NEW YORK STATE | Department of Health | Wadsworth Center

Clinical Laboratory Evaluation Program

eCLEP Manual

GAR Reporting

March 2023

eCLEP Manual

Gross Annual Revenue Reporting

Table of Contents

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.

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.

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.

HCS Access Permissions

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

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

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

Clinical Laboratory Directors and HCS Coordinators without HCS accounts

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

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

Requesting HCS Accounts for Other Individuals

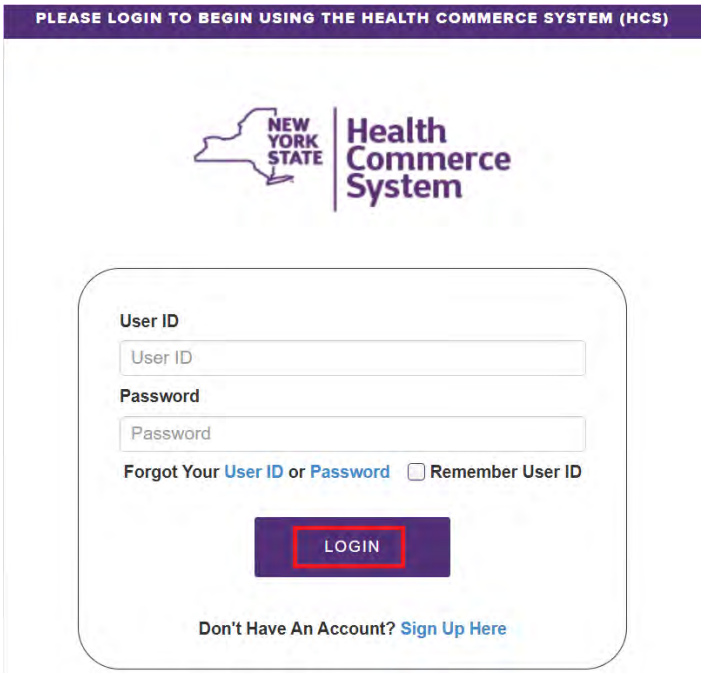
The Laboratory Director or HCS Coordinator for the laboratory can electronically request an account for additional laboratory staff. The Laboratory Director or HCS Coordinator needs to log into the Health Commerce System at https://commerce.health.state.ny.us, select the Coordinator's Account Tools (left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

Delegated Submitter

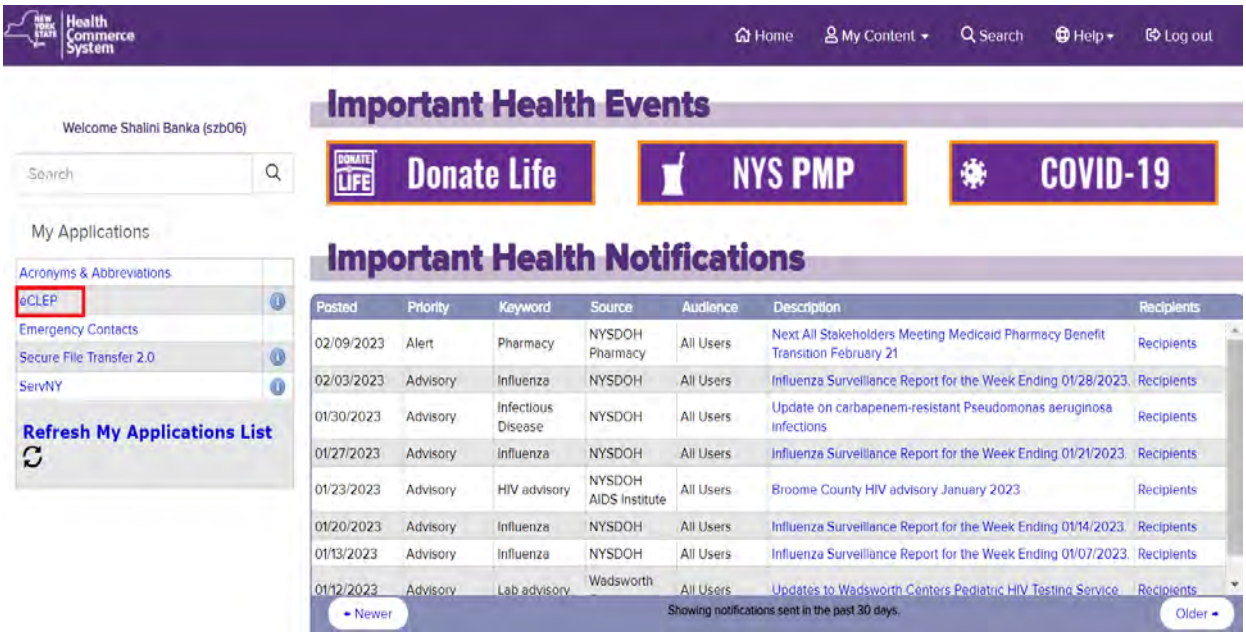
The Laboratory Director may delegate data submission privileges to a staff member who already has an HCS account by signing and completing a Delegated Submitter Request form. The form is available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce.

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**:



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



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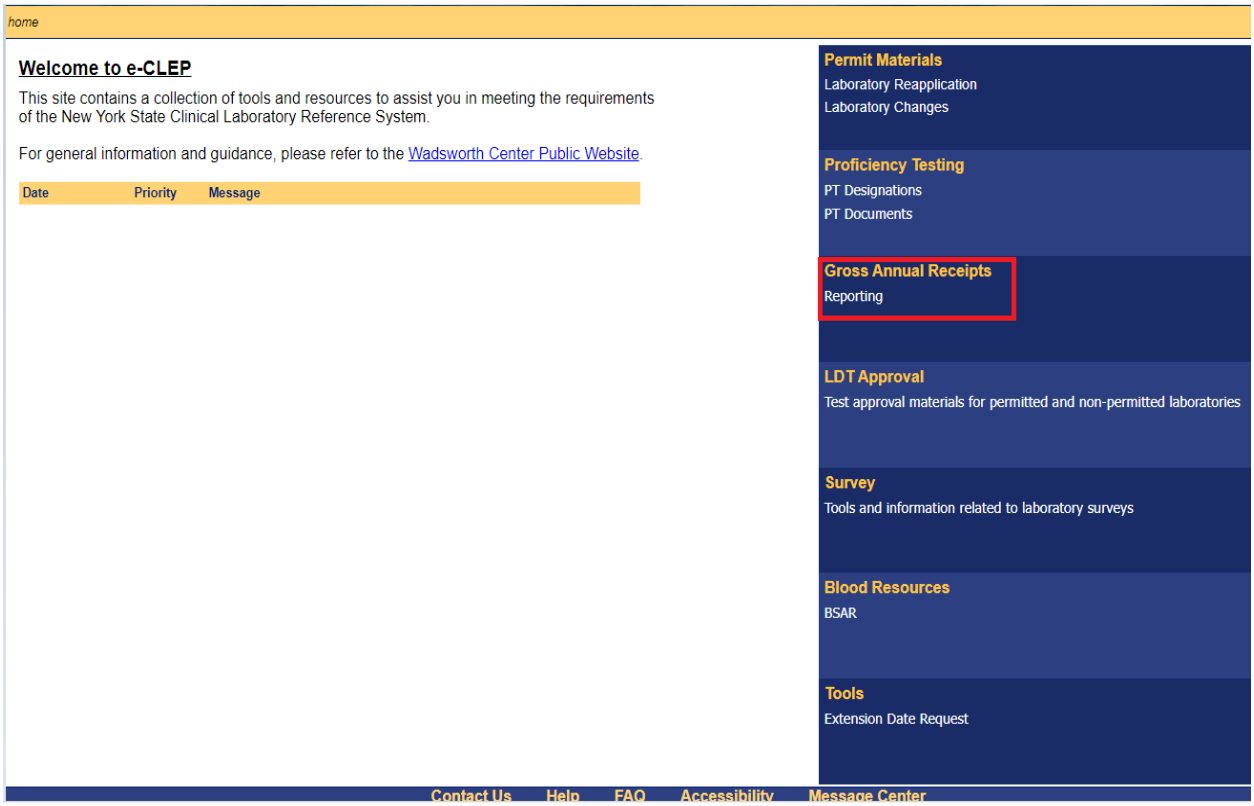
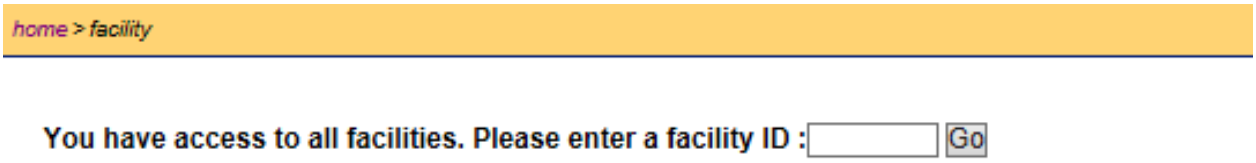
4. Click on **eCLEP** in the left frame and the eCLEP Home Page will display. Click on **GAR** area at the middle right.



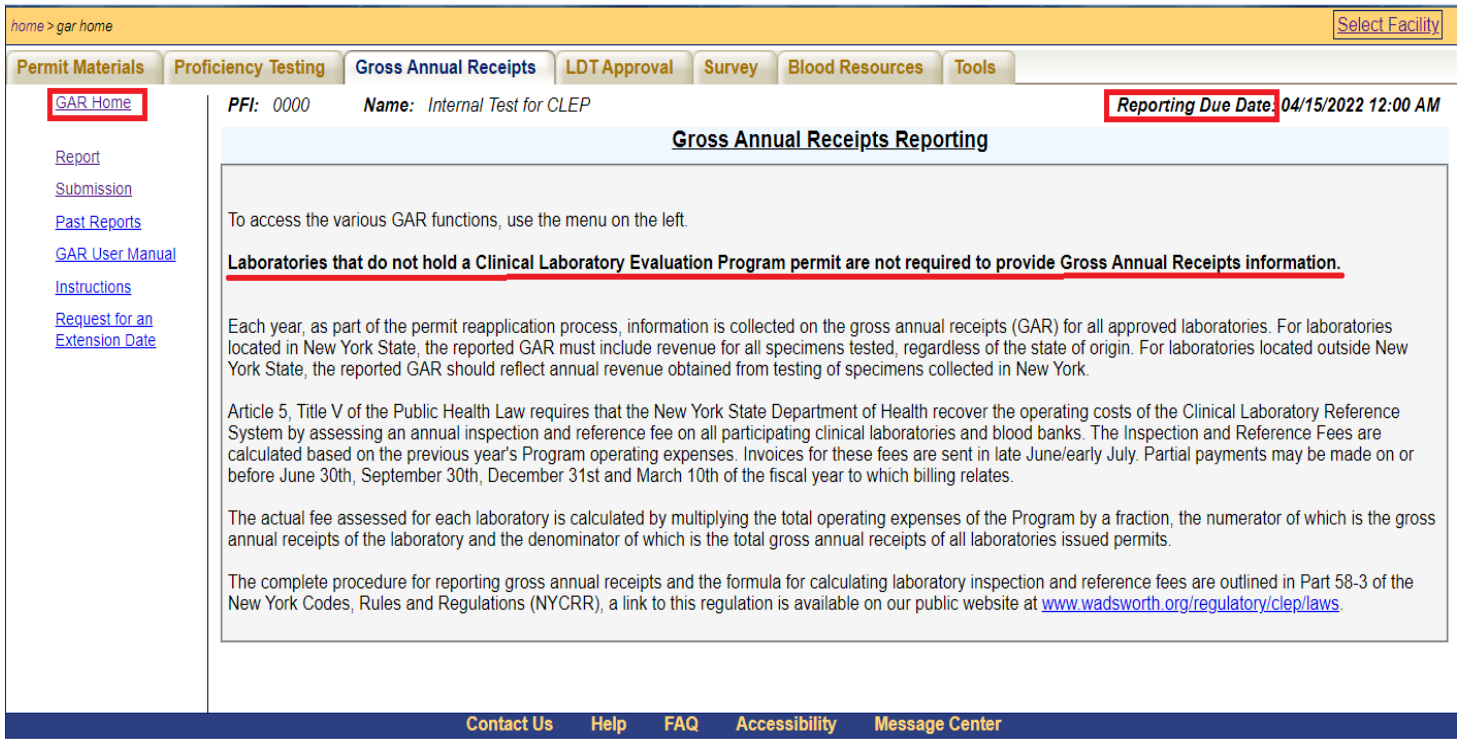
5. HCS account holders affiliated with more than one laboratory will be required to enter an appropriate 4-digit numeric Permanent Facility Identifier **(PFI)**.

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



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.**



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.

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. 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.

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.

Please enter only whole numbers.

Gross revenue earned for testing specimens: $0

Amount paid to reference labs for specimens: $0

Calculate

This is your 2019 reportable Gross Annual Receipts:

Comment

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

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.

☐ 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.

☐ I have read the above, and request confidentiality.

Save Submit Reset

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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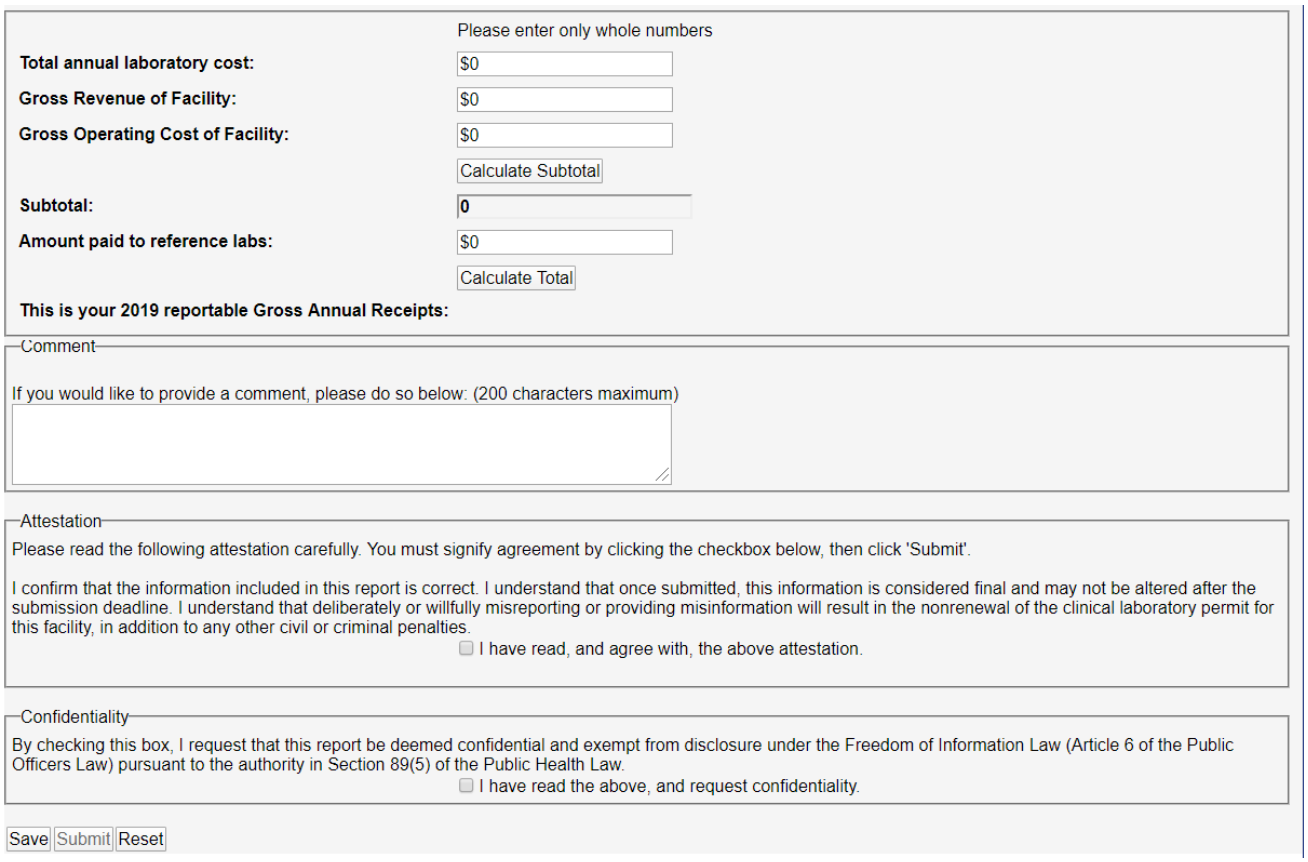
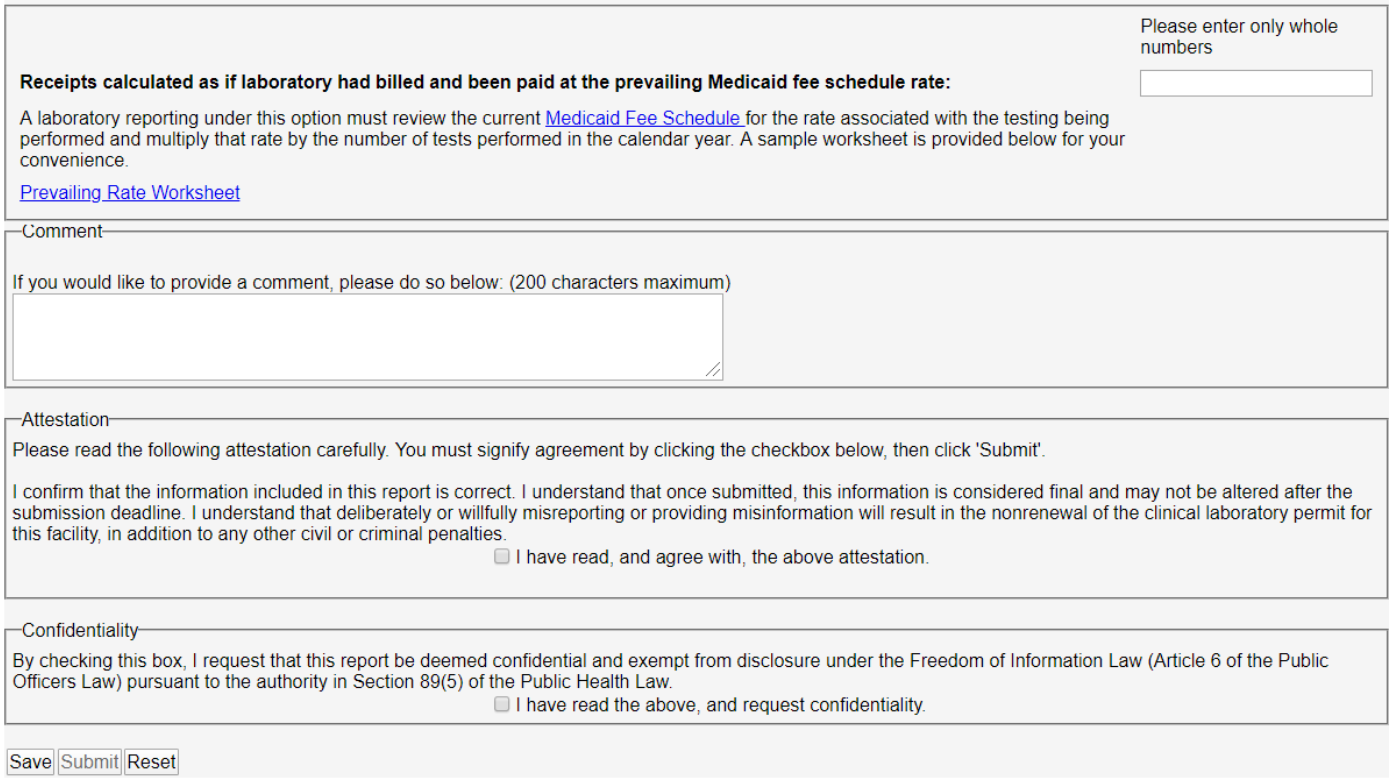
- *Institutional Cost Report location: Reclassification and Adjustment of Trial Balance Expenses; Exhibit 11; CMS Line Code 118; Column Reclassified Trial Balance 5, Class 20030.*

- 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.



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.



Please enter only whole numbers

Receipts calculated as if laboratory had billed and been paid at the prevailing Medicaid fee schedule rate:

A laboratory reporting under this option must review the current Medicaid Fee Schedule 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.

Prevailing Rate Worksheet

Comment

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

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.

I have read, and agree with, the above attestation.

Confidentiality

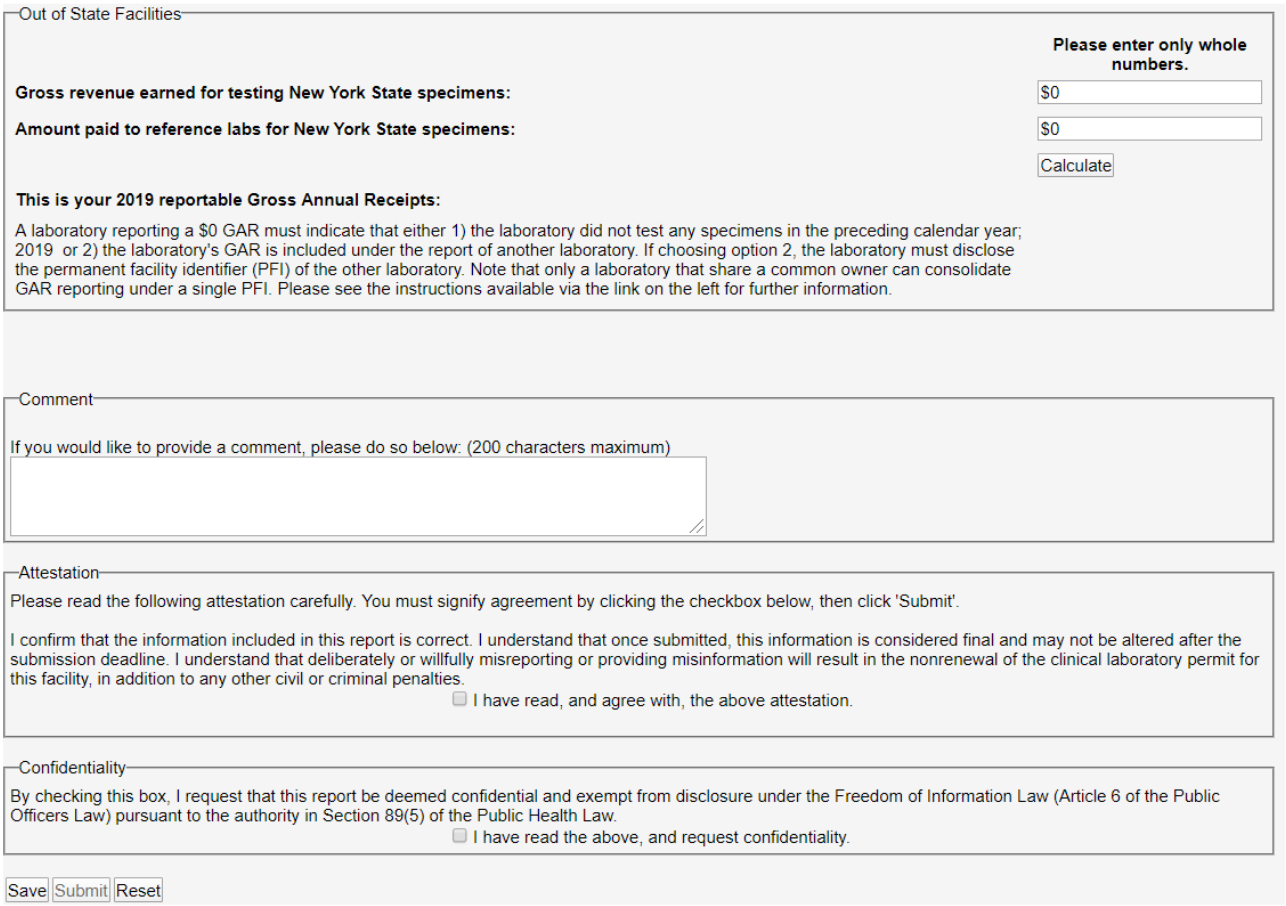
By checking this box, I request that this report be deemed confidential and exempt from disclosure under the Freedom of Information Law (Article 6 of the Public Officers Law) pursuant to the authority in Section 89(5) of the Public Health Law.

I have read the above, and request confidentiality.

Save Submit Reset

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

Please enter only whole numbers.

Gross revenue earned for testing New York State specimens: $0

Amount paid to reference labs for New York State specimens: $0

Calculate

This is your 2019 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; 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.

Comment

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

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.

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.

I have read the above, and request confidentiality.

Save Submit Reset

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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.

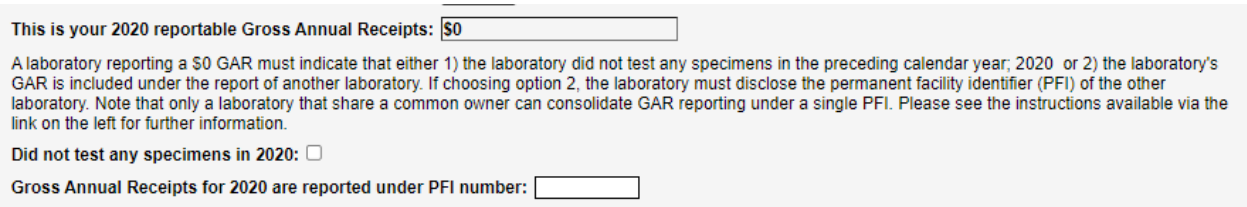
Reporting $0 GAR:

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: $0

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 for guidance.

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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.

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.

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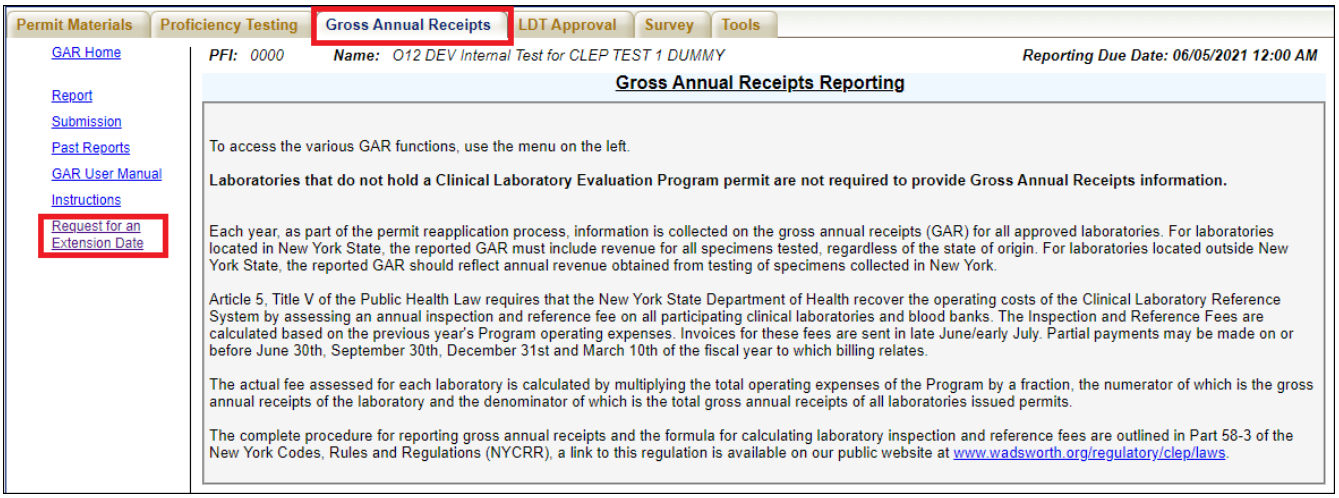
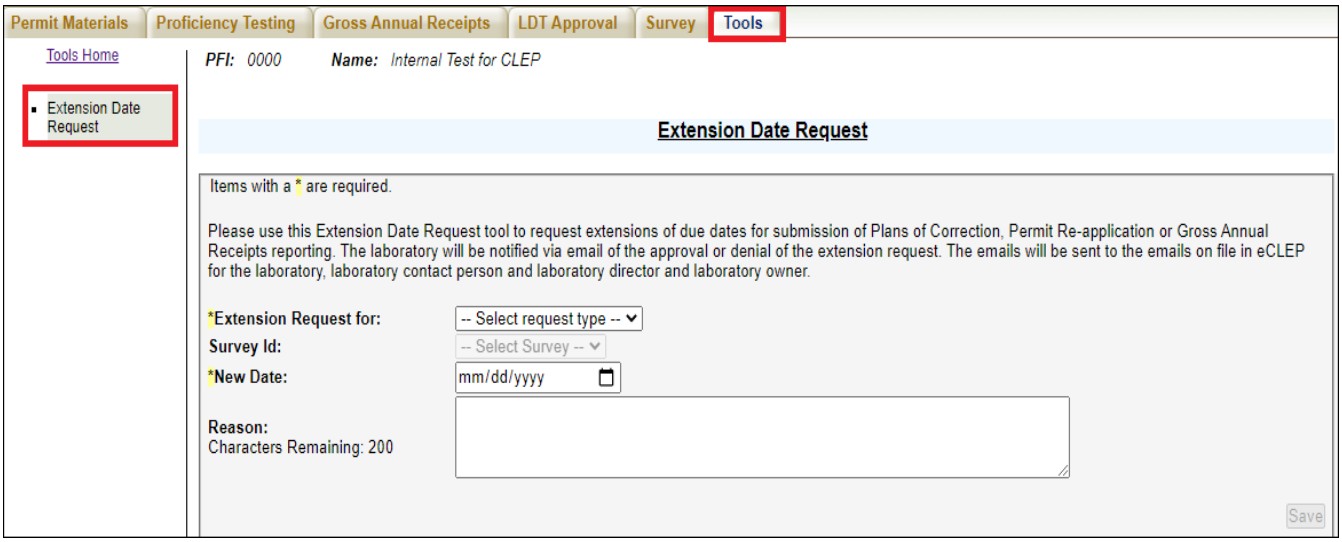
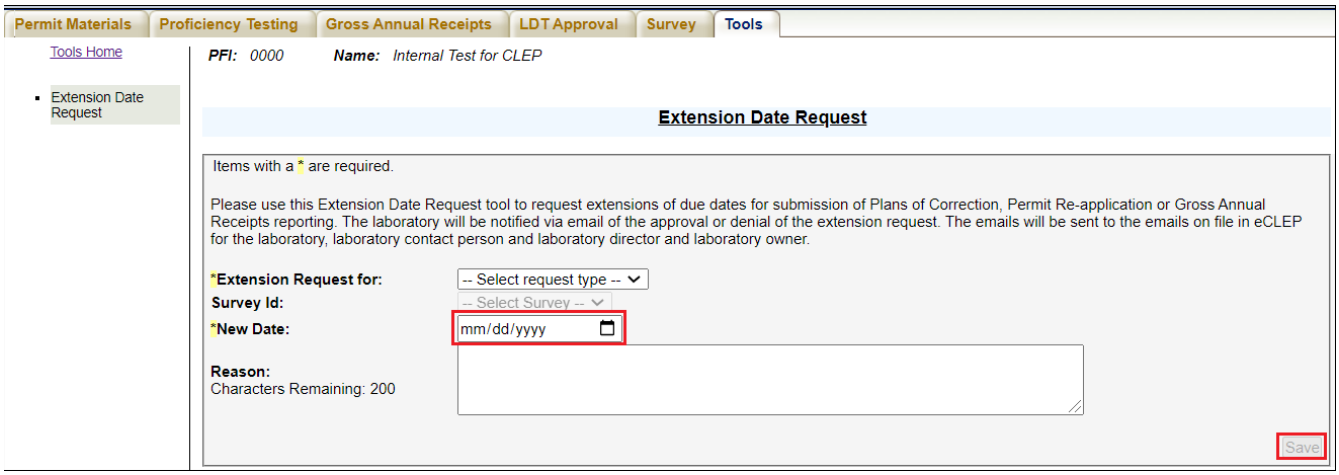


From the Tools tab in eCLEP, click on the **Extension Date Request** link on the left panel.



- 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:



- Use the **Reason** field to add any notes if deemed necessary.
    - ***Requests for extensions beyond May 31st 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

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.

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

Help with eCLEP

For additional assistance contact the Clinical Laboratory Evaluation Program:

- E-mail support at **CLEP@health.ny.gov**.

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