Fair Test** from the left side of the screen.

Click **Remove** under Health Fair Tests on the left side of the screen.

Choose the test to remove from the dropdown menu and enter effective date of removal. Click **Next**.

eCLEP MANUAL**Tools****Request for an Extension Date**

An extension date may be requested for:

- Reapplication – only available during active reapplication period each spring
- Survey(s) with a pending Plan of Correction (POC) from the facility.
- GAR – If it is an active GAR period.
- Blood Services Activity Report (BSAR)

To use this tool, click on the **Extension Date Request** link on the left panel.

The screenshot displays the 'Extension Date Request' tool within the eCLEP system. The top navigation bar includes tabs for 'Permit Materials', 'Proficiency Testing', 'Gross Annual Receipts', 'LDT Approval', 'Survey', and 'Tools', with 'Tools' currently selected. The sidebar on the left contains a link for 'Extension Date Request'. The main content area shows the following details:

- PFI:** 0000
- Name:** Internal Test for CLEP
- Section Header:** Extension Date Request
- Instructions:** Items with a * are required. Please use this Extension Date Request tool to request extensions of due dates for submission of Plans of Correction, Permit Re-application or Gross Annual Receipts reporting. The laboratory will be notified via email of the approval or denial of the extension request. The emails will be sent to the emails on file in eCLEP for the laboratory, laboratory contact person and laboratory director and laboratory owner.
- *Extension Request for:** -- Select request type --
- Survey Id:** -- Select Survey --
- *New Date:** mm/dd/yyyy
- Reason:** Characters Remaining: 200
- Save** button

- Select the request type from the drop-down menu, **Extension Request for**. Please note that if the type **Plan of Correction** is selected, then the Survey ID must be selected in the next field. The **Survey ID** is the unique ID that is used to identify a Survey and it is available on all the Laboratory Evaluation Report (LER) sent to the Laboratory.

eCLEP MANUAL

Extension Date Request

Items with a * are required.

Please use this Extension Date Request tool to request extensions of due dates for submission of Plans of Correction, Permit Re-application or Gross Annual Receipts reporting. The laboratory will be notified via email of the approval or denial of the extension request. The emails will be sent to the emails on file in eCLEP for the laboratory, laboratory contact person and laboratory director and laboratory owner.

*Extension Request for: Plan of Correction

*Survey Id: -- Select Survey --

*New Date: -- Select Survey --

Reason:
Characters Remaining: 200

Save

- Enter a proposed date for the extension date in the **New Date** field:

Extension Date Request

Items with a * are required.

Please use this Extension Date Request tool to request extensions of due dates for submission of Plans of Correction, Permit Re-application or Gross Annual Receipts reporting. The laboratory will be notified via email of the approval or denial of the extension request. The emails will be sent to the emails on file in eCLEP for the laboratory, laboratory contact person and laboratory director and laboratory owner.

*Extension Request for: -- Select request type --

Survey Id: -- Select Survey --

*New Date: mm/dd/yyyy

Reason:
Characters Remaining: 200

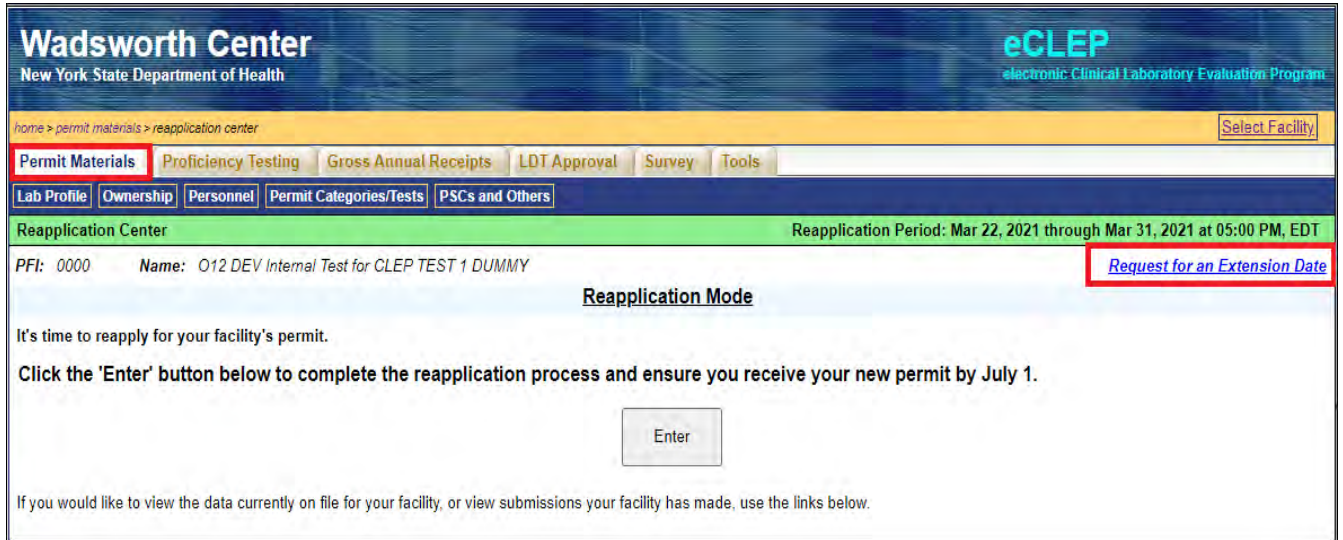
Save

- Use the **Reason** field to add any notes if deemed necessary.
- Clicking the **Save** button, completes the request process for an extension date. No extra step is required.

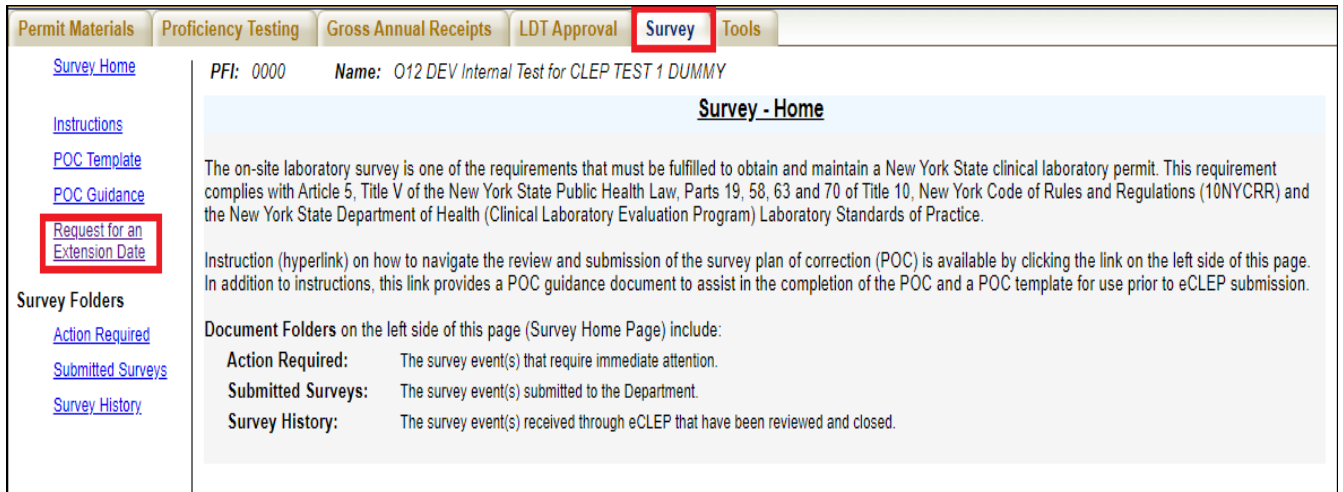
eCLEP MANUAL

Additional shortcuts across eCLEP to the Extension Date Request page

On the **Permit Materials** Home page, there is a link to the top right that points to the Extension Request Date page:



On the **Survey** Home page, there is a link that points to the **Extension Request Date** page on the left panel:



ECLP MANUAL

On the **Gross Annual Receipts Reporting** Home page, there is a link that points to the **Extension Request Date** page on the left panel:

Permit Materials Proficiency Testing **Gross Annual Receipts** LDT Approval Survey Tools

GAR Home PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY Reporting Due Date: 06/05/2021 12:00 AM

Gross Annual Receipts Reporting

To access the various GAR functions, use the menu on the left.

Laboratories that do not hold a Clinical Laboratory Evaluation Program permit are not required to provide Gross Annual Receipts information.

Each year, as part of the permit reapplication process, information is collected on the gross annual receipts (GAR) for all approved laboratories. For laboratories located in New York State, the reported GAR must include revenue for all specimens tested, regardless of the state of origin. For laboratories located outside New York State, the reported GAR should reflect annual revenue obtained from testing of specimens collected in New York.

Article 5, Title V of the Public Health Law requires that the New York State Department of Health recover the operating costs of the Clinical Laboratory Reference System by assessing an annual inspection and reference fee on all participating clinical laboratories and blood banks. The Inspection and Reference Fees are calculated based on the previous year's Program operating expenses. Invoices for these fees are sent in late June/early July. Partial payments may be made on or before June 30th, September 30th, December 31st and March 10th of the fiscal year to which billing relates.

The actual fee assessed for each laboratory is calculated by multiplying the total operating expenses of the Program by a fraction, the numerator of which is the gross annual receipts of the laboratory and the denominator of which is the total gross annual receipts of all laboratories issued permits.

The complete procedure for reporting gross annual receipts and the formula for calculating laboratory inspection and reference fees are outlined in Part 58-3 of the New York Codes, Rules and Regulations (NYCRR), a link to this regulation is available on our public website at www.wadsworth.org/regulatory/clep/laws.

On the **Blood Services Activity Report** Home Page, there is a link that points to the **Extension Request Date** page on the left panel:

Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey **Blood Resources** Tools

Blood Resources Home PFI: 1906 Name: Samaritan Hospital - Albany Memorial Campus Due Date:

Blood Services Activity Report

Please click on the pages listed on the left to complete the Blood Services Activity Report (BSAR). Data must be reported for the prior calendar year, (January - December).

Suggested sequence for completion:

1. Complete the Responsible Parties section to identify the blood bank director and blood bank supervisor.
2. Complete the Transfusion Complications page (Required for institutions hold Transfusion Service or Transfusion - Storage Only).
3. Complete the Blood Components pages.
4. Complete the Blood Suppliers pages.
5. Complete the Other pages (Donor Testing and IBR).
6. Complete the Submission using the link on the left.
7. After the initial submission, review past submission using the Past Submissions page. (Not available for inaugural year.)

eCLEP MANUAL

Miscellaneous

Error Messages

1. Error messages are bordered in red and will appear at the top of the screen after you click **Save** or **Next** or **Finish**, as appropriate. Most text fields without pre-populated information will require a response in order for the page to be saved. Error messages will also prompt you to provide information in the appropriate format, e.g. telephone numbers need to be entered in this format: 123-456-7890.

The screenshot displays the eCLEP application interface. At the top, there are navigation tabs: Lab Profile, Ownership, Personnel, Permit Categories/Tests, PSCs and Others, and Tools. Below these is a green bar indicating the 'Reapplication Period: Mar 05, 2012 through Mar 12, 2012 at 05:00 PM, EDT' and a 'Reapplication Center' button. The main content area shows 'PFI: 6705' and 'Name: eCLEP Test 5'. On the left, there is a sidebar with 'General Information' selected, and links for 'Regulatory Information' and 'Hours'. A red-bordered box at the top of the main content area contains the following error messages:

Errors:

1. 'Phone' is a required field
2. 'Fax' is a required field
3. 'Email' is a required field
4. 'Facility Type' is a required field

Below the error messages, the form is divided into sections: 'Name and Address Information', 'General Information', and 'Contact Information'. The 'Name and Address Information' section includes fields for Name (eCLEP Test 5), Address (Lincoln St), City (Buffalo), Country (United States), State/Province (New York), NY County (Unknown), and Zip Code (12798). The 'General Information' section includes a Facility Type dropdown menu (set to 'Select') and a Fac Status (Open). The 'Contact Information' section includes fields for Telephone, Fax, and Email. At the bottom of the form, there are 'Save' and 'Clear' buttons. A red oval highlights the 'Facility Type' dropdown menu in the General Information section.

eCLEP MANUAL

Pending Changes

2. Saved changes are displayed in the beige/mustard area at the top. It is possible to cancel previously entered changes by selecting one or more of them (click in white box next to name of change) and clicking **Cancel Selected Changes**.

- General Information
- [Regulatory Information](#)
- [Hours](#)
- [Alternate Address](#)
- [Contact Person](#)

Pending Changes:

<input type="checkbox"/> Name : Internal Test for CLEP TEST2 <input type="checkbox"/> Facility Type : Hospice <input type="checkbox"/> City : Albany Test <input type="checkbox"/> Zip Code : 12200 <input type="checkbox"/> Telephone : 345645756756 <input type="checkbox"/> Ext : 12345 <input type="checkbox"/> Fax : 2343467457 <input type="checkbox"/> Email : mabraham@wadsworth.com, email@test.com	Old Name : Internal Test for CLEP TEST(WCQA) Old Facility Type : Ancil Testing Site in Health Care Fac / Hosp Ext Clinic Old City : Albany Old Zip Code : 12203 Old Telephone : 1234567890 Old Ext : 1234 Old Fax : 0987654321 Old Email : mabraham@wadsworth.org
---	--

PFI: 0000 **Name:** Internal Test for CLEP TEST2

Name and Address Information

Name: Internal Test for CLEP TEST2

Address: PO Box 509, Empire State Plaza

City: Albany Test

Country: United States

State/Province: New York

NY County: Albany

Zip Code: 12200

All name/address changes effective: 12/23/2015

* Effective Date is required for any name/address change

General Information

Facility Type: Hospice **Fac Status:** Open

Lab Contact Information

Telephone (###-###-####): 345-645-756756 **Ext:** 12345

Fax (###-###-####): 234-346-7457

Email: mabraham@wadsworth.com, email@tes

Note: **Pending Changes** are saved so that the reapplication may be continued at a later date/time. To continue a reapplication at a later date/time repeat steps in Steps 1-6 to in *Accessing eCLEP and the Permit Materials Module* of this manual.

If changes are entered but not submitted within one week, the laboratory will begin receiving reminder emails every Monday until the change is either cancelled or submitted.

eCLEP MANUAL

Request to Re-Open eCLEP

To re-open the eCLEP system from Read-Only mode to either the Reapplication mode or Open mode, please email CLEP at clep@health.ny.gov. Please indicate the laboratory's four digit PFI and the words "Re-Open eCLEP Permit Materials" in the subject line.

HCS Timeout

For security reasons, there are session timeouts after one hour of inactivity and HCS timeouts after eight hours of total connectivity. These timeouts occur without warning. Timeouts take you back to the login page and force you to re-enter your User ID and Password. If a timeout occurs before you hit **Save** on the data entry page, you will lose all your data entry. It is recommended to hit **Save** often while working on long data entry forms.

Exiting eCLEP

There are two ways to exit eCLEP:

1. Close your browser by selecting **File** and **Close** from the browser's menu.
2. Click **Logout** at the top right.
 - a. The **You are now logged off** message page displays.

Technical Support

Technical Support is available for eCLEP and for the NYSDOH Health Commerce System (HCS) in the following areas:

Help with HCS Enrollment

For additional assistance contact the Commerce Account Management Unit (CAMU) Help Desk:

(866) 529-1890 (Mon-Fri 8am – 4:45pm)

camu@its.ny.gov

Help with eCLEP

For additional assistance contact the Clinical Laboratory Evaluation Program at CLEP@health.ny.gov.

eCLEP MANUAL**Glossary**

Certificate of Qualification (CQ) – a certificate issued by NYSDOH to an individual after the applicant has documented that s/he meets the minimum qualifications as a Laboratory Director set forth in Part 19 of 10NYCRR.

CLEP – Clinical Laboratory Evaluation Program

Delegated Submitter – a person who has been given written authorization by the Laboratory Director to electronically submit facility information on behalf of the Director. A Delegated Submitter will be authorized to enter and submit data electronically using the eCLEP system.

DOH – Department of Health

eCLEP – Electronic Clinical Laboratory Evaluation Program application located on the HCS

Enter Data – Filling out the forms for eCLEP

HCS – Health Commerce System – the Department of Health’s secure Internet network that provides data interchange between health care providers and the NYSDOH.

HCS Coordinator – An individual at the laboratory, designated by the laboratory director, who has the responsibility of requesting additional HCS accounts for data entry individuals. The HCS Coordinator also affiliates HCS User IDs with the laboratory for new users and removes the affiliations for users who have left the laboratory.

Laboratory Director – an individual who is responsible for the administration of the technical and scientific operation of a clinical laboratory or blood bank, including the supervision of procedures, reporting of results and responsibilities specified in Subpart 19.3 of 10 NYCRR and Article 5 Title V Section 571 of the Public Health Law. Such person shall possess a Certificate of Qualification issued pursuant to Part 19 of 10 NYCRR. A Director will be authorized to enter, submit and attest to information entered using the eCLEP system.

NYCRR – New York Codes, Rules and Regulations

NYSDOH – New York State Department of Health

PDF – Portable Document Format file – a file format which creates documents with a consistent look. The PDF file format was created by Adobe Systems. Adobe Reader software may be downloaded free-of-charge from: <http://www.adobe.com>.

Persistent Data – Data which is saved in the database and displayed in eCLEP, such as

PFI – Permanent Facility Identifier that identifies a laboratory

Submit Data – Confirming that the data entered is accurate and submitted.

User ID – An identification for logging on to the HCS