



Department
of Health

Wadsworth
Center

Clinical Laboratory Evaluation Program



eCLEP Manual

Revised January 2019

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 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.

ECLEP MANUAL**Roles and Responsibilities**

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

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

Laboratory Director

- View Laboratory information
- Update data
- Review the “eCLEP Summary”
- Attest to the accuracy of the entered data and submit it electronically.

Assistant Director / Delegated Submitter

- View Laboratory information
- Update data
- Review the “eCLEP Summary”
- Attest to the accuracy of the entered data and submit it electronically.

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 eCLEP 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 eCLEP 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 eCLEP 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, 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**:

NEW YORK STATE Health Commerce System

- As of Wednesday, January 2, 2019, Microsoft Internet Explorer version 10 will be blocked from accessing the Health Commerce System.
- Difficulties signing in? Use the self-service **Forgot your Password?** or **Forgot your User ID?** links below.

User ID

Password

Remember HCS ID ☐ OFF

Sign In

OR

Create an HCS Account

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

Welcome Sharon Banks

Search

My Applications

- Acronyms & Abbreviations
- eCLEP**
- Emergency Contacts
- ServiceNY

Refresh My Applications List

System Notices

- The Electronic Death Registration System (EDRS) will be down on **Thur, Jan 19th, 9am-5pm**, for system upgrades. EDRS users should use certificate to process deaths during this downtime only. For more information [Click Here](#).
- Since the **old SFT upload option** was turned off Jan 9th, 2017, you must register for your name to be listed in the new SFT 2.0 address book. All Applications > S > Secure File Transfer 2.0 for more information. This does not affect the group uploads at this time.

Important Health Events

ZIKA VIRUS RESPONSE

NYS PMP

Important Health Notifications

Posted	Priority	Keyword	Source	Audience	Description
12/28/2016	Advisory	Influenza	NYS DOH		Influenza Prevalent in NYS
12/23/2016	Advisory	Commissioner's Letter	NYS DOH		Dr. Zuckers December 2016 Monthly Letter: Looking Back and Looking Ahead

Showing notifications sent in the past 30 days.

Newsroom Highlights...

New Items

Date	Title
01/12/2017	DH-DTC DAL 16-21 EO Overcrowding
01/12/2017	01-07-17 Weekly Influenza Report
01/09/2017	DAL DAL 17-03 ACP Legal Services Agency...

Newsletters

Date	Title
01/04/2017	In the Field Newsletter - Winter 2017
01/03/2017	January 2017 Avian Influenza Update
01/03/2017	Jan 2017 eDistance Learning Communique

Events/Calendar

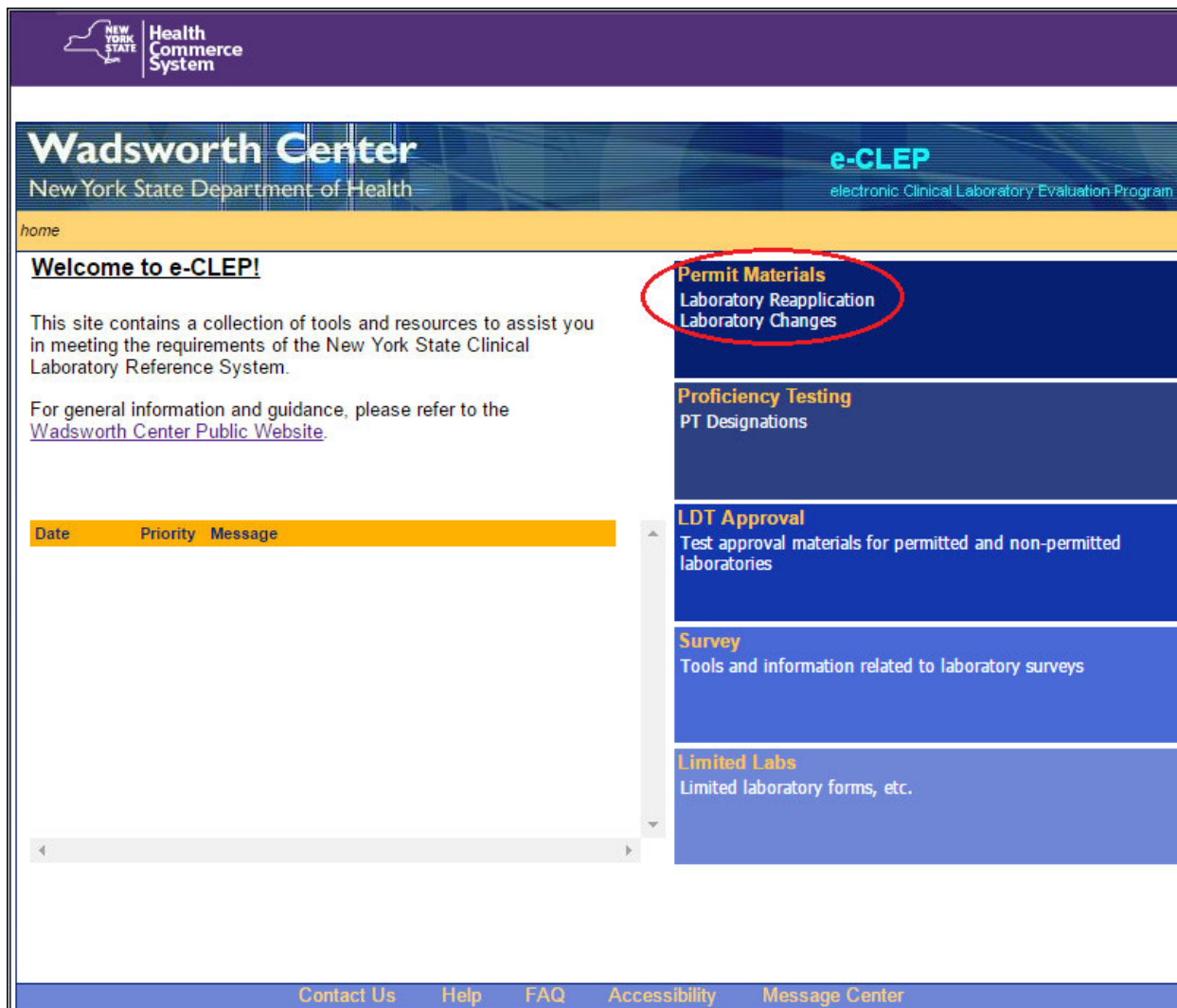
Date	Title
01/11/2017	Introduction to the Health Commerce Syst...
01/10/2017	County Health Rankings & Roadmap 101
01/06/2017	Memory Loss and the Public Health Burden

Press Releases

Date	Title
01/12/2017	NY State of Health Enrollment Continues...
01/10/2017	NY State of Health and NYS Department of...
01/06/2017	NY State of Health Releases Mid-Open Enr...

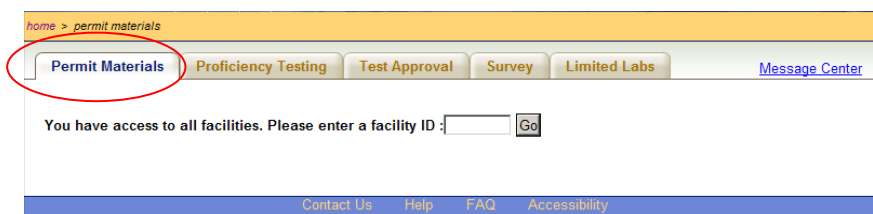
eCLEP MANUAL

- 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



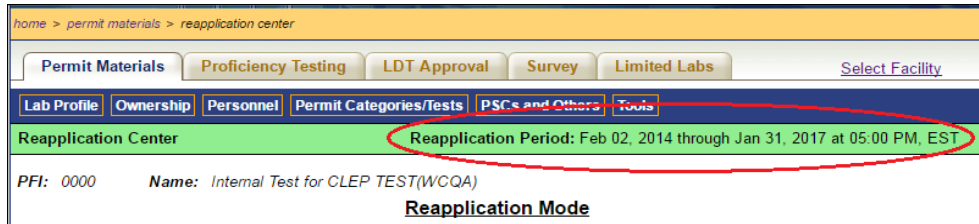
- HCS account holders affiliated with more than one laboratory will be required to enter an appropriate 4 digit numeric Permanent Facility Identifier (**PFI**).

(An alphanumeric PFI denotes a Limited Service Laboratory (LSL). LSLs are not serviced by the eCLEP application.)

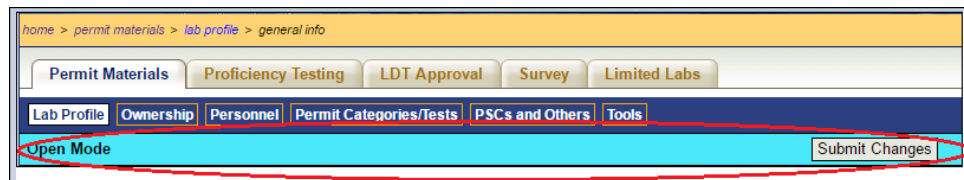


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6. Most users, however, will be brought directly to the **Reapplication Mode** or **Open Mode** page. The reapplication period occurs in April, actual dates will vary year to year. Open Mode is available the rest of the year, provided there are no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

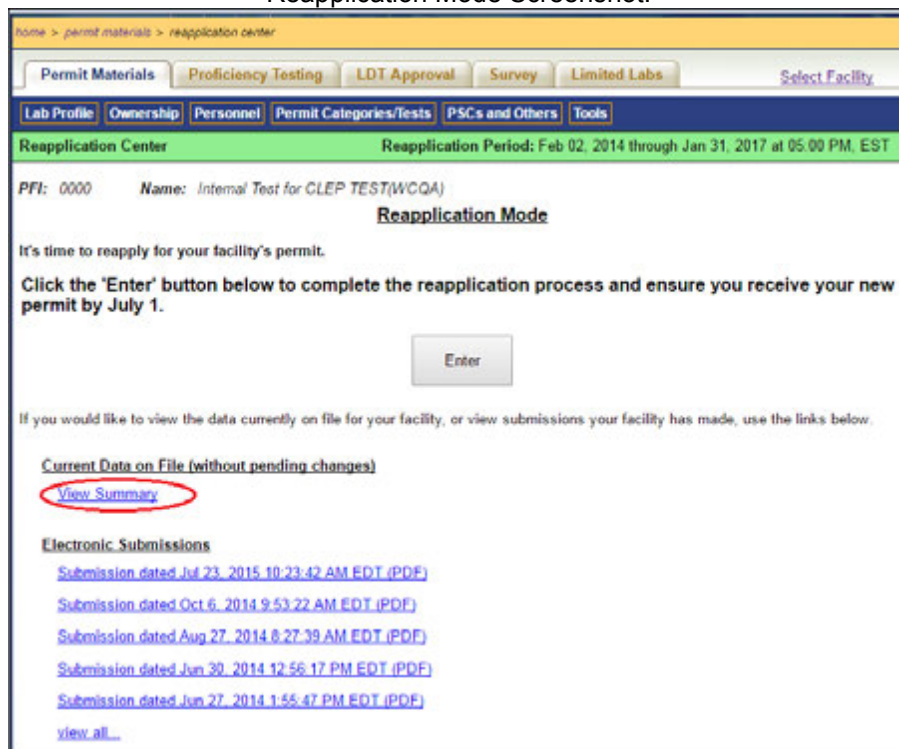


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7. On the **Reapplication Mode** or **Open Mode** page, you may want to review the Current Data on File (without pending changes) using the “**View Summary**” link and print it out to use as a worksheet.

Reapplication Mode Screenshot:



ECLEP MANUAL

ECLEP MANUAL

Open Mode Screenshot:

Wadsworth Center
New York State Department of Health

e-CLEP
electronic Clinical Laboratory Evaluation Program

home > permit materials > reapplication center

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

Open Mode

You may make changes as needed by visiting the appropriate area indicated in the blue menu bar above. Please refer to the eCLEP Training Manual, available in the Tools area for assistance.

Once you are finished making changes, click the "Enter" button below to complete the process by formally submitting your changes to CLEP.

Enter

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

[Submission dated May 10, 2016 4:21:03 PM EDT \(PDF\)](#)
[Reapplication Submission dated Apr 15, 2016 10:02:13 AM EDT \(PDF\)](#)
[Reapplication Submission dated Apr 1, 2016 12:13:11 PM EDT \(PDF\)](#)
[Submission dated Mar 17, 2016 3:12:27 PM EDT \(PDF\)](#)
[Submission dated Feb 23, 2016 10:39:43 AM EST \(PDF\)](#)
[view all...](#)

Contact Us Help FAQ Accessibility Message Center

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).

home > permit materials > reapplication center

Permit Materials Proficiency Testing LDT Approval Survey Limited Labs [Select Facility](#)

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

Reapplication Center Reapplication Period: Feb 02, 2014 through Jan 31, 2017 at 05:00 PM, EST

PFI: 0000 Name: Internal Test for CLEP TEST(WCQA)

Reapplication Mode

Wadsworth Center
New York State Department of Health

e-CLEP
electronic Clinical Laboratory Evaluation Program

home > permit materials > reapplication center

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

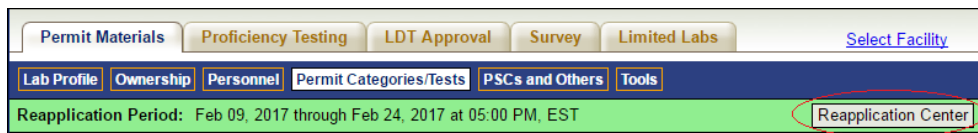
Open Mode

You may make changes as needed by visiting the appropriate area indicated in the blue menu bar above. Please refer to the eCLEP Training Manual, available in the Tools area for assistance.

ECLEP MANUAL**Reapplication Mode Submissions**

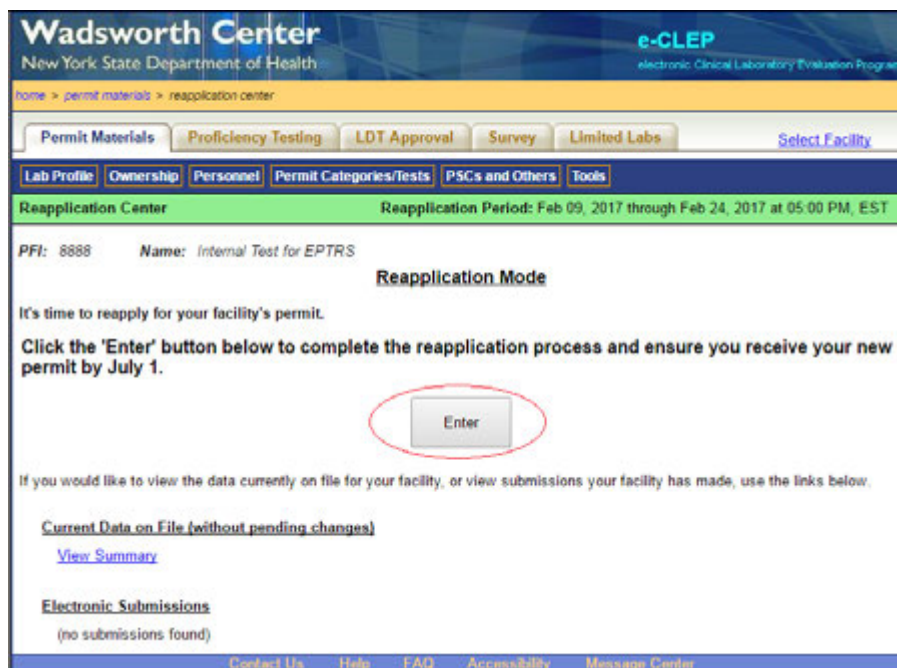
NOTE: All eCLEP submissions are reviewed by the Clinical Laboratory Evaluation Program prior to acceptance. The Program reserves the right to request additional information, request re-submission to obtain missing information, or to reject the request in total if the eCLEP submission is not acceptable.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



1. 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 **Enter** to begin the reapplication submission process.



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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.

Permit Materials Proficiency Testing LDT Approval Survey Limited Labs [Select Facility](#)

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 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, 2017

Submitted On not submitted	Submitter's HCS ID not submitted	Generated On Feb 13, 2017 1:05:56 PM EST
-------------------------------	-------------------------------------	---

SECTION I – GENERAL LABORATORY INFORMATION

Field Name	Current Data	Changes
Laboratory PFI:	8888	
Contact Person (other than director):		
Phone:		
E-mail:		

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.

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home > permit materials > reapplication center > reapplication wizard

Permit Materials Proficiency Testing LDT Approval Survey Limited Labs [Select Facility](#)

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
General Information	Email address must be provided	Visit the Lab Profile General Information area, provide an email address in the Contact Information section and click the Save button.
Owner	Question 1 must be answered.	Visit the Ownership Owner area, answer question 1 and click the Save button.
Ownership / Declaration Upload	Changes in laboratory owner also require the submission of a Disclosure of Ownership and Controlling Interest Statement.	Visit the Ownership / Declaration Upload area, and upload the required Owner Changes document(s). Then click the Save button.
Declaration	Questions 1, 2, 3 and 4 must be answered.	Visit the Ownership Declaration area, and answer questions 1, 2, 3 and 4. 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.

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.

Permit Materials Proficiency Testing LDT Approval Survey Limited Labs [Select Facility](#)

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

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

[Reapplication Center](#)

ECLEP MANUAL

Click **Enter**, 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 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

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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 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
<u>Step 4: Print For Your Records</u>			
You may print the application submission for your records using the link below.			
<u>Most Recent Submission for 2017</u>			
Submission dated Feb 13, 2017 1:32:18 PM EST (PDF)			
<div>Finished</div>			
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 **Submit Changes** button to begin the Open Mode submission process.

The screenshot shows the Wadsworth Center e-CLEP interface. At the top, it says "Wadsworth Center New York State Department of Health" and "e-CLEP electronic Clinical Laboratory Evaluation Program". Below this is a breadcrumb trail: "home > permit materials > lab profile > general info". A blue menu bar contains several tabs: "Permit Materials", "Proficiency Testing", "LDT Approval", "Survey", "Limited Labs", and "Select Facility". Below the menu bar, there are several buttons: "Lab Profile", "Ownership", "Personnel", "Permit Categories/Tests", "PSCs and Others", and "Tools". At the bottom, there is a red bar with the text "Open Mode" and a button labeled "Submit Changes" which is circled in red.

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

The screenshot shows the "Open Mode" submission process page. At the top, it displays "PFI: 2222" and "Name: Lab Alliance of Snowy CNY Upstate University Hosp at Community General". Below this, the text "Open Mode" is centered. A paragraph states: "You may make changes as needed by visiting the appropriate area indicated in the blue menu bar above. Please refer to the eCLEP Training Manual, available in the Tools area for assistance." Another paragraph states: "Once you are finished making changes, click the 'Enter' button below to complete the process by formally submitting your changes to CLEP." Below this text is a button labeled "Enter" which is circled in red. At the bottom, there is a section titled "Current Data on File (without pending changes)" with a link "View Summary". Below that is a section titled "Electronic Submissions" with several links: "Submission dated Mar 25, 2016 2:18:56 PM EDT (PDF)", "Reapplication Submission dated Jun 3, 2015 7:45:35 AM EDT (PDF)", "Submission dated Jun 26, 2014 10:44:18 AM EDT (PDF)", "Submission dated Jun 20, 2014 11:37:40 AM EDT (PDF)", "Reapplication Submission dated Apr 11, 2014 12:54:27 PM EDT (PDF)", and a link "view all_".

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 on PDF Format" link.

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

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 Jan 18, 2017 2:34:25 PM EST
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SECTION I -- GENERAL LABORATORY INFORMATION

Field Name	Current Data	Changes
Laboratory PFI:	0000	
Address:	PO Box 509	
City, State, Zip:	Albany NJ 12203	AlbanyA NJ 12203
County (NY state labs only):	Albany	
Country:	United States	
Effective Date:		11/18/2016

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](#)

Required Data

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 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.

PFI: 2222 Name: Lab Alliance of Snowy CNY Upstate University Hosp at Community General

[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.

Most Recent Submission for 2017

[Submission dated Feb 13, 2017 1:40:07 PM EST \(PDF\)](#)

[Finished](#)

ECLEP MANUAL**Navigating in the Permit Materials Module****Lab Profile****General Information section**

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**.

The screenshot shows the 'General Information' section of the ECLEP system. The 'Lab Profile' tab is selected, and the 'General Information' sub-tab is highlighted with a red box. The page displays the following information and form fields:

- Reapplication Period:** Mar 20, 2017 through Mar 29, 2017 at 05:00 PM, EDT
- Reapplication Center:** [Link]
- Pending Changes:**
 - ☐ Fax : 5189632566
 - Old Fax : none
 - [Cancel Selected Changes](#)
- PFI:** 1219 **Name:** APOLLO CLINIC
- Name and Address Information:**
 - Name:** APOLLO CLINIC
 - Address:** 777 HIGH STREET
 - City:** ALBANY
 - Country:** United States
 - State/Province:** New York [Refresh List](#)
 - NY County:** New York [Refresh List](#)
 - Zip Code:** 12896
 - All name/address changes effective:** [Calendar icon]
 - * Effective Date is required for any name/address change
- General Information:**
 - Facility Type:** Hospital [Refresh List](#)
 - Fac Status:** Open
- Lab Contact Information:**
 - Telephone (###-###-####):** 518-963-4789 **Ext:** [Field]
 - Fax (###-###-####):** 518-963-2566
 - Email:** xyz@apolloclinic.com
- [Save](#) [Clear](#)

ECLEP MANUAL**Regulatory Information section**

The **Regulatory Information** webpage allows you to revise the CLIA registration and Medicaid number for the laboratory. Enter the required information and click **Save**.

Lab Profile	Ownership	Personnel	Permit Categories/Tests	PSCs and Others	Tools	
Reapplication Period: Mar 20, 2017 through Mar 29, 2017 at 05:00 PM, EDT						Reapplication Center
General Information						PFI: 1219 Name: APOLLO CLINIC
<div>Regulatory Information</div> <div>CLIA Registration No: <input type="text" value="5411666262"/></div> <div>Medicaid No: <input type="text" value="12454542"/></div> <div><input type="button" value="Save"/> <input type="button" value="Clear"/></div>						

Hours section

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.

Permit Materials	Proficiency Testing	LDT Approval	Survey	Limited Labs	Select Facility	
Lab Profile	Ownership	Personnel	Permit Categories/Tests	PSCs and Others	Tools	
Reapplication Period: Mar 20, 2017 through Mar 29, 2017 at 05:00 PM, EDT						Reapplication Center
General Information						Pending Changes:
Regulatory Information						<input type="checkbox"/> Thursday: 09:00 AM - 06:00 PM was: 08:00 AM - 05:00 PM <input type="button" value="Cancel Selected Changes"/>
<div>Hours</div> <div>Lab Hours</div> <div>Monday: <input type="text" value="08:00"/> <input type="text" value="AM"/> to <input type="text" value="05:00"/> <input type="text" value="PM"/> <input type="radio"/> 24 Hrs <input type="radio"/> Closed <input checked="" type="radio"/> Select Hours</div> <div>Tuesday: <input type="text" value="08:00"/> <input type="text" value="AM"/> to <input type="text" value="05:00"/> <input type="text" value="PM"/> <input type="radio"/> 24 Hrs <input type="radio"/> Closed <input checked="" type="radio"/> Select Hours</div> <div>Wednesday: <input type="text" value="08:00"/> <input type="text" value="AM"/> to <input type="text" value="05:00"/> <input type="text" value="PM"/> <input type="radio"/> 24 Hrs <input type="radio"/> Closed <input checked="" type="radio"/> Select Hours</div> <div>Thursday: <input type="text" value="09:00"/> <input type="text" value="AM"/> to <input type="text" value="06:00"/> <input type="text" value="PM"/> <input type="radio"/> 24 Hrs <input type="radio"/> Closed <input checked="" type="radio"/> Select Hours</div> <div>Friday: <input type="text" value="08:00"/> <input type="text" value="AM"/> to <input type="text" value="05:00"/> <input type="text" value="PM"/> <input type="radio"/> 24 Hrs <input type="radio"/> Closed <input checked="" type="radio"/> Select Hours</div> <div>Saturday: <input type="text" value="12:00"/> <input type="text" value="AM"/> to <input type="text" value="12:00"/> <input type="text" value="AM"/> <input type="radio"/> 24 Hrs <input checked="" type="radio"/> Closed <input type="radio"/> Select Hours</div> <div>Sunday: <input type="text" value="12:00"/> <input type="text" value="AM"/> to <input type="text" value="12:00"/> <input type="text" value="AM"/> <input type="radio"/> 24 Hrs <input checked="" type="radio"/> Closed <input type="radio"/> Select Hours</div> <div>Hours Note: <input type="text"/></div> <div><input type="button" value="Save"/> <input type="button" value="Clear"/></div>						

ECLEP MANUAL

Contact Person section

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	LDT Approval	Survey	Limited Labs	Select Facility
Lab Profile	Ownership	Personnel	Permit Categories/Tests	PSCs and Others	Tools
Reapplication Period: Mar 20, 2017 through Mar 29, 2017 at 05:00 PM, EDT					Reapplication Center

[General Information](#)
[Regulatory Information](#)
[Hours](#)
▪ [Contact Person](#)

PFI: 0000 **Name:** Internal Test for CLEP TEST 1
Contact Person
Salutation:
First Name:
Middle Name:
Last Name:
Telephone (###-###-####): Ext:
Email:

ECLEP 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.

- **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.

ECLEP MANUAL

- **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.

ECLEP MANUAL

Owner section

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.

The screenshot shows the ECLEP web application interface. At the top, there are tabs for 'Permit Materials', 'Proficiency Testing', 'LDT Approval', 'Survey', and 'Limited Labs'. Below these are sub-tabs for 'Lab Profile', 'Ownership', 'Personnel', 'Permit Categories/Tests', 'PSCs and Others', and 'Tools'. The 'Ownership' sub-tab is active, and the 'Owner' option within it is circled in red. The 'Open Mode' button is visible in the top right of the sub-tab area. The main content area is divided into several sections:

- Pending Changes:** Includes a checkbox for 'Owner Other Lab : Y' and a button for 'Cancel Selected Changes'.
- PF#: 0000 Name: Internal Test for CLEP TEST 1**
- Question 1:** 'Do any of the owners of the facility have direct or indirect ownership or controlling interest in any other clinical laboratory(ies) licensed by NYS?'. The 'Yes' radio button is selected.
- Instruction:** 'If yes, identify the laboratories in which the owner(s) has a controlling interest on a separate sheet, which includes the PFI of this facility, and upload the document on the upload page (left menu item).'.
- Owner Information:** A form with fields for 'Owner Type' (dropdown, set to 'Gov't State'), 'EIN' (text box, '123456567'), 'Name' (text box, 'bhr test test'), '*EIN/Name Change effective' (calendar icon), '* Effective Date is required for EIN/Name Change', 'Address' (text box, 'st addr'), 'City' (text box, 'a city'), 'Country' (dropdown, 'United States'), 'State/Province' (dropdown, 'New York'), and 'Zip' (text box, '12201').
- Owner Contact Information:** A form with fields for 'Title' (text box, 'dr. aaaa'), 'Salutation' (dropdown, 'Dr.'), 'First Name' (text box, 'fname'), 'Middle Name' (text box), 'Last Name' (text box, 'lname'), 'Telephone (###-###-####)' (text box, '518-479-2222'), 'Ext' (text box), 'Fax (###-###-####)' (text box), and 'Email' (text box, 'dar03@health.state.ny.us').

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

ECLEP 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.

ECLEP MANUAL**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 LDT Approval Survey Limited Labs Select Facility	
Lab Profile Ownership Personnel Permit Categories/Tests PSCs and Others Tools	
Reapplication Period: Mar 20, 2017 through Mar 29, 2017 at 05:00 PM, EDT Reapplication Center	
Owner • Declaration Upload	Pending Changes: <input type="checkbox"/> Owner Violation : Y Old Owner Violation : N <input type="checkbox"/> Owner Crime : Y Old Owner Crime : N <input type="checkbox"/> Owner Licensed Health Professional : Y Old Owner Licensed Health Professional : N Cancel Selected Changes
PFI: 0000 Name: Internal Test for CLEP TEST 1	
<p>1. Has the director, any assistant director(s), or those having a direct or indirect ownership or controlling interest in the applying clinical facility ever been charged with violations of local, state or federal laws, rules and regulations, including, but not limited to, the Public Health Law or related statutes, concerning the provision of health care services or reimbursement for such services? To the extent that such charges are currently pending, respond "yes".</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>On a separate sheet, identify the individuals (directors or owners) who have sustained charges and the details of such charges. The PFI number 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.</p> <p>2. Has the director, any assistant director(s), or those having a direct or indirect ownership or controlling interest in the applying clinical facility ever been charged with any crime, including, but not limited to any offense related to furnishing of or billing for clinical laboratory services and 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".</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>On a separate sheet, identify the individuals (directors or owners) who have convictions and the details of such convictions. The PFI number 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.</p> <p>3. Are any individuals, with direct or indirect ownership or controlling interest in the laboratory or blood bank, licensed health professionals, authorized by law to order clinical laboratory tests and receive results?</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>On a separate sheet, identify the individuals with greater than ten (10) percent controlling interest who are authorized to by law to order clinical laboratory tests. The PFI number 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.</p>	

ECLEP MANUAL

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

Salutation:

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 22 for definitions of direct and indirect owners and page 25 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	<p>PFI: 1219 Name: APOLLO CLINIC</p> <p align="center"><u>Ownership / Declaration Upload</u></p> <p>Please upload the requested documents in the fields below. <u>The PFI number and name of the laboratory (ies) must be indicated on each document.</u> If more than one upload field is displayed, be certain to upload the correct document in the relevant field. For example, upload the list of direct/indirect owners in the upload field labeled "List of Owners".</p> <p>* Note that only one document may be uploaded in a given upload field. Each time you upload a document into the field, it overwrites ANY previous document that was uploaded in that field. Only the most recent document uploaded is submitted to CLEP when you Submit Changes.</p> <div><p>Items with an asterisk (*) are required.</p><div><p>List of Owners</p><p>* File Name: <input type="text"/> <input type="button" value="Browse..."/></p><p>Use this upload field to list direct owners and indirect owners who hold greater than ten (10) percent controlling interest in the laboratory.</p></div><div><p>List of Other Labs Owned</p><p>* File Name: <input type="text"/> <input type="button" value="Browse..."/></p><p>Use this upload field for the list of other NYS-permitted laboratories owned by the owner/indirect owner(s) of this laboratory, in response to Question 1 on the Owner page.</p></div><div><p>Director/Owner Violation or Charges</p><p>* File Name: <input type="text"/> <input type="button" value="Browse..."/></p><p>Use this upload field to provide additional information in response to Question 1 on the Declaration page.</p></div><div><p>Director/Owner Crime Conviction</p><p>* File Name: <input type="text"/> <input type="button" value="Browse..."/></p><p>Use this upload field to provide additional information in response to Question 2 on the Declaration page.</p></div><div><p>List of Authorized Individuals</p><p>* File Name: <input type="text"/> <input type="button" value="Browse..."/></p><p>Use this upload field to provide additional information in response to Question 3 on the Declaration page.</p></div></div> <p><input type="button" value="Save"/> <input type="button" value="Clear"/></p>
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ECLEP 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, please call **(518) 485-5378** or 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 as needed and click **Save**. Note: The Clinical Laboratory Evaluation Program may seek clarification of the Director's work schedule before accepting the proposed change.

On-site hours for a Laboratory Director may not overlap with hours at another facility. The laboratory will be required to submit new hours to eliminate such overlaps. The other laboratory(ies) where the director is employed may also need to revise the director's work schedule.

ECLEP MANUAL

To appoint a new Director, enter the CQ Code of the new director and the effective dates of the change, 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.

home > permit materials > personnel > appoint director

Permit Materials Proficiency Testing LDT Approval Survey Limited Labs

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

Open Mode Submit Changes

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

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

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

PFI: 0000 Name: Internal Test for CLEP TEST 1

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 (mm/dd/yyyy):

☐ 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 (mm/dd/yyyy):

Next Cancel

- 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 or (518) 485-5378 for alternate instruction.**

ECLEP MANUAL

On the following screen, enter the new director's on-site hours, click **Next**. **Note:** The Clinical Laboratory Evaluation Program may seek clarification of the Director's work schedule before accepting the proposed change.

On-site hours for a Laboratory Director may not overlap with hours at another facility. The laboratory will be required to submit new hours to eliminate such overlaps. The other laboratory(ies) where the director is employed may also need to revise the director's work schedule.

Monday: 12:00 AM to 12:00 AM ☒ Off ☐ Select Hours

Tuesday: 12:00 AM to 12:00 AM ☒ Off ☐ Select Hours

Wednesday: 12:00 AM to 12:00 AM ☒ Off ☐ Select Hours

Thursday: 12:00 AM to 12:00 AM ☒ Off ☐ Select Hours

Friday: 12:00 AM to 12:00 AM ☒ Off ☐ Select Hours

Saturday: 12:00 AM to 12:00 AM ☒ Off ☐ Select Hours

Sunday: 12:00 AM to 12:00 AM ☒ Off ☐ Select Hours

Time on-site must be represented in quantifiable hours (e.g. 5 hours per week). "As needed" or "on-call" will not be accepted.

Hours Note:

Next Cancel

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:

Next Cancel

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**.

ECLEP MANUAL

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:

Finish Cancel

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

Director

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

Assistant Directors

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

Responsibilities

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

Pending Changes:

☐ Director: Lawrence S Sturman (STURL1) was: Todd Lee (LEEXT3)

[Cancel Selected Changes](#)

PFI: 0000 Name: Internal Test for CLEP

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: Lawrence S Sturman MD, PhD
CQ Code: STURL1 CQ Expiration Date: 03/18/2013

Director's Hours

Monday:	08:45	AM	to	12:00	PM	<input type="radio"/> Off <input checked="" type="radio"/> Select Hours
Tuesday:	12:00	AM	to	12:00	AM	<input checked="" type="radio"/> Off <input type="radio"/> Select Hours
Wednesday:	12:00	AM	to	12:00	AM	<input checked="" type="radio"/> Off <input type="radio"/> Select Hours
Thursday:	12:00	AM	to	12:00	AM	<input checked="" type="radio"/> Off <input type="radio"/> Select Hours
Friday:	08:45	AM	to	12:00	PM	<input type="radio"/> Off <input checked="" type="radio"/> Select Hours
Saturday:	12:00	AM	to	12:00	AM	<input checked="" type="radio"/> Off <input type="radio"/> Select Hours
Sunday:	12:00	AM	to	12:00	AM	<input checked="" type="radio"/> Off <input type="radio"/> Select Hours

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).

ECLEP MANUAL

To add an Assistant Director, please follow the steps as presented above for appointing a new Laboratory Director.

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

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

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

PFI: 0000 Name: Internal Test for CLEP TEST(WCQA)

Add Assistant Director

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

New Assistant Director

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

* Starting Date (mm/dd/yyyy):

- 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**.

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

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

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

PFI: 0000 Name: Internal Test for CLEP

Choose Assistant Director to Update

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

ABRAM1 Mark E Abrahamson

- 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. On-site hours for an Assistant Director may not overlap with hours at another facility. The laboratory will be required to submit new hours to eliminate such overlaps.

ECLEP MANUAL

PFI: 0000 Name: Internal Test for CLEP

Assistant Director

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

Assistant Director's Hours

Monday:	12:00	AM	to	07:00	AM	<input type="radio"/> Off <input checked="" type="radio"/> Select Hours
Tuesday:	12:00	AM	to	12:00	AM	<input checked="" type="radio"/> Off <input type="radio"/> Select Hours
Wednesday:	12:00	AM	to	12:00	AM	<input checked="" type="radio"/> Off <input type="radio"/> Select Hours
Thursday:	12:00	AM	to	12:00	AM	<input checked="" type="radio"/> Off <input type="radio"/> Select Hours
Friday:	12:00	AM	to	07:15	AM	<input checked="" type="radio"/> Off <input type="radio"/> Select Hours
Saturday:	12:00	AM	to	12:00	PM	<input checked="" type="radio"/> Off <input type="radio"/> Select Hours
Sunday:	12:00	AM	to	12:00	AM	<input checked="" type="radio"/> Off <input type="radio"/> Select Hours

Time on-site must be represented in quantifiable hours (e.g. 5 hours per week). "As needed" or "on-call" will not be accepted.

Hours Note:

- 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 dropdown list presented on the **Remove** page, click **Next**.

Director

[View/Update](#)

[Appoint New](#)

Assistant Directors

▪ [View](#)

[Update Hours](#)

[Add New](#)

[Remove](#)

Responsibilities

[View](#)

[Update](#)

PFI: 0000 Name: Internal Test for CLEP TEST(WCQA)

Assistant Directors

ABRAM1	Mark E Abrahamson	* hours updated *	remove
RYANM1	Michael P Ryan		remove

Director

[View/Update](#)

[Appoint New](#)

Assistant Directors

[View](#)

[Update Hours](#)

[Add New](#)

▪ [Remove](#)

Responsibilities

[View](#)

[Update](#)

PFI: 0000 Name: Internal Test for CLEP TEST(WCQA)


Choose Assistant Director to Remove

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

ABRAM1 Mark E Abrahamson ▼

- On the following page, enter the effective date of the Assistant Director's departure, click **Remove**.

ECLEP MANUAL

Director View/Update Appoint New	PFI: 0000 Name: Internal Test for CLEP TEST(WCQA)
Assistant Directors View Update Hours Add New ▪ Remove	<div style="border: 1px solid orange; padding: 5px;">Warnings:<ul style="list-style-type: none">• This director is the SOLE DIRECTOR for the following permit categories:<ul style="list-style-type: none">◦ Clinical Chemistry</div>
Responsibilities View Update	<div><u>Remove Assistant Director</u> To remove this director, please fill in the data requested below; items with an asterisk (*) are required. Name: Mark E Abrahamson CQ Code: ABRAM1 CQ Expiration Date: 05/26/2017 <div style="border: 1px solid blue; padding: 5px;">* Ending Date (mm/dd/yyyy): <input type="text"/> </div><div><input type="button" value="Remove"/> <input type="button" value="Cancel"/></div></div>

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 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.

ECLEP MANUAL**Responsibilities Section**

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


Permit Materials Proficiency Testing LDT Approval Survey Limited Labs Select Facility																						
Lab Profile Ownership Personnel Permit Categories/Tests PSCs and Others Tools																						
Reapplication Period: Mar 20, 2017 through Mar 29, 2017 at 05:00 PM, EDT Reapplication Center																						
Director View/Update Appoint New Assistant Directors View Update Hours Add New Remove Responsibilities ▪ View ▪ Update	Pending Changes: <table border="0"><tr><td><input type="checkbox"/> Add to Todd Lee:</td><td>Bacteriology -- Comprehensive</td><td>was: N/A</td></tr><tr><td><input type="checkbox"/> Add to Todd Lee:</td><td>Endocrinology</td><td>was: N/A</td></tr><tr><td><input type="checkbox"/> Add to Michael P Ryan:</td><td>Cellular Immunology -- Malignant Leukocyte Immunophenotyping</td><td>was: N/A</td></tr><tr><td><input type="checkbox"/> Add to Michael P Ryan:</td><td>Ther. Sub. Mon./Quant. Tox.</td><td>was: N/A</td></tr></table> Cancel Selected Changes PFI: 0000 Name: Internal Test for CLEP TEST 1 <u>Responsible Directors</u> <table border="0"><tr><td>LEEXT3</td><td>Todd Lee</td><td>Bacteriology -- Comprehensive Endocrinology</td></tr><tr><td>RYANM1</td><td>Michael P Ryan</td><td>Cellular Immunology -- Malignant Leukocyte Immunophenotyping Ther. Sub. Mon./Quant. Tox.</td></tr><tr><td>TAYLJ1</td><td>Jill Taylor</td><td>pending Bacteriology -- Restricted Cellular Immunology -- Leukocyte Function Cellular Immunology -- Non-Malignant Leukocyte Immunophenotyping Clinical Chemistry Cytogenetics -- Cancer Fetal Defect Markers Immunohematology Virology</td></tr></table>	<input type="checkbox"/> Add to Todd Lee:	Bacteriology -- Comprehensive	was: N/A	<input type="checkbox"/> Add to Todd Lee:	Endocrinology	was: N/A	<input type="checkbox"/> Add to Michael P Ryan:	Cellular Immunology -- Malignant Leukocyte Immunophenotyping	was: N/A	<input type="checkbox"/> Add to Michael P Ryan:	Ther. Sub. Mon./Quant. Tox.	was: N/A	LEEXT3	Todd Lee	Bacteriology -- Comprehensive Endocrinology	RYANM1	Michael P Ryan	Cellular Immunology -- Malignant Leukocyte Immunophenotyping Ther. Sub. Mon./Quant. Tox.	TAYLJ1	Jill Taylor	pending Bacteriology -- Restricted Cellular Immunology -- Leukocyte Function Cellular Immunology -- Non-Malignant Leukocyte Immunophenotyping Clinical Chemistry Cytogenetics -- Cancer Fetal Defect Markers Immunohematology Virology
<input type="checkbox"/> Add to Todd Lee:	Bacteriology -- Comprehensive	was: N/A																				
<input type="checkbox"/> Add to Todd Lee:	Endocrinology	was: N/A																				
<input type="checkbox"/> Add to Michael P Ryan:	Cellular Immunology -- Malignant Leukocyte Immunophenotyping	was: N/A																				
<input type="checkbox"/> Add to Michael P Ryan:	Ther. Sub. Mon./Quant. Tox.	was: N/A																				
LEEXT3	Todd Lee	Bacteriology -- Comprehensive Endocrinology																				
RYANM1	Michael P Ryan	Cellular Immunology -- Malignant Leukocyte Immunophenotyping Ther. Sub. Mon./Quant. Tox.																				
TAYLJ1	Jill Taylor	pending Bacteriology -- Restricted Cellular Immunology -- Leukocyte Function Cellular Immunology -- Non-Malignant Leukocyte Immunophenotyping Clinical Chemistry Cytogenetics -- Cancer Fetal Defect Markers Immunohematology Virology																				

Form the "Update" screen, choose a Director from the dropdown to make edits to responsibilities.

Director View/Update Appoint New Assistant Directors View Update Hours Add New Remove Responsibilities View ▪ Update	PFI: 0000 Name: Internal Test for CLEP TEST 1 <u>Choose Director to Update</u> <div>To begin, choose a director from the list and click 'Next': <table border="1"><tr><td>LEEXT3 Todd Lee</td><td>▼</td></tr></table> Next Cancel</div>	LEEXT3 Todd Lee	▼
LEEXT3 Todd Lee	▼		

ECLEP MANUAL

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'.

Director View/Update Appoint New	PFI: 1067 Name: Wadsworth Center - Biggs Laboratory
Assistant Directors View Update Hours Add New Remove	<u>Update Responsibilities</u>
Responsibilities View	Name: Jill Taylor PhD CQ Code: TAYLJ1 CQ Expiration Date: 03/08/2016
▪ Update	Please select all categories this Director is responsible for (at least 1 must be specified); items with an asterisk (*) are required.
	<div>Effective Date of Changes * Effective Date (mm/dd/yyyy): <input type="text"/> </div> <div>Director's Responsibilities (select all that apply):<ul style="list-style-type: none"><input type="checkbox"/> Bacteriology -- Restricted<input type="checkbox"/> Clinical Chemistry<input type="checkbox"/> Cytokines<input type="checkbox"/> Endocrinology<input type="checkbox"/> Hematology -- Cellular Hematology<input type="checkbox"/> Hematology -- Coagulation<input type="checkbox"/> Hematology -- Cytohematology Diagnostic<input checked="" type="checkbox"/> Oncology -- Human Papillomavirus (HPV) Testing<input type="checkbox"/> Oncology -- Molecular and Cellular Tumor Markers<input type="checkbox"/> Oncology -- Soluble Tumor Markers<input type="checkbox"/> Toxicology -- Blood Lead-Comprehensive<input type="checkbox"/> Toxicology -- Clinical Toxicology-Comprehensive<input type="checkbox"/> Trace Elements<input type="checkbox"/> Ther. Sub. Mon./Quant. Tox.<input type="checkbox"/> Urinalysis<input type="checkbox"/> Urine Pregnancy Testing<input type="checkbox"/> Virology</div> <div><input type="button" value="Save"/> <input type="button" value="Cancel"/></div>

ECLEP MANUAL

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	Bacteriology		No responsible AD/DI for this Category
Pending	Blood pH and Gases		No responsible AD/DI for this Category
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, Jill Taylor
Pending	Cytopathology Gynecological Testing		Todd Lee

eCLEP MANUAL

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.

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

Add/Remove Responsibilities

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):**

[Add](#) [Clear](#)

ECLEP MANUAL**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 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 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 <div style="border: 1px solid red; padding: 2px;"> Upload </div> Remove	PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY <u>Category / Cytopathology Upload</u> 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. 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. Uploaded Files <table border="1"> <thead> <tr> <th>File</th> <th>Name</th> <th>Uploaded By</th> <th>Time</th> </tr> </thead> <tbody> <tr> <td>Cytopathology</td> <td>2017 reapplication cyto pt.pdf</td> <td>bah04</td> <td>29-Jun-2017 8:38 AM</td> </tr> </tbody> </table> 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. Cytopathology * File Name: <input type="button" value="Choose File"/> No file chosen <div> <input type="button" value="Save"/> <input type="button" value="Clear"/> </div>			File	Name	Uploaded By	Time	Cytopathology	2017 reapplication cyto pt.pdf	bah04	29-Jun-2017 8:38 AM
File	Name	Uploaded By	Time								
Cytopathology	2017 reapplication cyto pt.pdf	bah04	29-Jun-2017 8:38 AM								

ECLEP MANUAL**Add a Category**

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

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 (highlighted) Upload Remove	Add New Category 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 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----"/> <small>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.</small> <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.

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 (highlighted) Upload Remove	Add New Category 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 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="Bacteriology"/> or <input type="text" value="Search for Category by Test Name"/> <input type="button" value="Search"/> CQ Code: <input type="text" value="LEEXT3 Todd Lee"/> <small>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.</small> <input type="button" value="Next"/>

ECLEP MANUAL

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.

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	Add New Category 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 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----"/> 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 tests that are described in CLIA Subpart I 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.

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.

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: 012 DEV Internal Test for CLEP TEST 1 DUMMY

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	
Identification of blood pathogens (bacterial) by molecular methods	Test Not Offered
Identification of gastrointestinal bacterial pathogens by molecular methods	Test Offered
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

ECLEP 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.

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

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

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

PFI: 0000 Name: 012 DEV Internal Test for CLEP TEST 1 DUMMY

Designate PT provider and product

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 Fai ▼	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 <div style="border: 1px solid red; padding: 2px;">Add New</div> Upload Remove					
Test Volume View Previous Edit Current					
PFI: 0000 Name: 012 DEV Internal Test for CLEP TEST 1 DUMMY					
<u>View Designations</u>					
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				
<div style="border: 1px solid red; padding: 2px; display: inline-block;">Next</div>					

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.

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 Test Volume View Previous Edit Current POC Testing Manage Locations Add Delete/Update Contact Person	PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY <hr/> All permit categories at this facility: <table border="1"> <thead> <tr> <th>Category status</th> <th>Permit Categories</th> <th>Responsibilities Status</th> <th>Responsible Directors</th> </tr> </thead> <tbody> <tr> <td>Pending Add</td> <td>Bacteriology</td> <td>Pending</td> <td>Todd Lee</td> </tr> <tr> <td>Approved</td> <td>Blood pH and Gases</td> <td></td> <td>Todd Lee</td> </tr> <tr> <td>Pending Add</td> <td>Clinical Chemistry</td> <td>Pending</td> <td>Todd Lee</td> </tr> <tr> <td>Pending Add</td> <td>Virology</td> <td></td> <td>Todd Lee</td> </tr> </tbody> </table>			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
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:

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 Test Volume View Previous Edit Current POC Testing Manage Locations Add Delete/Update Contact Person	Pending Changes: <input type="checkbox"/> Todd Lee: ADD was: N/A Cancel Selected Changes <hr/> PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY <hr/> <h3 style="text-align: center;">Add/Remove Responsibilities</h3> <hr/> Category Name: Bacteriology Responsible AD/DI: • Todd Lee <hr/> Available AD/DI: <table border="1"> <thead> <tr> <th>Person Id</th> <th>Person Name</th> <th>Add/Remove Responsibility</th> </tr> </thead> <tbody> <tr> <td>LEEXT3</td> <td>Todd Lee</td> <td>Pending</td> </tr> <tr> <td>PARKM1</td> <td>Monica M. Parker</td> <td>Add</td> </tr> <tr> <td>TAYLJ1</td> <td>Jill Taylor</td> <td>Add</td> </tr> </tbody> </table>			Person Id	Person Name	Add/Remove Responsibility	LEEXT3	Todd Lee	Pending	PARKM1	Monica M. Parker	Add	TAYLJ1	Jill Taylor	Add
Person Id	Person Name	Add/Remove Responsibility													
LEEXT3	Todd Lee	Pending													
PARKM1	Monica M. Parker	Add													
TAYLJ1	Jill Taylor	Add													

ECLEP 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 Add New Upload Remove	Pending Changes: <table border="1"><tr><td><input type="checkbox"/> Bacteriology: PT Changes</td><td>Add</td><td>was: ~</td></tr><tr><td><input type="checkbox"/> Clinical Chemistry: PT Changes</td><td>Add</td><td>was: ~</td></tr><tr><td><input type="checkbox"/> Virology: PT Changes</td><td>Add</td><td>was: ~</td></tr></table> Cancel Selected 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: ~
<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: ~								
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' form in the ECLEP system. The top navigation bar includes tabs for Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, and Limited Labs. Below this is a sub-navigation bar with Lab Profile, Ownership, Personnel, Permit Categories/Tests (selected), 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 shows 'PFI: 0000' and 'Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY'. Under the 'Category' section, there is a dropdown menu for 'Permit Category' and a date picker for 'Effective Date'. The left sidebar contains links for View, Update, Pending Changes, Add New, Upload, and Remove (highlighted with a red box).

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 shows the same 'Delete Permit Category' form, but with the 'Effective Date' date picker open. The date picker displays a calendar for December 2018, with the 4th of the month highlighted. The 'Remove' button in the left sidebar remains highlighted with a red box. The rest of the form and navigation elements are identical to the previous screenshot.

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 or call (518) 485-5378 for questions on reporting test volumes.

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

The screenshot shows the 'Open Mode' interface for a laboratory. The top navigation bar includes tabs for Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, and Limited Labs. Below this is a sub-navigation bar with Lab Profile, Ownership, Personnel, Permit Categories/Tests, PSCs and Others, and Tools. The main content area is titled 'Open Mode' and includes a 'Submit Changes' button. The left sidebar contains links for Responsibilities, Category, Test Volume, and POC Testing. The 'Test Volume' section is highlighted, and the 'View Previous' link is selected. The main content area displays the 'Test Volume for January 1, 2016 through December 31, 2016' for PFI: 1914, Name: Jones Memorial Hospital Laboratory. A table shows the 'Total Tests/Specimens per Specialty/SubSpecialty' for various categories, including HISTOCOMPATIBILITY and MICROBIOLOGY.

Test Specialty/SubSpecialty	Total Tests/Specimens per Specialty/SubSpecialty
HISTOCOMPATIBILITY	0
Total	0
MICROBIOLOGY	
Bacteriology	19017
Mycobacteriology	0
Mycology	0
Parasitology	0
Virology	928
HPV Testing	0
Total	19945

- In Reapplication mode, you can view the information currently in the database as well as enter the previous year's testing volumes. 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.

The screenshot shows the 'Reapplication Mode' interface for a laboratory. The top navigation bar includes tabs for Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, and Limited Labs. Below this is a sub-navigation bar with Lab Profile, Ownership, Personnel, Permit Categories/Tests, PSCs and Others, and Tools. The main content area is titled 'Reapplication Mode' and includes a 'Reapplication Center' button. The left sidebar contains links for Responsibilities, Category, Test Volume, and POC Testing. The 'Test Volume' section is highlighted, and the 'Edit Current' link is selected. The main content area displays the 'Test Volume for January 1, 2017 through December 31, 2017' for PFI: 0000, Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY. A table shows the 'Total Tests/Specimens per Specialty/SubSpecialty' for various categories, including HISTOCOMPATIBILITY and MICROBIOLOGY. The 'No Tests' section is also visible, with a checkbox for 'No tests performed this year' and a text field for 'Reason for not performing any tests this year:'.

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

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- 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.

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.

Enter

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

[Submission dated Aug 30, 2013 12:44:49 PM EDT \(PDF\)](#)

[Submission dated Apr 23, 2013 1:50:40 PM EDT \(PDF\)](#)

[Reapplication Submission dated Mar 29, 2013 2:37:07 PM EDT \(PDF\)](#)

[Submission dated Mar 1, 2013 2:31:20 PM EST \(PDF\)](#)

[Reapplication Submission dated Jul 31, 2012 2:43:05 PM EDT \(PDF\)](#)

ECLEP 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.

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

The screenshot shows the 'Manage Point-of-Care Testing Locations' page in the ECLEP system. The top navigation bar includes tabs for Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, and Limited Labs. Below this, a sub-navigation bar has tabs for Lab Profile, Ownership, Personnel, Permit Categories/Tests, PSCs and Others, and Tools. The main content area is titled 'Manage Point-of-Care Testing Locations' and includes a 'Reapplication Period' of Apr 01, 2018 through Dec 15, 2018 at 05:00 PM, EST. The page is divided into two main sections: 'Point-Of-Care Testing Questions' and 'Existing Locations'. The 'Point-Of-Care Testing Questions' section contains a question: '1. Does this facility perform point-of-care testing?' with radio buttons for 'Yes' and 'No'. The 'Existing Locations' section contains a table with columns for Location ID, Location Type, Location Desc, and CLIA No. Below the table, there is a section for 'Add New Location' with fields for Location ID, Location Type, Location Desc, and CLIA Number.

- 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**.

The screenshot shows the 'Add' page in the ECLEP system, which is used to add a test to a POCT location. The top navigation bar and sub-navigation bar are the same as in the previous screenshot. The main content area is titled 'Add' and includes a 'Reapplication Period' of Apr 01, 2018 through Dec 15, 2018 at 05:00 PM, EST. The page is divided into two main sections: 'Enter Test Details' and 'Select Staff'. The 'Enter Test Details' section contains fields for Testing Location, Types of tests provided, and Instruments/Test systems Used. The 'Select Staff' section contains a list of staff roles with checkboxes next to them, including 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, and Aide.

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- 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.

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

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

Open Mode Submit Changes

Responsibilities
View
Update

Category
Pending Changes
Add New
Upload
Remove
Test Volume
View Previous
POC Testing
Manage Locations
Add
Delete/Update
Contact Person

PFI: 0000 Name: 012 DEV Internal Test for CLEP TEST 1 DUMMY
Point-Of-Care-Testing

Select to view in Detail:

Test Loc	Test Type	Instrument	Staff
<input checked="" type="radio"/> 4Cke	Glucose	Accucheck Inform	PCA/PCT, Registered Nurse
<input type="radio"/> 5Cke	Glucose	Accucheck Inform	PCA/PCT, Registered Nurse
<input type="radio"/> 5SPL-SCU	Glucose	Accucheck Inform	PCA/PCT, Registered Nurse
<input type="radio"/> 6Cke	Glucose	Accucheck Inform	PCA/PCT, Registered Nurse
<input type="radio"/> ASC	Glucose	Accucheck Inform	PCA/PCT, Registered Nurse
<input type="radio"/> ASC	Pregnancy Test (Urine)	Beckman Coulter ICON25	PCA/PCT, Registered Nurse
<input type="radio"/> BAR	Glucose	Accucheck Inform	PCA/PCT, Registered Nurse
<input type="radio"/> CardiacCath	Activated Clotting Time	Hemochron Signature Elite	Registered Nurse, Tech
<input type="radio"/> CardiacCath	Glucose	Accucheck Inform	PCA/PCT, Registered Nurse
<input type="radio"/> DETOX	Glucose	Accucheck Inform	PCA/PCT, Registered Nurse
<input type="radio"/> EDU	Glucose	Accucheck Inform	PCA/PCT, Registered Nurse

Update Delete Clear

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

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

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

Open Mode Submit Changes

Responsibilities
View
Update

Category
Pending Changes
Add New
Upload
Remove
Test Volume
View Previous
POC Testing
Manage Locations
Add
Delete/Update
Contact Person

PFI: 0000 Name: 012 DEV Internal Test for CLEP TEST 1 DUMMY
Point-Of-Care-Testing

Enter Test Details:

Testing Location : 4Cke - Medical/Surgical floors

Types of tests provided :

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

ECLEP MANUAL

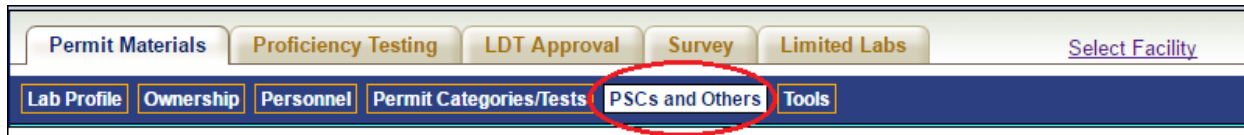
The **Point-Of-Care Contact Person** page allows you to indicate a POCT Coordinator for the laboratory. Enter the appropriate contact information and click **Save**.

Permit Materials		Proficiency Testing		Gross Annual Receipts		LDT Approval		Survey		Limited Labs	
Lab Profile		Ownership		Personnel		Permit Categories/Tests		PSCs and Others		Tools	
Open Mode Submit Changes											
Responsibilities		PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY									
View Update		Point-Of-Care Contact Person									
Category		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									
Pending Changes Add New Upload Remove		POC Contact Person Details									
Test Volume		Salutation: <input type="text" value="Ms."/> Title: <input type="text" value="Clinical Lab Manager"/>									
View Previous		First Name: <input type="text" value="Patricia"/>									
POC Testing		Middle Name: <input type="text"/>									
Manage Locations Add Delete/Update		Last Name: <input type="text" value="Jones"/>									
Contact Person		Telephone (###-###-####): <input type="text" value="456-456-4562"/>									
		Email: <input type="text" value="xyz@test.com"/>									
		<input type="button" value="Save"/> <input type="button" value="Clear"/>									

ECLEP 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.

A screenshot of the 'PSCs and Others' form. The form has a title bar 'PSCs and Others'. Below the title bar, there are fields for 'PFI: 0000' and 'Name: ABC Lab'. On the left side, there is a sidebar with three links: 'Health Fair', 'Health Fair Test', and 'PSC'. The 'PSC' link is circled in red. The main content area contains the following text: '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 text is a checkbox with the label '* 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 of the form are two buttons: 'Save' and 'Clear'.

ECLEP 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	PFI: 0000 Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY	Print PSC Listing
New / Select	Patient Service Centers on File	
▪ Stations on File	Station ID: 0000-0001 Status: N/A - Open	
	Station Info POBox 509 Empire State Plaza Albany, NY, 12201-0509	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
	Contact Info Frodo Khan p@w.com 518-445-8877	
	Station ID: 0000-0002- Test PSC Status: Approved - Open	
	Station Info Test PSC 30 South Broadway in the basement ALBANY, NY, 12208	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
	Contact Info Frodo Khan p@w.com 518-445-8877	

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

The screenshot shows a web application interface. On the left is a vertical menu with links: [PSCs and Others](#), [Home](#), [New / Select Stations on File](#), [Manage PSC](#), [Address](#) (highlighted with a bullet point), [Contact](#), [Hours](#), [Self Assessment](#), and [Upload](#). The main content area has a header with 'PFI: 0000 Station: W0427 Name: Internal Test for CLEP TEST(WCQA)' and 'Station Status: N/A Permit Status: N/A'. Below this is the title 'Patient Service Center Application' and a note: 'Items with an asterisk (*) are required.' The form contains several fields: 'Name' (text box), '* Address' (text box with '1313 Mockingbird Lane'), '* City' (text box with 'Amityville'), '* State' (text box with 'New York'), '* County' (dropdown menu with 'Nassau'), and '* Zip Code' (text box with '18924'). At the bottom is a 'Comment' section with a text area containing the text 'If you would like to provide a comment, please do so below. (200 characters max) why are you making me do all of this'. At the very bottom are 'Save' and 'Clear' buttons.

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**.

The screenshot shows a web application interface. On the left is a vertical menu with links: [Health Fair](#), [Health Fair Test](#), and [PSC](#). The main content area has a header with 'PFI: 0000 Name: ABC Lab' and the title 'PSCs and Others'. Below this is a text area containing the text '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 the text area is a checkbox with a red circle around it, followed by 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 are 'Save' and 'Clear' buttons.

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**.

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

New / Select

[Stations on File](#)

PFI: 0000 Name: Internal Test for CLEP TEST(WCQA)

Station Status: Permit Status:

Patient Service Center Application

Items with an asterisk (*) are required.

New PSC

☐ *New:

Select PSC

W0427 - 1313 Mockingbird Lane , Amityville ▼

Next

Clear

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.

[PSCs and Others Home](#)

New / Select Stations on File

PFI: 0000
Station:
Name: Internal Test for CLEP TEST(WCQA)

Station Status:
Permit Status: N/A

Patient Service Center Application

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

Date:

* Expected opening date:

Contact Person Information:

* Salutation:
Select ▼

* First Name:

Middle Name:

* Last Name:

* Telephone :
Ext:

Fax :

* Email:

PSC Contact Information:

Telephone :
Ext:

Address:

Name:

* Address:

* City:

* State:
New York

* County:
Select NY County ▼

* Zip Code:

Hours of Operation:

Monday:
12:00 ▼ AM ▼ to 12:00 ▼ AM ▼
24 Hrs
Closed
Select Hours

Tuesday:
12:00 ▼ AM ▼ to 12:00 ▼ AM ▼
24 Hrs
Closed
Select Hours

Wednesday:
12:00 ▼ AM ▼ to 12:00 ▼ AM ▼
24 Hrs
Closed
Select Hours

Thursday:
12:00 ▼ AM ▼ to 12:00 ▼ AM ▼
24 Hrs
Closed
Select Hours

Friday:
12:00 ▼ AM ▼ to 12:00 ▼ AM ▼
24 Hrs
Closed
Select Hours

Saturday:
12:00 ▼ AM ▼ to 12:00 ▼ AM ▼
24 Hrs
Closed
Select Hours

Sunday:
12:00 ▼ AM ▼ to 12:00 ▼ AM ▼
24 Hrs
Closed
Select Hours

Hours Note:

Comment:

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

Save

Clear

ECLEP 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](#)

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.

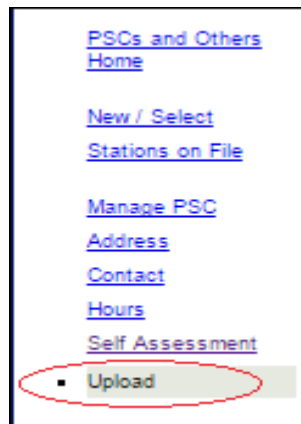
Self Assessment	
*	Will or do PSC phlebotomists or other employees of the parent laboratory perform duties for any referring health services purveyor? <input type="radio"/> Yes <input type="radio"/> No *
1	Is the PSC located within the offices of, or otherwise share space with, the practice of a physician 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**.

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 *
<input type="button" value="Save"/> <input type="button" value="Clear"/>	

ECLEP MANUAL

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 **Browse** to navigate to the electronic file on your computer, then click **Open** to upload. Once both documents have been uploaded, click **Save**.



A screenshot of the 'Patient Service Center Application Upload' form. The form is divided into a left sidebar and a main content area. The sidebar contains the same menu as the previous image, with 'Upload' highlighted. The main content area has a header with the following information: 'PFI: 0000', 'Station: W0427', 'Name: Internal Test for CLEP TEST(WCQA)', 'Station Status: N/A', and 'Permit Status: N/A'. Below this is the title 'Patient Service Center Application Upload'. A section titled 'Uploaded Files' contains a table with columns 'File', 'Name', 'Uploaded By', and 'Time'. Below the table is a note: 'Each file uploaded represents the latest file of that type to be uploaded. The previous version of the file has been overwritten.' A note below that states: 'Items with an asterisk (*) are required.' There are two required fields: 'Floor Plan' and 'Lease/Ownership'. Each field has a sub-section with a yellow asterisk icon, a 'File Name' label, a 'Choose File' button (circled in red), and the text 'No file chosen'. At the bottom left of the form is a 'Save/Clear' button (circled in red). At the bottom right is a small square icon.

ECLEP MANUAL**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.

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

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: Select ▼

* First Name: Cathy

Middle Name:

* Last Name: Tillman

* Telephone (###-###-####): 315-482-1101

* Email:

Additional Information

Date of First Event (mm/dd/yyyy): 07/27/1993

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

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

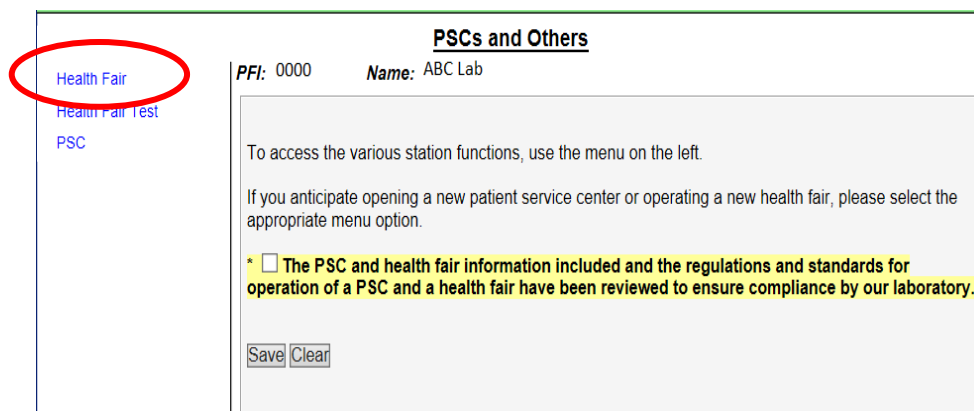
PSCs and Others Home Health Fair View/Update Remove Health Fair Tests View Update Add New Remove	Pending Changes:		
	<input type="checkbox"/> Remove:	alpha-1 antitrypsin	was: N/A
	<input type="checkbox"/> Add:	HbsAg	was: N/A
	<input type="checkbox"/> Add:	Bilirubin Total	was: N/A
	Cancel Selected Changes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

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

PSCs and Others Home Health Fair View/Update Remove Health Fair Tests View Update Add New Remove	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: <input type="radio"/> Yes <input checked="" type="radio"/> No	
	* Test at Lab: <input checked="" type="radio"/> Yes <input type="radio"/> No	
	* Test Referred to Another Lab: <input type="radio"/> Yes <input checked="" type="radio"/> No	
	If yes, please provide the PFI of the lab referred to, and any comments: (100 characters max)	
	<input type="text"/>	
	Please provide any other comments about this test: (200 characters max)	
	<input type="text"/>	

ECLEP MANUAL**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

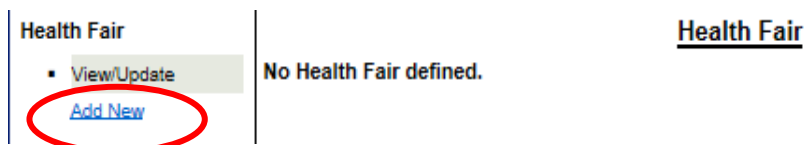
[Health Fair](#)
[Health Fair Test](#)
[PSC](#)

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.

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



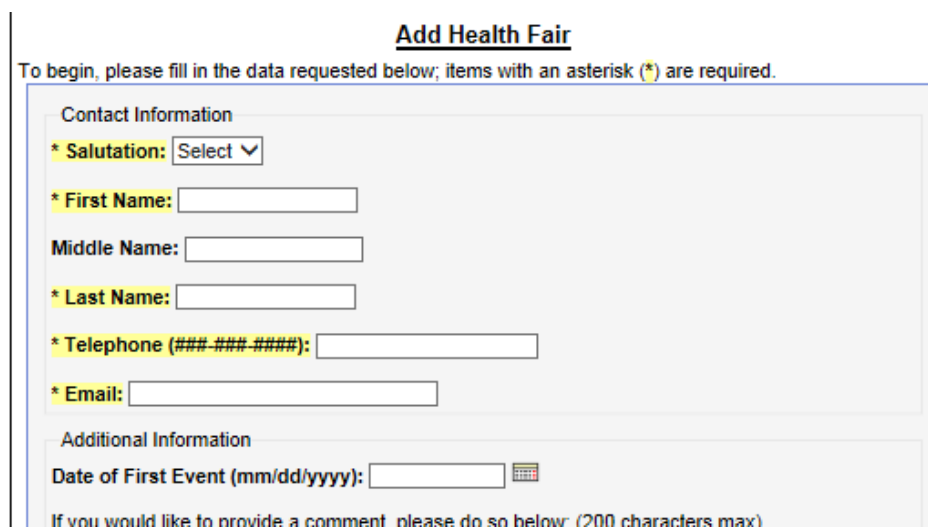
Health Fair

▪ [View/Update](#)
[Add New](#)

Health Fair

No Health Fair defined.

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)

ECLEP MANUAL

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.

PSCs and Others Home
Health Fair
New Update
Remove
Health Fair Tests
View
Update
Add New
Remove

Pending Changes:

☐ Add: Health Fair was: Cancel Selected Changes

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

Health Fair

Items with an asterisk (*) are required.

Contact Information

* Salutation: Mr.

* 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:

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.

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.

Save Clear

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

Choose Health Fair Test to Update

Please fill in the data requested below; items with an asterisk (*) are required.

* Health Fair Test To Update: HIV Screening ▼

Next Cancel

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

Choose Health Fair Test to Remove

Please fill in the data requested below; items with an asterisk (*) are required.

* Health Fair Test To Remove: HIV Screening ▼

* Date of Removal (mm/dd/yyyy):

Next Cancel

ECLEP MANUAL**Miscellaneous****Error Messages**

2. 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 Test 5' form. At the top, a navigation bar includes tabs for 'Lab Profile', 'Ownership', 'Personnel', 'Permit Categories/Tests', 'PSCs and Others', and 'Tools'. Below this, a green banner shows the 'Reapplication Period: Mar 05, 2012 through Mar 12, 2012 at 05:00 PM, EDT' and a 'Reapplication Center' button. The left sidebar has a tree view with 'General Information' selected, and links for 'Regulatory Information' and 'Hours'. The main content area shows 'PFI: 6705' and 'Name: eCLEP Test 5'. A red-bordered box at the top of the form lists four errors: '1. Phone is a required field', '2. Fax is a required field', '3. Email is a required field', and '4. Facility Type is a required field'. The form is divided into sections: 'Name and Address Information' (with fields for Name, Address, City, Country, State/Province, NY County, and Zip Code), 'General Information' (with Facility Type and Fac Status), and 'Contact Information' (with Telephone, Fax, and Email fields). A red oval highlights the 'Contact Information' section. At the bottom, there are 'Save' and 'Clear' buttons.

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

Reapplication Period: Mar 05, 2012 through Mar 12, 2012 at 05:00 PM, EDT Reapplication Center

General Information

Regulatory Information

Hours

PFI: 6705 Name: eCLEP Test 5

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

Name and Address Information

Name: eCLEP Test 5

Address: Lincoln St

City: Buffalo

Country: United States

State/Province: New York Refresh List

NY County: Unknown Refresh List

Zip Code: 12798

All name/address changes effective:

* Effective Date is required for any name/address change

General Information

Facility Type: Select Fac Status: Open

Contact Information

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

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

Email:

Save Clear

ECLEP MANUAL**Pending Changes**

3. 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**.

<ul style="list-style-type: none"> General Information Regulatory Information Hours Alternate Address Contact Person 	Pending Changes: <table> <tr> <td><input type="checkbox"/> Name : Internal Test for CLEP TEST2</td> <td>Old Name : Internal Test for CLEP TEST(WCOA)</td> </tr> <tr> <td><input type="checkbox"/> Facility Type : Hospice</td> <td>Old Facility Type : Ancil Testing Site in Health Care Fac / Hosp Ext Clinic</td> </tr> <tr> <td><input type="checkbox"/> City : Albany Test</td> <td>Old City : Albany</td> </tr> <tr> <td><input type="checkbox"/> Zip Code : 12200</td> <td>Old Zip Code : 12203</td> </tr> <tr> <td><input type="checkbox"/> Telephone : 345645756756</td> <td>Old Telephone : 1234567890</td> </tr> <tr> <td><input type="checkbox"/> Ext : 12345</td> <td>Old Ext : 1234</td> </tr> <tr> <td><input type="checkbox"/> Fax : 2343467457</td> <td>Old Fax : 0987654321</td> </tr> <tr> <td><input type="checkbox"/> Email : mabraham@wadsworth.com, email@test.com</td> <td>Old Email : mabraham@wadsworth.org</td> </tr> </table> <p align="right"><input type="button" value="Cancel Selected Changes"/></p>	<input type="checkbox"/> Name : Internal Test for CLEP TEST2	Old Name : Internal Test for CLEP TEST(WCOA)	<input type="checkbox"/> Facility Type : Hospice	Old Facility Type : Ancil Testing Site in Health Care Fac / Hosp Ext Clinic	<input type="checkbox"/> City : Albany Test	Old City : Albany	<input type="checkbox"/> Zip Code : 12200	Old Zip Code : 12203	<input type="checkbox"/> Telephone : 345645756756	Old Telephone : 1234567890	<input type="checkbox"/> Ext : 12345	Old Ext : 1234	<input type="checkbox"/> Fax : 2343467457	Old Fax : 0987654321	<input type="checkbox"/> Email : mabraham@wadsworth.com, email@test.com	Old Email : mabraham@wadsworth.org
	<input type="checkbox"/> Name : Internal Test for CLEP TEST2	Old Name : Internal Test for CLEP TEST(WCOA)															
<input type="checkbox"/> Facility Type : Hospice	Old Facility Type : Ancil Testing Site in Health Care Fac / Hosp Ext Clinic																
<input type="checkbox"/> City : Albany Test	Old City : Albany																
<input type="checkbox"/> Zip Code : 12200	Old Zip Code : 12203																
<input type="checkbox"/> Telephone : 345645756756	Old Telephone : 1234567890																
<input type="checkbox"/> Ext : 12345	Old Ext : 1234																
<input type="checkbox"/> Fax : 2343467457	Old Fax : 0987654321																
<input type="checkbox"/> Email : mabraham@wadsworth.com, email@test.com	Old Email : mabraham@wadsworth.org																
<p>PFI: 0000 Name: Internal Test for CLEP TEST2</p> <div> <div>Name and Address Information</div> <div> Name: Internal Test for CLEP TEST2 Address: PO Box 509, Empire State Plaza City: Albany Test Country: United States State/Province: New York Refresh List NY County: Albany Refresh List Zip Code: 12200 All name/address changes effective: 12/23/2015 * Effective Date is required for any name/address change </div> </div> <div> <div>General Information</div> <div> Facility Type: Hospice Fac Status: Open </div> </div> <div> <div>Lab Contact Information</div> <div> Telephone (###-###-####): 345-645-756756 Ext: 12345 Fax (###-###-####): 234-346-7457 Email: mabraham@wadsworth.com, email@tes </div> </div> <p align="center"><input type="button" value="Save"/> <input type="button" value="Clear"/></p>																	

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 contact CLEP and please have the four digit PFI number available.

Telephone:

518-485-5378

or

E-mail:

clep@health.ny.gov

Be sure to have your PFI number when calling or emailing! For emails, please indicate "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:

- Telephone support at (518) 485-5378
- E-mail support 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