

Clinical Laboratory Evaluation Program



eCLEP Manual Single Use Permits

January 2026



Department of Health
Wadsworth Center

eCLEP Manual

Single Use Permit

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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.

Getting Started: An Overview

The 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 Clinical Laboratory Evaluation Program (CLEP) and acts as a single repository for the data.

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

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

Documented Delivery – Submissions are electronically transmitted; the time of the submission and username submitting the data is recorded.

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Requirements for Use

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

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

Browser Requirements and Configuration

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

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

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

It is strongly advised that the HCS User clear out their internet browser cache regularly.

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eCLEP-SUP Access

ECLEP is accessible through the Department's Health Commerce System. Access to Single Use Permit module of eCLEP is limited to **Laboratory Directors**, **eCLEP Delegated Submitters** and HCS Users with **CLRS Single Use Permit/Test Entry Coordinator role** for a specific clinical laboratory record.

See CLEP's Single Use Permit webpage for more information on obtaining an HCS accounts for your laboratory.

www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce

- Laboratory Directors are required to obtain an HCS account and affiliate that account with the clinical laboratory they direct.
- Additional users may obtain and affiliate HCS accounts AFTER the laboratory director account has been affiliated with a specific clinical laboratory record.

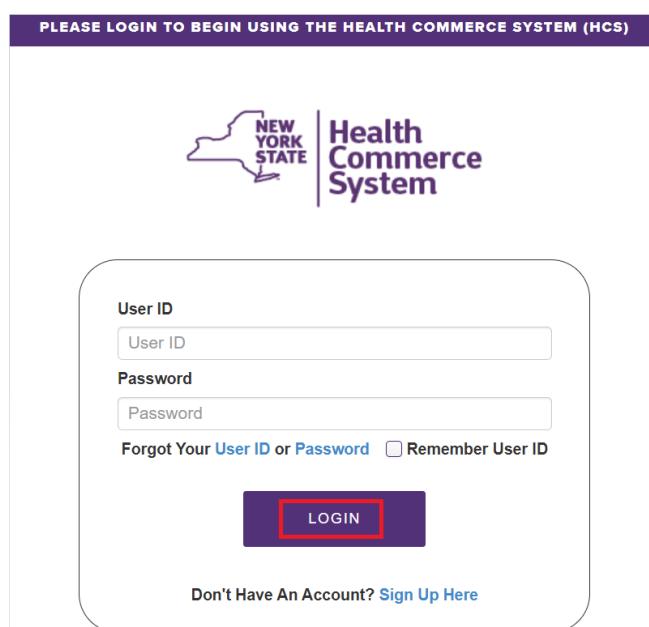
As the HCS contains confidential information, safeguard your HCS User ID and password by not revealing them to other users. Violation of the security and use agreement (e.g. sharing your User ID and password with someone else) will result in the temporary suspension of your account privileges and repeat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

Roles and Responsibilities of eCLEP-SUP Users

- A **Laboratory Director** is an individual who is responsible to bind the laboratory to meet the security requirements for the use of the Health Commerce 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.
- An HCS User with the **CLRS Single Use Permit/Test Entry Coordinator role** is a person who has been given authorization by the HCS Coordinator at the laboratory.

eCLEP MANUAL**Accessing eCLEP and the Single Use Permit Module**

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



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

Health Commerce System

User ID

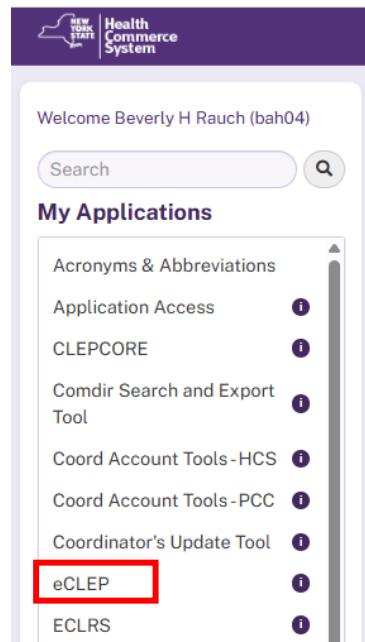
Password

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

LOGIN

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

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



Welcome Beverly H Rauch (bah04)

Search

My Applications

Acronyms & Abbreviations	i
Application Access	i
CLEPCORE	i
Comdir Search and Export Tool	i
Coord Account Tools-HCS	i
Coord Account Tools-PCC	i
Coordinator's Update Tool	i
eCLEP	i
ECLRS	i

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4. Click on **eCLEP** in the left frame and the eCLEP Home Page will display. Click on **Single Use Permit** area at the middle right.

Wadsworth Center
New York State Department of Health

eCLEP
electronic Clinical Laboratory Evaluation Program

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

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

Date Priority Message

Permit Materials
Laboratory Reapplication
Laboratory Changes

Proficiency Testing
PT Designations
PT Documents

Gross Annual Receipts
Reporting

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

Survey
Tools and information related to laboratory surveys

Blood Resources
BSAR

Single Use Permit
SUP

Tools
Extension Date Request

Contact Us Help FAQ Accessibility Message Center

NOTE: If Single Use Permit is not shown, click on any other module and then choose Single Use Permit from the tabs at the top.

home > permit materials > reapplication center

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

5. If you have permissions at more than one facility, click on the desired facility from the displayed list.

Example:

PFI	Name	Status
0000	Internal Test for CLEP CNSE O19 EVAL	Open
4987	Versiti Wisconsin, Inc	Open
A024	Stanford Clinical Laboratories at Hillview	Open

ECLEP MANUAL

6. Most users will be brought directly to the **Single Use Permit** home page. If not immediately brought to this page, click on the Single Use Permit tab at the top.

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

• Single Use Permit
Profile

Orders

[New Orders](#)
[Active Orders](#)
[Order History](#)

PFI: A024 Name: Stanford Clinical Laboratories at Hillview

Single Use Permit

A Single Use Permit must be requested by the testing laboratory to perform testing on a specimen originating from New York if:

- The testing laboratory does not hold a New York State clinical laboratory permit and offers a novel assay, or
- The testing laboratory holds a New York State clinical laboratory permit but does not hold approval to perform a novel assay.

Approval of the request will be considered if:

- The use of the assay is medically necessary and/or clinical circumstances exist that prevent submission of the specimen to a laboratory holding a NYS clinical laboratory permit and approval for a similar test.
- A similar test is not available from a laboratory holding a NYS clinical laboratory permit.
- There is a declared state disaster emergency that requires a quick expansion of testing availability from additional laboratories.
- The testing is performed in support of an approved clinical trial.

(Note: Single Use Permits replace the Restricted Permits issued under the now discontinued Non-Permitted Laboratory Test Request Process.)

Laboratories that do not hold a New York State clinical laboratory permit must review the laboratory profile using the Profile link on the left to verify the information. Please ensure that the laboratory director is correct in the laboratory profile. If this field is blank, you will not be able to submit a Single Use Permit request.

Click on [New Orders](#) to apply for a Single Use Permit.

- Answer the questions, follow the prompts and type in required information. Fields highlighted in yellow and framed in red are mandatory.
- Progress can be saved for later completion. Saved, unsubmitted requests can be accessed from the [Active Orders](#) link.
- You will receive a confirmation email when the request is successfully submitted.

Click on [Active Orders](#) to track the progress of your open requests. You can:

- Continue with an [Unsubmitted order](#).
- View [Submitted order](#). You will receive an email notification when a decision is made.
- Respond to a [Request for Additional Information](#)
- Appeal to a [Denial](#) (within 2 weeks from denial date)

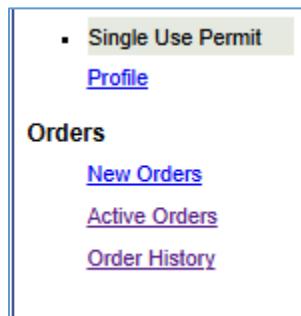
Click on [Order History](#) to see completed requests and retrieve the decision document. (We will NOT fax any documents to you). Decision document may be a Single Use Permit, Rejection letter or Denial letter.

- Rejection letters indicate that a Single Use Permit is not necessary to perform the testing because the laboratory already holds approval.
- Denial letters typically indicate that a similar test is approved at another NYS-permitted laboratory and therefore the test requested does not meet the requirement as unique. A denial can be appealed within 2 weeks; additional justification must be provided.

Contact Us Help FAQ Accessibility Message Center

ECLEP MANUAL**Navigating in the Single Use Permit reporting module**

- I. On the left side of the Single Use Permit home page, there are links to the Profile page, New Orders page, Active Orders page and Order History page.

**Profile:**

This is a read-only page. To request changes please follow the steps below appropriate to your facility type.

1. Laboratories that have applied for or hold a NYS clinical laboratory permit (all numeric PFI): Staff with Delegated Submitter permissions in eCLEP may request changes using the Permit Materials tab in eCLEP. Staff without this permission must contact appropriate eCLEP users within their facility to request changes.
2. Laboratories that have not applied for a clinical laboratory permit (alpha-numeric PFI): You must email clepsup@health.ny.gov to request changes.

ECLEP MANUAL**New Orders:**

Use this page to begin entering a request for a Single Use Permit.

Respond to the two questions, then click Continue.

PFI: 0000 Name: Internal Test for CLEP CNSE O19 EVAL

Questions

Please respond to the questions below.

Laboratories with PFI starting with "A" or "B" must respond "No" to Question 1. 

1. Has a laboratory-developed test (LDT) method validation package been submitted to CLEP for the assay being requested?: * Yes No
If the response to the above question is yes, provide [LDT Package ID](#).

2. Is the test being performed in support of an approved clinical trial?: * Yes No

[Clear](#) [Continue](#)

Question 1: This question is intended for laboratories that have applied for or hold a NYS clinical laboratory permit (all numeric PFI), have submitted their method validation materials to CLEP for review AND have been notified of the Project ID. If you have not yet been informed of the Project ID, please respond "No" to this question.

- At this time, only one Project ID is allowed in the text box. If more than one test will be performed on the specimen, please enter to other relevant Project IDs in the "Justification" field on the next screen.

Question 2: A National Clinical Trial (NCT) or IRB approval number will be required on the next screen if you respond "Yes" to this question.

- Responding "Yes" to the question and clicking Continue will direct you to the Clinical Trial Application form.
- Responding "No" to this question and clicking Continue will direct you to the Single Use Permit Application form.

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Complete the Application Form. Yellow fields are mandatory.

Single Use Permit Application Form:

It is highly recommended to include your laboratory's test code (how the test is identified in your laboratory information system) for identification purposes.

Only one specimen is allowed per request. However, you may request more than one test per specimen.

PFI: 0000 Name: Internal Test for CLEP CNSE O19 EVAL Order Id:

Single Use Permit Application

When entering a Test Name, please avoid using acronyms or abbreviations or the request may be returned to you for clarification. The test name field will only accept the following special characters: , ; ? ! @ \$ % ^ () [] _ = / . This field accepts up to 250 characters, including spaces.

Single Use Permits are issued based on a single specimen. If more than one test is requested for that specimen, please click on Add Another Test and enter the required information. Repeat for all tests requested for the specific specimen (i.e., single specimen, single collection date). This cannot be used for serial / longitudinal testing. A separate request must be submitted for each unique specimen.

Test Information

Test Name: * Add Another Test

Test Code:

Specimen Type: * Other:

Specimen Collection Date: * mm/dd/yyyy

Symptoms/Dx: *

Genetic Testing Panel Name:

Number of Genes:

Justification: Justification for requesting use of a facility without a NYS Permit.

Patient Information

First Name: * Middle Initial: Last Name: *

Medical Reference Number: * Date of Birth: * mm/dd/yyyy

Referring Entity Information

Entity Name:

Physician First Name: Physician Last Name:

Testing Laboratory Contact Information

First Name: * Last Name: *

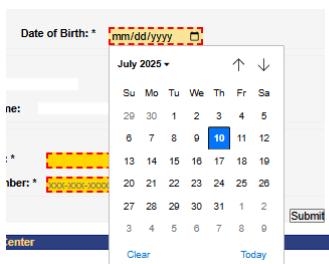
Email Address: * Phone Number: * XXX-XXX-XXXX

Click Save to save your progress and return later to complete the request. If you Save the request, you can retrieve it from the Active Orders list.

Click Submit once all mandatory fields are satisfied.

Quick Tip: To find specimen type quickly, start typing in Specimen Type field.

Quick Tip: To choose the Date of Birth quickly, click in the date field, to open the date widget.

ECLEP MANUAL

Date of Birth: * mm/dd/yyyy

July 2025

Su	Mo	Tu	We	Th	Fr	Sa
29	30	1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31	1	2
3	4	5	6	7	8	9

Clear Today

Then click on the Month Year



Date of Birth: * mm/dd/yyyy

2025

Jan	Feb	Mar	Apr
May	Jun	Jul	Aug
Sep	Oct	Nov	Dec

2026
2027
2028
2029

Scroll through to find the desired year, then click on the desired month.



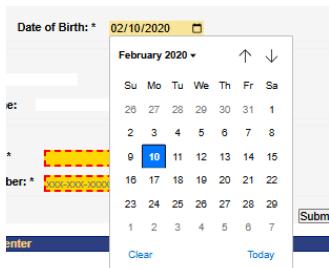
Date of Birth: * 02/10/2020

February 2020

Jan	Feb	Mar	Apr
May	Jun	Jul	Aug
Sep	Oct	Nov	Dec

2021
2022
2023
2024

Finally, choose the desired day of month.



Date of Birth: * 02/10/2020

February 2020

Su	Mo	Tu	We	Th	Fr	Sa
26	27	28	29	30	31	1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
1	2	3	4	5	6	7

Clear Today

If you Save the request, you can retrieve it from the Active Orders list.

ECLEP MANUAL**Clinical Trial Application Form:**

Click Save to save your progress and return later to complete the request. If you Save the request, you can retrieve it from the Active Orders list.

Click Submit once all mandatory fields are satisfied.

PFI: 0000 Name: Internal Test for CLEP CNSE O19 EVAL Order Id:

Clinical Trial Application

When entering a Test Name, please avoid using acronyms or abbreviations or the request may be returned to you for clarification. The test name field will only accept the following special characters: . , ; ? ! @ \$ % * () [] _ = !. This field accepts up to 250 characters, including spaces.
All mandatory fields (highlighted in yellow) must be completed before the order can be saved or submitted.

Test Information

Name of Clinical Trial Study: *

Name of Clinical Trial Sponsor: *

National Clinical Trial (NCT) number or IRB approval Number: *

Study Start Date (estimated): * mm/dd/yyyy

Study Completion Date (estimated): * mm/dd/yyyy

Estimated Number of NY Participants: *

Test Name: *

Specimen Type(s): *

Investigational Device Exemption (IDE) number of test: *

Testing Laboratory Contact Information

First Name: * Last Name: *

Email Address: * Phone Number: * 1234-5678-XXXX

ECLEP MANUAL**Active Orders:**

This page will display Single Use Permit requests that are in progress. Please see the table below for information on the various order statuses and definitions.

Example:

The screenshot shows a web-based application interface for managing Single Use Permit requests. On the left, a sidebar menu includes 'Single Use Permit Profile', 'Orders' (with sub-options 'New Orders', 'Active Orders', and 'Order History'), and a search bar. The main content area is titled 'Active Orders' and contains a table with the following data:

Order Id	Submitted Date	Application Type	Status Date	Status	Action
761	Single Use Permit	07/10/2025	Unsubmitted	Continue	

Below the table, a message indicates 'Showing 1 to 1 of 1 entry'. The page includes navigation buttons for the table.

Active Order Status	Definition
Unsubmitted	The order has been saved but not submitted to CLEP for review.
Submitted	The order is pending review by CLEP.
Denied	This status indicates that an order does not meet the required criteria for the eligibility of a Single Use Permit. Denied orders are visible in the Active Order view for 14 days to allow the applicant to appeal. After 14 days, the denial is final and these orders are visible in the Order History view.
Additional Info Requested	This status indicates that additional information is needed from the applicant. Applicant must respond within 14 days.

ECLEP MANUAL**Order History**

This page displays all completed requests and provides access to the final document appropriate to the status (e.g., Permit for approved orders, Denial letter for denied orders). Please see the table below for information on the various order statuses and definitions.

Example:

Single Use Permit Profile		Order History						
Orders	Select Order		Search: <input type="text"/>					
	10	entries per page						
	Order Id	Submitted Date	Application Type	Status Date	Status	Issued Document		
	21	09/11/2023	Clinical Trial	07/02/2025	Approved	Permit		
	281	08/28/2024	Clinical Trial	08/28/2024	Denied	Denial Document		
	381	09/10/2024	Clinical Trial	09/10/2024	Denied	Denial Document		
	441	10/02/2024	Clinical Trial	10/02/2024	Denied	Denial Document		
	442	10/02/2024	Clinical Trial	10/02/2024	Denied	Denial Document		
	461	10/02/2024	Single Use Permit	10/03/2024	Denied	Denial Document		
Showing 1 to 6 of 6 entries								1

Order History Status	Definition
Approved	The order has met all the required criteria for the eligibility of a Single Use Permit.
Rejected	The order is rejected because no approval is required. The laboratory already holds approval to perform this test. There is no path to appeal a rejected order.
Denied	This status indicates that an order does not meet the required criteria for the eligibility of a Single Use Permit. Applicant can appeal within 14 days from denial date.

eCLEP MANUAL

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 a data entry page, you will lose all your data entry.

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 and HCS Accounts:

See CLEP's Health Commerce System webpage

www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce

Help with HCS password expiration:

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

(866) 529-1890 (Mon-Fri 8am – 4:45pm EST/EDT)
camu@health.ny.gov

Help with eCLEP

For additional assistance contact the Clinical Laboratory Evaluation Program:

- E-mail support at CLEPSUP@health.ny.gov.