CLINICAL LABORATORY EVALUATION PROGRAM
WADSWORTH CENTER
NEW YORK STATE DEPARTMENT OF HEALTH
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NEW YORK STATE 2022-2023
LABORATORY PERMIT
REAPPLICATION INSTRUCTIONS
VIA *eCLEP*

GENERAL INFORMATION	DUE DATE APRIL 29, 2022 at 5:00PM EDT

Clinical laboratory and blood bank permits are valid for one year, commencing on July 1st and extending through to June 30th 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 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 3, 2022 WILL BE REJECTED. Contact clepcert@health.ny.gov if the laboratory is not able to submit a permit reapplication by June 3, 2022.

REQUIRED STEPS FOR COMPLETING THE APPLICATION

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. If necessary, laboratory directors may change their work email address by sending an email to clepcq@health.ny.gov, as this record is managed via the director's Certificate of Qualification.

- 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 3 A.M. to 7 A.M."

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 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:

- Director Standard of Practice 3 defines involvement and time commitment.

- Director Standard of Practice 4 defines responsibilities of directors and expectations for written job duties that demonstrate assistant directors are actively engaged in tasks specific to their assigned category(ies). It is the laboratory director's responsibility to designate specific responsibilities to each assistant director.

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

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 2022-2023 permit year.

Requests for additional categories may be made as part of this reapplication.

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 2021. 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, or add more HF tests to an existing HF permit.

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

REQUIRED SUPPLEMENTAL DOCUMENTATION

GROSS ANNUAL RECEIPTS REPORTING

All laboratories are required to calculate, verify, and submit their gross annual receipts (GAR) for calendar year 2021 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, 2022.** 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.

<mark>Submission deadline extensions may be requested using the Extension Request feature in eCLEP.</mark>   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

Note: REQUESTED SUBMISSION DEADLINE EXTENSIONS LATER THAN JUNE 3, 2022 WILL BE REJECTED. Contact clep@health.ny.gov if the laboratory will be unable to report GAR by June 3, 2022.

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, 2022.** Failure to submit GAR data will result in a delay in receiving your clinical laboratory permit.

NEW FOR 2022!

The BSAR is now captured in 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.

<mark>Submission deadline extensions may be requested using the Extension Request feature in eCLEP.</mark> 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 3, 2022 WILL BE REJECTED. Contact clep@health.ny.gov if the laboratory will be unable to submit the BSAR by June 3, 2022.

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
ONCOLOGY – Soluble 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

WET MOUNTS

LABORATORY AND BLOOD BANK STATUTES, REGULATIONS AND STANDARDS

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

Links to all materials can be found on our website at https://www.wadsworth.org/regulatory/clep/laws.

Statutes-Public Health Law:

Title I of the Public Health Law - Communicable Disease, Laboratory Reports and Records (11/93)
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 (11/92)
Article 2, Title II-D of the Public Health Law - Health Care Practitioner Referrals (2/95)
Article 27-F - HIV and AIDS Related Information (9/1/10)

Civil Rights Law:

Section 79-L - New York State Civil Rights Law – Confidentiality of Records of Genetics Tests (1/02)

New York Code of Rules and Regulations (NYCRR):

Part 2 of 10 NYCRR - Communicable Diseases (2/6/20)
Part 19 of 10 NYCRR - Duties and Qualifications of Clinical Laboratory Directors (6/12/19)
Part 22 of 10 NYCRR - Environmental Diseases (5/25/16)
Subpart 34-1 of 10 NYCRR - Health Care Practitioner Referrals (12/04)
Subpart 34-2 of 10 NYCRR - Laboratory Business Practices (11/22/17)
Subpart 58-1 of 10 NYCRR - Clinical Laboratories (12/23/15)
Subpart 58-2 of 10 NYCRR - Blood Banks (9/27/15)
Subpart 58-3 of 10 NYCRR - Clinical Laboratory Inspection and Reference Fees (12/23/95)
Subpart 58-8 of 10 NYCRR - Human Immunodeficiency Virus (HIV) Testing (12/23/15)
Part 63 of 10 NYCRR - AIDS Testing and The Confidentiality of HIV-Related Information (5/17/17)
Part 70 of 10 NYCRR - Regulated Medical Waste (3/15/06)

Standards

Part 1 - General Standards (Adopted August 2020)
Part 2 - Specialty Standards (Adopted August 2020)

Guidelines

Laboratory Reporting of Communicable Diseases (2016)
Persons Authorized to Order Tests and Receive Directly the Results (9/14/11)
Prohibited Items Under Subpart 34-2 (4/10/02)

ANNUAL PERMIT CERTIFICATE

Laboratories holding a valid New York State clinical laboratory permit expiring on June 30, 2022, may expect to receive a 2022-2023 permit if the 2022 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 2022-2023 clinical laboratory permits, patient service center registrations, and health fair permits via first class United States postal service to arrive *as close to July 1st as possible*.

If your laboratory currently holds a clinical laboratory permit and has met the reapplication conditions stated above, but **does not receive new documents by July 31, 2022**, please contact the Program via email to 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 practical.