

## GENERAL INFORMATION

**DUE DATE APRIL 28, 2023 at 5:00PM EDT**

Clinical laboratory and blood bank permits are valid for one year, commencing on July 1<sup>st</sup> and expiring June 30<sup>th</sup> of the following year. All permitted laboratories **and laboratories in applied status** must complete the reapplication process to maintain enrollment in the Program and remain eligible for a New York State clinical laboratory permit. If there are any questions, contact us at [clepreapp@health.ny.gov](mailto:clepreapp@health.ny.gov) and remember to include your Permanent Facility Identifier (PFI) number with any correspondence.

### Submission deadline extensions may be requested using the Extension Request feature in eCLEP.

Log into the Health Commerce System, click on eCLEP, click on Extension Date Request under Tools.

Extension Request for: choose "Reapplication"

New Date: enter date requested

Reason: provide a brief justification for the extension

**Note:** REQUESTED SUBMISSION DEADLINE EXTENSIONS LATER THAN JUNE 2, 2023 WILL BE REJECTED. Contact [clepreapp@health.ny.gov](mailto:clepreapp@health.ny.gov) or [clepcert@health.ny.gov](mailto:clepcert@health.ny.gov) if the laboratory is not able to submit a permit reapplication by June 2, 2023.

## REQUIRED STEPS FOR COMPLETING THE APPLICATION

### Successful completion of the permit reapplication process includes:

- Review/verification of laboratory information and submission of requested information/documentation in eCLEP Permit Materials.
- Completion of **REQUIRED SUPPLEMENTAL DOCUMENTATION** (see page 4 below), as applicable to your laboratory.
- Acceptable response to any requests for additional information made following a review of submitted material.

To access eCLEP through the Health Commerce System, go to <https://commerce.health.state.ny.us> and log in using your HCS User ID and password. Choose **eCLEP** from the My Applications list and click on **Permit Materials**. If you have access to eCLEP for more than one facility, you must enter the PFI for only one facility. *An eCLEP Permit Materials User Manual is available under the Tools button on the blue task bar in eCLEP and is also available on our public website at <https://www.wadsworth.org/regulatory/clep/clinical-labs/change-permit>.*

\*\*If eCLEP will not allow you to save or does not display dropdowns, please attempt to use a different internet browser to access the HCS and eCLEP. Older versions of Internet Explorer do not work well.

### Step 1: Review and Update

Visit each of the areas indicated in the blue task bar to review and update the laboratory's information as needed.

#### **Upload all required documents.**

**\*\*Special Note:** Please remove all **spaces** and **special characters** from the filename when uploading a document. There should be only one period in the filename, immediately before the filetype.

### Step 2: Provide Required Data

All areas that require updated information are presented on this page.

### Step 3: Attest and Submit

### Step 4: Print for your records and click the **Finish** button!

## NAVIGATING eCLEP

### LABORATORY PROFILE

Review and update the current data on file as needed.

- The department primarily uses e-mail to correspond with the laboratory. If the e-mail address of the laboratory or contact person changes and the department is not notified as required, the laboratory may experience delays in receiving valuable information. **New for 2023:** A laboratory-specific email for all directors and assistant directors is required. Please see instructions under Personnel section below.
- The laboratory address must be the physical location where testing is performed. Due to mailing requirements, the address must include a street number.
- The Laboratory Hours must reflect the actual hours of testing at the facility. "Testing" includes the reading of slides by a pathologist. Do not include hours when only specimen collection is performed. If your laboratory operates 24/7, check the corresponding box. If the laboratory is closed part of the day and then reopens, use the 'other' line to make notations; for example, "closed from 0300 to 0700." **New for 2023:** We have moved to a 24-hour (aka military) format when entering operational hours.

### OWNERSHIP

Please review the current data on file and answer the questions related to ownership.

**All laboratories are required to upload a complete listing of direct and indirect owners of the laboratory. An Instructions document is available for reference on the left of the screen.**

#### Notes:

There are two parts to this tab: "Owner" and "Declaration." Click 'Save' after making changes under "Owner". Then answer the questions under "Declaration", click 'Save' again. On the Upload page, upload the required ownership list and any supplemental documentation to support your responses to the Declaration questions.

**\*\*Special Note: Please remove all spaces and special characters from the filename when uploading a document. There should be only one period in the filename, immediately before the filetype.**

If your laboratory operates under a management contract, indicate the name and address of the company that holds the contract. If this is a new contract, submit a copy of the management contract with the laboratory's PFI clearly marked. Submission of the management contract can be made via email to [clepreapp@health.ny.gov](mailto:clepreapp@health.ny.gov) or via fax at (518) 485-5414 or (518) 449-6901.

### PERSONNEL

Review the director and assistant director(s) and their assigned permit category responsibilities.

When making changes to this section, ensure that each permit category has at least one responsible director/assistant director with a Certificate of Qualification in a corresponding category.

For the director's and assistant director(s)' hours, please provide the average number of hours and frequency (e.g., weekly, every other week) the individual will be on-site in the laboratory. Please indicate hours as a quantifiable whole number; 'as needed' or 'on call' is not an acceptable response.

Review the Clinical Laboratory Standards of Practice to understand expectations for director and assistant director oversight: (<https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-standards>)

- Director Standard of Practice 3 (DR S3): Director and Assistant Director Involvement and Time Commitment
- Director Standard of Practice 4 (DR S4): Director Responsibilities

Compliance with these requirements will be monitored through the permit application process and during on-site survey.

**NEW FOR 2023:** A laboratory-specific email for all directors and assistant directors is required. Please enter the email address for the laboratory director and all assistant directors under the **Personnel tab**, using the [Email link](#) on the left under **Updates**.

## PERMIT CATEGORIES

Review the categories currently held and the director/assistant director responsibilities. Please see page 5 for a list of available permit categories for the 2023-2024 permit year. **Requests for additional categories may be made as part of this reapplication.**

**ONCOLOGY – SOLUBLE TUMOR MARKERS:** This category is being discontinued effective July 1, 2023. Soluble tumor markers testing will be categorized under Clinical Chemistry.

**URINALYSIS:** This category is being added effective July 1, 2023. Laboratories currently performing urinalysis under the permit category of Clinical Chemistry are asked to submit a request to Add Category for Urinalysis. Note that such requests will be processed with a July 1, 2023 effective date.

## **CYTOPATHOLOGY – GYNECOLOGICAL TESTING**

All laboratories holding the permit category of Cytopathology – Gynecological Testing are required to upload proof of enrollment in a CMS-approved proficiency testing (PT) program for the **calendar year 2023**. The enrollment confirmation must reference the laboratory name and address. The PFI number of the laboratory must be handwritten on the paper if the CLIA number is not already included.

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

## TEST VOLUME

Laboratories located in New York State must enter the Test Volume for each area of testing. For hospital-based laboratories, this must include all testing performed at point of care that is performed under permit, but not the testing performed under a limited service laboratory registration. Please refer to the Guidelines for Reporting Test Volumes document under Tools in eCLEP.

## POINT OF CARE (POC)

Hospital-based laboratories in New York State are required to review and update the POC Testing area in eCLEP. Include POC testing performed under the laboratory permit (but not under a limited service laboratory registration) in the test volume calculation. **POC testing data reported here DOES NOT fulfill requirements for renewal of the Limited Service Laboratory registration at the same location.**

## PATIENT SERVICE CENTERS (PSC) AND HEALTH FAIRS (HF)

Under the tab **PSCs and Others**, laboratories must re-apply for any PSCs and HF currently on record with CLEP. Laboratories may also request a new PSC, add a HF, add more HF tests to an existing HF permit, or close a PSC or HF.

When applying for a new PSC or relocating an existing PSC, a floor plan and lease (when applicable) must be uploaded as part of the application process.

## REQUIRED SUPPLEMENTAL DOCUMENTATION

### **GROSS ANNUAL RECEIPTS REPORTING**

All laboratories holding a permit as of 12/31/2022 are required to calculate, verify, and submit their gross annual receipts (GAR) for calendar year 2022 using the GAR feature on eCLEP. **Please refer to the eCLEP GAR Reporting Manual available at <https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-fees>. Submission of the information is due May 15, 2023.** Failure to submit GAR data will result in a delay in receiving your clinical laboratory permit.

This submission process is separate from the permit reapplication. On the eCLEP home page, under Gross Annual Receipts, click on Reporting. If you have access to eCLEP for more than one facility, you must enter the PFI for only one facility.

**Submission deadline extensions may be requested using the Extension Request feature in eCLEP.** Log into the Health Commerce System, click on eCLEP, click on Extension Date Request under Tools.

Extension Request for: choose "Gross Annual Receipts"

New Date: enter date requested

Reason: provide a brief justification for the extension

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### **BLOOD SERVICES ACTIVITY REPORT**

All laboratories holding the permit categories Blood Services – Collection, Blood Services – Collection Autogeneic Only, Blood Services – Transfusion or Blood Services – Transfusion Storage Only are required to submit a Blood Services Activity Report (BSAR) annually. **Submission of the information is due May 15, 2023.** Failure to submit BSAR data will result in a delay in receiving your clinical laboratory permit.

**The BSAR is captured via eCLEP.** This submission process is separate from the permit reapplication. On the eCLEP home page, under Blood Resources, click on BSAR. If you have access to eCLEP for more than one facility, you must enter the PFI for only one facility. Failure to submit the BSAR will result in a delay in receiving your clinical laboratory permit.

**Submission deadline extensions may be requested using the Extension Request feature in eCLEP.** Log into the Health Commerce System, click on eCLEP, click on Extension Date Request under Tools.

Extension Request for: choose "Blood Services Activity Report"

New Date: enter date requested

Reason: provide a brief justification for the extension

**Note:** REQUESTED SUBMISSION DEADLINE EXTENSIONS LATER THAN JUNE 2, 2023 WILL BE REJECTED. Contact [clepreapp@health.ny.gov](mailto:clepreapp@health.ny.gov) or [brp@health.ny.gov](mailto:brp@health.ny.gov) if the laboratory will be unable to submit the BSAR by June 2, 2023.

### **HIV TESTING SURVEY**

All laboratories holding any of the permit categories listed below are **required** to participate in this survey:

<https://www.surveymonkey.com/r/WP6C8X7>

- Diagnostic Immunology – Diagnostic Services Serology
- Diagnostic Immunology – Donor Services
- Cellular Immunology – Non-malignant Leukocyte Immunophenotyping
- Virology

**Even if the laboratory is not performing HIV-related assays, participation is still required.**

If you have any questions regarding the HIV survey, please contact the Bureau of HIV/AIDS Epidemiology at 518-474-4284 or [bhaelab@health.ny.gov](mailto:bhaelab@health.ny.gov).

## LABORATORY PERMIT CATEGORIES

For each category included on the permit there must be at least one responsible director/assistant director with a Certificate of Qualification in the corresponding category.

**ANDROLOGY**

**BACTERIOLOGY**

**BLOOD pH AND GASES**

**BLOOD SERVICES – Collection**

**BLOOD SERVICES – Collection – Autogeneic Only**

**BLOOD SERVICES – Transfusion Service**

**BLOOD SERVICES – Transfusion/Storage Only**

**CELLULAR IMMUNOLOGY – Leukocyte Function**

**CELLULAR IMMUNOLOGY – Non-Malignant Leukocyte Immunophenotyping**

**CELLULAR IMMUNOLOGY – Malignant Leukocyte Immunophenotyping**

**CLINICAL CHEMISTRY**

**CYTOGENETICS**

**CYTOKINES**

**CYTOPATHOLOGY – Gynecological Testing**

**CYTOPATHOLOGY – Non-Gynecological Testing**

**DIAGNOSTIC IMMUNOLOGY – Diagnostic Services Serology**

**DIAGNOSTIC IMMUNOLOGY – Donor Services Serology**

**ENDOCRINOLOGY**

**FETAL DEFECT MARKERS**

**FORENSIC IDENTITY**

**GENETIC TESTING – Biochemistry**

**GENETIC TESTING – Molecular**

**HEMATOLOGY**

**HISTOCOMPATIBILITY**

**HISTOPATHOLOGY – General**

**HISTOPATHOLOGY – Dermatopathology**

**HISTOPATHOLOGY – Oral Pathology**

**IMMUNOHEMATOLOGY**

**MYCOBACTERIOLOGY**

**MYCOLOGY**

**ONCOLOGY – Molecular and Cellular Tumor Markers**

**PARASITOLOGY**

**PARENTAGE / IDENTITY TESTING**

**THERAPEUTIC SUBSTANCE MONITORING / QUANTITATIVE TOXICOLOGY**

**TOXICOLOGY – Blood Lead – Comprehensive**

**TOXICOLOGY – Blood Lead – ASV Using Screen Printed Sensors**

**TOXICOLOGY – Clinical Toxicology – Comprehensive**

**TOXICOLOGY – Clinical Toxicology – Qualitative Testing Only**

**TOXICOLOGY – Forensic Toxicology – Comprehensive**

**TOXICOLOGY – Forensic Toxicology – Initial Testing Only**

**TRACE ELEMENTS**

**TRANSPLANT MONITORING**

**VIROLOGY**

**URINALYSIS**

**WET MOUNTS**

## LABORATORY AND BLOOD BANK STATUTES, REGULATIONS AND STANDARDS

**All laboratories must comply with the applicable New York State statutes, regulations, guidance and standards.**

Statutes-Public Health Law: <https://www.wadsworth.org/regulatory/clep/laws>

Title I of the Public Health Law - Communicable Disease, Laboratory Reports and Records  
Article 5, Title V of the Public Health Law - Clinical Laboratory and Blood Banking Services  
Article 5, Title VI of the Public Health Law - Laboratory Business Practices  
Article 2, Title II-D of the Public Health Law - Health Care Practitioner Referrals  
Article 27-F - HIV and AIDS Related Information

Civil Rights Law: <https://www.wadsworth.org/regulatory/clep/laws>

Section 79-L - New York State Civil Rights Law – Confidentiality of Records of Genetics Tests

New York Code of Rules and Regulations (NYCRR): <https://www.wadsworth.org/regulatory/clep/laws>

Part 2 of 10 NYCRR - Communicable Diseases  
Part 19 of 10 NYCRR - Duties and Qualifications of Clinical Laboratory Directors  
Part 22 of 10 NYCRR - Environmental Diseases  
Subpart 34-1 of 10 NYCRR - Health Care Practitioner Referrals  
Subpart 34-2 of 10 NYCRR - Laboratory Business Practices  
Subpart 58-1 of 10 NYCRR - Clinical Laboratories  
Subpart 58-2 of 10 NYCRR - Blood Banks  
Subpart 58-3 of 10 NYCRR - Clinical Laboratory Inspection and Reference Fees  
Subpart 58-8 of 10 NYCRR - Human Immunodeficiency Virus (HIV) Testing  
Part 63 of 10 NYCRR - AIDS Testing and The Confidentiality of HIV-Related Information  
Part 70 of 10 NYCRR - Regulated Medical Waste

Guidelines: <https://www.wadsworth.org/regulatory/clep/laws>

Communicable Diseases Reporting Guidelines 2020  
Persons Authorized to Order Tests and Receive Directly the Results  
Prohibited Items Under Subpart 34-2

Clinical Laboratory Standards of Practice: <https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-standards>

Part 1 - General Standards  
Part 2 - Specialty Standards

## ANNUAL PERMIT CERTIFICATE

Laboratories holding a valid New York State clinical laboratory permit expiring on June 30, 2023, may expect to receive a 2023-2024 permit **if** the permit reapplication was completed in a timely manner **and** any issues raised during the review of the submitted application have been resolved to the Program's satisfaction.

**Please note that failure on the part of the laboratory to provide accurate and current laboratory contact information which results in the inability of the Program to notify the laboratory of issues with the reapplication may result in the non-renewal of the laboratory permit.**

The Program will mail 2023-2024 clinical laboratory permits, patient service center registrations, and health fair permits via first class United States Postal Service to arrive **as close to July 1<sup>st</sup> as possible**.

**If your laboratory currently holds a clinical laboratory permit, has met the reapplication conditions stated above, including timely response/resolution to inquiries from the Program, but does not receive new documents by July 15, 2023**, please contact the Program via email to [clepcert@health.ny.gov](mailto:clepcert@health.ny.gov) to request a duplicate. The email should include your permanent facility identifier (PFI) and the words "Duplicate Permit Request" in the subject line. In the body of the email, detail which permit(s) – laboratory, patient service center (include station number) and/or health fair – were not received. The Program will review the laboratory's reapplication file and respond to your email as soon as practicable.