



**Department of Health**  
**Wadsworth Center**

# Clinical Laboratory Evaluation Program



## eCLEP Manual Permit Materials

*March 2025*

# eCLEP Manual

## Permit Materials Module

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## eCLEP MANUAL

### **Introduction**

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

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

### **Getting Started: An Overview**

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

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

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

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

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

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

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

**eCLEP MANUAL****Requirements for Use**

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

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

**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.**

The eCLEP application is tested on 'evergreen browsers' (Google Chrome, Mozilla Firefox, Microsoft Edge) that are constantly updated to include the latest features and security patches. Tests are performed on the last two versions of each evergreen browser.

**File Upload Requirements**

1. File formats accepted in eCLEP:

Microsoft Word

Microsoft Excel

Portable Document Format (PDF)

2. File name must contain **only**:

Letters

Numbers

One (1) period preceding the file format extension (e.g., docx, xls, or pdf)

➤ For example, 145BroadStreetfloorplan.pdf **Valid** ✓

3. File name may not contain:

Spaces

Control characters

Unicode characters

➤ For example, 145 Broad Street floorpan.pdf **Not Valid** ✗

ECLIP MANUAL**Roles and Responsibilities**

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

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

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

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

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

ECLIP MANUAL**HCS Access Permissions**

You will need access to the New York State Health Commerce System (HCS) at <https://commerce.health.state.ny.us>.

**For more information on HCS Accounts, refer to our webpage at [www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce](http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce).**

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.

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**.

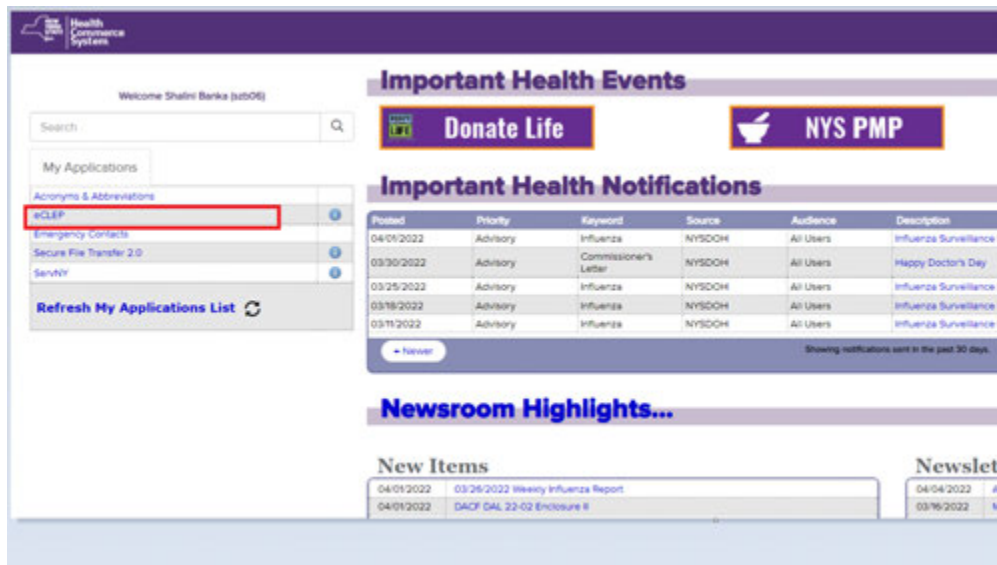
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**Accessing eCLEP and the Permit Materials Module**

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



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





**eCLEP MANUAL**

4. 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.



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

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

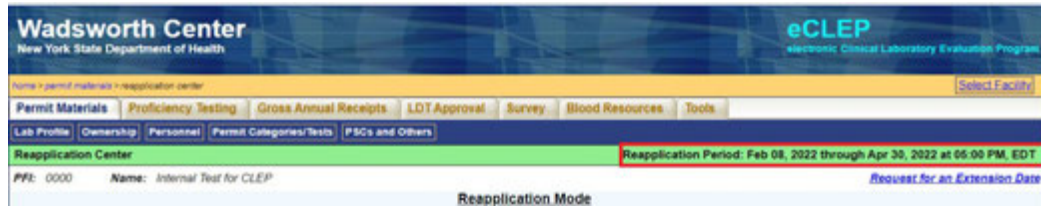
home > facility

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

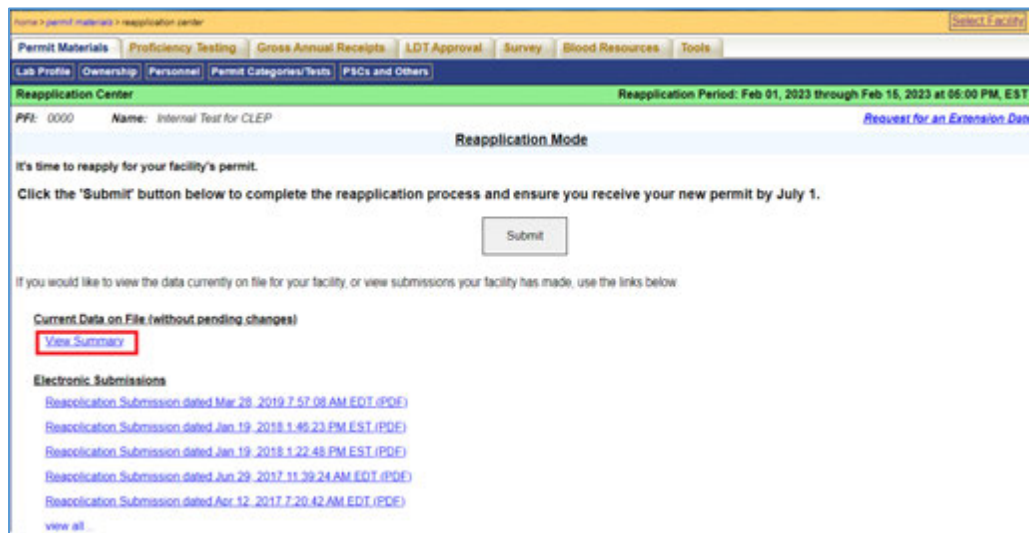
ECLP MANUAL

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

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

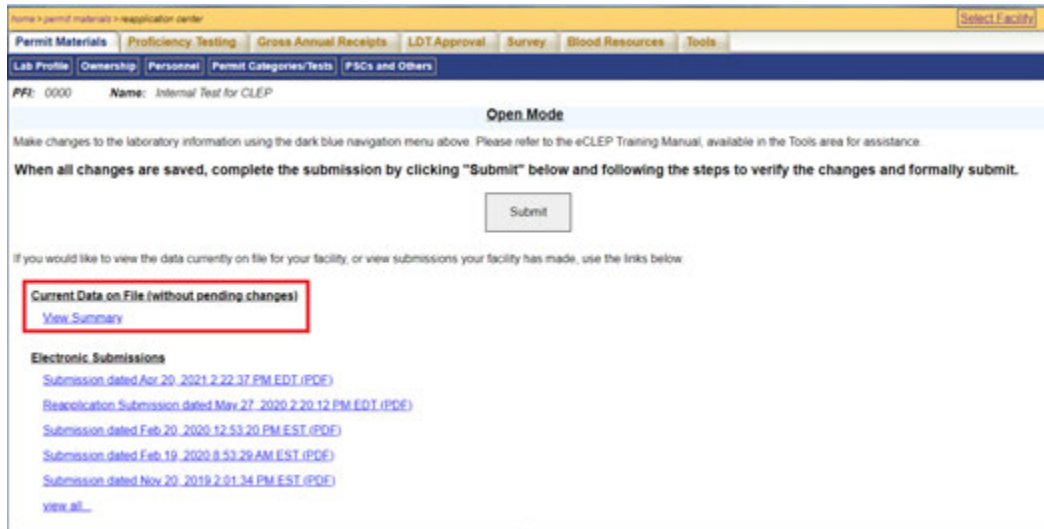


- On the **Reapplication Mode** or **Open Mode** page, you may want to review the Current Data on File (without pending changes) using the “**View Summary**” link and print it out to use as a worksheet. Reapplication Mode Screenshot:

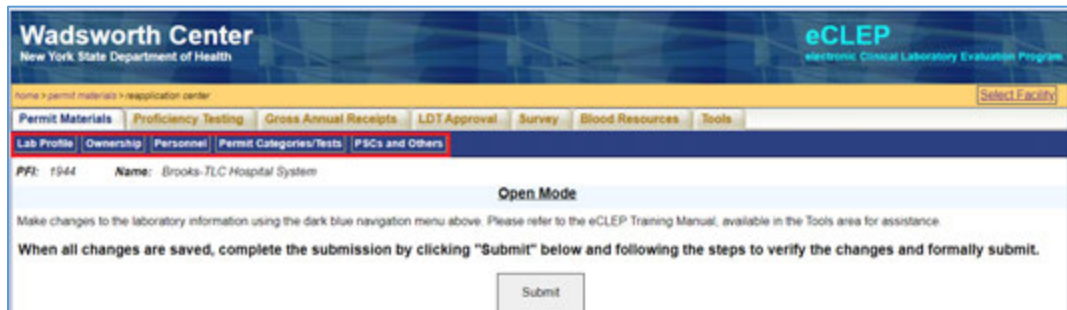
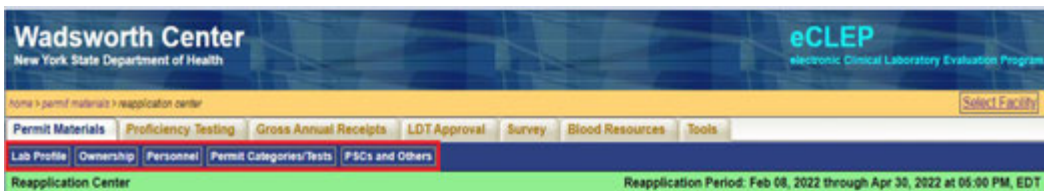


# eCLEP MANUAL

## Open Mode Screenshot:



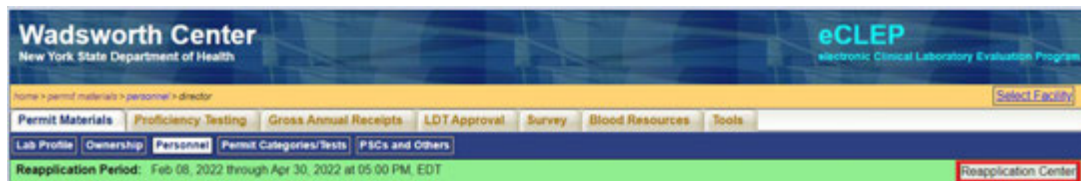
8. Make changes to laboratory information as required using the links on the dark blue menu bar (Lab Profile, Ownership, Personnel, Permit Categories/Tests, and PSCs and Others).



eCLEP MANUAL**Reapplication Mode Submissions**

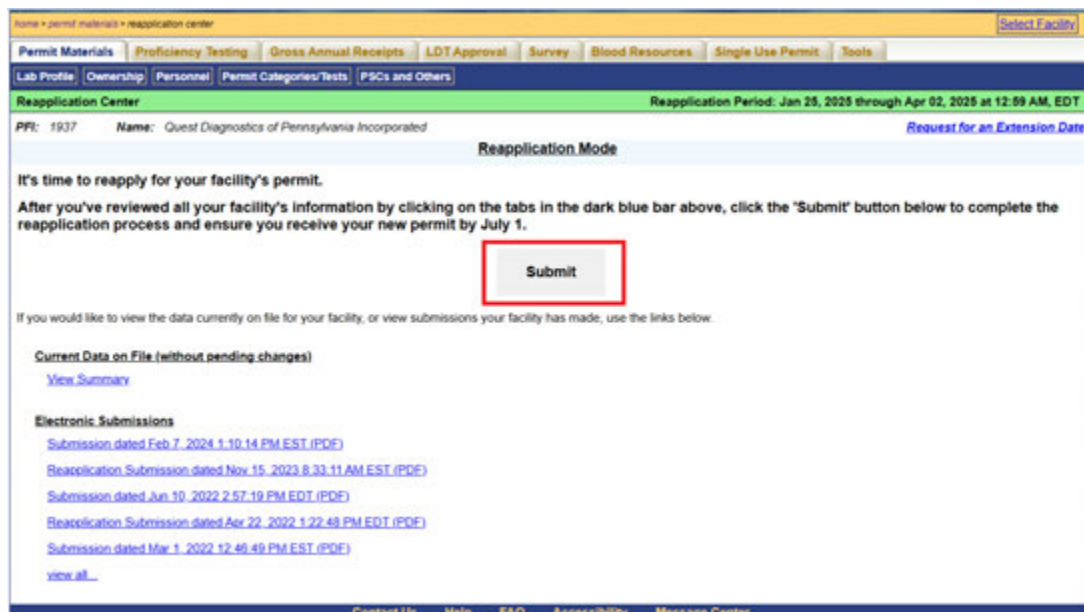
**NOTE: All eCLEP submissions are reviewed by the Clinical Laboratory Evaluation Program prior to acceptance. The Program reserves the right to request additional information, request re-submission to obtain missing information, or to reject the request in total if the eCLEP submission is not acceptable.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

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



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

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



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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.

none > permit materials > reapplication center > reapplication wizard Select Facility

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

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

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

PFI: 0000 Name: Internal Test for CLEP 1

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

**Step 1: Review and Update**

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

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

**Next** Cancel

[Printable Summary in PDF format](#)

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

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

**SECTION I -- GENERAL LABORATORY INFORMATION**

Field Name	Current Data	Changes
Laboratory PFI:	0000	

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

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

**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

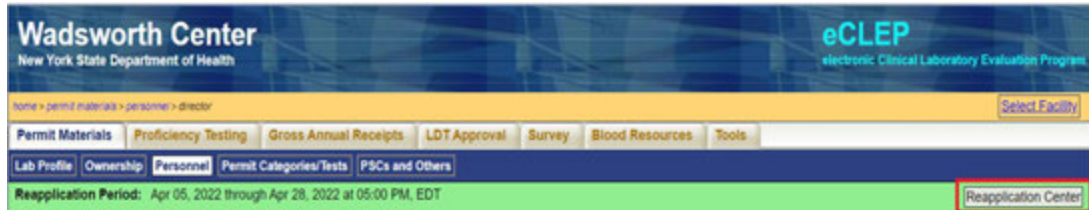
Area	Data Requirement	How to Resolve
Owner	Question 1 must be answered.	Visit the Ownership <a href="#">Owner</a> area, answer question 1 and click the Save button.
Ownership / Declaration Upload	Changes in laboratory owner also require the submission of a Disclosure of Ownership and Controlling Interest Statement.	Visit the <a href="#">Ownership / Declaration Upload</a> 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 <a href="#">Declaration</a> area, and answer questions 1, 2, 3 and 4. Then click the Save button.
Contact Person	An email address must be provided for the facility contact person.	Visit the Lab Profile <a href="#">Contact Person</a> area, provide an email address, then click the Save button.
Test Volume	Test volume data must be entered, or the lab must indicate that no tests were performed.	Visit the <a href="#">Test Volume</a> 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.

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

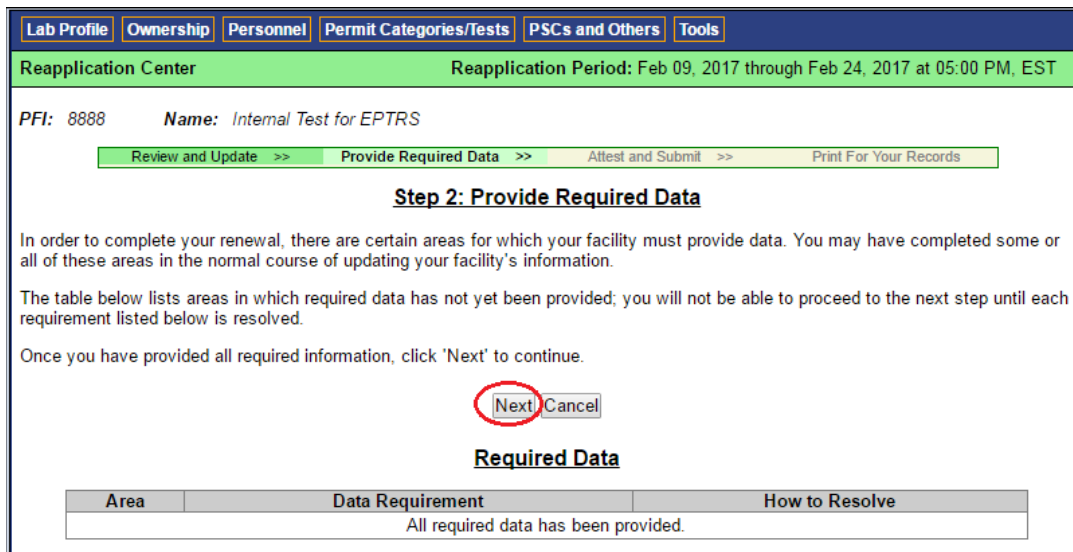
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- a) Navigate to each section by clicking the links in the blue menu bar near the top, e.g., **Lab Profile, Ownership, Personnel, Permit Categories/Tests, PSCs and Others.**
- b) If there are no, or few, owner/personnel/testing changes during this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

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.



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



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**.

**eCLEP MANUAL**

<a href="#">Lab Profile</a>	<a href="#">Ownership</a>	<a href="#">Personnel</a>	<a href="#">Permit Categories/Tests</a>	<a href="#">PSCs and Others</a>	<a href="#">Tools</a>
<b>Reapplication Center</b>			Reapplication Period: Feb 09, 2017 through Feb 24, 2017 at 05:00 PM, EST		
PFI: 8888		Name: Internal Test for EPTRS			
<a href="#">Review and Update &gt;&gt;</a>		<a href="#">Provide Required Data &gt;&gt;</a>		<a href="#">Attest and Submit &gt;&gt;</a>	
<b>Step 3: Attest and Submit</b>					
Please read the following attestation carefully. If you agree, signify by clicking the checkbox below (required), then click 'Next'.					
I understand that signing and submitting this record in this fashion is the legal equivalent of having placed my handwritten signature on the submitted record and this affirmation. I understand and agree that by electronically signing and submitting this record in this fashion I am affirming to the truth of the information contained therein.					
I, the laboratory director or delegated submitter, as a representative of the owner and laboratory director, understand that under section 577.1(a) of the Public Health Law the permit of this laboratory may be revoked, suspended, limited or annulled if any fact is misrepresented in this application. I acknowledge that Article 5, Title V, Section 575 of New York State Public Health Law stipulates that a laboratory permit is automatically void upon a change of director, owner or location. Any changes of the information in this application must be reported to the Clinical Laboratory Evaluation Program immediately by the laboratory director(s) or owner. I also understand that additional penalties may apply if facts or information regarding the initial and continuing eligibility for said laboratory permit are misrepresented, concealed, or undisclosed. Further, I understand that offering a false instrument constitutes a crime under the penal law of the State of New York (NYS Penal Law Article 175). Such misrepresentation may subject parties who file a false instrument to criminal prosecution.					
I, the laboratory director or delegated submitter, as a representative of the owner and laboratory director, understand that by signing this attestation I have agreed, on the behalf of the laboratory, to any investigation made by the Department of Health to verify or confirm the information provided in this application, any other investigation in connection with the laboratory permit or any complaint filed with the Department. If additional information is requested, it will be provided in a timely manner by the appropriate staff under the direction of the laboratory director and owner. Further, I understand that should the laboratory permit status be investigated at any time, cooperation in such an investigation will be provided by all staff under the direction of the laboratory director and owner.					
In signing this attestation I, the laboratory director or the delegated submitter, as a representative of the owner and laboratory director, certify that the information provided to the Department of Health as a basis for obtaining a laboratory permit is true and correct, that the laboratory director has received and read the rules and regulations pertaining to the clinical laboratories, and that the laboratory director and/or applicable assistant directors accept responsibility for the oversight of the laboratory permit categories listed in this application. Please note that as described in the Clinical Laboratory Standards of Practice, Director Standard of Practice 3: Responsibilities, the responsibilities of assistant directors must be delegated in writing by the laboratory director. If an assistant director is attesting to responsibility for a category, it is expected that documentation is available to demonstrate that the individual is actively engaged in tasks specific to the category or categories. Compliance with this requirement will be monitored during on-site survey.					
<input checked="" type="checkbox"/> I have read, and agree with, the above attestation					
<input type="button" value="Next"/> <input type="button" value="Cancel"/>					

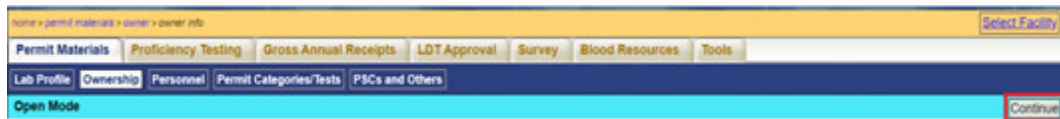
The **Step 4: Print for Your Records** page allows access to the eCLEP summary in PDF format. Click on the **Submission dated [date, time] (PDF)** and print or save this document for your records, if desired. Then click **Finished**. You will be directed to the main Read-Only mode page.

<b>Reapplication Center</b>			Reapplication Period: Feb 09, 2017 through Feb 24, 2017 at 05:00 PM, EST		
PFI: 8888		Name: Internal Test for EPTRS			
<a href="#">Review and Update &gt;&gt;</a>		<a href="#">Provide Required Data &gt;&gt;</a>		<a href="#">Attest and Submit &gt;&gt;</a>	
<b>Step 4: Print For Your Records</b>					
You may print the application submission for your records using the link below.					
<b>Most Recent Submission for 2017</b>					
<a href="#">Submission dated Feb 13, 2017 1:32:18 PM EST (PDF)</a>					
<input type="button" value="Finished"/>					
<a href="#">Contact Us</a>	<a href="#">Help</a>	<a href="#">FAQ</a>	<a href="#">Accessibility</a>	<a href="#">Message Center</a>	

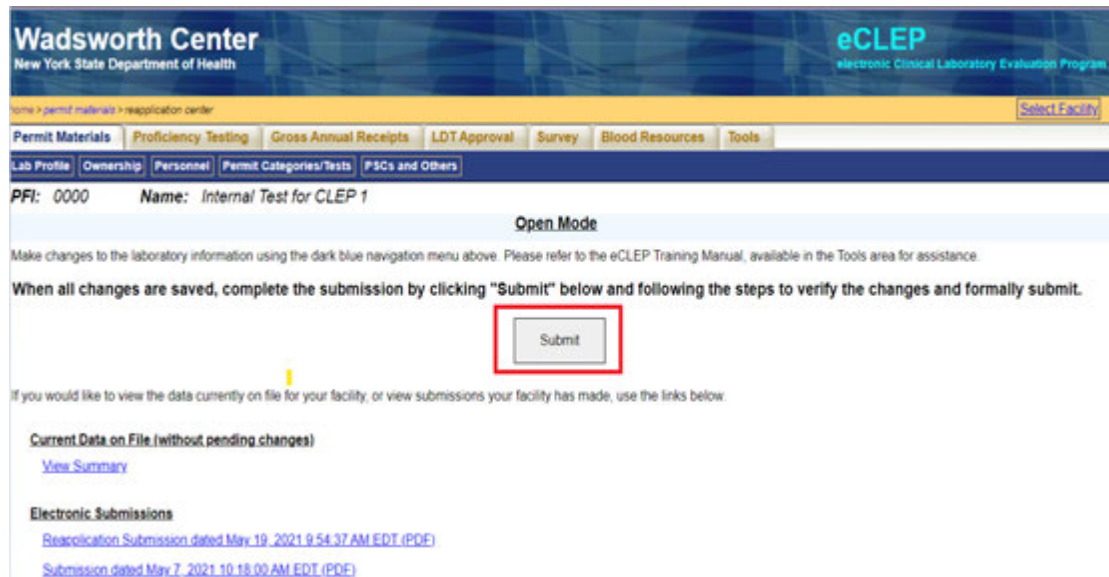
ECLP MANUAL**Open Mode Submissions**

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

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



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





ECLP MANUAL

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

**Wadsworth Center**  
New York State Department of Health

**eCLEP**  
Electronic Clinical Laboratory Evaluation Program

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

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

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

PFI: 0000 Name: Internal Test for CLEP 1

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

**Step 1: Review and Update**

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

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

**Printable Summary in PDF format** **Next** **Cancel**

**SUMMARY OF PENDING CHANGES**

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

**SECTION I -- GENERAL LABORATORY INFORMATION**

Field Name	Current Data	Changes
Laboratory PFI	0000	

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.

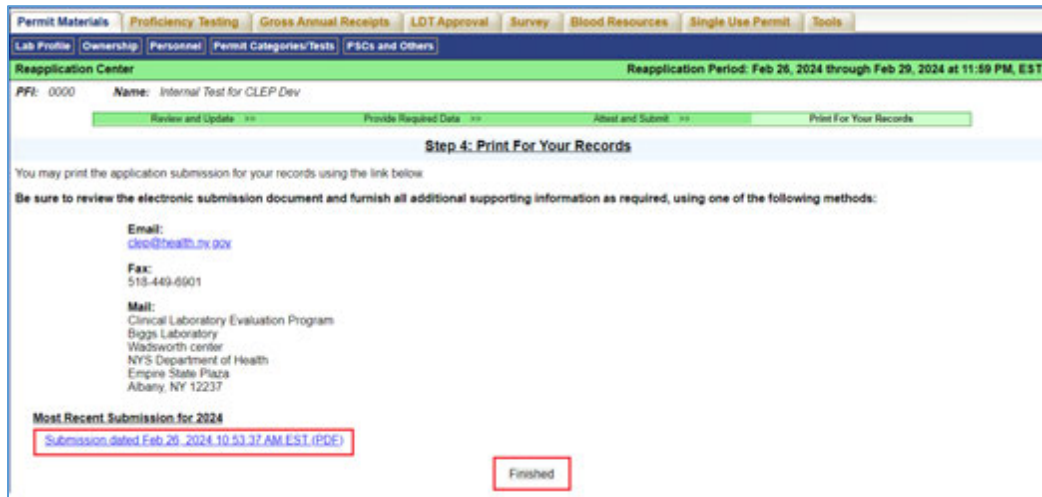
I, the laboratory director or delegated submitter, as a representative of the owner and laboratory director, understand that by signing this attestation I have agreed, on the behalf of the laboratory, to any investigation made by the Department of Health to verify or confirm the information provided 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**

### ECLP MANUAL

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.



ECLP MANUAL**Navigating in the Permit Materials Module****Lab Profile****General Information link**

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 tab before clicking **Save**.

The screenshot displays the 'General Information' page for a lab profile. The page is titled 'Internal Test for CLEP Dev CNSE 19'. The 'Name and Address Information' section includes fields for Name, Address, City, Country, State/Province, and Zip Code. The 'General Information' section includes a dropdown for Facility Type (set to 'Hospital') and a 'Fac Status' field (set to 'Open'). The 'Lab Contact Information' section includes fields for Telephone, Fax, and Email. A 'Save' button is highlighted with a red box.

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

ECLIP MANUAL

**Regulatory Information link**

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

Permit Materials Proficiency Testing Gross Annual Receipts LDT Approval Survey Tools

Lab Profile Ownership Personnel Permit Categories/Tests PSCs and Others

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

General Information  
 • Regulatory Information  
 Hours  
 Alternate Address  
 Contact Person  
 Accounting Information

Pending Changes:  
 CLIA No. : 000000001 Old CLIA No. : 000000000  
 Medicaid No : NA Old Medicaid No. : none  
 Cancel Selected Changes

PFI: 0000 Name: Internal Test for CLEP

Regulatory Information  
 CLIA Registration No: 000000001  
 Medicaid No: NA  
 Save Clear

**Hours link**

The **Hours** section allows you to change laboratory testing hours. Click on **Edit** button. Enter the required information and click **Save**.

Note: The Clinical Laboratory Evaluation Program may seek clarification of information entered in the “Hours Note” field before accepting the proposed change.

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

Home > permit materials > lab profile > hours Select Facility

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

Lab Profile Ownership Personnel Permit Categories/Tests PSCs and Others

Reapplication Period: Mar 13, 2025 through Apr 01, 2025 at 12:59 AM, EDT Reapplication Center

General Information  
 Regulatory Information  
 • Hours  
 Contact Person  
 Accounting Information

PFI: 0000 Name: Internal Test for CLEP Dev CNSE 19

Lab Hours  
 Enter hours in military (24-hour) format. Example: 11:00 pm is 23:00 hours

Monday	00:00	24:00	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	Select Hours
Tuesday	01:00	22:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	Select Hours
Wednesday	02:00	21:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	Select Hours
Thursday	03:00	20:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	Select Hours
Friday	04:00	19:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	Select Hours
Saturday	05:00	18:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	Select Hours
Sunday	06:00	17:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	Select Hours

Hours Note: Open as needed trigger test  
 Edit Save Clear

ECLEP MANUAL

home > permit materials > lab profile > hours Select Facility

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

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

Reapplication Period: Mar 13, 2025 through Apr 01, 2025 at 12:59 AM, EDT Reapplication Center

General Information  
Regulatory Information  
Hours  
Contact Person  
Accounting Information

PFI: 0000 Name: Internal Test for CLEP Dev CNSE 19

Lab Hours

Enter hours in military (24-hour) format. Example: 11:00 pm is 23:00 hours.

Monday	00:00	24:00	<input checked="" type="radio"/> 24 Hours	<input type="radio"/> Closed	<input type="radio"/> Select Hours
Tuesday	01:00	22:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours
Wednesday	02:00	21:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours
Thursday	03:00	20:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours
Friday	04:00	19:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours
Saturday	05:00	18:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours
Sunday	00:00	24:00	<input checked="" type="radio"/> 24 Hours	<input type="radio"/> Closed	<input type="radio"/> Select Hours

Hours Note: Open as needed trigger test

Edit Save Clear

home > permit materials > lab profile > hours Select Facility

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

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

Reapplication Period: Mar 13, 2025 through Apr 01, 2025 at 12:59 AM, EDT Reapplication Center

General Information  
Regulatory Information  
Hours  
Contact Person  
Accounting Information

**Pending Changes:**

Sunday: 00:00 - 24:00 was: 06:00 - 17:30 Cancel Selected Changes

PFI: 0000 Name: Internal Test for CLEP Dev CNSE 19

Lab Hours

Enter hours in military (24-hour) format. Example: 11:00 pm is 23:00 hours.

Monday	00:00	24:00	<input checked="" type="radio"/> 24 Hours	<input type="radio"/> Closed	<input type="radio"/> Select Hours
Tuesday	01:00	22:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours
Wednesday	02:00	21:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours
Thursday	03:00	20:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours
Friday	04:00	19:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours
Saturday	05:00	18:30	<input type="radio"/> 24 Hours	<input type="radio"/> Closed	<input checked="" type="radio"/> Select Hours
Sunday	00:00	24:00	<input checked="" type="radio"/> 24 Hours	<input type="radio"/> Closed	<input type="radio"/> Select Hours

Hours Note: Open as needed trigger test

Edit Save Clear

## ECLEP MANUAL

### *Contact Person link*

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 semicolon.

The screenshot displays the ECLEP web application interface. At the top, there are navigation tabs: Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, Blood Resources, and Tools. Below these are sub-tabs: Lab Profile, Ownership, Personnel, Permit Categories/Tests, and PSCs and Others. A green banner indicates the 'Reapplication Period: Mar 10, 2023 through Mar 31, 2023 at 05:00 PM, EDT' with a 'Reapplication Center' link. The left sidebar contains a menu with 'Contact Person' highlighted in red. The main area shows a 'Pending Changes' section for a contact person with the following details: First Name: Janette, Last Name: Doe, Telephone: 5183309999, and Email: dummyemail@test.com, hello@test.com. A 'Cancel Selected Changes' button is visible. Below this is the 'Contact Person' form with input fields for First Name (Janette), Middle Name, Last Name (Doe), Telephone (518-330-9999), and Email (dummyemail@test.com, hello@test.com). A 'Save' button is highlighted in red at the bottom left of the form.

## ECLP MANUAL

### **Accounting Information link**

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

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

**Reference fee invoices are emailed to the laboratory and are not mailed in hard copy. Please see our [Laboratory Fees webpage](#) for more information.**

The screenshot shows a web application interface with a top navigation bar containing links like 'Permit Materials', 'Proficiency Testing', 'Gross Annual Receipts', 'LDT Approval', 'Survey', 'Blood Resources', 'Single Use Permit', and 'Tools'. Below this is a sub-navigation bar with 'Lab Profile', 'Ownership', 'Personnel', 'Permit Categories/Tests', and 'PSCs and Others'. The main content area is titled 'Accounting Information' and includes a 'Save' button highlighted with a red box. The form contains fields for 'Entity Name', 'First Name', 'Last Name', 'Telephone', 'Email', 'Street Address', 'Suite/Room/Building Number', 'City', 'Country', 'State/Province', and 'Zip Code'. A 'Save' button is also highlighted with a red box at the bottom left of the form area.

## ECLEP MANUAL

### Ownership

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

Please reference the [Instructions](#) document, available from the list on the left side of the screen, for definitions and examples of ownership structures.

**\*\*Reapplication Period: Laboratories are required to upload a list of direct and indirect owners using the Upload Feature.**

#### Definitions:

- **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.



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**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.
- **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 link**

This webpage 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 and indirect owners 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.

**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):

ECLEP MANUAL

- **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.

**PLEASE NOTE:** If a laboratory has declared a change in ownership at the time of renewal, the laboratory must submit a new Disclosure of Ownership, Controlling Interest, and Corporate Membership Statement (DOS). This document should be uploaded with the list of direct and indirect owners.

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**Declaration link**

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

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

[Instructions](#)  
[Cancel](#)  
• Declaration  
[Upload](#)

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

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

Yes    No

On a separate sheet, list the name and address of the individual(s) or entity(ies), a description of the charge(s) and dispositions of the charge(s), including dates. The PFI of the laboratory must be included on this sheet. This sheet must be uploaded in the field labeled "Director/Owner Violation or Charges" on the Upload page.
- Has the director, any assistant director(s), or those having direct or indirect ownership, controlling interest, or corporate membership in the applying clinical facility ever been charged with any crime, including but not limited to any offense related to the furnishing of, or billing for, clinical laboratory services, medical care, services, or supplies, or which is considered an offense involving theft or fraud? To the extent that such charges are currently pending, respond "Yes".

Yes    No

On a separate sheet, list the name and address of the individual(s) or entity(ies), a description of the charge(s) and dispositions of the charge(s), including dates. The PFI of the laboratory must be included on this sheet. This sheet must be uploaded in the field labeled "Director/Owner Crime Conviction" on the Upload page.
- Is any individual with a direct or indirect ownership or controlling interest in the applying clinical facility a licensed health professional authorized by law to order clinical laboratory tests and receive results? Note that a "Yes" response is expected if any direct or indirect owners are licensed physicians with 10% or greater ownership or controlling interest.

Yes    No

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

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

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

Yes  No

Management Company

**Name:**

**Address:**

**City:**

**Country:**

**State/Province:**  **Zip:**

Management Contact Information

**First Name:**

**Middle Name:**

**Last Name:**

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

**Email:**

ECLEP MANUAL

**Upload link**

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

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

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

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

**Ownership / Declaration Upload**

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

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

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

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

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

Items with an asterisk (\*) are required.

-List of Owners-

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

-List of Other Labs Owned-

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

-Director/Owner Violation or Charges-

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

-Director/Owner Crime Conviction-

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

-List of Authorized Individuals-

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

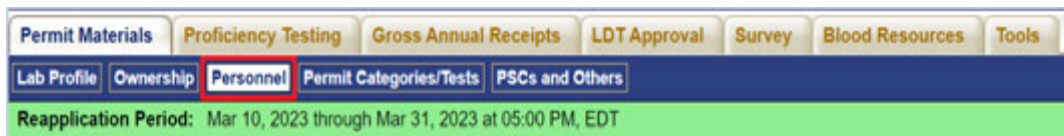
Save Clear

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**Personnel**

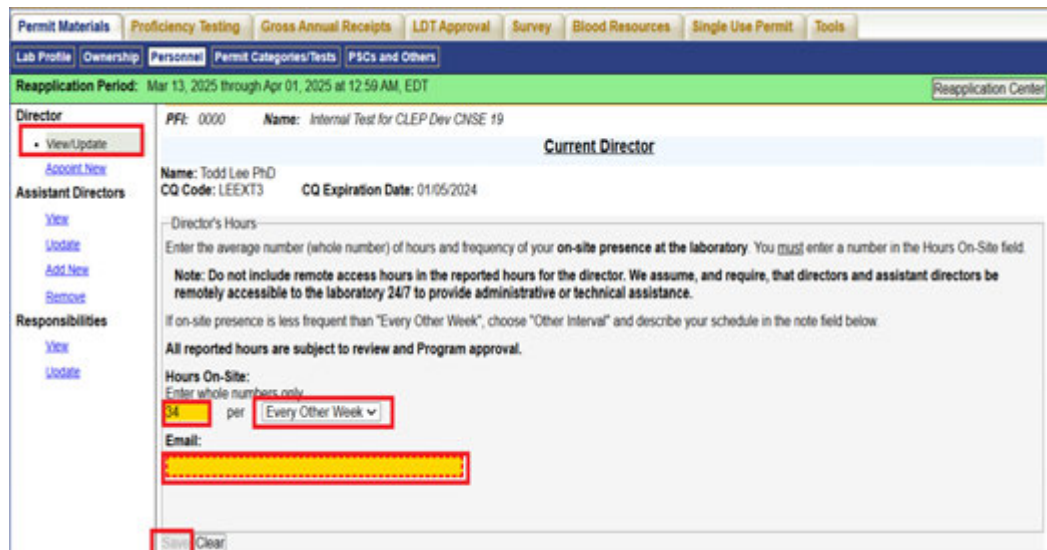
The **Personnel** section has many subsections, including Director, Assistant Director, and Responsibilities. Note that any **yellow highlighted** areas are required. You will need to know the Certificate of Qualification (**CQ**) code of any new directors or assistant directors. The CQ code (five letters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

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



**Director subsection**

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



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

The screenshot displays the 'Director's Hours' section of the ECLEP application. The interface includes a navigation menu on the left with options like 'View/Update', 'Assistant Directors', and 'Responsibilities'. The main content area shows 'Pending Changes' for 'Hours On-Site' with a value of 34 and a weekly total of 26. Below this, the 'Current Director' information is listed: Name: Todd Lee PhD, CQ Code: LEEXT3, and CQ Expiration Date: 01/05/2024. The 'Director's Hours' section contains instructions and a form. The 'Hours On-Site' field is set to 20 per 'Other Interval'. A note field is highlighted with a red box, indicating where the user should describe the frequency if 'Other Interval' is chosen. The 'Email' field is also visible at the bottom of the form.



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

**Note:** The incoming director must hold a valid Certificate of Qualification and their 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](mailto:CLEPCERT@health.ny.gov) for alternate instructions.

The screenshot shows the eCLEP system interface. At the top, there are tabs for 'Lab Profile', 'Ownership', 'Personnel', 'Permit Categories/Tests', and 'PBCs and Others'. Below the tabs, the 'Personnel' tab is active, showing a 'Director' profile for 'Internal Test for CLEP/CLNSE Q19 EVAL'. The 'Appoint New' option is highlighted in the left-hand navigation menu. A warning box is displayed, stating that the incoming director must hold a valid Certificate of Qualification and that the CQ code must be entered. Below the warning box, the 'Appoint A New Director' form is visible, with fields for 'Outgoing Director', 'New Director', 'CQ Code of New Director', 'Starting Date', and 'Email'. The 'CQ Code of New Director' field is highlighted in yellow.

- Note, when a new Laboratory Director is appointed, they must also complete and submit an HCS Affiliation Request form available at [www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce](http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce). The completed, signed document must be scanned and emailed to [CLEP@health.ny.gov](mailto:CLEP@health.ny.gov).
- 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](mailto:CLEPCERT@health.ny.gov) for alternate instruction.

**New York State Public Health Law at Section 575 states that a permit shall become void by a change in the director, owner, or location. Therefore, timely transition to a new qualified director is essential. Please email [CLEPCERT@health.ny.gov](mailto:CLEPCERT@health.ny.gov) for assistance.**

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On the following screen, enter the new director's on-site hours (whole number ONLY), select the frequency from the drop-down menu, enter the new director's email address. Click **Next**.

The screenshot shows the 'Appoint A New Director' form. The 'Hours On-Site' section has a text input field containing '8' and a dropdown menu set to 'Weekly'. The 'Email' field is empty. The 'Next' button is highlighted with a red box.

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

The screenshot shows the 'Appoint A New Director' form with the frequency dropdown set to 'Other Interval'. A text input field below the dropdown contains the text: 'Describe On-Site Frequency if "Other Interval" is chosen: "As needed" or "on-call" will not be accepted.' The 'Email' field is empty. The 'Next' button is highlighted with a red box.

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

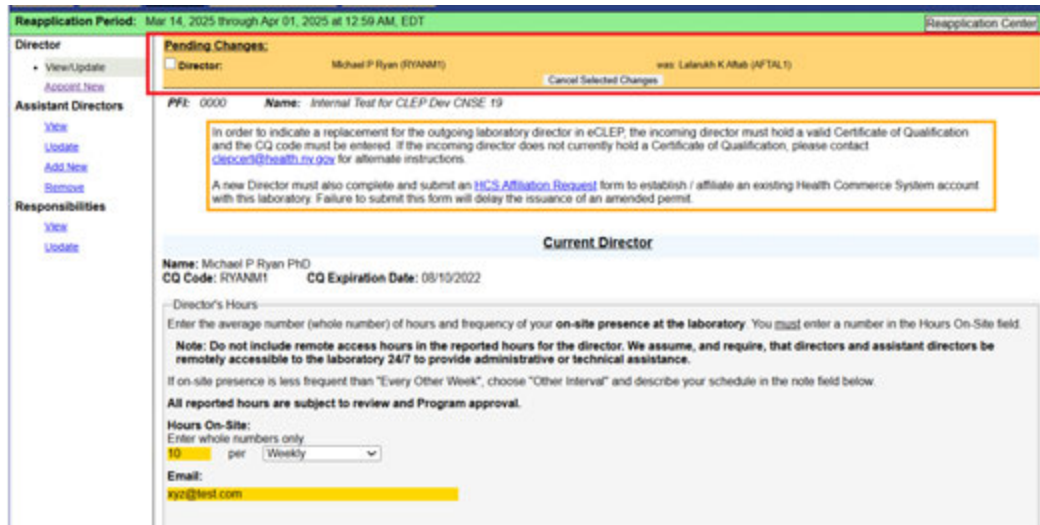
Indicate the permit categories in which the new director will have responsibilities, click **Finish**. The check box list includes all categories either held or in applied status for the laboratory.

**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 their 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 they are 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**.

The next page will display the new director change. Review the information for accuracy.

ECLP MANUAL

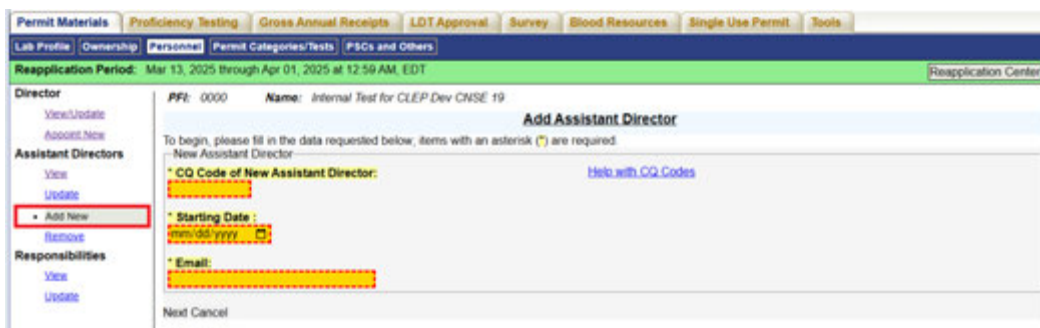


**Assistant Director subsection**

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).

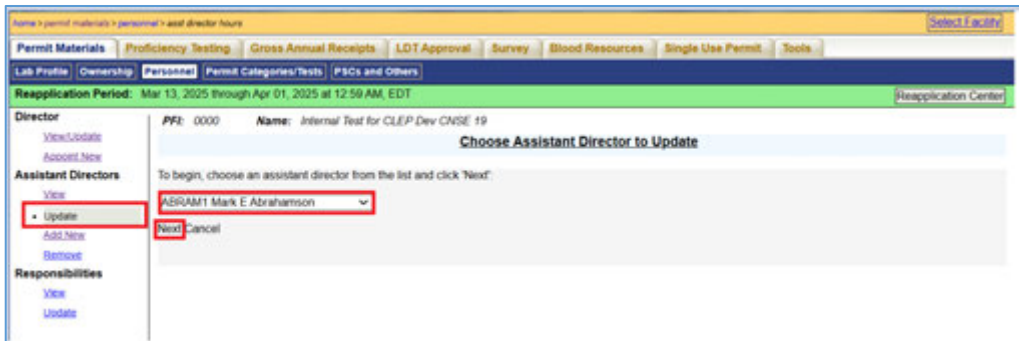


To add an **Assistant Director**, please follow the steps as presented above for appointing a new Laboratory Director.

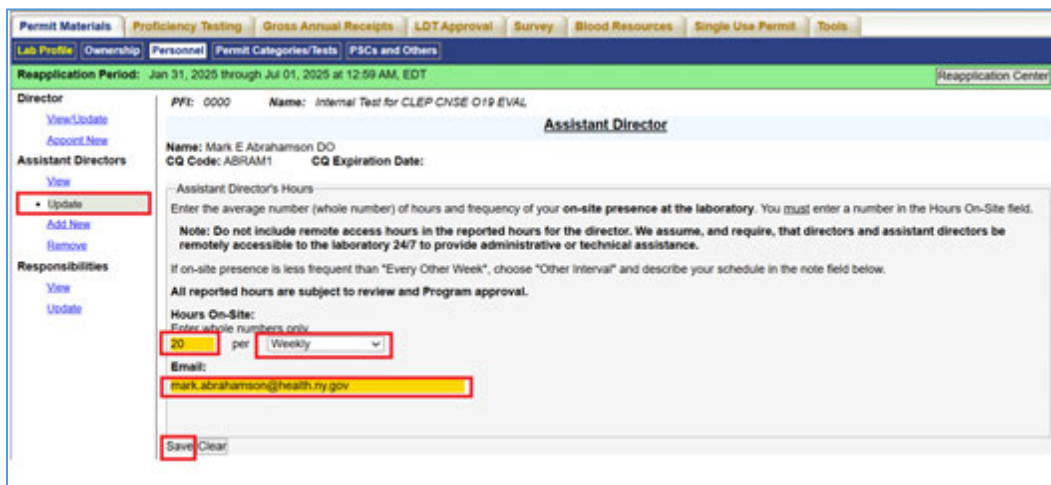


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- To update the on-site hours for an Assistant Director, either click on the individual's name in the **View** page (see above) or choose the individual from the drop-down list presented on the **Update** page, click **Next**.



- On the next screen, update the hours and/or email 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.



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

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

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

Reapplication Period: Jan 31, 2025 through Jul 01, 2025 at 12:59 AM, EDT [Reapplication Center]

Director: PFE: 0000 Name: Internal Test for CLEP CNSE O19 EVAL

**Assistant Director**

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

Assistant Director's Hours:  
Enter the average number (whole number) of hours and frequency of your on-site presence at the laboratory. You must enter a number in the Hours On-Site field.  
Note: Do not include remote access hours in the reported hours for the director. We assume, and require, that directors and assistant directors be remotely accessible to the laboratory 24/7 to provide administrative or technical assistance.  
If on-site presence is less frequent than "Every Other Week", choose "Other Interval" and describe your schedule in the note field below.  
All reported hours are subject to review and Program approval.

Hours On-Site:  
Enter whole numbers only  
20 per Other Interval

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

Email:  
mark.abrahamson@health.ny.gov

Save Clear

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

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

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

Reapplication Period: Jan 31, 2025 through Jul 01, 2025 at 12:59 AM, EDT [Reapplication Center]

Director: PFE: 0000 Name: Internal Test for CLEP CNSE O19 EVAL

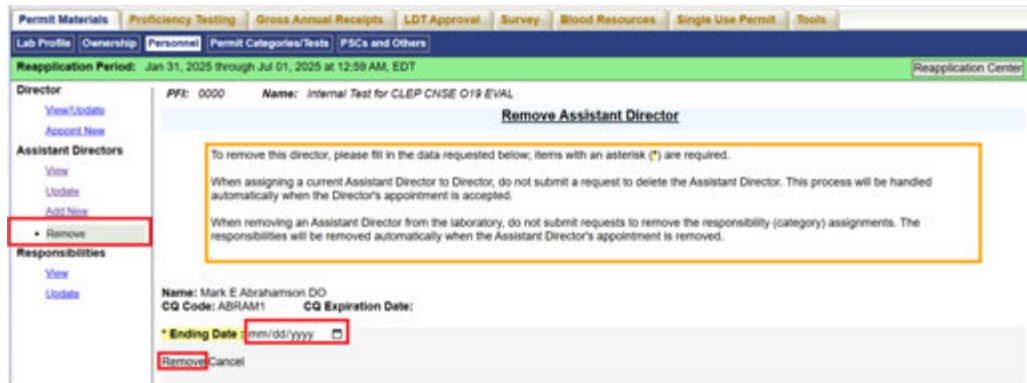
**Assistant Directors**

ABRAM1	Mark E. Abrahamson	remove
--------	--------------------	--------

View/Update  
Appoint New  
Assistant Directors  
View  
Update  
Add New  
Remove  
Responsibilities  
View  
Update

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

ECLEP MANUAL

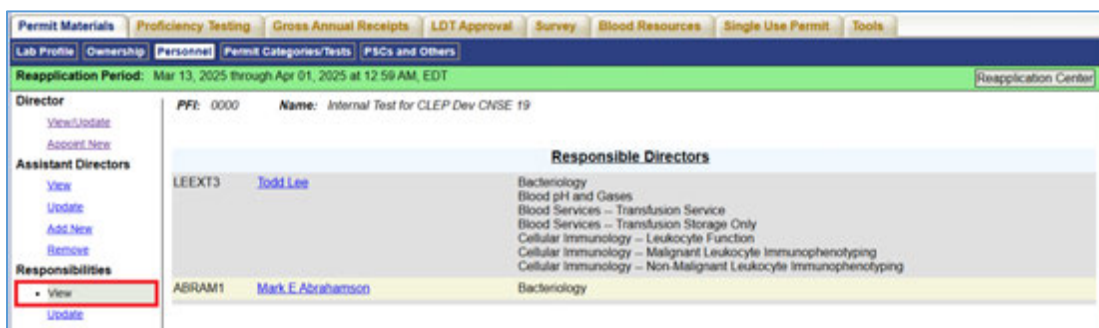


**Note:** If the departing assistant director is the sole individual responsible for a permit category(ies), the Clinical Laboratory Evaluation Program will notify the director that the laboratory is in jeopardy of losing an approved (or pending) permit category unless a timely arrangement is made for assigning a qualified person (current or new) to be responsible for the permit category.

**New York State Public Health Law at Section 575 states that a permit shall become void by a change in the director, owner, or location. Therefore, timely transition to a new qualified director is essential. Please email [CLEPCERT@health.ny.gov](mailto:CLEPCERT@health.ny.gov) for assistance.**

**Responsibilities subsection**

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



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

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'.

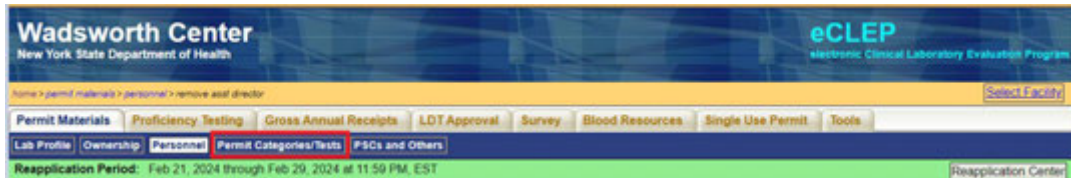


## ECLP MANUAL

### Permit Categories/Tests

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

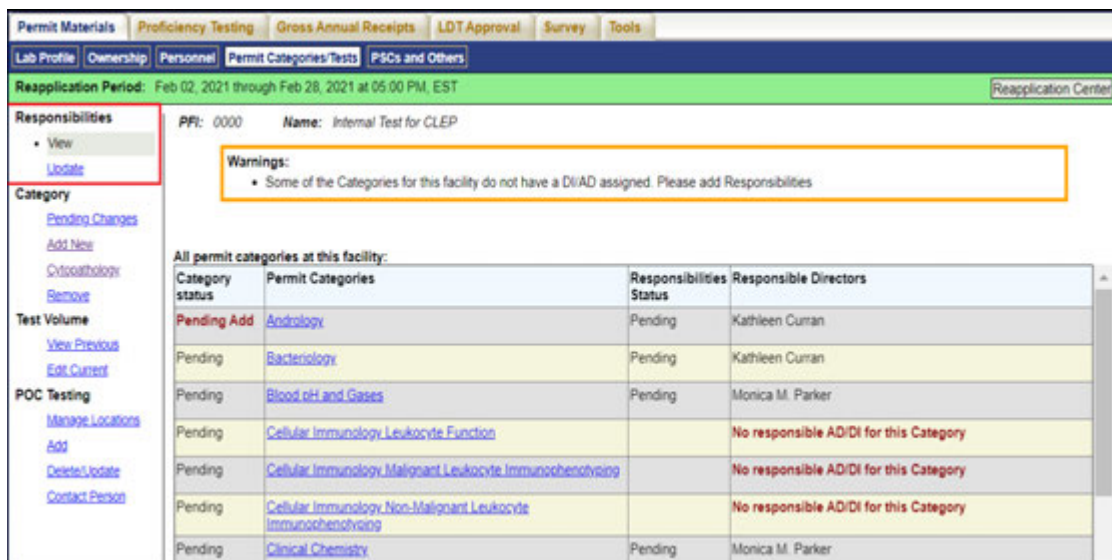
- add permit categories to the laboratory permit;
- change permit category responsibilities for the laboratory director and/or assistant director(s);
- remove permit categories from the laboratory permit;
- enter test volumes (required for laboratories located in NYS during permit reapplication).



### Responsibilities subsection

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.



**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.

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

ECLP 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 PFI or CLIA number is not already included.
- If the laboratory personnel participate in PT at another site, the order confirmation for “paper enrollment” must be provided.

The screenshot shows a web application interface with a top navigation bar containing tabs: Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, and Tools. Below this is a sub-navigation bar with tabs: Lab Profile, Ownership, Personnel, Permit Categories/Tests, and PSCs and Others. A green banner indicates the 'Reapplication Period: Feb 02, 2021 through Feb 28, 2021 at 05:00 PM, EST' and a 'Reapplication Center' button.

The main content area is titled 'Cytopathology Gynecological Proficiency Testing'. It includes a 'Responsibilities' section with links for 'View', 'Update', and 'Add New'. A 'Category' section has links for 'Pending Changes', 'Add New', and 'Cytopathology' (which is highlighted with a red box). A 'Test Volume' section has links for 'View Previous' and 'Get Current'.

The 'Add New' section contains the following text:
 

- PFI: 0000 Name: Internal Test for CLEP
- 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.
- If all of your laboratory's employees take the test elsewhere, your laboratory must still be enrolled ("paper enrollment" or "laboratory enrollment only") to maintain the category. Please submit proof of paper enrollment with notification that the test is taken elsewhere. Please contact your proficiency test provider about obtaining a proof of enrollment when all employees take a PAP PT elsewhere. PT enrollment confirmations from the site where the PT is taken will not be accepted as confirmation for your laboratory.

An 'Uploaded Files' table is shown with the following data:

File	Name	Uploaded By	Time
Cytopathology	ECLP SURVEY FILE NET FLOW DIAGRAM.pdf	-	02-Jan-2019 9:48 AM

Below the table, there 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. The file name can contain only numbers, letters and a period. Spaces and special characters are not allowed.' A note below that states: 'Items with an asterisk (\*) are required -Cytopathology-'. At the bottom, there is a 'File Name' field with a 'Choose File' button and 'No file chosen' text, along with 'Save' and 'Clear' buttons.

ECLP MANUAL**Add a Category**

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

The screenshot shows the 'Add New Category' form in the ECLP system. The form is titled 'Add New Category' and is part of a 'Permit Categories/Tests' section. The left navigation menu has 'Add New' highlighted. The main form area contains the following fields and instructions:

- Permit Category:** A dropdown menu with the text '---Select a Category---'.
- or**
- Search for Category by Test Name:** A search box with a 'Search' button.
- CQ Code:** A dropdown menu with the text '---Select a CQ Code---'.
- Are you testing using a Laboratory-developed test?:** Radio buttons for 'Yes' and 'No'.
- Additional Information:** A text area with a placeholder: 'If you would like to provide additional information regarding this Add Category request, please enter below. (200 characters max)'.

Instructions on the page state: '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](http://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 the Certificate of Qualification or be in the process of adding the category to the CQ. If the responsible person for the new permit category is a new Assistant Director, you must add them via the Personnel tab before their CQ code is visible in the dropdown list. If your laboratory is proposing to offer laboratory developed tests (LDT) in the new permit category you must submit the materials specified in the Test Approval section of the Clinical Laboratory Evaluation Program's public website [Test Approval](#) for each LDT and receive explicit approval prior to initiating patient testing.'

Choose the desired permit category from the dropdown menu. Add a responsible director or assistant director for the new category using the individual's CQ code and indicate whether testing is being performed using a Laboratory-developed test. 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 **Permit Category** and **CQ Code** and the question "**Are you testing using a Laboratory-developed test?**" fields are mandatory.

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

ECLP MANUAL

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

**Category**

[Pending Changes](#)

[Add New](#)

[Cytopathology](#)

[Remove](#)

**Test Volume**

[View Previous](#)

[Edit Current](#)

### 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](http://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 the Certificate of Qualification or be in the process of adding the category to the CQ. If the responsible person for the new permit category is a new Assistant Director, you must add them via the Personnel tab before their CQ code is visible in the dropdown list.

If your laboratory is proposing to offer laboratory developed tests (LDT) in the new permit category you must submit the materials specified in the Test Approval section of the Clinical Laboratory Evaluation Program's public website [Test Approval](#) for each LDT and receive explicit approval prior to initiating patient testing.

**Permit Category:** Andrology

or

Search for Category by Test Name

**CQ Code:** ABRAM1 Mark E Abraha

**Are you testing using a Laboratory-developed test?:** Yes:  No:

LDTs are non-FDA cleared or approved assays that are developed by the laboratory offering the assay. LDTs may include a combination of reagents and/or kits prepared by the laboratory, labeled as Analyte Specific Reagents (ASR), Research Use Only (RUO), or Investigational Use Only (IUO) that are NOT covered under an explicit FDA Investigational Device Exemption (IDE).

**Additional Information**

If you would like to provide additional information regarding this Add Category request, please enter below. (200 characters max)

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.

Next

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

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

**Category**

[Pending Changes](#)

[Add New](#)

[Cytopathology](#)

[Remove](#)

**Test Volume**

[View Previous](#)

[Edit Current](#)

### 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](http://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 the Certificate of Qualification or be in the process of adding the category to the CQ. If the responsible person for the new permit category is a new Assistant Director, you must add them via the Personnel tab before their CQ code is visible in the dropdown list.

If your laboratory is proposing to offer laboratory developed tests (LDT) in the new permit category you must submit the materials specified in the Test Approval section of the Clinical Laboratory Evaluation Program's public website [Test Approval](#) for each LDT and receive explicit approval prior to initiating patient testing.

**Permit Category:** Andrology

or

Search for Category by Test Name

**CQ Code:** ABRAM1 Mark E Abraha

**Are you testing using a Laboratory-developed test?:** Yes:  No:

LDTs are non-FDA cleared or approved assays that are developed by the laboratory offering the assay. LDTs may include a combination of reagents and/or kits prepared by the laboratory, labeled as Analyte Specific Reagents (ASR), Research Use Only (RUO), or Investigational Use Only (IUO) that are NOT covered under an explicit FDA Investigational Device Exemption (IDE).

**Additional Information**

If you would like to provide additional information regarding this Add Category request, please enter below. (200 characters max)

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.

Next

## ECLP MANUAL

### Indicate Tests Offered on NYS Specimens

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

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

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

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

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

**Responsibilities**

[View](#)

[Update](#)

**Category**

[Pending Changes](#)

[Add New](#)

[Upload](#)

[Remove](#)

**Test Volume**

[View Previous](#)

[Edit Current](#)

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

**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	<span style="border: 1px solid gray; padding: 2px;">▼</span>
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	<span style="border: 1px solid gray; padding: 2px;">▼</span>
Identification of respiratory bacterial pathogens by molecular methods	<span style="border: 1px solid gray; padding: 2px;">▼</span>
Chlamydia/Neisseria gonorrhoeae by direct detection	<span style="border: 1px solid gray; padding: 2px;">▼</span>
Clostridium difficile direct detection	<span style="border: 1px solid gray; padding: 2px;">▼</span>
Group A Streptococcus direct detection	<span style="border: 1px solid gray; padding: 2px;">▼</span>
Gram stains	<span style="border: 1px solid gray; padding: 2px;">▼</span>
Susceptibility (bacterial) testing (AST)	<span style="border: 1px solid gray; padding: 2px;">▼</span>

Showing 1 to 11 of 11 entries    1 row selected

Previous 1 Next

Next Clear

ECLP MANUAL

**Designate PT Provider and Product**

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

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

All fields in this form are mandatory.

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

The screenshot shows a web application interface for designating PT providers and products. The main content area is titled "Designate PT provider and product" and includes a "Name" field with the value "D12 DEV Internal Test for CLEP TEST 1 DUMMY". Below this is a table of test designations. The table has three columns: "Test Name", "Provider", and "Product". The "Edit New" button in the left sidebar and the "Save" button at the bottom left are highlighted with red boxes.

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 E	Genital Culture - 200623
Identification of genital pathogens (bacterial) by molecular methods	College of American Path	Vaginitis Screen - VS
Identification of respiratory bacterial pathogens by molecular methods	College of American Path	Infectious Disease Respir
Group A Streptococcus direct detection	American Academy of Fa	Group A Strep - 783
Gram stains	Medical Laboratory Evalu	Bacteriology 2 - 640
Susceptibility (bacterial) testing (AST)	Accutest Inc	Bacterial Identification - B

ECLP 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																														
<b>Responsibilities</b> PFI: 0000    Name: Q12 DEV Internal Test for CLEP TEST 1 DUMMY <a href="#">View</a> <a href="#">Update</a>																																			
<b>View Designations</b>																																			
<b>Category</b> 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.																																			
<a href="#">Pending Changes</a> <span style="border: 1px solid red; padding: 2px;">Add New</span> <a href="#">Upload</a> <a href="#">Remove</a>																																			
<b>Test Volume</b> <a href="#">View Previous</a> <a href="#">Edit Current</a>																																			
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<b>Category</b>	<b>Test</b>																																		
<span style="border: 1px solid red; padding: 2px;">Next</span>																																			



## ECLP MANUAL

### Adding More Than One CQ Holder to a New Category

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

The screenshot shows the ECLP interface with the 'View' option highlighted under the 'Responsibilities' section. The main content area displays a table of permit categories at the facility:

Category status	Permit Categories	Responsibilities Status	Responsible Directors
Pending Add	<a href="#">Bacteriology</a>	Pending	Todd Lee
Approved	<a href="#">Blood pH and Gases</a>		Todd Lee
Pending Add	<a href="#">Clinical Chemistry</a>	Pending	Todd Lee
Pending Add	<a href="#">Virology</a>		Todd Lee

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

The screenshot shows the 'Add/Remove Responsibilities' dialog box. At the top, it indicates 'Pending Changes' for 'Todd Lee' with an 'ADD' button and 'was: N/A'. Below this, the 'Category Name' is 'Bacteriology' and the 'Responsible AD/DI' is 'Todd Lee'. A table of 'Available AD/DI' is shown below:

Person Id	Person Name	Add/Remove Responsibility
LEEXT3	Todd Lee	Pending
PARKM1	Monica M. Parker	<a href="#">Add</a>
TAYLJ1	Jill Taylor	<a href="#">Add</a>

### 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.

The screenshot shows a web application interface with a top navigation bar containing tabs: Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, and Limited Labs. Below this is a secondary navigation bar with tabs: Lab Profile, Ownership, Personnel, Permit Categories/Tests, PSCs and Others, and Tools. A green banner displays the 'Reapplication Period: Apr 01, 2018 through Dec 15, 2018 at 05:00 PM, EST' and a 'Reapplication Center' button. The main content area is divided into sections: 'Responsibilities' (with links for View, Update, Add New, Upload, Remove), 'Category' (with a sub-section for 'Pending Changes' highlighted by a red box), and 'Test Volume' (with links for View Previous, Edit Current). The 'Pending Changes' section lists three items: Bacteriology: PT Changes, Clinical Chemistry: PT Changes, and Virology: PT Changes. Each item has a checkbox, the text 'Add', and 'WBS: ~'. A 'Cancel Selected Changes' button is located at the bottom of this list.

## 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 interface includes a top navigation bar with 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 displays 'Reapplication Period: Apr 01, 2018 through Dec 15, 2018 at 05:00 PM, EST' and a 'Reapplication Center' button. The 'Delete Permit Category' form includes a 'Category Information' section with a 'Permit Category' dropdown menu (currently showing '---Select a Category---') and an 'Effective Date' field. A 'Delete' button and a 'Clear' button are located below the form. On the left side, there is a sidebar with 'Responsibilities' and 'Category' sections. The 'Remove' button in the 'Category' section is 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 as the previous one, but with a calendar pop-up open over the 'Effective Date' field. The calendar is for December 2018, with the 4th day highlighted in yellow. The 'Delete' button and 'Clear' button are visible below the form. The sidebar on the left remains the same, with the 'Remove' button highlighted.

**eCLEP MANUAL****Test Volume**

**NEW FOR 2025: All laboratories holding a permit must report Test Volume.**

**Test Volume** reporting is required 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 [CLEPREAPP@health.ny.gov](mailto:CLEPREAPP@health.ny.gov) 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 viewing test volume data. The main content area displays a table titled 'Specialty/SubSpecialty Total' with the following data:

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

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

ECLP MANUAL

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

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

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

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

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

Category:  No Tests performed this year  
Reason for not performing any tests this year:

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

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

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

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

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

PFI: 0000 Name: Internal Test for CLEP 1

**Reapplication Mode** [Request for an Extension Date](#)

It's time to reapply for your facility's permit.  
Click the 'Enter' button below to complete the reapplication process and ensure you receive your new permit by July 1.

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

**Current Data on File (without pending changes)**  
[View Summary](#)

**Electronic Submissions**

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

ECLP MANUAL

**POC Testing**

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

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

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

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

Responsibilities PFI: 0000 Name: Internal Test for CLEP 1

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

Category

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

Test Volume

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

POC Testing

**Manage Location**

[Add](#)  
[Delete/Update](#)  
[Contact Person](#)

### Manage Point-of-Care Testing Locations

Point-Of-Care Testing Questions

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

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

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

Yes  No

Existing Locations

\* Deleting an existing location will delete all the associated data

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

Add New Location

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

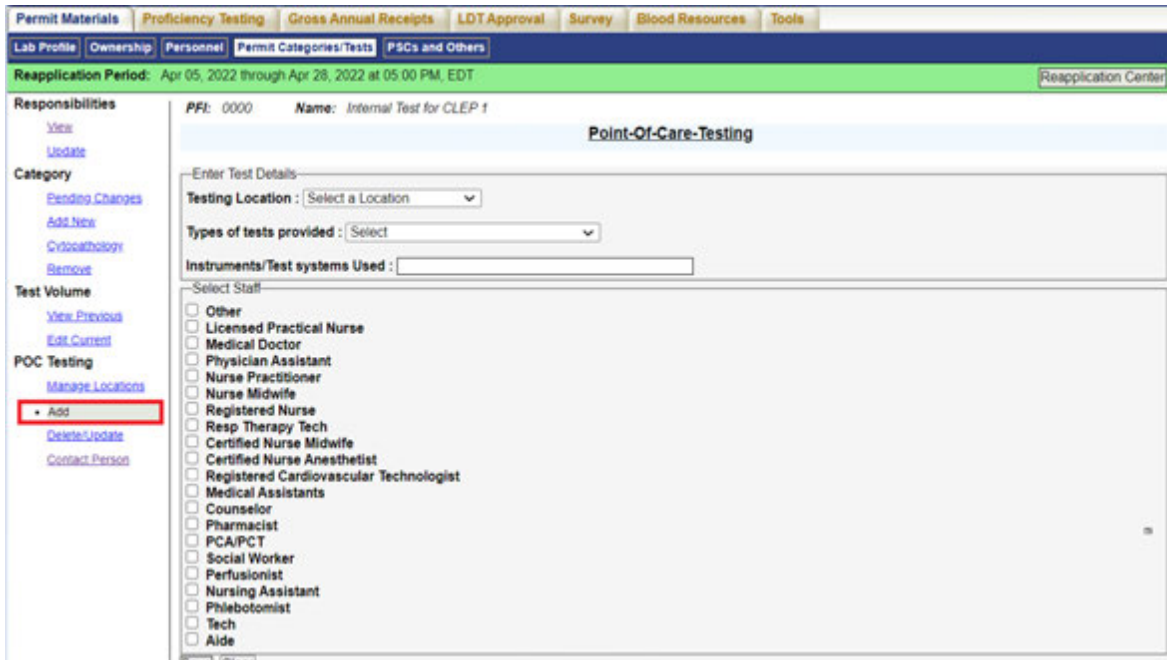
Location Type:

Location Desc:

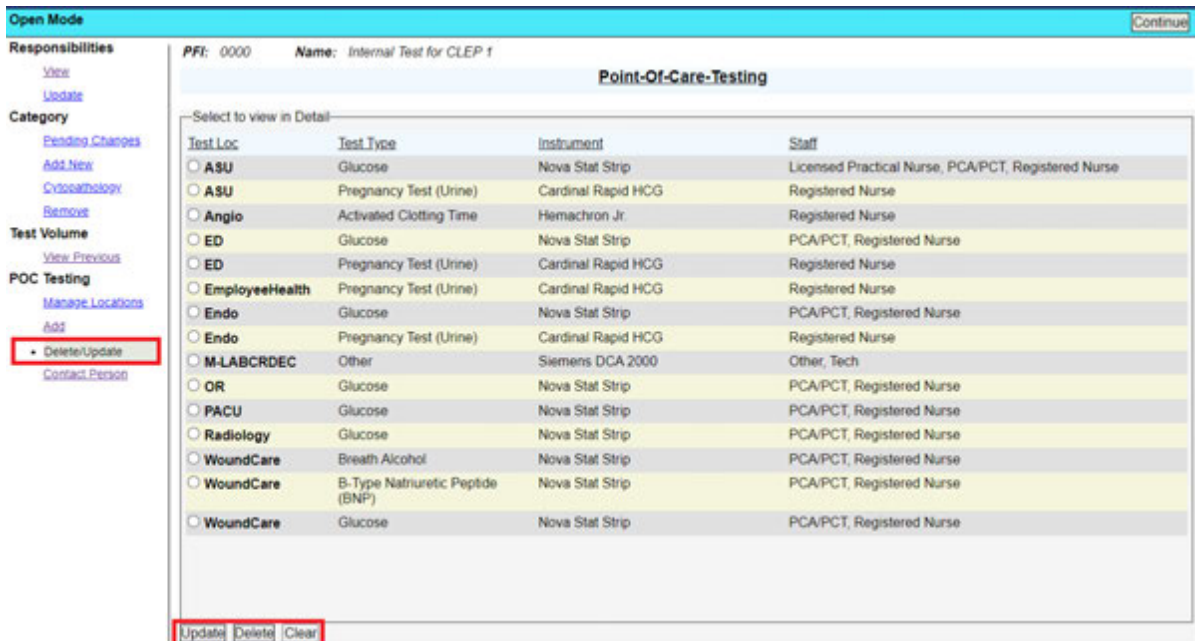
CLIA Number:  (If separate number for this site)

- 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**.

ECLP MANUAL



- 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.



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

ECLEP MANUAL

**Open Mode** Continue

Responsibilities PFI: 0000 Name: Internal Test for CLEP 1

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

**Category**

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

**Test Volume**

[View Previous](#)

**POC Testing**

[Manage Locations](#)

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

**Point-Of-Care-Testing**

Enter Test Details

Testing Location :

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](#)

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

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

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

**Open Mode** Continue

Responsibilities PFI: 0000 Name: Internal Test for CLEP

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

**Category**

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

**Test Volume**

[View Previous](#)

**POC Testing**

[Manage Locations](#)

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

**Point-Of-Care Contact Person**

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

POC Contact Person Details

Salutation:

Title:

First Name:

Middle Name:

Last Name:

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

Email:

Save [Clear](#)



## ECLP MANUAL

### PSCs and Others

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



### *PSC Reapplication*

During the reapplication period, 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. Contact [CLEPPSC@health.ny.gov](mailto:CLEPPSC@health.ny.gov) with any questions.

A screenshot of a web form titled 'PSCs and Others'. On the left side, there is a vertical menu with three links: 'Health Fair', 'Health Fair Test', and 'PSC'. The 'PSC' link is circled in red. The main content area shows 'PFI: 0000' and 'Name: ABC Lab'. Below this, there is a text box containing instructions: 'To access the various station functions, use the menu on the left. If you anticipate opening a new patient service center or operating a new health fair, please select the appropriate menu option.' A yellow highlighted line contains a mandatory checkbox: '\*  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 'Save' and 'Clear' buttons.

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.

<a href="#">PSCs and Others Home</a> <a href="#">New / Select</a> <ul style="list-style-type: none"> <li>Stations on File</li> </ul>	PFI: 0000    Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY <b>Patient Service Centers on File</b>	<a href="#">Print PSC Listing</a>	
	Station ID: 0000-0001    Status: N/A - Open <b>Station Info</b> POBox 509 Empire State Plaza Albany, NY, 12201-0509 <b>Contact Info</b>	<b>Hours</b> Mon 05:30 AM to 03:30 PM Tue 05:30 AM to 03:30 PM Wed 05:30 AM to 03:30 PM Thu 05:30 AM to 03:30 PM Fri 05:30 AM to 03:30 PM Sat Off/Closed Sun Off/Closed Note	
	Station ID: 0000-0002- Test PSC    Status: Approved - Open <b>Station Info</b> Test PSC 30 South Broadway in the basement ALBANY, NY, 12208 <b>Contact Info</b> Frodo Khan p@w.com 518-445-8877	<b>Hours</b> Mon Open 24 hours Tue Off/Closed Wed Open 24 hours Thu Open 24 hours Fri Off/Closed Sat Off/Closed Sun Off/Closed Note	

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

<a href="#">PSCs and Others Home</a> <ul style="list-style-type: none"> <li>New / Select</li> <li>Stations on File</li> </ul>	PFI: 0000    Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY Station Status:    Permit Status: <b>Patient Service Center Application</b>
	Items with an asterisk (*) are required. New PSC: <input type="radio"/> *New: Select PSC: 0002 - 30 South Broadway in the basement , ALBANY ▼ Next Clear

### ECLEP MANUAL

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

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

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

[Manage PSC](#)

- Address
- Contact
- Hours
- Self Assessment
- Upload
- Comment

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

#### Patient Service Center Application

Items with an asterisk (\*) are required.

Address

\* **Street Address:**

**Suite/Room/Building Number:**

\* **City:**

\* **State:**

\* **County:**

\* **Zip Code:**

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

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

#### PSCs and Others

**PFI:** 0000 **Name:** ABC Lab

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

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

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

ECLEP MANUAL

**Request a New PSC**

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

PSCs and Others Home

- New / Select
- Stations on File

PFI: 0000 Name: Internal Test for CLEP 1  
 Station Status: Permit Status:

**Patient Service Center Application**

Items with an asterisk (\*) are required.

New PSC  
 \*New:

Select PSC  
 W3403 - 45 Reade Placebo Street test , Poughkeepsie

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  
 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: mm/dd/yyyy

Contact Person Information  
 \* First Name:   
 Middle Name:   
 \* Last Name:   
 Telephone: (###-###-####)   
 Fax: (###-###-####)   
 \* Email:

PSC Contact Information  
 Telephone: (###-###-####)

Address  
 PSC Station Name:   
 \* Street Address:   
 Suite/Room/Building Number:   
 \* City:   
 \* State: New York  
 \* County: Select NY County  
 \* Zip Code:

Hours of Operation  
 Monday: Set Start Time Set End Time  24 Hours  Closed  Select Hours  
 Tuesday: Set Start Time Set End Time  24 Hours  Closed  Select Hours  
 Wednesday: Set Start Time Set End Time  24 Hours  Closed  Select Hours  
 Thursday: Set Start Time Set End Time  24 Hours  Closed  Select Hours  
 Friday: Set Start Time Set End Time  24 Hours  Closed  Select Hours  
 Saturday: Set Start Time Set End Time  24 Hours  Closed  Select Hours  
 Sunday: Set Start Time Set End Time  24 Hours  Closed  Select Hours

Hours Note:

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

Save Clear

ECLP MANUAL

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

**Initial view:**

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

**Current view:**

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

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

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

PFI: 0000    Station: W9623    Name: Internal Test for CLEP  
 Station Status: N/A    Permit Status: N/A

### Patient Service Center Application

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

Self Assessment

1	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 *
2	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.) A health services purveyor is defined in New York State Public Health Law Regulations ? Title 10, NYCRR Subpart 34-2.2	<input type="radio"/> Yes <input type="radio"/> No *
3	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 *
4	Is PSC space subleased from a physician or other health services purveyor, i.e., one who has leasehold interest in the building, in a position to make referrals 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 *
5	Is the PSC located in a building owned or leased by the same laboratory that operates the PSC?	<input type="radio"/> Yes <input type="radio"/> No *
6	Do you have a lease/rental agreement? Please upload a copy of the lease/rental agreement using the upload feature on the left of the screen.	<input type="radio"/> Yes <input type="radio"/> No *
7	Is the PSC open to the general public?	<input type="radio"/> Yes <input type="radio"/> No *
8	Are the hours the PSC is open independent and not restricted to the hours of any health services purveyor indicated in question 1, 2 or 3 above?	<input type="radio"/> Yes <input type="radio"/> No *
9	Are specimens drawn from health services purveyors other than those indicated in question 1, 2 or 3 above?	<input type="radio"/> Yes <input type="radio"/> No *
10	Does the PSC have its own entrance and exit?	<input type="radio"/> Yes <input type="radio"/> No *

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

ECLP MANUAL

PFI: 0000 Station: W9623 Name: Internal Test for CLEP  
 Station Status: N/A Permit Status: N/A

**Patient Service Center Application**

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

28 A	Does the PSC dispose of all specimens and contaminated or potentially contaminated materials or supplies in a manner that would minimize the likelihood of transmission of infectious agents to personnel or to the public?	<input type="radio"/> Yes <input type="radio"/> No *
28 B	Does the PSC store regulated medical waste in a manner and location which affords protection from the environment and limits exposure to the public?	<input type="radio"/> Yes <input type="radio"/> No *
28 C	Does the PSC arrange for regulated medical waste removal from the premises at least every 60 days, or more frequently if greater than 50 lbs per month is generated?	<input type="radio"/> Yes <input type="radio"/> No *
28 D	Does the PSC utilize containers for medical waste which have prominent warning signs using the word "Biohazard"?	<input type="radio"/> Yes <input type="radio"/> No *
28 E	Does the PSC dispose of medical waste, except for discarded sharps, in clearly marked bags which are impervious to moisture and have strength sufficient to resist ripping, tearing, or bursting under normal conditions of usage and handling, and secure them in a manner that prevents leakage during storage, transport, or handling?	<input type="radio"/> Yes <input type="radio"/> No *
28 F	Does the PSC dispose of potentially infectious articles that might cause punctures or cuts in leakproof, rigid, puncture-resistant containers that are secured in a manner to preclude content loss?	<input type="radio"/> Yes <input type="radio"/> No *
29	Does the PSC collect specimens requiring chain of custody protocols (i.e. pre-employment, incident/accident related, return-to-work or paternity testing)?	<input type="radio"/> Yes <input type="radio"/> No *
30 A	Has this PSC been inspected by the laboratory prior to opening?	<input type="radio"/> Yes <input type="radio"/> No *
30 B	Is the inspection record available on-site for review by the Department?	<input type="radio"/> Yes <input type="radio"/> No *

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

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

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

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

[Self Assessment](#)

[Comment](#)

ECLP MANUAL

PSCs and Others Home

New / Select Stations on File

Manage PSC Address Contact Hours Self Assessment

- Upload
- Comment

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

**Patient Service Center Application Upload**

Uploaded Files

File	Name	Uploaded By	Time
Each file uploaded represents the latest file of that type to be uploaded. The previous version of the file has been overwritten.			
The file name can contain only numbers, letters and a period. Spaces and special characters are not allowed.			

Items with an asterisk (\*) are required.

Floor Plan

Please upload a scale floor plan of the PSC that illustrates the relationship between the PSC and any other health services purveyor(s) on the same floor.

\* File Name  No file chosen

Lease/Ownership

\* File Name  No file chosen

**Contact Change at a PSC**

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

PSCs and Others Home

- New / Select
- Stations on File

PFI: 0000 Name: Internal Test for CLEP Dev  
 Station Status: Permit Status:

**Patient Service Center Application**

Items with an asterisk (\*) are required.

New PSC

\*New:

Select PSC

W3403 - 45 Reade Placebo Street test , Poughkeepsie

Click on the **Contact** link on the left panel. Make the necessary changes. Click on **Save**.

PSCs and Others Home

- New / Select
- Stations on File
- Manage PSC
- Address
- Contact
- Hours
- Open / Close
- Comment

Pending Changes:

Email:	q@w.com	was
First Name:	Bo	was
Last Name:	Bo	was
Contact Phone Number:	518-333-2255	was

PFI: 0000 Station: 0001 Name: Internal Test for CLEP  
 Station Status: Open Permit Status: Approved

**Patient Service Center Application**

Items with an asterisk (\*) are required.

Contact Person Information

\* First Name: Bo

Middle Name:

\* Last Name: Bo

\* Telephone: 518-333-2255

Fax:

\* Email: q@w.com

PSC Contact Information

Telephone:

ECLEP MANUAL

**PSC Hours Change**

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

Click on the **Hours** link on the left panel:

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

Click on **Edit** button to enable the fields for editing.

Day	Start Time	End Time	24 Hours	Closed	Select Hours
Monday	05:30	15:30	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Tuesday	05:30	15:30	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Wednesday	05:30	15:30	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Thursday	05:30	15:30	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Friday	05:30	15:30	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Saturday	--	--	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Sunday	--	--	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Modify the information as required and click **Save**.



### ECLP MANUAL

The screenshot shows the 'PSCs and Others' tab selected. The 'Reapplication Period' is Mar 13, 2024 through Jun 29, 2024 at 12:59 AM, EDT. The application details include PFI: 0000, Station: 0001, Name: Internal Test for CLEP, Station Status: Open, and Permit Status: Approved. The 'Patient Service Center Application' section has a note: '(\*) A time entry or a note entry is required.' Below this is the 'Hours of Operation' table:

Day	Start Time	End Time	24 Hours	Closed	Select Hours
Monday	05:30	15:30	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Tuesday	05:30	15:30	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Wednesday	05:30	15:30	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Thursday	05:30	15:30	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Friday	05:30	15:30	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Saturday	00:00	24:00	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sunday	00:00	24:00	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

At the bottom of the hours section, there is a 'Hours Note' field and buttons for 'Edit', 'Save', and 'Clear'.

### Temporary or Permanent Closure of a PSC

Navigate to the PSC webpage:

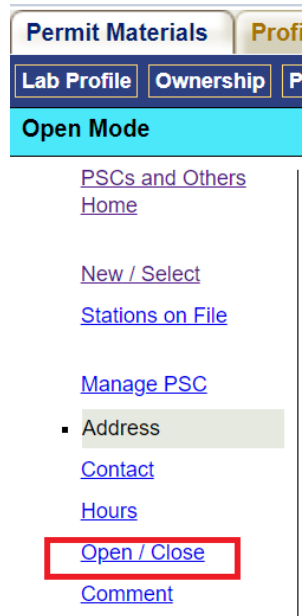
The screenshot shows the 'Permit Materials' page with tabs for 'Lab Profile' and 'Ownership'. Under the 'Open Mode' section, there is a list of items: 'Health Fair', 'Health Fair Test', and 'PSC'. The 'PSC' item is highlighted with a red box.

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

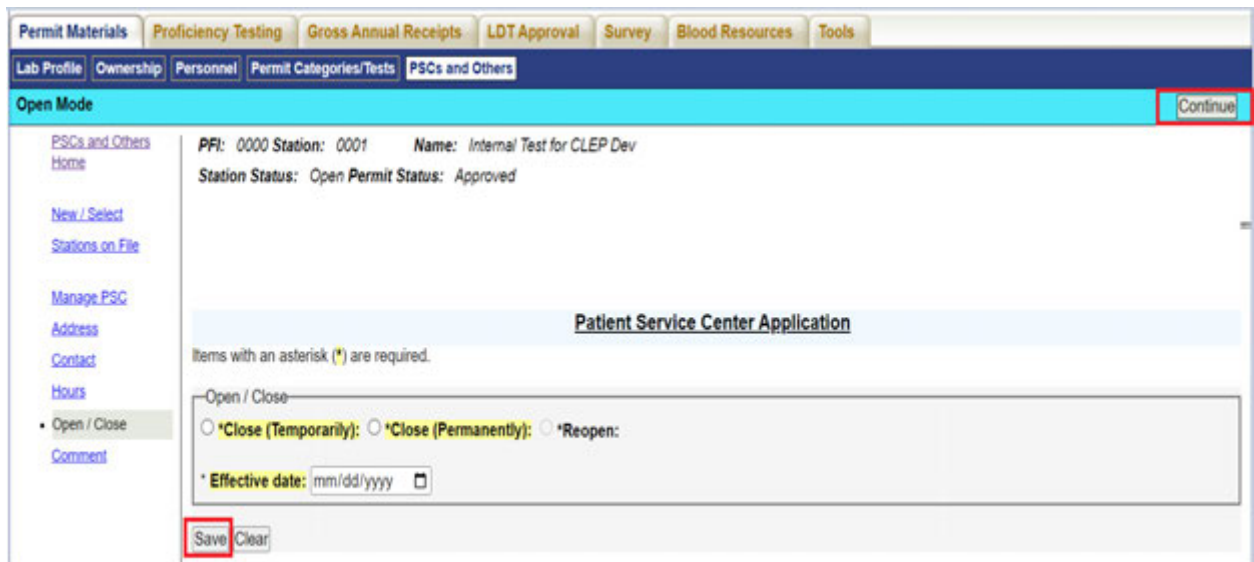
The screenshot shows the 'New/Select' page for a 'Patient Service Center Application'. The 'New PSC' section has a radio button for '\*New:'. The 'Select PSC' section has a dropdown menu with the selected option 'W3403 - 45 Reade Placebo Street test , Poughkeepsie'. The 'Next' button is highlighted with a red box.

ECLP MANUAL

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



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



ECLEP MANUAL

**Health Fair Reapplication**

During the reapplication period, 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 **P#:** 0000 **Name:** ABC Lab  
Health Fair Test  
PSC

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

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

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

Save Clear

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.

<a href="#">PSCs and Others Home</a> <b>Health Fair</b> <a href="#">View/Update</a> <a href="#">Remove</a> <b>Health Fair Tests</b> <a href="#">View</a> <a href="#">Update</a> <a href="#">Add New</a> <a href="#">Remove</a>	<b>Pending Changes:</b> <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 <a href="#">Cancel Selected Changes</a>					
	<b>PFI:</b> 0000 <b>Name:</b> Internal Test for CLEP TEST(WCQA) <b>Health Fair Tests</b> <table border="1"><tr><td><a href="#">LDL Cholesterol</a></td><td><a href="#">remove</a></td></tr><tr><td><a href="#">HbsAg</a></td><td>pending</td></tr><tr><td><a href="#">Bilirubin Total</a></td><td>pending</td></tr></table>	<a href="#">LDL Cholesterol</a>	<a href="#">remove</a>	<a href="#">HbsAg</a>	pending	<a href="#">Bilirubin Total</a>
<a href="#">LDL Cholesterol</a>	<a href="#">remove</a>					
<a href="#">HbsAg</a>	pending					
<a href="#">Bilirubin Total</a>	pending					

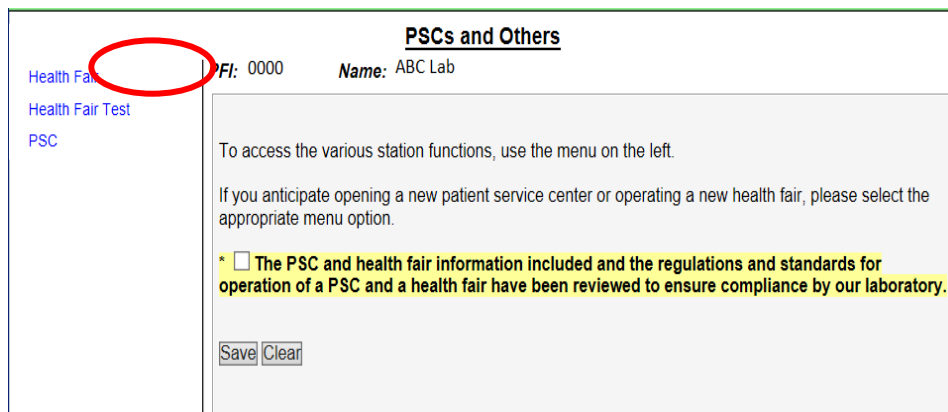
Review and update the test information as needed. If changes are made, click **Save**.

<a href="#">PSCs and Others Home</a> <b>Health Fair</b> <a href="#">View/Update</a> <a href="#">Remove</a> <b>Health Fair Tests</b> <a href="#">View</a> <a href="#">Update</a> <a href="#">Add New</a> <a href="#">Remove</a>	<b>PFI:</b> 0000 <b>Name:</b> Internal Test for CLEP TEST(WCQA) <b>Health Fair Test</b> Items with an asterisk (*) are required. Health Fair Test Information Test: LDL Cholesterol <b>* Test at Health Fair:</b> <input type="radio"/> Yes <input checked="" type="radio"/> No <b>* Test at Lab:</b> <input checked="" type="radio"/> Yes <input type="radio"/> No <b>* Test Referred to Another Lab:</b> <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"/>
--	---

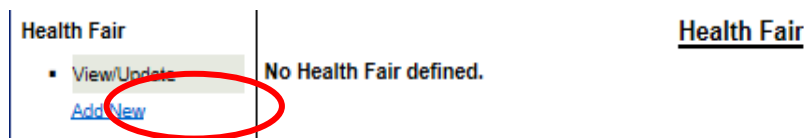
### ECLEP MANUAL

#### **Request a Health Fair Permit**

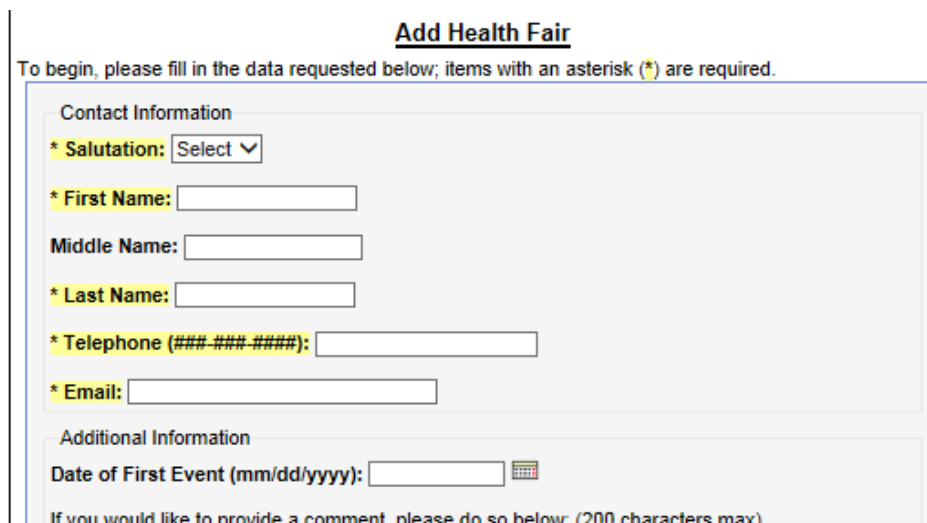
To request approval to operate health fairs, click on the **Health Fair** link on the left of the screen.



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



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




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


## ECLEP MANUAL

### 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](mailto: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**

**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**

- View/Update
- Remove**

[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**

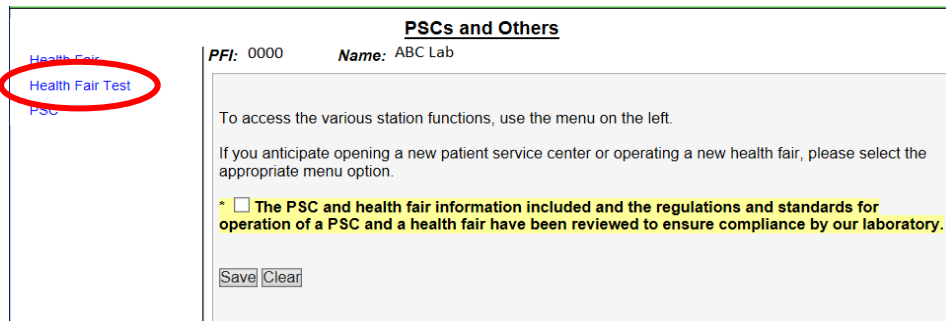
**Telephone :** (### ### ####)  **Ext:**

Save Clear

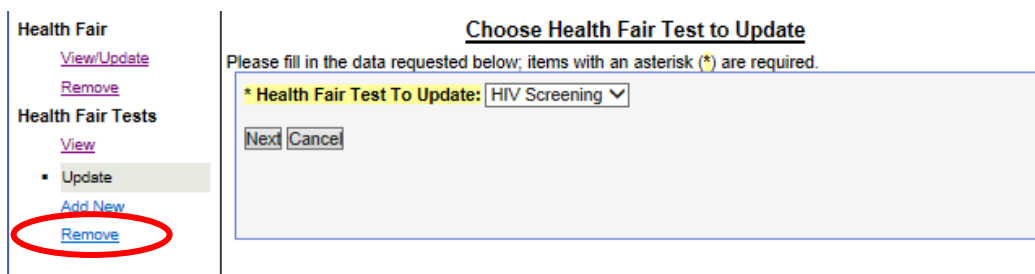
### ECLEP MANUAL

#### **Remove a Health Fair Test**

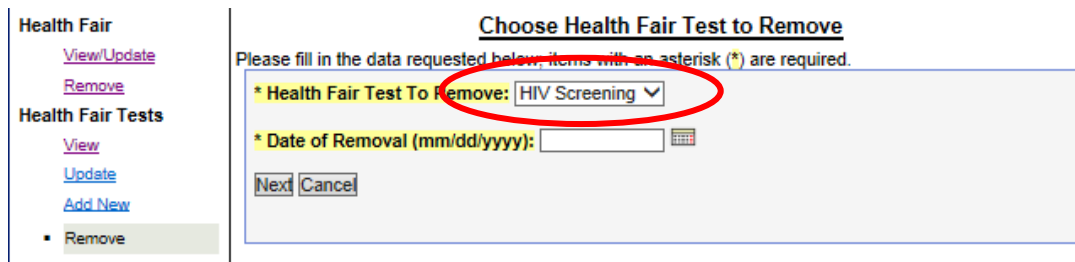
To remove a test from an approved Health Fair permit, click **Health Fair** of **Health Fair Test** from the left side of the screen.



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



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





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

An extension date may be requested for:

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

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

The screenshot shows the 'Extension Date Request' tool interface. The top navigation bar includes tabs for 'Permit Materials', 'Proficiency Testing', 'Gross Annual Receipts', 'LDT Approval', 'Survey', and 'Tools'. The 'Tools' tab is active. The left sidebar contains a link to 'Tools Home' and a menu item for 'Extension Date Request'. The main content area is titled 'Extension Date Request' and contains the following text: 'Items with a \* are required. Please use this Extension Date Request tool to request extensions of due dates for submission of Plans of Correction, Permit Re-application or Gross Annual Receipts reporting. The laboratory will be notified via email of the approval or denial of the extension request. The emails will be sent to the emails on file in eCLEP for the laboratory, laboratory contact person and laboratory director and laboratory owner.' Below this text are the form fields: '\*Extension Request for:' with a dropdown menu showing '-- Select request type --'; '\*Survey Id:' with a dropdown menu showing '-- Select Survey --'; '\*New Date:' with a calendar icon and a text input field showing 'mm/dd/yyyy'; and 'Reason:' with a text area and a 'Characters Remaining: 200' indicator. A 'Save' button is located in the bottom right corner.

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

The screenshot shows the 'Extension Date Request' tool interface with the 'Survey Id' dropdown menu open. The 'Plan of Correction' option is selected in the 'Extension Request for' dropdown. The 'Survey Id' dropdown menu shows a list of survey IDs: '117657' and '36870'. The 'New Date' field is empty. The 'Reason' text area and 'Characters Remaining: 200' indicator are also visible. A 'Save' button is located in the bottom right corner.

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

**eCLEP MANUAL**

The screenshot shows the 'Extension Date Request' form in the eCLEP system. At the top, there are navigation tabs: Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, and Tools. The 'Survey' tab is active. The form header shows 'PFI: 0000' and 'Name: Internal Test for CLEP'. Below this is the title 'Extension Date Request'. A note states: 'Items with a \* are required. Please use this Extension Date Request tool to request extensions of due dates for submission of Plans of Correction, Permit Re-application or Gross Annual Receipts reporting. The laboratory will be notified via email of the approval or denial of the extension request. The emails will be sent to the emails on file in eCLEP for the laboratory, laboratory contact person and laboratory director and laboratory owner.' The form contains the following fields:
 

- '\*Extension Request for:': A dropdown menu with the text '-- Select request type --'.
- 'Survey Id:': A dropdown menu with the text 'Select Survey'.
- '\*New Date:': A date input field with a calendar icon and a red box around it, containing the placeholder 'mm/dd/yyyy'.
- 'Reason:': A large text area with a 'Characters Remaining: 200' indicator.
- 'Save': A red button at the bottom right.

- Enter a justification for the extension request in the **Reason** box.
- Clicking the **Save** button, completes the request process for an extension date. No extra step is required.

**Additional shortcuts across eCLEP to the Extension Date Request page**

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

The screenshot shows the 'Reapplication Center' page in the eCLEP system. The header includes 'Wadsworth Center New York State Department of Health' and 'eCLEP electronic Clinical Laboratory Evaluation Program'. There are navigation tabs: Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, and Tools. Below these are sub-tabs: Lab Profile, Ownership, Personnel, Permit Categories/Tests, PSCs and Others. The main content area shows 'Reapplication Center' with a 'Reapplication Period: Mar 22, 2021 through Mar 31, 2021 at 05:00 PM, EDT'. It also displays 'PFI: 0000' and 'Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY'. A red box highlights a link labeled 'Request for an Extension Date' in the top right corner. Below the main content is an 'Enter' button and a note: '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.'

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

The screenshot shows the 'Survey - Home' page in the eCLEP system. The navigation tabs at the top are Permit Materials, Proficiency Testing, Gross Annual Receipts, LDT Approval, Survey, and Tools. The 'Survey' tab is active. The left-hand navigation panel contains several links: Survey Home, Instructions, POC Template, POC Guidance, Request for an Extension Date (highlighted with a red box), Survey Folders, Action Required, Submitted Surveys, and Survey History. The main content area shows 'Survey - Home' with the following text:
 

The on-site laboratory survey is one of the requirements that must be fulfilled to obtain and maintain a New York State clinical laboratory permit. This requirement complies with Article 5, Title V of the New York State Public Health Law, Parts 19, 58, 63 and 70 of Title 10, New York Code of Rules and Regulations (10NYCRR) and the New York State Department of Health (Clinical Laboratory Evaluation Program) Laboratory Standards of Practice.

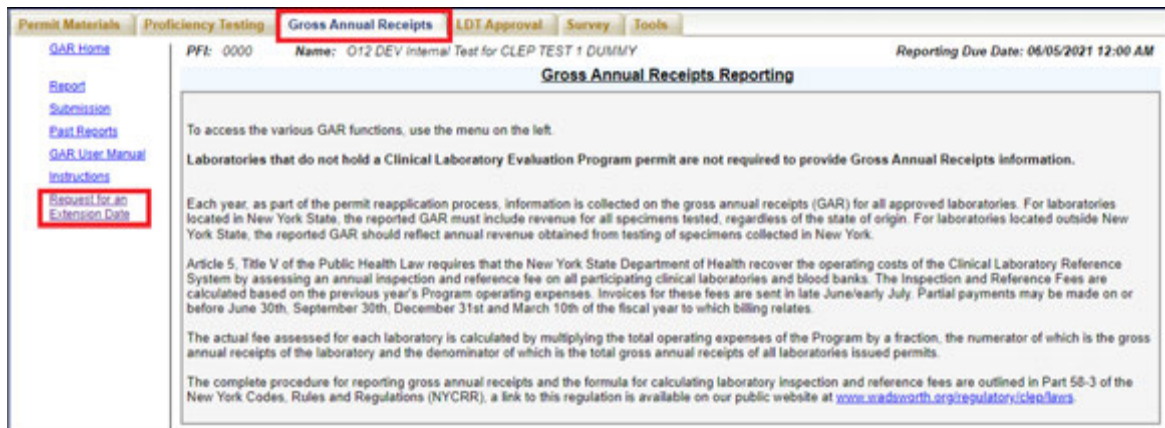
Instruction (hyperlink) on how to navigate the review and submission of the survey plan of correction (POC) is available by clicking the link on the left side of this page. In addition to instructions, this link provides a POC guidance document to assist in the completion of the POC and a POC template for use prior to eCLEP submission.

Document Folders on the left side of this page (Survey Home Page) include:

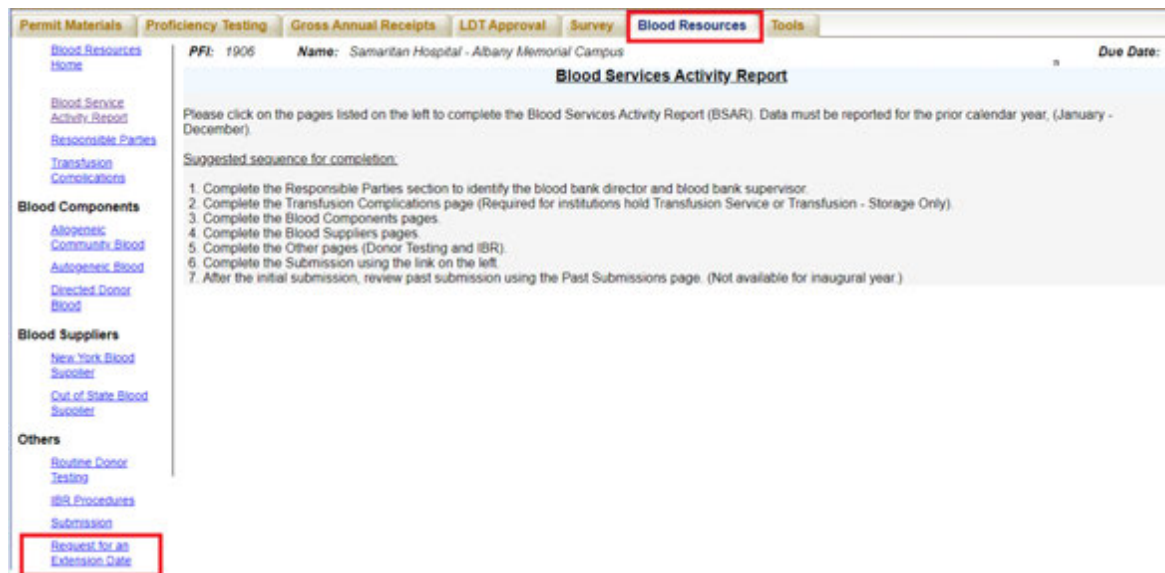
- Action Required:** The survey event(s) that require immediate attention.
- Submitted Surveys:** The survey event(s) submitted to the Department.
- Survey History:** The survey event(s) received through eCLEP that have been reviewed and closed.

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



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



eCLEP MANUAL

**Miscellaneous**

**Error Messages**

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

The screenshot displays the eCLEP web application interface. At the top, there are navigation tabs: Lab Profile, Ownership, Personnel, Permit Categories/Tests, PSCs and Others, and Tools. Below these is a green banner showing the Reapplication Period: Mar 05, 2012 through Mar 12, 2012 at 05:00 PM, EDT, and a Reapplication Center button. The main content area shows a sidebar with General Information, Regulator information, and Hours. The main panel displays PFI: 6705 and Name: eCLEP Test 5. A red-bordered box highlights the following error messages:

**Errors:**

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

Below the errors, the form is divided into sections:

- Name and Address Information:** Name: eCLEP Test 5, Address: Lincoln St, City: Buffalo, Country: United States, State/Province: New York, NY County: Unknown, Zip Code: 12798. A note states: "All name/address changes effective: [calendar icon] \* Effective Date is required for any name/address change".
- General Information:** Facility Type: Select, Fac Status: Open.
- Contact Information:** Telephone (### ### ####): [input], Ext: [input], Fax (### ### ####): [input], Email: [input].

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

**eCLEP MANUAL**

**Pending Changes**

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

**Pending Changes:**

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

PFI: 0000      Name: Internal Test for CLEP TEST2

**Name and Address Information**

Name: Internal Test for CLEP TEST2

Address: PO Box 509, Empire State Plaza

City: Albany Test

Country: United States

State/Province: New York

NY County: Albany

Zip Code: 12200

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

\* Effective Date is required for any name/address change

**General Information**

Facility Type: Hospice      Fac Status: Open

**Lab Contact Information**

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

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

Email: mabraham@wadsworth.com, email@tes

To continue with a submission in Reapplication or Open Mode, click on the **Reapplication Center** or **Continue** button located at the top right.

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

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

Reapplication Period: Mar 13, 2024 through Jun 29, 2024 at 12:59 AM, EDT

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

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

Open Mode

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

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

## eCLEP MANUAL

### **Request to Re-Open eCLEP**

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

### **HCS Timeout**

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

### **Exiting eCLEP**

There are two ways to exit eCLEP:

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

### **Technical Support**

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

#### ***Help with HCS Enrollment***

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

(866) 529-1890 (Mon-Fri 8am – 4:45pm)

[camu@its.ny.gov](mailto:camu@its.ny.gov)

#### ***Help with eCLEP***

For additional assistance contact the Clinical Laboratory Evaluation Program at [CLEP@health.ny.gov](mailto:CLEP@health.ny.gov).

E C L E P M A N U A L**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