CLINICAL LABORATORY EVALUATION PROGRAM
WADSWORTH CENTER
NEW YORK STATE DEPARTMENT OF HEALTH
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NEW YORK STATE 2024-2025 LABORATORY PERMIT REAPPLICATION INSTRUCTIONS VIA eCLEP

OPENS: APRIL 8, 2024 **DUE: APRIL 25, 2024**

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; include your Permanent Facility Identifier (PFI) number in the subject line.

Clinical laboratory and blood bank permits are valid for one year, from July 1st to June 30th of the following year.

Permits approved for renewal will be mailed the last week of June.

See *Annual Permit Certificate* section below for more information.

REQUIRED STEPS FOR COMPLETING THE APPLICATION

To complete the permit reapplication process:

- Review current ***eCLEP*** information and make changes as necessary. *Do not enter changes that take effect **AFTER** July 1, 2024.*
- Submit REQUIRED SUPPLEMENTAL DOCUMENTATION (see below), as applicable.
- ***Respond promptly to any requests for additional information made by the Program.***

Access eCLEP at https://commerce.health.state.ny.us; login with HCS User Id and password. Click on **'eCLEP'** from My Applications, then click on **Permit Materials**. If you have access to eCLEP for more than one facility, you must enter the PFI for one facility, then click Go.

Submitting in eCLEP:

Click Submit in the center of the Permit Materials Home Page.

Step 1: Review and Update

Visit each of the tab (Lab Profile, Ownership, Personnel, Permit Categories/Tests, PSCs and Others) on the blue task bar to review and update the laboratory's information as needed. **Upload all required documents as prompted**. 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!

An eCLEP Permit Materials User Manual is available under the Tools tab in eCLEP or our public website at https://www.wadsworth.org/regulatory/clep/clinical-labs/change-permit.

**We recommend the internet browsers Chrome, Edge or Firefox. Use of Internet Explorer is not supported.

REQUESTING AN EXTENSION

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

In eCLEP, click on Tools tab, then click on Extension Date Request.

Extension Request for: choose "Reapplication"
New Date: enter date requested (NOT LATER THAN MAY 31, 2024)
Reason: provide a brief justification for the extension

Note: *EXTENSION DATE REQUESTS LATER THAN MAY 31, 2024 WILL BE REJECTED.*
Contact clepreapp@health.ny.gov if the laboratory is unable to submit a permit reapplication by May 31, 2024.

NAVIGATING eCLEP

LAB PROFILE

Review and update the current data on file as needed.

- A laboratory-specific email for all directors, assistant directors and laboratory contact persons is **required**. Email is our primary method for communication with laboratories. **Failure to update email address will lead to delays in receiving valuable information.**
- 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."

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:

You must review both the "**Owner**" and "**Declaration**" links on the left of the screen. Click 'Save' after making changes under "Owner". You must answer the questions under "Declaration" **every year**, 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.

Each permit category must have at least one responsible director/assistant director with a Certificate of Qualification in a corresponding category.

For the director's and assistant director(s)'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.

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 2024-2025 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 2024**. 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.

"Paper Enrollment" or "Laboratory Enrollment Only" is required for the laboratory when all cytopathology employees take the PT at another location (e.g., CAP PPTENR). *Please contact your proficiency test provider about obtaining a proof of enrollment when all employees take a PAP PT elsewhere. PT enrollment confirmations for another location will not be accepted as confirmation for your laboratory.*

TEST VOLUME

Required only for laboratories located in New York State. 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 the Tools tab 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 **PSCs and Others tab**, 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 uploaded as part of the application process.

REQUIRED SUPPLEMENTAL DOCUMENTATION

GROSS ANNUAL RECEIPTS (GAR) REPORTING – DUE MAY 15, 2024

Required for all laboratories holding a permit as of April 8, 2024. Failure to submit GAR data will result in a delay in receiving your clinical laboratory permit.

From 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. *This is separate from the Permit Materials section*.

Please refer to the eCLEP GAR Reporting Manual available at https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-fees**.**

Submission deadline extensions may be requested using the Extension Request feature in eCLEP.
In eCLEP, click on Tools tab, then click on Extension Date Request.
Extension Request for: choose "Gross Annual Receipts"
New Date: enter date requested (NOT LATER THAN MAY 31, 2024)
Reason: provide a brief justification for the extension

Note: EXTENSION DATE REQUESTS LATER THAN MAY 31, 2024 WILL BE REJECTED.
Contact clepreapp@health.ny.gov if the laboratory will be unable to report GAR by May 31, 2024.

BLOOD SERVICES ACTIVITY REPORT (BSAR) – DUE MAY 15, 2024

Required for all laboratories holding the permit categories *Blood Services – Collection, Blood Services – Collection Autogeneic Only, Blood Services – Transfusion or Blood Services – Transfusion Storage Only*. Failure to submit BSAR data will result in a delay in receiving your clinical laboratory permit.

From 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. *This is separate from the Permit Materials section*.

Submission deadline extensions may be requested using the Extension Request feature in eCLEP.
In eCLEP, click on Tools tab, then click on Extension Date Request.
Extension Request for: choose "Blood Services Activity Report"
New Date: enter date requested (NOT LATER THAN MAY 31, 2024)
Reason: provide a brief justification for the extension

Note: EXTENSION DATE REQUESTS LATER THAN MAY 31, 2024 WILL BE REJECTED.
Contact brp@health.ny.gov if the laboratory will be unable to submit the BSAR by May 31, 2024.

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
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

The Program will mail 2024-2025 clinical laboratory and blood bank permits, patient service center registrations, and health fair permits via first class United States Postal Service during the last full week of June.

Laboratories are notified via email in early June if there are issues with the reapplication. Failure to respond and/or address the issues in the email may result in non-renewal of the laboratory/blood bank permit. You must review your email Junk or SPAM folder for emails from addresses ending in “health.ny.gov”.

If your laboratory currently holds a clinical laboratory permit, and has provided timely response/resolution to inquiries from the Program, but does not receive new documents by July 8, 2024, 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.