



## A close-up, blue-tinted photograph featuring a silver and black pen resting on a spreadsheet. To the right, a portion of a white calculator with black buttons is visible. The spreadsheet contains various numerical data points, including 9 030,67, 31 475,38, 38 471,62, 909,95, 133 735,01, 19 728,67, 7 760,52, 232 081,15, 1 083,80, 2 817,26, 1 607 455,97, 7 474,49, 26 325,97, 22 139,25, 0.00, 53 520,83, 136 059,72, 929 206,82, 6 275,44, 321,39, 278 761,88, 40 817,95, 16 056,25, 482 236,69, 2 242,36, 7 897,80, 6 641,78, 0.00, 689,76, 471,70, 1 004 691, 4 144,54, 15 466,7, 13 848, 65, 1, and 4. The image is used as a background for the 'Financial Accounting' section of the document.

*March 2023*

# eCLEP Manual

## Gross Annual Revenue Reporting

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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.
- **Making a Submission** provides detailed directions for accessing the Gross Annual Revenue Reporting section of eCLEP and entering data.

### **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.

**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:

**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.

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

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

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

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

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

**Browser Requirements and Configuration**

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

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

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

eCLEP MANUAL**Roles and Responsibilities**

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

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

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

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

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

## ECLEP MANUAL

### **HCS Access Permissions**

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

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

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

### ***Clinical Laboratory Directors and HCS Coordinators without HCS accounts***

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

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

### ***Requesting HCS Accounts for Other Individuals***

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


### ***Delegated Submitter***

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

eCLEP MANUAL**Accessing eCLEP and the GAR Reporting Module**

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

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



User ID

Password

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

**LOGIN**

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

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

Welcome Shalini Banka (szb06)

Search

My Applications

- Acronyms & Abbreviations
- eCLEP**
- Emergency Contacts
- Secure File Transfer 2.0
- ServNY

[Refresh My Applications List](#)

**Important Health Events**

**Donate Life** **NYS PMP** **COVID-19**

**Important Health Notifications**

Posted	Priority	Keyword	Source	Audience	Description	Recipients
02/09/2023	Alert	Pharmacy	NYSDOH Pharmacy	All Users	Next All Stakeholders Meeting Medicaid Pharmacy Benefit Transition February 21	Recipients
02/03/2023	Advisory	Influenza	NYSDOH	All Users	Influenza Surveillance Report for the Week Ending 01/28/2023	Recipients
01/30/2023	Advisory	Infectious Disease	NYSDOH	All Users	Update on carbapenem-resistant Pseudomonas aeruginosa infections	Recipients
01/27/2023	Advisory	Influenza	NYSDOH	All Users	Influenza Surveillance Report for the Week Ending 01/21/2023	Recipients
01/23/2023	Advisory	HIV advisory	NYSDOH AIDS Institute	All Users	Broome County HIV advisory January 2023	Recipients
01/20/2023	Advisory	Influenza	NYSDOH	All Users	Influenza Surveillance Report for the Week Ending 01/14/2023	Recipients
01/13/2023	Advisory	Influenza	NYSDOH	All Users	Influenza Surveillance Report for the Week Ending 01/07/2023	Recipients
01/12/2023	Advisory	Lab advisory	Wadsworth	All Users	Updates to Wadsworth Centers Pediatric HIV Testing Service	Recipients

Showing notifications sent in the past 30 days.

## eCLEP MANUAL

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

home

**Welcome to e-CLEP**

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

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

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

**Permit Materials**  
Laboratory Reapplication  
Laboratory Changes

**Proficiency Testing**  
PT Designations  
PT Documents

**Gross Annual Receipts Reporting**

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

**Survey**  
Tools and information related to laboratory surveys

**Blood Resources**  
BSAR

**Tools**  
Extension Date Request

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

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 :



ECLEP MANUAL

6. Most users will be brought directly to the **GAR** home page.

Gross Annual Revenue for the previous calendar year is required to be submitted by **May 15** of the current year. **Requests for extensions may be made using the 'Request for an Extension Date' link on the left side of the webpage. This link is also available under the Tools tab. Follow the prompts to complete the extension request.**

[home](#) > [gar home](#)

Select Facility

Permit MaterialsProficiency TestingGross Annual ReceiptsLDT ApprovalSurveyBlood ResourcesTools

[GAR Home](#)[Report](#)[Submission](#)[Past Reports](#)[GAR User Manual](#)[Instructions](#)[Request for an Extension Date](#)

PFI: 0000Name: Internal Test for CLEPReporting Due Date: 04/15/2022 12:00 AM

Gross Annual Receipts Reporting

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

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

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

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

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

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

Contact UsHelpFAQAccessibilityMessage Center

RELEASE 1.4

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ECLEP MANUAL**Navigating in the GAR reporting module**

- I. On the left side of the GAR home page, there are links to the reporting page, submission page, past reports, user manual, instructions, and request for an extension date.

[GAR Home](#)

[Report](#)

[Submission](#)

[Past Reports](#)

[GAR User Manual](#)

[Instructions](#)

[Request for an  
Extension Date](#)

**Instructions:**

Click on the instructions link for information on the requirements for reporting GAR. Additional questions related to GAR reporting can be sent to [CLEP@health.ny.gov](mailto:CLEP@health.ny.gov). Section 576 of New York Public Health Law requires that regulated parties report gross annual receipts for all activities performed pursuant to a New York State clinical laboratory permit issued by the department. A link to the law can be found at <https://www.wadsworth.org/regulatory/clep/laws>. The implementing regulation for Section 576 of PHL is Subpart 58-3 of Title 10 of the New York Codes, Rules and Regulations. A link to the regulation can be found at <https://www.wadsworth.org/regulatory/clep/laws>.

**Report:**

Click on the report link to begin the GAR reporting process.

**DO NOT enter decimals – only whole numbers are acceptable.**

Laboratories located in New York have three options for reporting:

- Able to Segregate Income
- Unable to Segregate Income - Article 28 Facility
- Unable to Segregate Income – All Others.

## ECLEP MANUAL

Choose a method by clicking on the corresponding radio button on the Report page.

### Gross Annual Receipts Reporting

A laboratory located in New York state is required to choose one of three reporting options. Please see the instruction available via the link on the left for further information. *Be reminded that GAR for a laboratory located in New York includes testing on all specimens received, regardless of origin.*

#### New York State Facilities

- ☐ Able to segregate laboratory income
- ☐ Unable to segregate laboratory income - Article 28 or similar facility

Available for facilities such as hospitals and clinics that are reimbursed by third-party payers for laboratory services as part of an all-inclusive rate. Please see the instructions available via the link on the left for further information.

- ☐ Unable to segregate laboratory income - All others facilities

Available to all facilities that are not designated under Article 28 that are unable to segregate income. This includes school-based clinics that are operated based on an all-inclusive health care fees collected from each student, or facilities that are funded by grants. Please see the instructions available via the link on the left for further information.

### New York Laboratories and Blood Banks Able to Segregate Income:

- **Enter** the value of all revenue earned from testing of specimens (regardless of origin) during the preceding calendar year. Do not report amounts collected and paid to New York State directly by your facility as part of the New York State Health Care Reform Act - Health Services Surcharge.
- **Enter** the amount paid to reference laboratories for tests that are referred.
- Click **Calculate**.
- The **Comment** section is optional and may be used to provide clarifying information related to the reporting of GAR.
- **Clear** button is to clear your entry if you have not clicked on the **Save** button.
- Click **Save**, if you want to save your entry and complete submission later.
- If you have already saved and want to re-enter the values again, click on the **Reset** button.
- Read the **Attestation**, click the check box to acknowledge the attestation, then click **Submit**.
- The laboratory or blood bank may also opt to request for the GAR information to remain confidential. Click on the check box corresponding to the **Confidentiality** before clicking Submit.

ECLEP MANUAL

Please enter only whole numbers.	
Gross revenue earned for testing specimens:	\$0
Amount paid to reference labs for specimens:	\$0
<input type="button" value="Calculate"/>	
<b>This is your 2019 reportable Gross Annual Receipts:</b>	
<div style="border: 1px solid black; height: 40px; margin-top: 5px;"></div>	
<p><b>Attestation</b></p> <p>Please read the following attestation carefully. You must signify agreement by clicking the checkbox below, then click 'Submit'.</p> <p>I confirm that the information included in this report is correct. I understand that once submitted, this information is considered final and may not be altered after the submission deadline. I understand that deliberately or willfully misreporting or providing misinformation will result in the nonrenewal of the clinical laboratory permit for this facility, in addition to any other civil or criminal penalties.</p> <p style="text-align: center;"><input type="checkbox"/> I have read, and agree with, the above attestation.</p>	
<p><b>Confidentiality</b></p> <p>By checking this box, I request that this report be deemed confidential and exempt from disclosure under the Freedom of Information Law (Article 6 of the Public Officers Law) pursuant to the authority in Section 89(5) of the Public Health Law.</p> <p style="text-align: center;"><input type="checkbox"/> I have read the above, and request confidentiality.</p>	
<div style="display: flex; justify-content: space-between; align-items: center;"> <span><input type="button" value="Save"/></span> <span><input type="button" value="Submit"/></span> <span><input type="button" value="Reset"/></span> </div>	

## New York Laboratories and Blood Banks Unable to Segregate Income - Article 28 Facility

- Refer to the Instructions page for a description of entities eligible to report in this manner.
- **Enter the value of the *total annual cost of the laboratory*.** For the purpose of this calculation, Total Annual Laboratory Cost means the total cost, both direct and indirect, salary and non-salary costs incurred in providing laboratory services for patient care on an annual basis. This total excludes the purchase of blood.
  - *Institutional Cost Report location: Cost Allocation - Ancillary Service Costs; AHA Ancillary Cost Allocation, Column, LABORATORY 106 Class 1155.*
- **Enter the *Gross Revenue of the Article 28 facility*.** This is the total annual patient services revenues less contractual adjustments, administrative write-offs, allowances, bad debt, charity care, etc., in the providing of patient care services (Net Patient Service Revenue).
  - *Institutional Cost Report location: Summary - All Services, Exhibit 46; ICR Line Code 300, Column: Sum of All Columns Total Services, Class 00036.*
- **Enter the *Operating Cost of the Article 28 facility*.** This is the total annual costs of providing patient services for the entire facility, including capital costs, but not to include non-patient related services areas, i.e., private physician's offices, or the non-reimbursable costs recognized by third party payers.

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- *Institutional Cost Report location: Reclassification and Adjustment of Trial Balance Expenses; Exhibit 11; CMS Line Code 118; Column Reclassified Trial Balance 5, Class 20030.*
- Click **Calculate Subtotal**.
- Enter the **amount paid to reference laboratories** for tests that are referred.
- Click **Calculate Total**.
- The **Comment** section is optional and may be used to provide clarifying information related to the reporting of GAR.
- **Clear** button is to clear your entry if you have not clicked on **Save** button.
- Click **Save**, if you want to save your entry and complete submission later.
- If you have already saved and want to re-enter the values again, click on the **Reset** button.
- Read the **Attestation**, click the check box to acknowledge the attestation, then click **Submit**.
- The laboratory or blood bank may also opt to request for the GAR information to remain confidential. Click on the check box corresponding to the **Confidentiality** before clicking Submit.

Please enter only whole numbers	
Total annual laboratory cost:	<input type="text" value="\$0"/>
Gross Revenue of Facility:	<input type="text" value="\$0"/>
Gross Operating Cost of Facility:	<input type="text" value="\$0"/>
	<input type="button" value="Calculate Subtotal"/>
Subtotal:	<input type="text" value="0"/>
Amount paid to reference labs:	<input type="text" value="\$0"/>
	<input type="button" value="Calculate Total"/>
This is your 2019 reportable Gross Annual Receipts:	
Comment	
If you would like to provide a comment, please do so below: (200 characters maximum)	
<input type="text"/>	
Attestation	
Please read the following attestation carefully. You must signify agreement by clicking the checkbox below, then click 'Submit'.	
I confirm that the information included in this report is correct. I understand that once submitted, this information is considered final and may not be altered after the submission deadline. I understand that deliberately or willfully misreporting or providing misinformation will result in the nonrenewal of the clinical laboratory permit for this facility, in addition to any other civil or criminal penalties.	
<input type="checkbox"/> I have read, and agree with, the above attestation.	
Confidentiality	
By checking this box, I request that this report be deemed confidential and exempt from disclosure under the Freedom of Information Law (Article 6 of the Public Officers Law) pursuant to the authority in Section 89(5) of the Public Health Law.	
<input type="checkbox"/> I have read the above, and request confidentiality.	
<input type="button" value="Save"/> <input type="button" value="Submit"/> <input type="button" value="Reset"/>	

ECLEP MANUAL**New York Laboratories and Blood Banks Unable to Segregate Income – All Others**

- GAR must be calculated as if the laboratory or blood bank had billed the client at the prevailing Medicaid rate for their services. The prevailing rate means the fee schedule for clinical laboratory services as provided at <https://www.emedny.org/ProviderManuals/Laboratory/index.aspx>.
- A worksheet is provided in the GAR Reporting Module to assist in the calculation.
- **Enter** the final estimated GAR value from the worksheet (or custom worksheet).
- The **Comment** section is optional and may be used to provide clarifying information related to the reporting of GAR.
- **Clear** button is to clear your entry if you have not clicked on **Save** button.
- Click **Save**, if you want to save your entry and complete submission later.
- If you have already saved and want to re-enter the values again, click on the **Reset** button.
- Read the **Attestation**, click the check box to acknowledge the attestation, then click **Submit**.
- The laboratory or blood bank may also opt to request for the GAR information to remain confidential. Click on the check box corresponding to the **Confidentiality** before clicking Submit.

<b>Receipts calculated as if laboratory had billed and been paid at the prevailing Medicaid fee schedule rate:</b>		Please enter only whole numbers
A laboratory reporting under this option must review the current <a href="#">Medicaid Fee Schedule</a> for the rate associated with the testing being performed and multiply that rate by the number of tests performed in the calendar year. A sample worksheet is provided below for your convenience.		<input type="text"/>
<a href="#">Prevailing Rate Worksheet</a>		
<b>Comment</b>		
If you would like to provide a comment, please do so below: (200 characters maximum)		
<input type="text"/>		
<b>Attestation</b>		
Please read the following attestation carefully. You must signify agreement by clicking the checkbox below, then click 'Submit'.		
I confirm that the information included in this report is correct. I understand that once submitted, this information is considered final and may not be altered after the submission deadline. I understand that deliberately or willfully misreporting or providing misinformation will result in the nonrenewal of the clinical laboratory permit for this facility, in addition to any other civil or criminal penalties.		
<input type="checkbox"/> I have read, and agree with, the above attestation.		
<b>Confidentiality</b>		
By checking this box, I request that this report be deemed confidential and exempt from disclosure under the Freedom of Information Law (Article 6 of the Public Officers Law) pursuant to the authority in Section 89(5) of the Public Health Law.		
<input type="checkbox"/> I have read the above, and request confidentiality.		
<input type="button" value="Save"/> <input type="button" value="Submit"/> <input type="button" value="Reset"/>		

ECLEP MANUAL**Laboratories and Blood Banks not located in New York:**

- **Enter** the value of all revenue earned from testing of specimens received from New York state during the preceding calendar year
- **Enter** the amount paid to reference laboratories for tests that are referred.
- Click **Calculate**.
- Click **Save**, if you want to save your entry and complete submission later.
- **Clear** button is to clear your entry if you have not clicked on **Save** button.
- If you have already saved and want to re-enter the values again, click on the **Reset** button.
- The **Comment** section is optional and may be used to provide clarifying information related to the reporting of GAR.
- Read the **Attestation**, click the check box to acknowledge the attestation, then click **Submit**.
- The laboratory or blood bank may also opt to request for the GAR information to remain confidential. Click on the check box corresponding to the **Confidentiality** before clicking Submit.

Out of State Facilities	
<b>Gross revenue earned for testing New York State specimens:</b>	<input type="text" value="\$0"/>
<b>Amount paid to reference labs for New York State specimens:</b>	<input type="text" value="\$0"/>
	<input type="button" value="Calculate"/>
<b>This is your 2019 reportable Gross Annual Receipts:</b> A laboratory reporting a \$0 GAR must indicate that either 1) the laboratory did not test any specimens in the preceding calendar year; 2019 or 2) the laboratory's GAR is included under the report of another laboratory. If choosing option 2, the laboratory must disclose the permanent facility identifier (PFI) of the other laboratory. Note that only a laboratory that share a common owner can consolidate GAR reporting under a single PFI. Please see the instructions available via the link on the left for further information.	
<b>Comment</b> If you would like to provide a comment, please do so below: (200 characters maximum) <div style="border: 1px solid black; height: 40px; width: 100%;"></div>	
<b>Attestation</b> Please read the following attestation carefully. You must signify agreement by clicking the checkbox below, then click 'Submit'.  I confirm that the information included in this report is correct. I understand that once submitted, this information is considered final and may not be altered after the submission deadline. I understand that deliberately or willfully misreporting or providing misinformation will result in the nonrenewal of the clinical laboratory permit for this facility, in addition to any other civil or criminal penalties. <div style="text-align: center;"><input type="checkbox"/> I have read, and agree with, the above attestation.</div>	
<b>Confidentiality</b> By checking this box, I request that this report be deemed confidential and exempt from disclosure under the Freedom of Information Law (Article 6 of the Public Officers Law) pursuant to the authority in Section 89(5) of the Public Health Law. <div style="text-align: center;"><input type="checkbox"/> I have read the above, and request confidentiality.</div>	
<div style="display: flex; justify-content: space-between;"><input type="button" value="Save"/><input type="button" value="Submit"/><input type="button" value="Reset"/></div>	



## ECLEP MANUAL

### Consolidating the Reporting of GAR under a Single Facility:

When one or more laboratories share a common owner, as evidenced by the sharing of a common federal employer identification number (EIN) or the same direct owner name and address as disclosed in the laboratories most recent List of Owners submitted as part of the annual permit reapplication, the Gross Annual Receipts for all those laboratories may be reported under a single laboratory. Direct ownership means the possession of stock, equity in the capital, or any interest in the profits of the clinical laboratory. In these instances, the consolidated GAR amount will be reported under one laboratory and all other associated laboratories will report a \$0 GAR.

**These associated laboratories must then enter the PFI of the laboratory that is reporting the non-zero consolidated GAR value. All laboratories are still required to submit a GAR report.**

Once consolidation of GAR is approved, all inspection and reference fee invoices and related financial correspondence will be combined and sent to the **reporting PFI**. This will not affect any other communication from the Clinical Laboratory Evaluation Program.

### Reporting \$0 GAR:

A laboratory may only report a \$0 GAR when either:

- they did not test any specimens in the preceding calendar year; or
- the laboratory's GAR is included under the report of another laboratory (See above).

If choosing option 2, the laboratory must disclose the permanent facility identifier (PFI) of the other laboratory. Note that only laboratories that share a common owner can consolidate GAR reporting under a single PFI. Please see the section titled Consolidating the Reporting of GAR under a Single Facility above.

- After entering \$0 in the '**Gross Revenue earned for testing specimens**' field, click **Calculate**. **You MUST enter "0" in the date field, the system does not recognize the default placeholder displayed.**
- The '**reportable Gross Annual Receipts**' field will populate and new text and data fields will appear:

This is your 2020 reportable Gross Annual Receipts:

A laboratory reporting a \$0 GAR must indicate that either 1) the laboratory did not test any specimens in the preceding calendar year, 2020 or 2) the laboratory's GAR is included under the report of another laboratory. If choosing option 2, the laboratory must disclose the permanent facility identifier (PFI) of the other laboratory. Note that only a laboratory that share a common owner can consolidate GAR reporting under a single PFI. Please see the instructions available via the link on the left for further information.

Did not test any specimens in 2020: ☐

Gross Annual Receipts for 2020 are reported under PFI number:

- If no specimens were tested in the prior calendar year, click the checkbox next to the text "Did not test any specimens in...".
- If Gross Annual receipts are consolidated under another laboratory's report that is under common ownership, then enter the PFI of the other laboratory in the field after "Gross Annual Receipts for (year) are reported under PFI number:".

**\*NOTE:** Reporting \$0 GAR is not acceptable for not-for-profit entities. If no monies are collected for testing, then the GAR Report must be estimated based on the Medicaid Prevailing Rate(s) for the testing performed. For all other situations, you must contact CLEP at [clep@health.ny.gov](mailto:clep@health.ny.gov) for guidance.



## ECLEP MANUAL

### Verifying your submission:

To verify that the system recorded your submission, click on **Submission** on the left. If the submission was successful the date, time of submission and the username (only if submitter is the DI or AD) of the person who submitted the report will be displayed.

The screenshot shows the 'Gross Annual Receipts Reporting - Submission' page in the ECLEP system. The page has a yellow header with a breadcrumb trail 'home > gar home > gar submission' and a 'Select Facility' button. Below the header is a navigation bar with tabs: 'Permit Materials', 'Proficiency Testing', 'Gross Annual Receipts' (selected), 'LDT Approval', 'Survey', 'Blood Resources', and 'Tools'. On the left is a sidebar with links: 'GAR Home', 'Report', 'Submission' (highlighted), 'Past Reports', 'GAR User Manual', 'Instructions', 'Request for an Extension Date', and 'Request for an Extension Date'. The main content area displays submission details for PFI: 0000, Name: Internal Test for CLEP, and Reporting Due Date: 04/15/2022 12:00 AM. A blue box indicates 'Submission Complete' with a checkmark. Below this, submission details are listed: Submitted for: 2021, Submitted on: 03/29/2022 8:22 AM, Submitted by: -. A table shows financial data: Gross Revenue of Facility (\$456,066), Amount paid to reference labs (\$50), and This is your 2021 reportable Gross Annual Receipts (\$456,016). At the bottom, it states 'Did not test any New York specimens in 2021:' and 'Gross Annual Receipts for 2021 are reported under PFI number:'. The footer contains links: 'Contact Us', 'Help', 'FAQ', 'Accessibility', and 'Message Center'.

Gross Revenue of Facility:	\$456,066
Amount paid to reference labs:	\$50
This is your 2021 reportable Gross Annual Receipts:	\$456,016

Did not test any New York specimens in 2021:  
Gross Annual Receipts for 2021 are reported under PFI number:

### Past Reports:

In 2019 and beyond, laboratories and blood banks will be able to view and print previous GAR Reporting submissions. This page only displays GAR Reports that have accepted by the department.

This feature will not be available for 2018 or prior years. Data from previous years that were submitted on hard copy forms will not be entered into the online GAR Reporting Module.

### Requesting an Extension for GAR Reporting

- On the **Gross Annual Receipts Reporting** Home page, there is a link that points to the **Extension Request Date** page on the left panel that will take you to the Tools tab.

**eCLEP MANUAL**

Permit Materials	Proficiency Testing	<b>Gross Annual Receipts</b>	LDT Approval	Survey	Tools
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[GAR Home](#)    PFI: 0000    Name: O12 DEV Internal Test for CLEP TEST 1 DUMMY    Reporting Due Date: 06/05/2021 12:00 AM

**Gross Annual Receipts Reporting**

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

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

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

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

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

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

From the Tools tab in eCLEP, click on the **Extension Date Request** link on the left panel.

Permit Materials	Proficiency Testing	Gross Annual Receipts	LDT Approval	Survey	<b>Tools</b>
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[Tools Home](#)    PFI: 0000    Name: Internal Test for CLEP

**Extension Date Request**

Items with a \* are required.

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

\*Extension Request for:

Survey Id:

\*New Date:

Reason:   
 Characters Remaining: 200

Save

- Select the request type (**GAR**) from the drop-down menu, **Extension Request for**.
- Enter a proposed date for the extension date in the **New Date** field:

**eCLEP MANUAL**

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

[Tools Home](#)

• Extension Date Request

PFI: 0000 Name: Internal Test for CLEP

### Extension Date Request

Items with a \* are required.

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

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

Survey Id: -- Select Survey --

\*New Date: mm/dd/yyyy

Reason:  
Characters Remaining: 200

Save

- Use the **Reason** field to add any notes if deemed necessary.
  - *Requests for extensions beyond May 31<sup>st</sup> must include a Reason or the request will be rejected.*
- Clicking the **Save** button, completes the request process for an extension date. No extra step is required.

**Re-opening the GAR Reporting Module**

To re-open the GAR reporting module, **E-mail:** [clep@health.ny.gov](mailto:clep@health.ny.gov)

Please indicate “Re-Open GAR” with your PFI number 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 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.

**eCLEP MANUAL****Technical Support**

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

***Help with HCS Enrollment, HCS Accounts, HCS access***

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](mailto:camu@health.ny.gov)

***Help with eCLEP***

For additional assistance contact the Clinical Laboratory Evaluation Program:

- E-mail support at [CLEP@health.ny.gov](mailto:CLEP@health.ny.gov).

**eCLEP MANUAL****Glossary**

**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

**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>.

**PFI** – Permanent Facility Identifier that identifies a laboratory

**User ID** – An identification for logging on to the HCS