NEW YORK STATE | Department of Health | Wadsworth Center

Clinical Laboratory Evaluation Program

eCLEP Manual

GAR Reporting

2021

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 Wadsworth Center 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 at every step, eliminating submission failures and the need for follow-up communications to correct minor errors such as missing entries.

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

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

Requirements for Use

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

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

Browser Requirements and Configuration

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

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

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

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Roles and Responsibilities

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

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

Laboratory Director

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

Assistant Director / Delegated Submitter

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

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

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

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

HCS Access Permissions

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

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

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

Clinical Laboratory Directors and HCS Coordinators without HCS accounts

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

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

Requesting HCS Accounts for Other Individuals

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

Delegated Submitter

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

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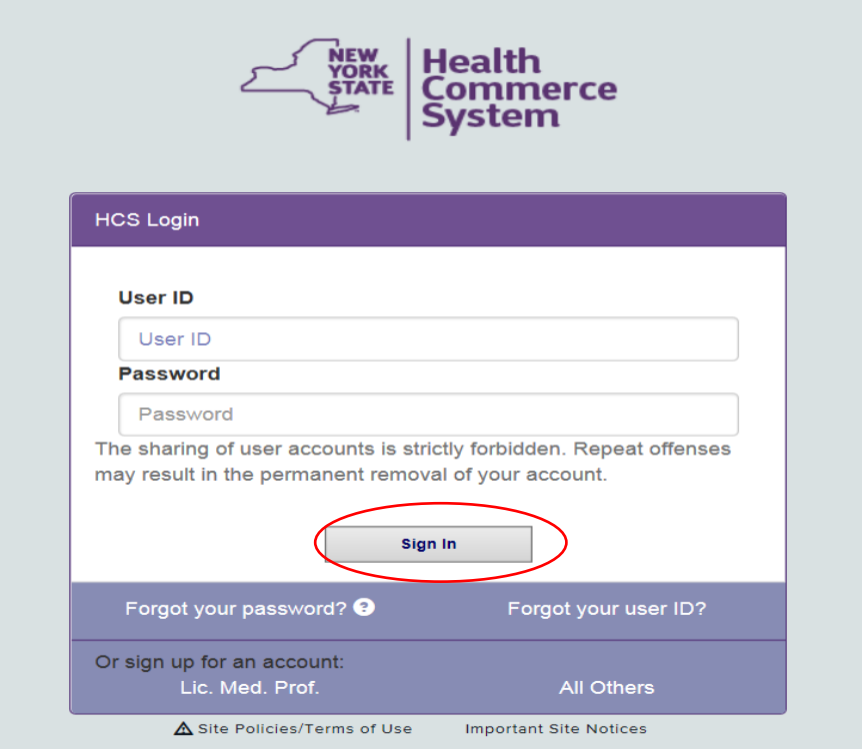
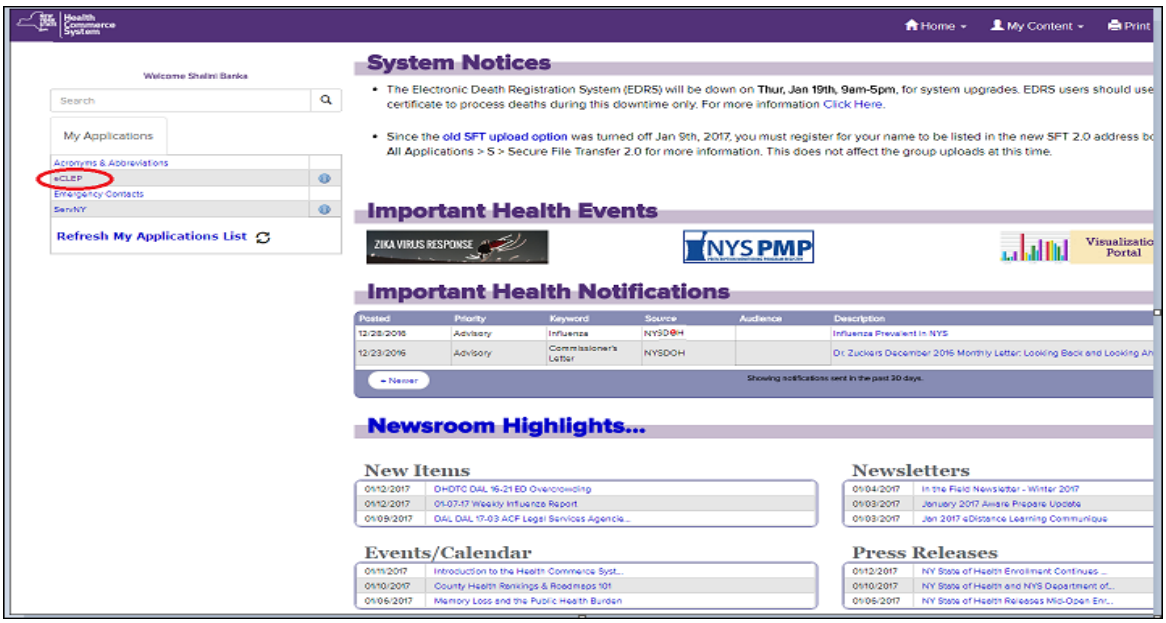
Accessing eCLEP and the GAR Reporting Module

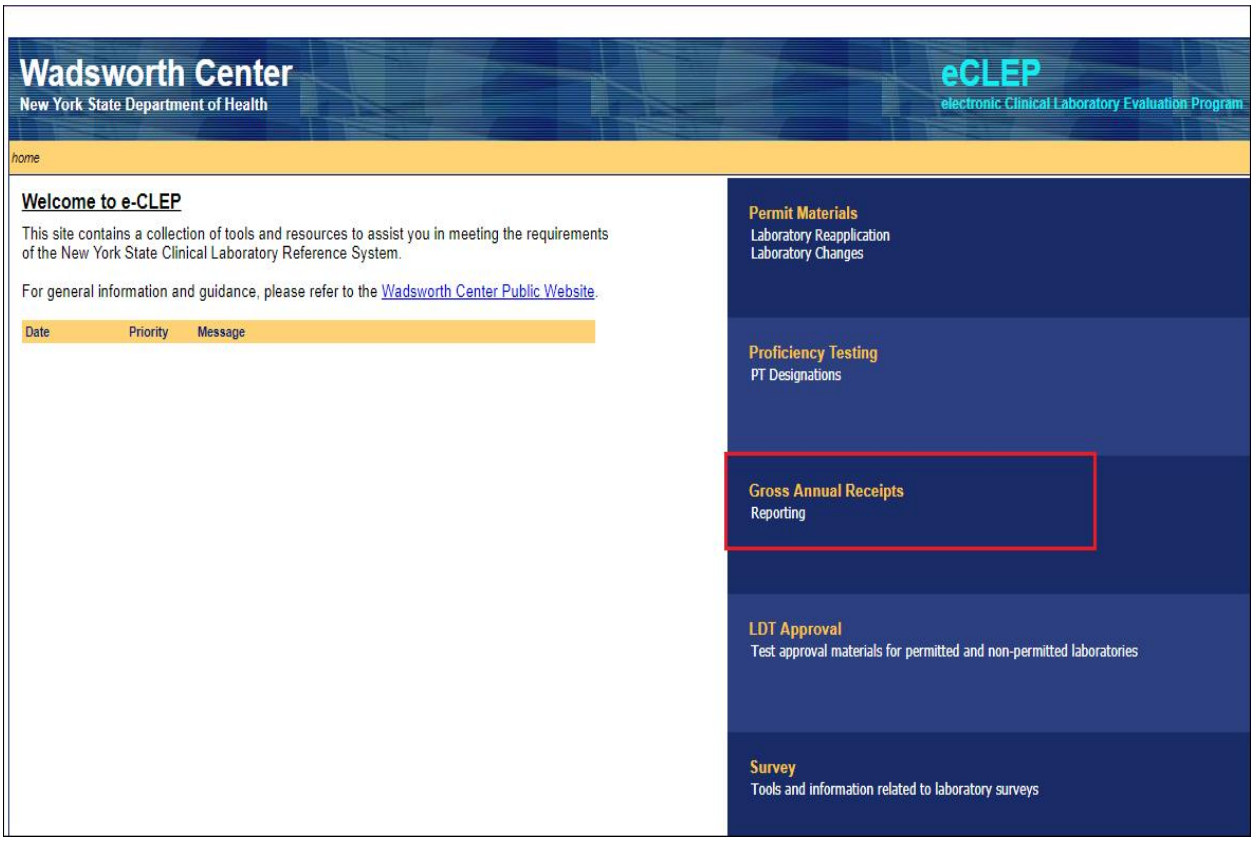
1. To access the eCLEP Home Page enter the following web address into an Internet browser:
   https://commerce.health.state.ny.us
2. Enter your User ID and Password into the **HCS Login screen** and click **Sign In**:



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

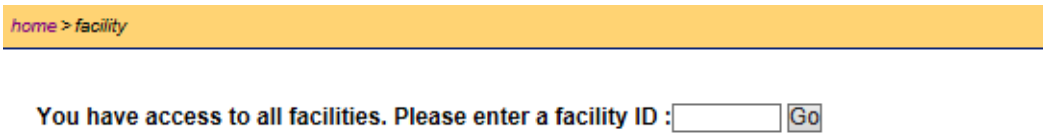


4. Click on **eCLEP** in the left frame and the eCLEP Home Page will display. Click on **GAR** area at the middle right.



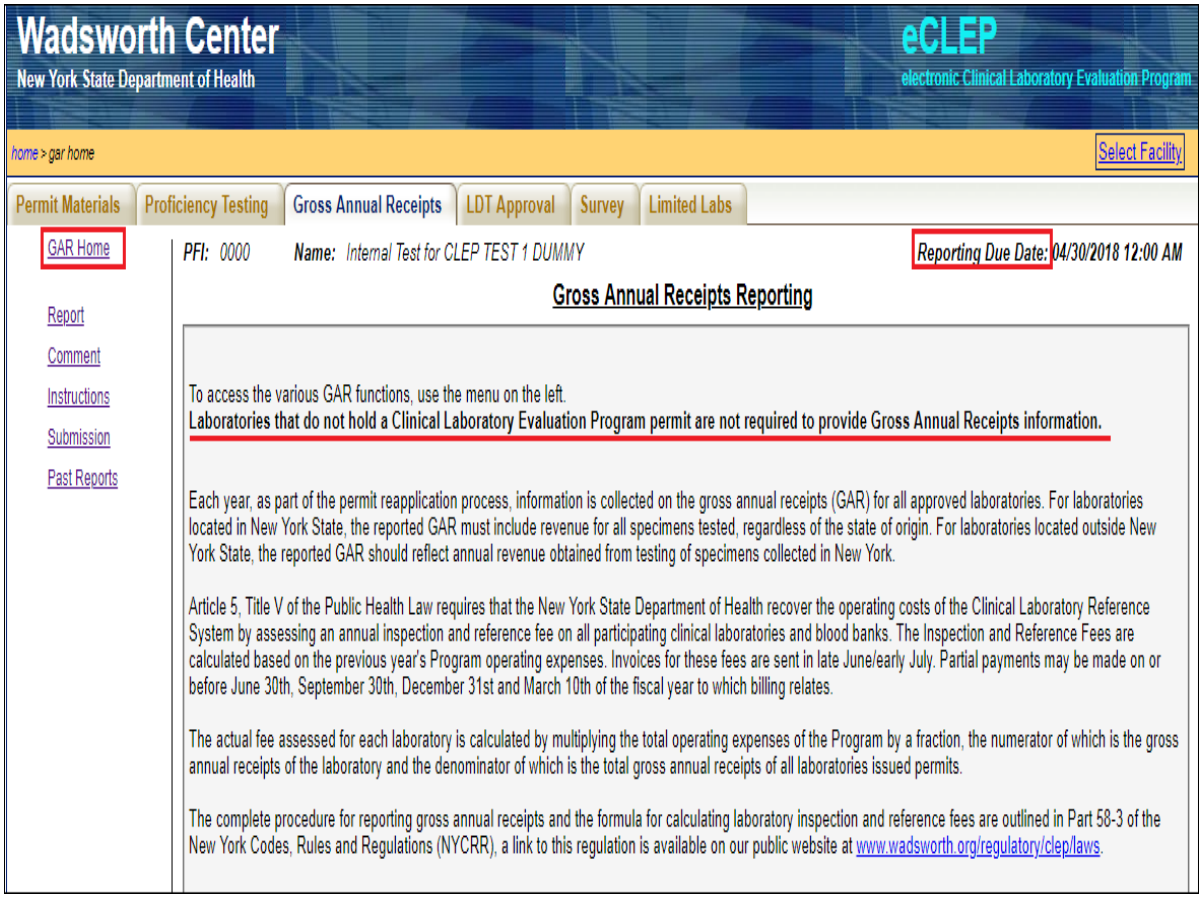
5. HCS account holders affiliated with more than one laboratory will be required to enter an appropriate 4-digit numeric Permanent Facility Identifier **(PFI)**.

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



6. Most users, however, 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 via email to clep@health.ny.gov with a subject line including the laboratory PFI and the words "GAR Extension", and the explanation and date of anticipated submission in the body of the email. The request must include the PFI, name, and address of the laboratory as well as an explanation of why an extension is being requested.**



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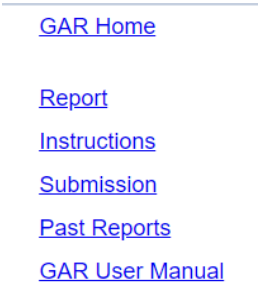
Navigating in the GAR reporting module

I. On the left side of the GAR home page, there are links to the reporting page, comment fields, instructions, submission page and past reports.



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:

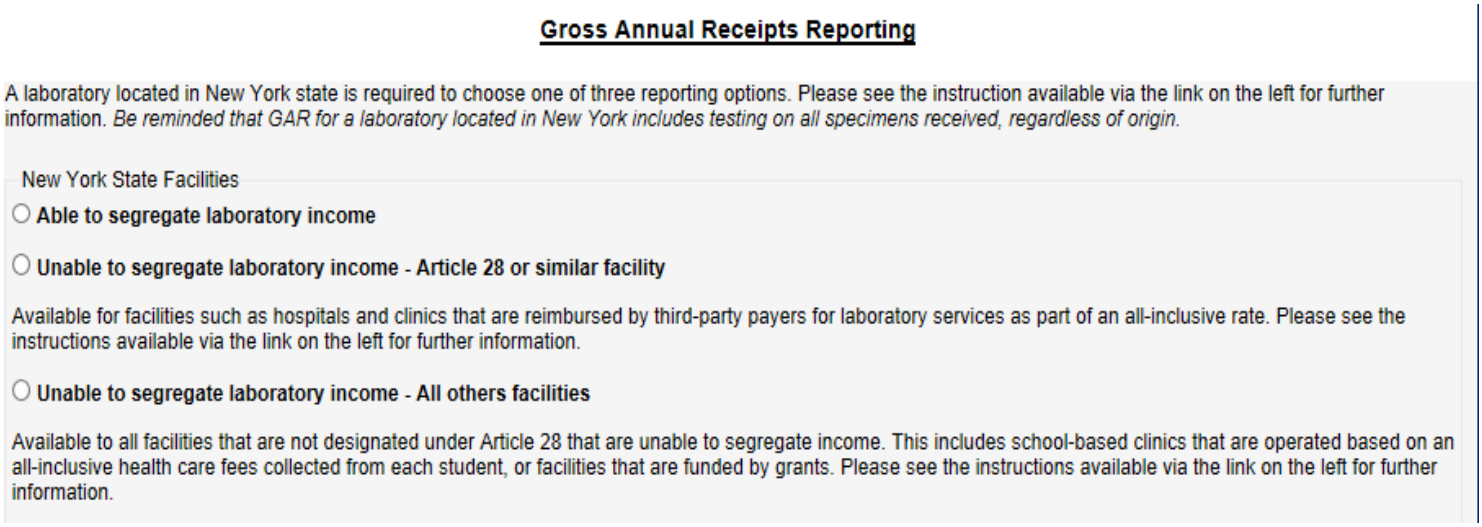
Click on the report link to begin the GAR reporting process.

Note: *Reporting of GAR is a* ***two-step*** *process: enter reporting data using the* ***Report*** *page, then submit the report using the* ***Submission*** *page.*

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**

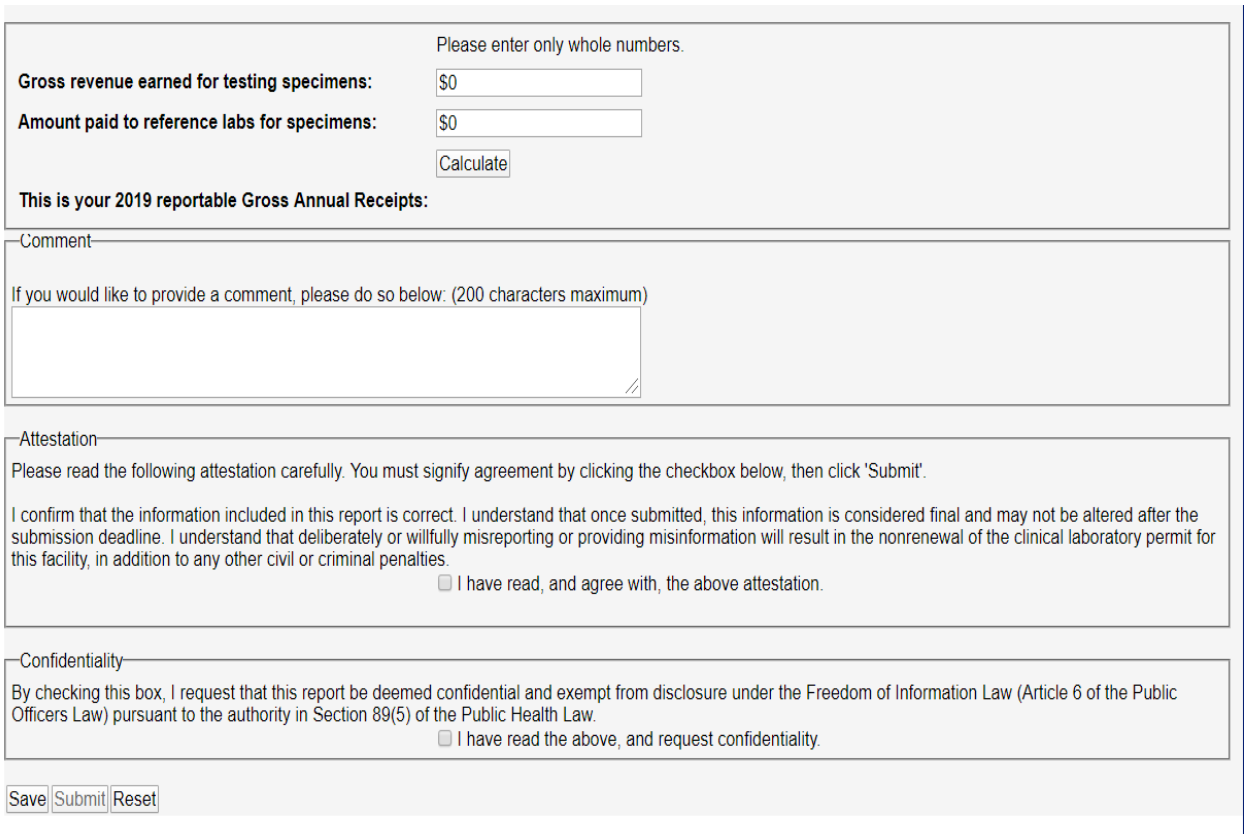
Available for facilities such as hospitals and clinics that are reimbursed by third-party payers for laboratory services as part of an all-inclusive rate. Please see the instructions available via the link on the left for further information.

○ **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.
- 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.
- Click **Save**.
- **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.



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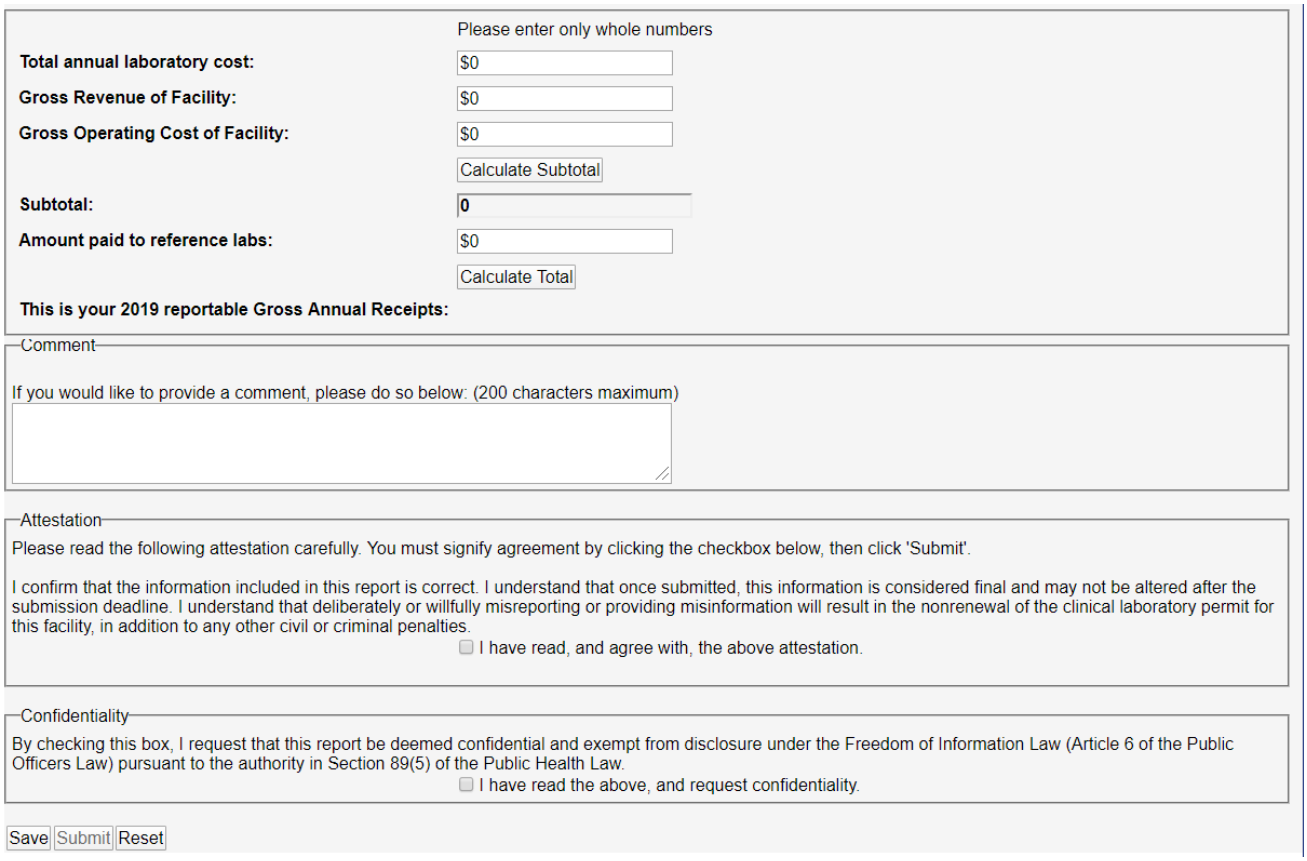
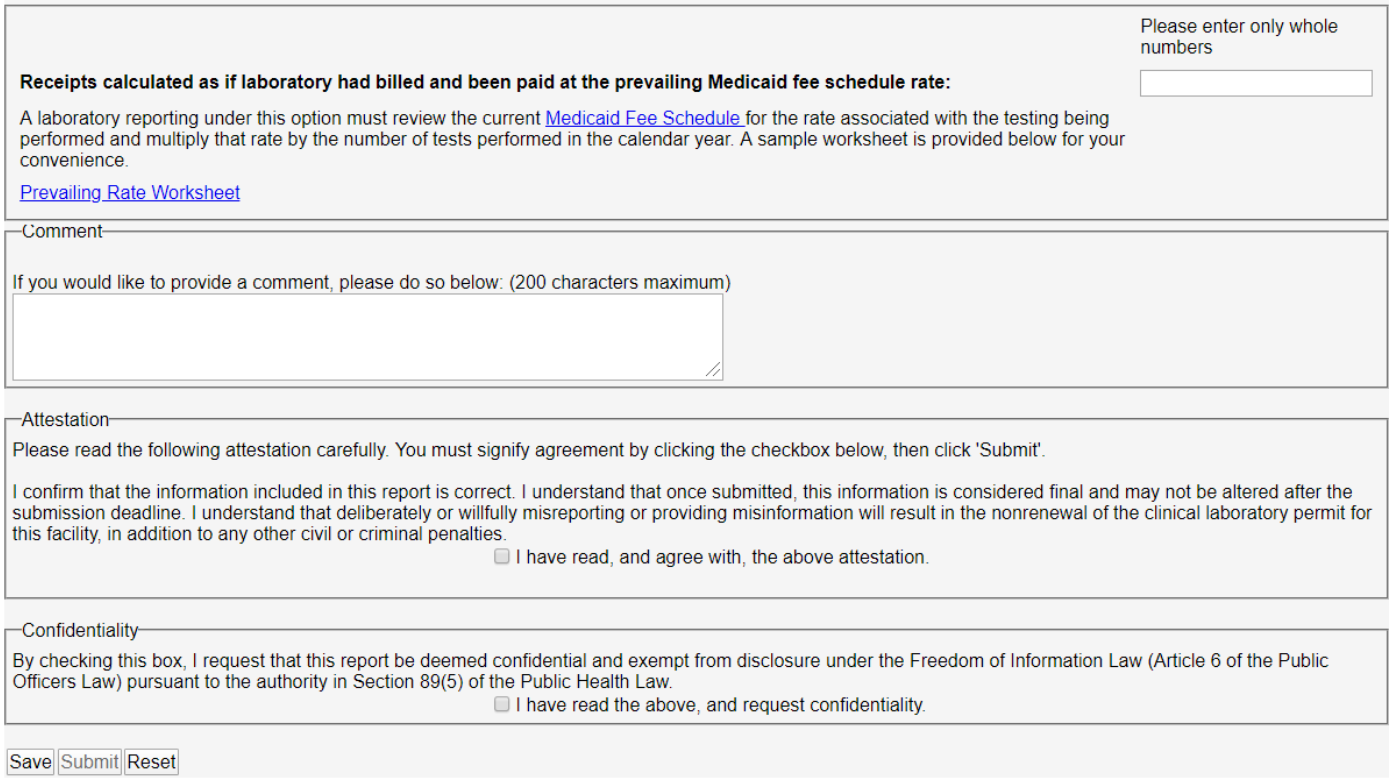
- *Institutional Cost Report location: Reclassification and Adjustment of Trial Balance Expenses; Exhibit 11; CMS Line Code 118; Column Reclassified Trial Balance 5, Class 20030.*

- 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.
- 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.
- 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.



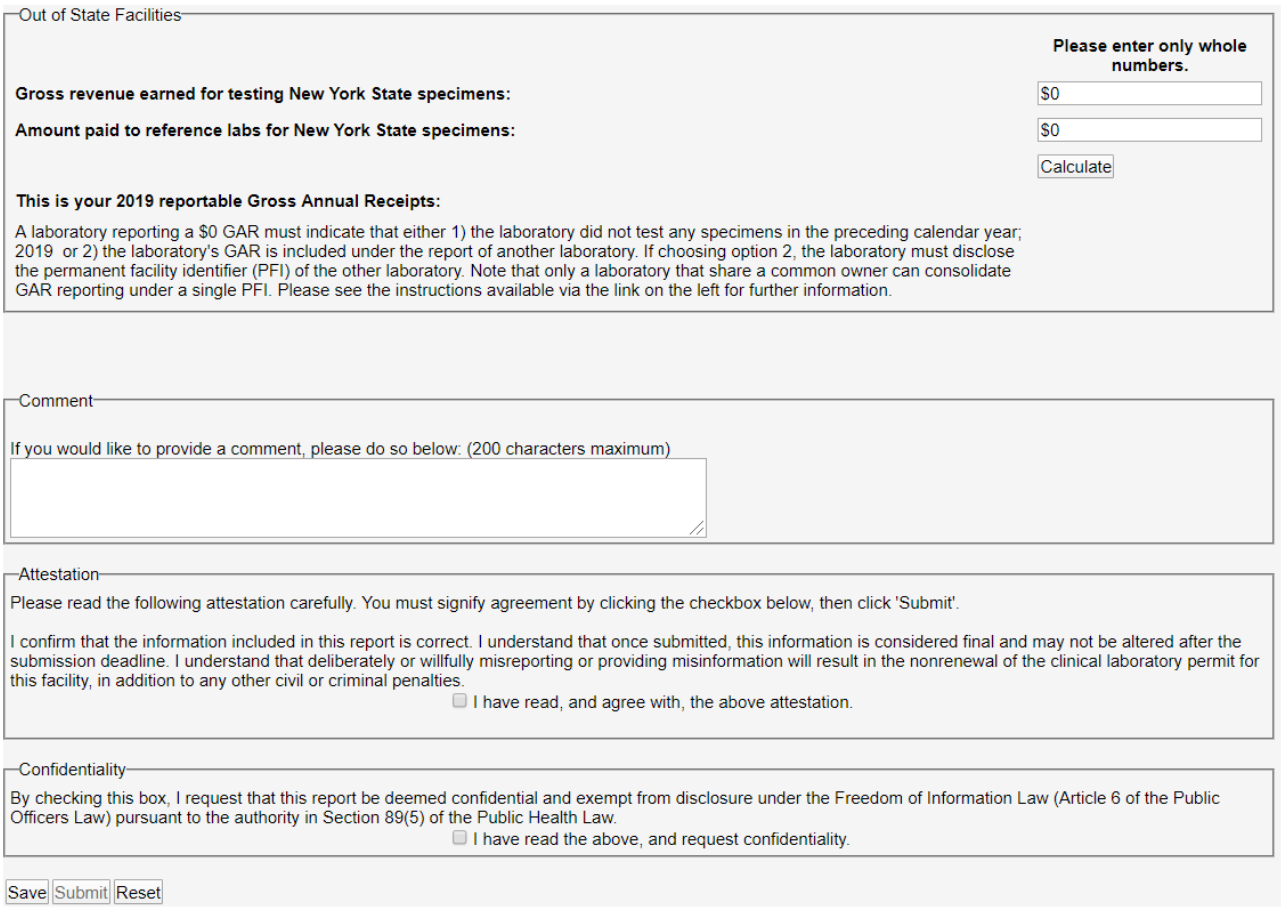
New York Laboratories and Blood Banks Unable to Segregate Income – All Others

- 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.
- 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.
- 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.



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.



Past Reports:

In 2019 and beyond, laboratories and blood banks will be able to view and print previous GAR Reporting submissions.

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.

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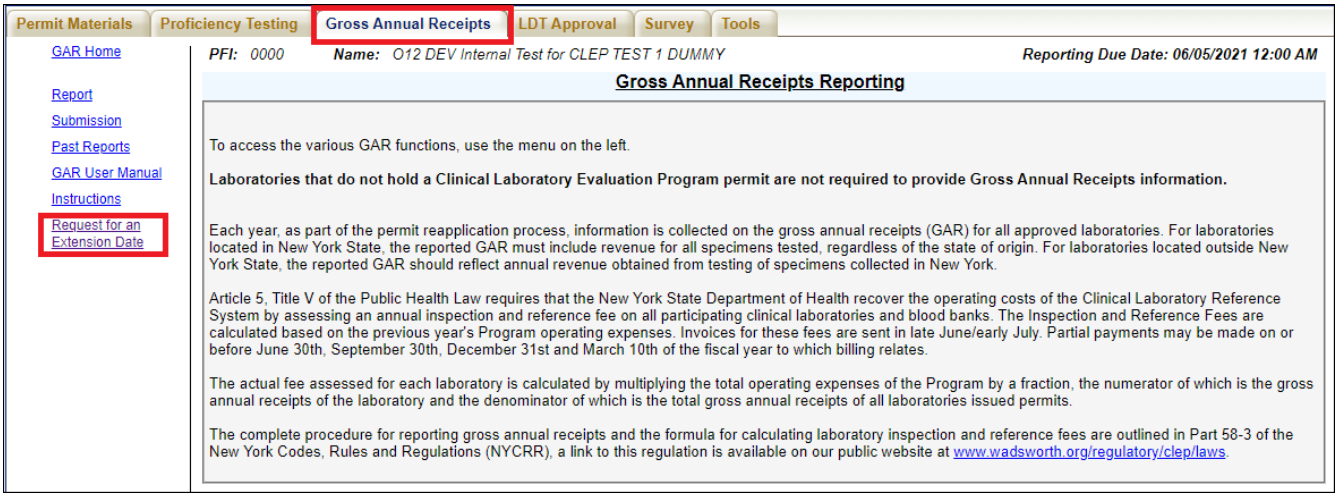
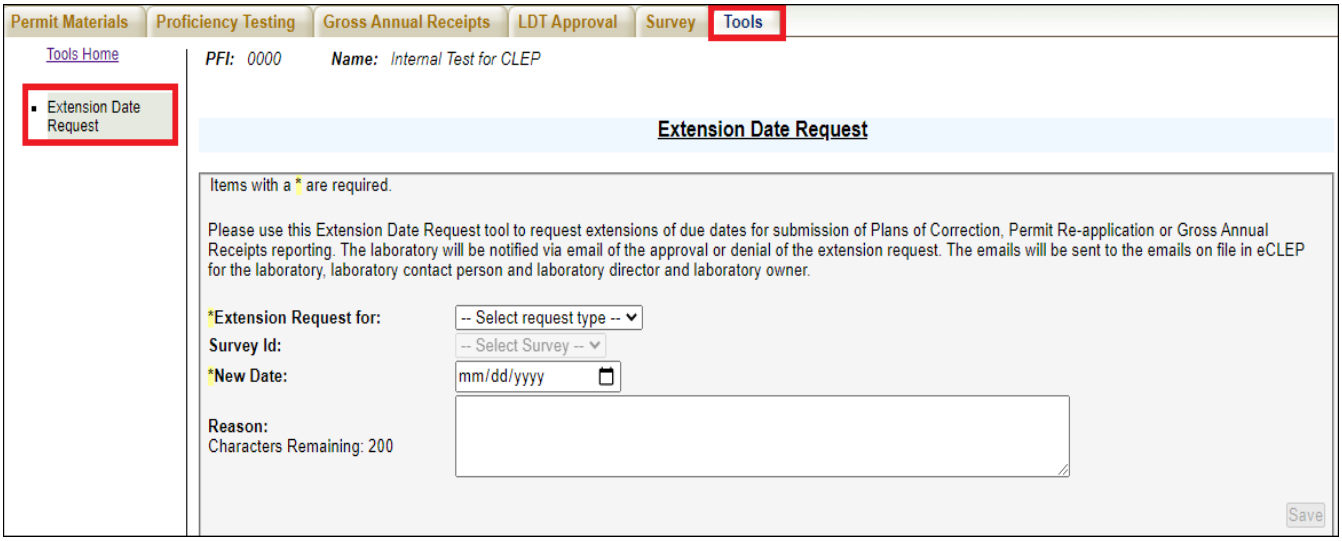
Requesting an Extension for GAR Reporting

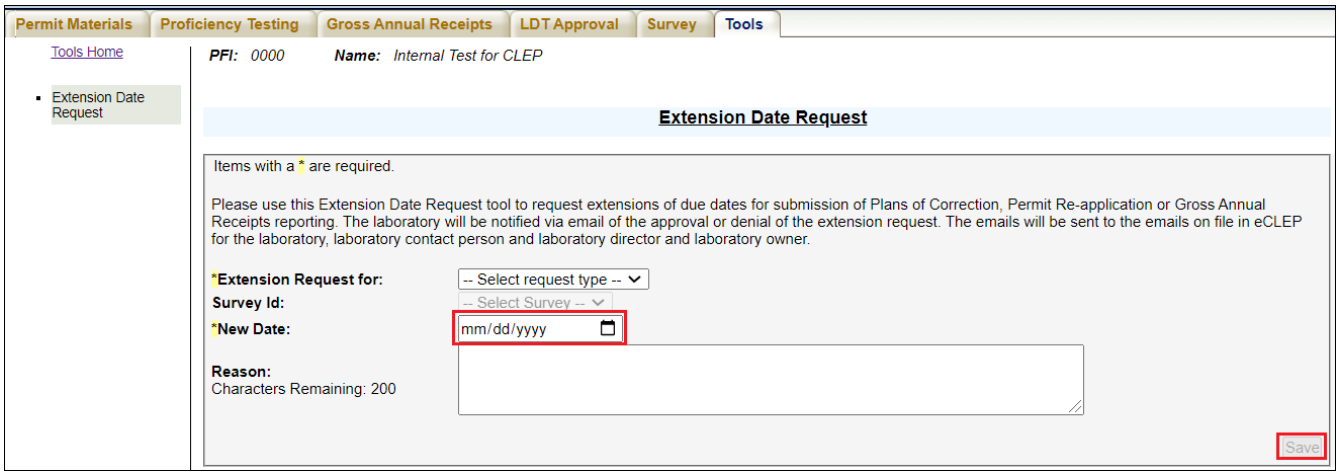
- On the **Gross Annual Receipts Reporting** Home page, there is a link that points to the **Extension Request Date** page on the left panel that will take you to the Tools tab.



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 be 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:** clepreapp@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)

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