# Clinical Laboratory Evaluation Program

## A Guide to Program Requirements and Services

*Revised February 2025*

NEW YORK STATE | Department of Health | Wadsworth Center

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# INTRODUCTION

Clinical laboratories located in New York State, and laboratories conducting clinical or forensic testing on specimens originating in New York State, regardless of location, must hold a New York State Department of Health clinical laboratory permit pursuant to Title V, Section 574 of the New York State Public Health Law.

## The Clinical Laboratory Reference System

The Clinical Laboratory Reference System (CLRS) was established to assist clinical laboratories and blood banks applying for licensure with the New York State Department of Health and to serve as a reference and a resource to all participants. CLRS is administered by the New York State Department of Health's public health laboratory, the Wadsworth Center. Mandated activities include collaborative research, method development and test approval, laboratory inspection, and monitoring of proficiency testing participation to ensure that laboratory services provided to health care providers in the state meet performance standards for good patient care. This guide outlines the policies and procedures by which the Clinical Laboratory Reference System meets the following objectives: (i) to monitor, improve, and broaden the clinical capabilities of participating laboratories and blood banks, (ii) to provide guidelines, quality control standards and procedures to be used by permit-holding clinical facilities, and (iii) to provide continuing education opportunities for technical personnel involved in the operation of clinical laboratories through training and remediation programs.

In recognition of the fact that the Clinical Laboratory Reference System has requirements that are equal to or more stringent than the Clinical Laboratory Improvement Amendments of 1988 (CLIA), the program was granted exempt status by the federal Centers for Medicare and Medicaid Services (CMS) in 1995. As a result, laboratories located in New York State meet CLIA accreditation requirements, as documented by a valid New York State permit, which includes a CLIA number; note that a separate CLIA certificate is not generated. Laboratories must enroll in a CMS-approved proficiency testing program to meet CLIA proficiency test requirements. Laboratories located in New York State are still subject to validation inspections performed by CMS staff and all records maintained by New York State regarding a laboratory are subject to disclosure to CMS. Eligibility for CLIA certification for laboratories located outside New York remains the responsibility of each state's regional CMS office.

## The Clinical Laboratory Evaluation Program

The Clinical Laboratory Evaluation Program (CLEP) administers the activities of the Clinical Laboratory Reference System and provides the oversight of over 1,000 clinical laboratories and blood banks, including out-of-state facilities that accept clinical specimens collected in New York State. CLEP seeks to ensure the accuracy and reliability of results of laboratory tests on specimens obtained within the state through on-site inspections, review of proficiency testing performance, review of laboratory-developed tests and evaluation of the laboratory director qualifications. Additionally, for out-of-state permit-holding clinical laboratories and blood banks, CLEP evaluates the qualifications of testing personnel and supervisor to meet New York State regulations.

The proper performance of diagnostic laboratory tests is a matter of vital concern, affecting the public health, safety and welfare of all NYS residents. Clinical laboratories and blood banks provide essential public health services in aiding the medical practitioner by furnishing information invaluable in the diagnosis and treatment of disease. Substandard performance of such tests may and has contributed to erroneous diagnoses and/or the selection of inappropriate treatment protocols.

For more information visit the website at www.wadsworth.org/regulatory/clep or contact us at clep@health.ny.gov.

# PERMIT REQUIREMENTS

## Program Scope and Exceptions

Laboratories located in New York State, and laboratories conducting clinical or forensic testing on specimens originating in New York State regardless of location, must hold a New York State Department of Health clinical laboratory permit pursuant to Article 5, Title V, Section 574 of the New York State Public Health Law.

*Research testing is considered clinical testing if a patient-identified result is generated.* This would include results used to make clinical decisions for patient management under an IRB-approved research protocol or clinical trial.

Although any examination performed by a state or local government on materials derived from the human body for use in criminal proceedings or for investigative purposes is exempt from permit requirements, tests for these purposes that are referred out must be sent to a laboratory holding a New York State clinical laboratory permit in the required permit category (a.k.a. testing specialty category; category of procedures).

Physician office laboratories (POLs) owned and/or operated by managed care organizations, hospitals or consulting firms, or POLs that perform testing on individuals other than their own patients must also obtain a clinical laboratory permit.

Laboratories operated by physicians, osteopaths, dentists, midwives, nurse practitioners or podiatrists performing testing only for their own patients are exempt from permit requirements; however, these facilities must obtain a CLIA number to operate in New York through the Physician Office Laboratory Evaluation Program (POLEP). Information on the requirements for physician office laboratories can be obtained from POLEP by contacting CLIA@health.ny.gov.

Facilities performing only those tests classified by federal CLIA regulations as waived and provider-performed microscopy procedures are exempt from permit requirements but must register with the Department and meet minimum standards to ensure the accuracy, reliability and accessibility of such tests. These requirements are described in the Additional Application Requirements section of this guide.

Facilities that collect plasma for use in manufacturing must register with the Department and meet applicable federal requirements. These requirements are described in the Additional Application Requirements section of this guide.

## Application Procedures

***Laboratories applying for a New York State clinical laboratory permit may not begin testing until all requirements have been met and a permit is issued.***

Permit application materials and complete instructions are available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit. An initial application for a clinical laboratory permit must be submitted with the required application materials and reference fees of $1,100. Application materials must be submitted in hard copy via mail (e.g., postal service or courier) with original signatures. Digital submissions are not currently accepted.

All permit application materials must be received, reviewed, and deemed acceptable before a laboratory is moved into applied status. In addition to initial application materials, certification of a director and/or assistant director(s) for each testing specialty category must be obtained. Submission of the laboratories proposed test menu must be completed and accurately identify proficiency test enrollment information, as applicable.

Once a laboratory is moved into an applied status the following requirements must be met before a permit

will be issued: participation in on-site inspection and correction of any deficiencies identified; successful performance in proficiency testing or alternate requirements for each analyte; submission and departmental review and approval of any in-house developed or non-FDA approved methods; and completion of HCS account affiliation by laboratory director. Laboratories located out-of-state must also pay any travel costs associated with the on-site inspection before a permit will be issued.

Clinical laboratory permits are valid for one year, commencing on July 1 of each year (initial permits can be issued at any time during the permit cycle of July 1 through June 30) and extending through June 30 of the following year. The permit reapplication process is performed using eCLEP on the Health Commerce System to all laboratories in the spring of each year. Please see the Permit Reapplication section below. The annual fee for the permit reapplication includes a $100 application fee plus an inspection and reference fee. Please see the Laboratory Inspection and Reference Fees section below for additional information.

**Facilities transitioning from POLEP to CLEP**

Facilities currently holding a CLIA certificate through the Physician Office Laboratory Evaluation Program (POLEP) that are transitioning to CLEP permit may not begin testing samples from outside their professional practice until all requirements have been met and a permit is issued.

When submitting CLEP permit application materials, transitioning laboratories must provide a written explanation of why they are transitioning (e.g., change in ownership, proposing to accept samples from outside of professional practice, etc.). Transitioning laboratories must submit a copy of their current CLIA certificate to include the laboratory's current specialties and subspecialities. In order to continue testing in all specialties and subspecialties once the CLEP permit is issued, the laboratory must apply for the corresponding permit category through CLEP.

Personnel performing testing, regardless of complexity, in transitioning laboratories must meet the requirements of the Clinical Laboratory Technology Practice Act, detailed in the section titled Laboratory Testing Personnel Requirements of this guide.

For laboratories currently offering waived testing or Provider Performed Microscopy Procedures (PPMP) through POLEP, this testing can be offered under the applicable CLEP permit category(ies) or the laboratory may apply for a Limited Services Laboratory registration for the purpose of performing these tests. Under a Limited Service Laboratory registration, only a mid-level practitioner or higher may perform PPMP – *clinical laboratory technology practitioners (e.g., technicians, technologists, cytotechnologists) may not perform PPMP under a LSL registration*.

## Health Commerce System

The Health Commerce System (HCS) is the secure website for web-based interactions with the New York State Department of Health and is accessible via the Internet. The HCS is used by a wide variety of health care providers to receive up-to-date information as well as to submit data to specialized programs for reporting or surveillance purposes.

The HCS houses the Program application, eCLEP. eCLEP includes a growing number of modules for the collection of information to include:

- **Permit Materials** module for reporting changes to laboratory operations and completing the annual permit reapplication;
- **Proficiency Testing (PT) module** for reporting the laboratory's chosen provider for each calendar year as well receipt of unsatisfactory performance notifications;
- **Gross Annual Receipts (GAR)** module for annual reporting of GAR;
- **LDT Approval** module for viewing the status of validation packages;
- **Survey** module for accessing the laboratory evaluation reports issued after laboratory surveys and unsuccessful PT participation and submission of plans of correction for any deficiencies;
- **Blood Resources** module for reporting the annual Blood Services Activity Report;
- Other applications located on the HCS include the Electronic Clinical Laboratory Report System (**ECLRS**) for mandatory reporting of communicable disease testing and the Clinical Laboratory Information Management System (**CLIMS**) for requesting confirmatory communicable disease testing by the Wadsworth Center Public Health Laboratory.

**Definitions with respect to the HCS:**

**CAMU** is the Commerce Accounts Management Unit of the New York State Department of Health, Health Commerce System.

**Delegated Submitter** is an individual with written authorization by the Laboratory Directors to electronically enter and submit data via the eCLEP application on the HCS information to the department in lieu of the director.

**Director** is the individual who can bind the organization with the Department in the Health Commerce System. ***Please note: an electronic request for a change in director through the HCS portal alone does not constitute notification of a change in director to the department for purposes of the New York State clinical laboratory permit. Notification MUST be made in eCLEP specifically.***

**eCLEP** is the application tool for laboratories to submit changes to the laboratory's operations as well as the laboratory permit reapplication and designation of required proficiency testing enrollment.

**HCS Coordinator (HCSC)** is, in addition to the Director, the individual who has the responsibility and authority to request and manage HCS accounts for additional laboratory staff and manage roles in the HCS Communication Directory.

**Health Commerce System (HCS)** is a secure online communications system operated by the NYS Department of Health. It supports the exchange of routine and emergency statewide health information by local health departments and health facilities, providers and practitioners

**User** is the person who has basic access to the Health Commerce System and can get to non-secure areas.

Laboratory Directors are required to obtain an HCS account or affiliate their HCS ID if they have an existing HCS account for **each Clinical Laboratory they direct** as part of the requirements for a clinical laboratory permit. Please refer to the website (www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce) for further information on this process.

Before requesting access to the eCLEP application on the HCS, one must have an HCS account (Director, HCSC, or User) that is affiliated with the clinical laboratory. The HCSC or Laboratory Director is responsible for requesting user accounts for the additional staff.

***Laboratories are strongly encouraged to assign at least one HCSC other than the laboratory director so that access to the HCS is ensured in the event the laboratory director is unexpectedly unavailable.***

The HCSC and other Users are required to have the Laboratory Director complete a Delegated Submitter Form, available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce, and submit it to clep@health.ny.gov or fax to 518-485-5414. The Delegated Submitter will receive a confirmation email from camu@health.ny.gov when your account has been given eCLEP permissions.

**When a new director is appointed at a New York State permitted laboratory, the laboratory is required to submit this change via eCLEP. Upon acceptance of the change, the Laboratory Director HCS Affiliation form will be emailed separately**. If eCLEP is in Read-Only Mode, please contact CLEP at clep@health.ny.gov.

***Please note: an electronic request for a change in director through the HCS portal using Coordinator Tools alone does not constitute notification of a change in director to the department for purposes of the New York State clinical laboratory permit. Notification MUST be made in eCLEP specifically.***

**Every individual accessing the Health Commerce System must have their own HCS account. Sharing of an account user id and password is a violation of the security user agreement, which will result in a termination of your HCS account privileges and possible prosecution if data security is compromised because of the violation. To reinstate your account privileges, remedial action must be taken by executives at your facility.**

## Proficiency Testing

All laboratories applying for or holding a New York State (NYS) clinical laboratory permit must participate in proficiency testing (PT) as defined by NYS. PT participation through a CMS–approved provider acceptable to NYS is required for the tests/analytes that are noted in the Proficiency Testing (PT) Guide as required (mandated) by NYS. For analytes with NYS mandated PT, an acceptable PT product must include 5 samples per event and offer 3 test events per year (2 events for Mycobacteriology).

**Products that are approved by CMS and *deemed acceptable to NYS* can be found on the Wadsworth Center's website**: https://www.wadsworth.org/regulatory/clep/pt/provider-search.

All laboratories must disclose to the Clinical Laboratory Evaluation Program (CLEP) the CMS–approved PT provider that is being utilized to fulfill federal proficiency testing requirements for NYS mandated analytes. This is reported to CLEP each fall/winter on the Health Commerce System (HCS) using the eCLEP Proficiency Testing module. Laboratories are notified via email when it is time to report.

Laboratories requesting a NYS clinical laboratory permit must meet all requirements for permit issuance including satisfactory participation in PT for each NYS mandated PT analyte for which a permit is being sought. PT participation must occur ***after*** the initial application for a permit has been received by CLEP. Likewise, for a laboratory requesting to add a category to an existing permit, the PT participation must occur ***after*** the request is submitted through eCLEP.

Satisfactory PT performance, and continued satisfactory PT participation and performance, with the PT provider on record with NYS must be maintained to fulfill PT requirements while waiting for all other permit requirements to be met.

For tests/analytes where PT is not mandated by NYS, laboratories are required to have an alternate system for verifying the reliability and accuracy of their test results at least twice a year through participation in external proficiency testing programs or through the implementation of an internal proficiency testing program. When external proficiency testing is used as the laboratory's alternate assessment tool for analytes not requiring PT, all NYS Clinical Laboratory Standards of Practice for proficiency testing apply.

**Please refer to the Proficiency Testing Guide available at www.wadsworth.org/regulatory/clep/pt for more detailed information.**

## Test Approval

New York State Public Health Law authorizes the Department to evaluate testing methods and procedures to assess compliance with state requirements. Laboratories are required to submit standard operating procedures (SOPs) and validation data for proposed test methods and procedures that are considered laboratory-developed for review and approval by the Department. This requirement applies to an FDA-approved test that has been modified by the laboratory; a non-FDA approved test, or a traditional laboratory-developed test (LDT). Please see the Adding or Deleting Permit Categories or Tests/Analytes section below for specific details. A full overview of the requirements for laboratory-developed test approval is available in the Test Approval page available on our website at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.

## On-Site Survey

Laboratories must have an on-site survey as a condition to obtaining and maintaining a valid New York State clinical laboratory permit. Surveys may also be conducted in response to reports of complaints or other incidents. Laboratories seeking a permit must have an initial on-site survey before a permit is issued and before specimen testing can be performed. A surveyor from the department will contact the laboratory to schedule the initial on-site survey. Subsequent routine surveys in laboratories located within the state are unannounced. All out-of-state surveys are announced.

The purpose of the survey is to ensure that the premises, laboratory practice, equipment, personnel, and record-keeping meet state requirements. These requirements are outlined in Article 5, Title V of the New York State Public Health Law, Parts 19, 58, 63 and 70 of Title 10, New York Code of Rules and Regulations (10NYCRR), and in the Department's Laboratory Standards of Practice, available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/on-site-survey/laboratory-standards.

New York State Public Health Law requires that out-of-state laboratories pay the travel expenses related to the on-site survey. Travel expenses are based on the number of surveyors involved in the survey, the number of days required for the survey, and the number of facilities surveyed. Laboratories are sent a bill for these expenses after the survey is completed.

Laboratory surveys are conducted within a standardized framework, to include an *entrance conference*, a *laboratory orientation*, the *survey* portion for all categories, and an *exit conference*. The surveyor will conduct direct observations of test practices and interviews with staff whenever possible. An outcome-oriented survey approach is used to conduct surveys, including a sampling of patient reports known as Recreation of the Test Process. This approach ensures laboratories are measured consistently and objectively by requiring the same documentation across testing methods. The Recreation of the Test Process is designed to recreate the entire path of testing for specific patient results. An example form used by surveyors is available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/on-site-survey.

The *entrance conference* allows the surveyor to explain the survey and Recreation of the Test Process to laboratory personnel. Key laboratory staff should attend, including the director and owner/administrator (by phone if necessary). During this conference the surveyor and laboratory staff will review findings from previous surveys and identify any areas of concern, discuss survey objectives, agree upon a survey schedule, discuss any documents that will be required, and identify contacts for the administrative portion of the survey. Laboratory personnel are expected to present changes in operations since the last survey, including new equipment, staffing, client base, additions and deletions to the test menu, and outreach services. The surveyor and laboratory staff will agree on the tests to be used for the Recreation of the Test Process survey tool.

For the *laboratory orientation* the surveyor will tour the facility while the laboratory assembles the Recreation of the Test Process packages. During this orientation, the laboratory will be expected to demonstrate the path of a specimen through the laboratory, starting with the point of collection/accession. Specimen handling and the integrity and proper identification of samples throughout the test process will be evaluated through a review of rejection logs, problem samples, STATs, etc. Safety practices, laboratory workflow, organization and data entry will also be observed during this phase. The laboratory orientation also provides an opportunity for survey staff to have informal discussions with laboratory personnel staff.

The *survey* will then be conducted in each testing area, centered on the sample patients used for the Recreation of the Test Process review. Particular attention will be paid to new methods and new instruments and to those analytes with poor history in proficiency testing, across permit categories. This part of the survey incorporates the following items:

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|---|---|
| Pre-Analytic: | requisition with authorized order source, specimen identity, and specimen integrity |
| Analytic: | quality control, calibration, reagent and validation verification |
| Personnel: | verify training and competency. Verify education and experience records, job descriptions and duties and documentation of continuing education |
| Post-Analytic: | reporting with all required elements, timeliness, and notification of critical values |
| Process Review: | review of quality control and patient reporting |

Additionally, in this phase of the survey, the surveyor will review supporting documentation, including but not limited to: the standard operating procedure manual, any bench excerpts for tests in use, the instrumentation maintenance and environmental controls records (such as refrigerator temperature and centrifuge calibration), and non-conformance records for any deviation in quality control and performance in proficiency tests or alternative quality assessments.

The surveyor will review the laboratory Quality Manual and determine if procedures need to be created or updated to conform to QMS Standards. Full QMS compliance will be evaluated to include, but not limited to, personnel, specimen integrity, proficiency test enrollment and handling, non-conformities and complaints. The Specialty Standards of Practice will be surveyed for compliance using Recreation of the Test Process packages. Audit documentation will also be reviewed.

Employees involved in the processing of samples selected for the Recreation of the Test Process packages may be interviewed and assessed for knowledge of their job descriptions, standard operating procedure manuals, and training and competency practices. Staff may be asked questions regarding the level of involvement of laboratory management in responding to their problems and concerns and the level of management and staff concern for quality of work and knowledge of QMS principles. Assessment of safety practices will be performed throughout the survey, with specific attention given to the biohazard risk assessment required for each permit category, the on-site safety manual, use of personal protective equipment, and training given to employees.

Laboratories located in New York State are assessed against state requirements for handling, storage, and disposal of regulated medical waste through observation and review of records. An integral part of the survey is the direct observation of specific test processes that include, but are not limited to, transfusions, radioactive labeling of blood components in nuclear medicine, blood salvage programs in the surgical area, and/or point of care testing, including limited service laboratory registration locations. The surveyor will inform the facility of specific observations that will be performed.

Laboratories should be aware of their vital role in public health reporting. The surveyor will verify compliance with the Department's requirements for reporting communicable and other reportable diseases and conditions. A guidance document summarizing requirements for reporting communicable diseases can be found at www.wadsworth.org/regulatory/clep/laws under Laws and Regulations. During the survey the laboratory will be expected to complete forms to document reporting for the following programs: Communicable Disease, Blood Lead, and Cancer Registry. Electronic reporting was mandatory as of July 2008 and all laboratories must be enrolled in the Electronic Clinical Laboratory Reporting System (ECLRS).

An additional area of review is preparedness - the need for protocols to address any impairment to routine laboratory operations, whether from natural, intentional or unintentional events. Procedures for preparedness in response to these events will be reviewed as part of the survey.

The end of the survey will conclude with an *exit conference*. The director and any assistant directors are expected to attend. Other attendees are at the discretion of the laboratory, but it is recommended that representatives from laboratory administration and laboratory technical staff attend. During this meeting, major areas of concern will be discussed, and findings will be reviewed. The surveyor will provide a *preliminary* assessment of the laboratory's level of compliance with General Standards of Practice as well as any applicable Specialty Standards of Practice.

The surveyor will then submit the survey report to the Program. After internal review, a laboratory evaluation report (LER) will be issued to the laboratory via the Survey module in eCLEP. An email is sent to laboratory contacts when the LER is available. The LER will be comprised of the listing of the Survey Findings (deficiencies) and a Fundamental Grade. Laboratories must respond to deficiencies identified in the LER with a Plan of Correction (POC) within ten business days of the issuance of the LER. The Plan of Correction response is entered directly into the eCLEP Survey module. Guidance for completion of the POC response form and a POC worksheet is available to the laboratory and can be found at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/on-site-survey. The laboratory will be contacted if there are any concerns with the POC (e.g. missing information or altered document) or to request submission of a revised POC if the initial plan is found unacceptable. Once the Laboratory Evaluation Report is issued, the survey findings noted therein will not be expunged.

## Issuing the Laboratory Permit

A New York State clinical laboratory permit will be issued when:

- The laboratory director and any assistant directors have been issued Certificates of Qualification
- The laboratory director's Health Commerce System account has been created and affiliated
- The facility has been inspected and any deficiencies have been corrected
- The laboratory has successfully met laboratory-developed test (LDT) approval requirement, if applicable
- The laboratory has successfully met proficiency testing or alternate requirements for all permit categories for which it has applied
- All applicable fees have been paid

## Changes in Laboratory Status

**Article 5, Title V of the New York State Public Health Law specifies that a laboratory permit is void upon a change in laboratory director, owner, or location. All changes in laboratory name, owner name, director, assistant director, ownership, or location must be submitted to the Clinical Laboratory Evaluation Program via eCLEP before the change occurs.** An Ownership and Controlling Interest Disclosure Statement must accompany notification of changes in owner. This form is available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit.

Submission of change in eCLEP, or on the appropriate notification of change form, is considered a new permit application. All changes are subject to Department approval. For example, an on-site survey may be required for a change in location, and approvals for changes in director are subject to review of the proposed director's commitments at other facilities and the performance of other laboratories under their direction. A new laboratory permit will be issued for approved changes in director, location, owner or name of the laboratory once requirements have been met.

## Adding or Deleting Permit Categories

Requests to add or delete permit categories must be submitted using eCLEP. To add a new permit category, a director or assistant director must be identified as the responsible individual who holds, or has applied for, a Certificate of Qualification in the appropriate category. Once the request has been reviewed, the laboratory will be notified of the requirements that must be met before the amended permit will be issued, this may include acceptable plan of correction to deficiencies identified during an on-site survey, successful participation in proficiency testing, test approval through method validation review, and payment of applicable fees. If an on-site survey is required, it will not be scheduled until the director responsible for the category holds the appropriate Certificate of Qualification.

Deleting a Category: Requests to delete a category must be made through eCLEP.

Laboratories in good standing may add new FDA - approved, cleared or exempt tests under an existing, approved permit category. Validation data for the new test(s) will be reviewed by a surveyor during the next on-site survey of the laboratory. Note that performance of a test without holding the required permit category will be deemed as testing without Department approval and the laboratory may be subject to administrative actions, per New York State Public Health Law §578.

Laboratories must successfully participate in proficiency testing for the tests/analytes offered by the laboratory that are listed in CMS 42 CFR 493 subpart I (CLIA subpart I) or noted in the Proficiency Testing Guide as required by NYS (NYS mandated PT). PT participation must be with a federal Centers for Medicaid and Medicare Services (CMS) – approved provider acceptable to NYS.

Laboratories seeking to add laboratory-developed tests (LDT) or tests not cleared or approved by the FDA for *in vitro* diagnostic use must submit validation materials for review by the Department. Validation materials include, but are not limited to, a validation summary, validation data, standard operating procedures, test reports and/or package inserts. Detailed requirements for test approval can be found at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.

## Permit Reapplication

Laboratories holding a permit or applying for a permit must complete a reapplication annually. Permit reapplication is accomplished via eCLEP on the New York State Department of Health's Health Commerce System (HCS). Laboratories are notified via email in Spring of the dates and duration of the reapplication period.

Laboratories are required to submit a $100 reapplication fee annually. This fee is invoiced and collected as part of the annual laboratory inspection and reference fees in July.

## Laboratory Inspection and Reference Fees

New York State Public Health Law Article 5, Title V establishes the authority for the Department to collect fees from clinical laboratories under permit to operate the Clinical Laboratory Evaluation Program. Information is collected on the gross annual receipts (GAR) for all laboratories each year as part of the annual reapplication process. Please also refer to Title 10, Subpart 58-3 of the New York Codes, Rules and Regulations.

GAR information is collected using the GAR Reporting module of eCLEP on the Health Commerce System. For laboratories located in New York State, the reported GAR must include revenue for all specimens tested, regardless of the state of origin. For laboratories located outside New York State, the reported GAR should reflect annual revenue obtained from testing of specimens collected in New York.

Fees are calculated based on the previous year's Program operating expenses. Invoices for these fees are sent in July. Partial payments may be made on or before July thirtieth, September thirtieth, December thirty-first and March tenth of the fiscal year to which billing relates. The actual fee assessed for each laboratory is calculated by multiplying the total operating expenses of the Program by a fraction, the numerator of which is the gross annual receipts of the laboratory and the denominator of which is the total gross annual receipts of all laboratories issued permits.

# LABORATORY DIRECTOR REQUIREMENTS

## Duties and Qualifications

Information on the duties and qualifications for laboratory directors can be found in Parts 19 and 58-1 of 10 NYCRR, available at our website at https://www.wadsworth.org/regulatory/clep/laws. A clinical laboratory director is defined in Section 19.1(a), as the individual responsible for administration of the technical and scientific operation of a clinical laboratory or blood bank, including supervision of test procedures, the reporting of results, and the duties and the responsibilities specified in Section 19.3 of this Part.

In order to obtain a New York State laboratory permit, a laboratory must name a doctoral-level individual who meets the training and education requirements outlined in Part 19 of 10 NYCRR and who qualifies for a New York State Certificate of Qualification (CQ) as a laboratory director in each permit category for which the laboratory seeks a permit. If the individual designated as the laboratory director does not qualify for a Certificate of Qualification in each permit category, the director may designate one or more individuals who hold a certificate in the appropriate category(ies) to serve as director for the category(ies). The eligibility of a laboratory to obtain approval to perform testing is dependent on the authorized scope of the laboratory director's Certificate of Qualification.

Laboratory directors are required to be on-site in the laboratory to perform the duties and responsibilities set forth in Part 19 and Subpart 58-1 of 10 NYCRR. Therefore, laboratory directors must indicate the average number of hours they will serve on-site at a given frequency. The adequacy of these hours will be evaluated commensurate with the laboratory workload, scope and complexity of test procedures; qualifications of on-site personnel; and availability of alternate monitoring and communication capabilities. An individual may serve as director or sole certificate holder (a.k.a., sole assistant director) for a permit category for no more than five clinical laboratories and/or blood banks. If the laboratory and blood bank are located on the same premises, this may be considered as one directorship. Assistant Directorships (provided the individual is not the sole certificate holder for a permit category) and directorships of Limited Service Laboratories, as described in the section of this guide titled Additional Application Requirements, are not included in the five-site limit.

## Applying for a Certificate of Qualification

A Certificate of Qualification application may be obtained from our website at www.wadsworth.org/regulatory/clep under Certificate of Qualification & Laboratory Director Requirements. The initial application fee is $150.00. Applicants must document an acceptable combination of education, training, and experience to qualify for a certificate including at least four years of postdoctoral training and/or experience in an acceptable laboratory, of which two or more years of training and/or experience must be demonstrated in the methods and techniques currently in use in the permit category(ies) sought and two years in general laboratory management. A portion of this training and/or experience must have been obtained within the previous six years.

Since a Certificate of Qualification is issued to an individual independent of laboratory affiliation, the home, rather than work, address of the applicant is used. Correspondence regarding the Certificate of Qualification is primarily directed to the applicant's email address, as provided on the application.

## Education Requirements

As outlined in Part 19 of 10NYCRR, the minimum education required to obtain a Certificate of Qualification as a New York State laboratory director is an M.D., D.O., or D.D.S. degree, or an earned doctoral degree (e.g., Ph.D., Sc.D.) from an accredited institution with a relevant chemical or biological science major. All medical schools, colleges and universities attended must be indicated in the application. Physicians and dentists must be currently registered in New York State and/or the state in which they practice and must provide a copy of their license and current registration to qualify for a certificate. *Please note that unlicensed physicians or dentists do not qualify for a Certificate of Qualification.*

## Foreign Education

For individuals educated in a college or university located outside the United States (U.S) or a U.S. Territory, a credentials equivalency evaluation by an approved agency is required. If an individual with a foreign degree has earned credits that have been accepted towards another degree in this country a credentials equivalency evaluation is not required. The Department will accept credential equivalency evaluations from any of the organizations listed as members of the National Association of Credential Evaluation Services (www.naces.org) or the Association of International Credential Evaluators, Inc. (www.aice-eval.org). U.S. Territories include District of Columbia, Commonwealth of Puerto Rico, Commonwealth of Northern Mariana Islands, Virgin Islands, Guam and American Samoa.

## Board Certification

Applicants are asked to indicate all appropriate boards for which they are certified (from a list included in the instructions), certification date and specialty, and provide a copy of each certificate and any re-certifications with their application.

## Training and Experience

Applicants for a Certificate of Qualification must provide a summary of their post-doctoral training and experience and current employment, including a detailed description of their laboratory duties and the areas of laboratory medicine in which their experience has been gained. All clinical laboratory experience subsequent to receipt of a doctoral degree should be included. A copy of the current curriculum vitae must also be submitted. Descriptions of medical internships, residencies and fellowships should include the discipline and duration of each rotation. Physicians must document the specific dates of the experience obtained from discipline rotations performed during residency and/or fellowship.

Applicants whose medical residency and/or fellowship occurred more than six years ago or those who are applying for categories for which education and laboratory experience are the only requirements, must provide documentation of their experience in the form of letters from current or previous laboratory directors or other individuals with whom the post-degree training and/or experience was acquired. Each letter should provide specific details about the dates of employment, type of training and experience acquired, methods and techniques of test procedures used, and volume of testing performed, supervised, and/or directed. Letters from responsible administrators at institutions where training or experience was acquired will be accepted only where it is established that other references are not available. Self-attestations of experience and training are not acceptable.

Applicants who apply for the purpose of directing a laboratory offering a novel laboratory-developed test (LDT), should include a brief description of the proposed LDT and provide any additional information requested as part of the review.

## Issuing the Certificate of Qualification

A Certificate of Qualification is valid for two years from the date it is issued and an application to renew must be submitted every two years. Additional categories of certification may be requested using the "Application to Amend Certificate of Qualification" form found on our website at www.wadsworth.org/regulatory/clep/certificate-requirements. Documentation of experience as described above is required and should be submitted along with the request for the amendment.

## Maintenance of the Certificate of Qualification

Approximately four months before the Certificate of Qualification expires, the certificate holder is sent a pre-printed reapplication to the home address on file with the department. This application must be completed and returned along with the $150.00 reapplication fee and a copy of the applicant's current curriculum vitae no later than 90 days prior to expiration.

In order to maintain a Certificate of Qualification, the applicant must demonstrate recent training and/or experience in each category currently held. If the applicant has not been assigned responsibility for a related clinical laboratory permit category at a New York State permitted laboratory, or the applicant is not listed as the director of record for a clinical laboratory with the appropriate specialty in the CLIA database if the laboratory is not located in New York State, they must provide documentation of experience in the form of letters from current or previous laboratory directors or other individuals with whom the post-degree training and/or experience was acquired in each Certificate of Qualification category. Letters should provide specific details about the dates of employment, type of training and experience acquired, methods and techniques of test procedures used, and volume of testing performed, supervised, and/or directed. Self-attestations of experience and training are not acceptable.

# LABORATORY TESTING PERSONNEL REQUIREMENTS

## The Clinical Laboratory Technology Practice Act

The Clinical Laboratory Technology Practice Act was signed into law on January 30, 2005. This act established licensure requirements through the New York State Department of Education, Office of the Professions (SED). The act, which was implemented on September 1, 2006, defines the practice of clinical laboratory technology, establishes licensure requirements for clinical laboratory technologists and cytotechnologists, and establishes certification requirements for clinical laboratory technicians.

The Clinical Laboratory Technology Practice Act is not applicable to personnel employed in laboratories located outside of New York State, to personnel employed in physician office laboratories (as defined in PHL 579), to personnel performing non-medical (forensic and paternity) testing, to personnel employed in research where no patient-identified results are generated, or to personnel employed by the New York State and New York City Public Health Laboratories. Questions about licensure requirements can be directed to SED at CLINLABD@mail.nysed.gov or by telephone at (518) 474-3817, ext. 150.

## Duties and Qualifications of Laboratory Personnel

Information on the requirements for licensure through SED as a clinical laboratory technology practitioner are available www.op.nysed.gov.

SED Licensure is not required for individuals employed in out-of-state laboratories. The credentials of individuals employed in out-of-state laboratories will be evaluated during the on-site survey to ensure they meet the requirements of Part 58-1 of 10NYCRR, which specifies minimum education and experience requirements for clinical laboratory technology practitioners (e.g., technicians, technologists, cytotechnologists) and supervisors.

Additional duties and qualifications for laboratory supervisors and cytology supervisors are described in regulation at Sections 58-1.4 and 58-1.5 of 10NYCRR. Individuals employed as supervisors must qualify at the technologist level (in New York State, they must be licensed through SED at the technologist level) and meet these additional requirements in order to qualify as a supervisor or cytology supervisor. Persons licensed as histological technicians do not qualify as supervisors.

## Evaluating Laboratory Personnel

Department review of the credentials and qualifications of laboratory personnel will be performed as part of the on-site survey. It is the responsibility of the laboratory director to employ individuals who meet the requirements of Part 58-1 of 10NYCRR and the New York State Education law, as applicable, and to assign duties appropriate to the individual's experience and qualifications. The laboratory must complete and submit a Facility Personnel Form (DOH-709), available at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/on-site-survey, as part of each biennial survey. Laboratories are encouraged to maintain this information electronically so it can be easily updated. During the initial on-site survey, a surveyor will evaluate the qualifications of all technical personnel.

A respiratory therapist is considered to be equivalent to a technologist and a respiratory therapist technician is considered to be equivalent to a technician when performing laboratory testing directly related to their job duties.

Individuals employed as respiratory therapists and respiratory therapy technicians in New York State must be licensed through the New York State Department of Education.

## Foreign Education

For individuals employed in out-of-state laboratories who have been educated in a college or university located outside the United States or a U.S. Territory and do not hold certification or licensure through the New York State Education Department, a credentials equivalency evaluation by an approved agency may be required to determine equivalency with New York State licensure or certification requirements. If an individual with a foreign degree has earned credits that are accepted towards another degree in this country, a credentials equivalency evaluation is not required. The Department will accept credential equivalency evaluations from any of the

organizations listed as members of the National Association of Credential Evaluation Services (www.naces.org) or the Association of International Credential Evaluators, Inc. (www.aice-eval.org). U.S. Territories include District of Columbia, Commonwealth of Puerto Rico, Commonwealth of Northern Mariana Islands, Virgin Islands, Guam and American Samoa.

## Training and Experience

The laboratory must maintain documentation of training and experience for all supervisors and technical personnel. Documentation of previous laboratory experience may be in the form of letters from former employers verifying dates of employment and duties and must indicate whether the experience was full or part-time. If the laboratory confirms previous experience by contacting references, this should be documented in the personnel files. Part-time experience can be prorated, with 2000 hours equaling one year of full-time experience. Pertinent full-time laboratory experience implies that the qualifying individual has knowledge of, exposure to, and experience with the laboratory specialties in which that individual will be functioning. Research experience is acceptable only if it is obtained while performing tests on human specimens. The tests performed should be of the same type as those that will be used in the laboratory.

## Personnel Record Retention Requirements

The laboratory is responsible for maintaining records that verify certification and licensure through the New York State Education Department for personnel employed in New York State and for education, experience, and training in compliance with Part 58 of 10NYCRR, for individuals employed in out-of-state laboratories. Generally, diplomas, resumes, transcripts, official letters from an institution of higher education attesting to the highest level of learning achieved, letters from former employers, or other records are sufficient to establish that education and experience requirements equivalent to those for certification or licensure through the New York State Education Department have been met. Documentation required for directors and assistant directors are a copy of their New York State Certificate of Qualification and a description of their duties (refer to the section of this guide titled Laboratory Director Requirements for information on the certification process for director-level personnel). Documentation required for respiratory technologists and technicians is a copy of their license from the New York State Education Department.

# PROFICIENCY TESTING REQUIREMENTS

Please refer to the Proficiency Testing Guide for information related to proficiency testing requirements, enrollment, participation, and monitoring of performance. The Guide is available at www.wadsworth.org/regulatory/clep/pt.

# ADDITIONAL APPLICATION REQUIREMENTS

## Limited Service Laboratories

A facility that only performs tests classified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as **waived** or provider-performed microscopy procedures (PPMP) must register as Limited Service Laboratory. Information on Limited Service Laboratory registrations is available at www.wadsworth.org/regulatory/clep/limited-service-lab-certs. A listing CLIA-waived analytes can be obtained from the FDA website at FDA Waived Analytes and a list of waived tests by specific kit and manufacturer is available at FDA Waived Tests.

Facilities performing CLIA-waived tests may include hospital extension clinics, blood centers, nursing homes, home health care agencies, school/student health services, dialysis facilities, ambulatory surgery centers, county health departments, correctional facilities, ambulance/rescue squads and other direct patient care facilities. Physician offices owned and/or operated by managed care organizations, hospitals or consulting firms are also included in this group.

Applications for a Limited Service Laboratory must include a registration fee of $200. Registrations are valid for two years. Approximately four months prior to the expiration date, a renewal application is sent via postal service to the laboratory. The renewal registration fee is $200.

Limited Service Laboratories that are operated by a not-for-profit corporation or by a state or local government, or programs engaged in public health testing may qualify for a multi-site registration not to exceed 15 waived tests per registration, which allows several locations to operate under a single registration; one location must be identified as the parent site. Multi-site registrants would pay a single initial registration fee of $200 and single renewal fees of $200, without regard to the number of sites covered by one registration.

A laboratory director of a Limited Service Laboratory may not provide oversight of more than five sites where either PPMP or non-waived testing is performed. There is no such limit on the number of sites that a laboratory director can direct where only CLIA-waived testing is performed.

Limited Service Laboratories may only collect specimens as indicated to perform confirmatory or supplemental testing when results from waived testing indicate such further testing is needed.

Physicians or groups of physicians, midwives or nurse practitioners operating independently-owned laboratories solely to perform waived or PPMP tests on their own patients are exempt from LSL registration requirements and must obtain CLIA certification through the Physician Office Laboratory Evaluation Program (POLEP). Information on CLIA certification for physician office laboratories may be obtained by visiting the POLEP website at www.wadsworth.org/regulatory/polep or by contacting POLEP at CLIA@health.ny.gov.

## Source Plasma Donation Centers

Facilities that perform only collection of plasma for use in manufacture are required to register as a source plasma donation center. Such sites may only perform hematocrit and total protein testing on-site. All other testing of the donor or collected plasma must be referred to facility holding a valid clinical laboratory permit as required in Article 5, Title 5 of New York State Public Health Law. Information on source plasma donation center registrations is available at www.wadsworth.org/regulatory/plasma.

Applications for a source plasma donation center must include a registration fee of $600. Registrations are valid for two years. Approximately four months prior to the expiration date, a renewal application is sent via postal service to the laboratory. The renewal registration fee is $600.

A laboratory director of a source plasma donation center may not provide oversight of more than five sites where non-waived testing is performed.

Facilities that perform plasma collection for intravenous use, collect any other blood components, or perform any other testing must obtain a blood bank or clinical laboratory permit from the Clinical Laboratory Evaluation Program.

Source plasma donation centers must have an on-site survey as a condition of maintaining a valid registration. Surveys may also be conducted in response to reports of complaints or other incidents. Surveys are unannounced and the first survey will typically occur within the first 120 days of operation. The purpose of the survey is to ensure that the premises, laboratory practice, equipment, personnel, and record-keeping meet the requirements set forth in Subpart 58-4 of Title 10 of the New York State Codes, Rules and Regulations.

## Limited Transfusion Service

A hospital's permit in Blood Services – Transfusion Service covers transfusions performed at any location that is owned and operated by, and physically attached to, the hospital. Non-hospital sites and satellite sites that do not meet these criteria, and do not hold a laboratory permit in the Blood Services – Transfusion Storage Only category, must be approved as a **LIMITED TRANSFUSION SERVICE** in order to perform transfusions. Inquiries regarding Limited Transfusion Services should be directed to the Blood Resources Program at brp@health.ny.gov. Please also see https://www.wadsworth.org/regulatory/blood-program.

## Health Fairs

A Health Fair is defined in Section 58-1.7 of 10NYCRR as a temporary collecting station, which is defined as a one-time, one-site facility, operated with the prior approval of the Department, which collects, draws and/or temporarily stores materials derived from the human body, as part of a health fair, health assessment or health risk reduction program, for the purpose of screening for health risk.

To qualify for approval to operate a health fair, a laboratory must hold a New York State clinical laboratory permit and must submit a health fair application via eCLEP on the Health Commerce System. A laboratory procedure manual should be developed for such fairs and must be available for review by the Department upon request. Unless the tests offered are eligible for direct access testing (*see* Direct Access Testing), a physician-in-charge must be named, who will request the tests for fair participants, give permission for results to be given directly to fair participants and be responsible for the referral of any abnormal results. Accession and report records for all fair participants are considered patient records and must be retained as required by Section 58-1.11 of 10NYCRR.

Tests performed should be those appropriate for a community screening setting, meeting criteria as set forth in Section 58-1.7 of 10NYCRR. The laboratory must hold a permit in the appropriate permit category for tests performed on-site and/or for tests performed on specimens collected and transported back to the laboratory for analysis, or must forward tests to a laboratory holding the appropriate permit. Procedures and documentation of validation and other quality control, as well as justification for offering the test as part of a community screening may be requested by the Department for review before a decision is made concerning the health fair application.

Health fair approvals are valid for one year, commencing on July 1st of each year and extending through June 30th of the following year. Laboratories may hold multiple health screening events throughout the year for any of

the tests approved as part of the initial application. Requests to perform additional tests must be submitted via eCLEP. Health fair approvals must be renewed in conjunction with the annual laboratory permit reapplication in the spring of each year. Facilities registered as Limited Service Laboratories may apply to conduct community screening as part of the registration process.

## Patient Service Centers

A patient service center (collecting station) is defined in Section 58-1.7 of 10 NYCRR as an off-site facility "operated by a clinical laboratory under permit, for the collection, drawing, and/or temporary storage of materials derived from the human body, until forwarded to the clinical laboratory for testing." With the exception of glucose and/or ketone screening prior to administration of glucose for a glucose tolerance test, testing of specimens is not allowed in a patient service center. Laboratories under permit may collect patient specimens at the same address as the laboratory without separate patient service center approval. Approval is not required for patient service centers located outside New York State.

To qualify for approval to operate a patient service center, a laboratory must hold a New York State clinical laboratory permit, and must submit a patient service center application through eCLEP on the Health Commerce System.

The application includes a self-assessment document that will be used to determine whether the facility meets the criteria outlined in Section 58-1.7 and Subpart 34-1 of 10NYCRR. If the application is complete and the responses to the self-assessment questions are satisfactory, a letter will be issued granting provisional approval to operate the Patient Service Center. An on-site survey will be conducted and if the Patient Service Center is found to be compliant with the requirements, an approval certificate will be issued.

Patient Service Center approvals are valid for one year, commencing on July 1 each year and extending through June 30 the following year. Laboratories must renew patient service center approvals in conjunction with the annual laboratory permit renewal application in the spring of each year. Patient service centers are subject to additional on-site surveys for the length of their operation.

Changes (address, hours, closure, etc.) to a current approved patient service center must be notified to the Department. Changes to patient service centers may be made through eCLEP on the Health Commerce System.

Approval to operate a Patient Service Center (PSC) or to receive interim approvals may be rescinded when one of the following conditions occurs:

1. When on-site survey identifies that the responses to questions answered on the PSC application and self-assessment were inaccurate or misrepresented and deficiencies are cited as a result;
2. When there is a repeated pattern of deficiencies that indicates the parent laboratory is not routinely monitoring the PSCs to demonstrate compliance with Department requirements;
3. When more than five (5) deficiencies have been cited for any one PSC during a survey event; and
4. When a physical and/or structural change has been made to the PSC without notification to the Department such that the original application is no longer reflective of the actual circumstances of the PSC.

## Direct Access Testing

Amendments to New York State Public Health Law (PHL) effective September 24, 2002 provides a clinical laboratory holding a New York State clinical laboratory permit the option of offering certain laboratory tests directly to consumers, without written authorization (i.e., an order) from a medical professional, provided the laboratory holds a permit in the appropriate categories. This direct access testing option is available for tests for which a Federal Food and Drug Administration (FDA) approved test kit or collection device is available over-the-counter (OTC) without a prescription, and for tests for the same purpose.

**Limited Service Laboratories are not eligible to offer direct access testing** and must continue to document authorization of the physician or other health care professional who orders testing ancillary to a medical encounter, or, for public health testing, authorization of the Commissioner or a designee.

A list of the tests approved for OTC sale by the FDA's Center for Devices and Radiologic Health (CDRH) is posted at FDA OTC Database. Guidance on direct access testing, including information on test orders, specimen collection, test reports, and special requirements for HIV testing, can be found on our website at www.wadsworth.org/regulatory/clep under Direct Access Testing.

## QUESTIONS

Clinical Laboratory Evaluation Program personnel are responsible for issuing Certificates of Qualification, scheduling and conducting on-site surveys, issuing laboratory permits, and similar administrative activities. For questions related to these functions or to request application materials, you may contact the Program by email to clep@health.ny.gov or in writing to the address below. Information and application materials may also be obtained at www.wadsworth/regulatory/clep.

The address for written correspondence is:

Clinical Laboratory Evaluation Program
Biggs Laboratory
Wadsworth Center
New York State Department of Health
Empire State Plaza
Albany, New York 12237

## COMPLAINTS/CONCERNS

Complaints or concerns about laboratory practices, or about laboratory employee or patient safety, can be directed (anonymously if preferred) to the Laboratory Investigative Unit at 1-800-682-6056, or by email to LIU@health.ny.gov. Please refer to their webpage at https://www.wadsworth.org/regulatory/liu for more information on filing complaints.

# DEFINITIONS

**Analyte:** A substance, component, feature, organism or disease entity for which a laboratory conducts testing.

**Applied approved status:** This term indicates a laboratory applying for a permit has met Department requirements in one or more categories, was issued a permit in these categories, and may commence testing once the permit is received.

**Applied pending status:** This term indicates that a laboratory applying for a permit has submitted all necessary application materials and has a director who holds a New York State certificate of qualification. A laboratory in applied pending status is eligible to receive proficiency test samples, if applicable, and be scheduled for an on-site survey.

**Assistant Director:** An individual holding a NYS certificate of qualification that the laboratory director has designated in writing to the Department as responsible for duties specified in Part 19 of 10NYCRR for a specific permit category or permit categories.

**Blood bank:** A facility for the collection, processing, storage or distribution of human blood, human blood components or blood derivatives, or the performance of reinfusion procedures.

**Category:** This term refers to an area or specialty of laboratory medicine specified in Part 58 of 10NYCRR or described in the NYS laboratory permit category descriptions included in this guide.

**Certificate of qualification:** A certificate issued by the Department to an individual after the applicant has documented that he/she meets the minimum qualifications as a laboratory director set forth in Part 19 of 10NYCRR.

**CLIA:** Acronym for the Clinical Laboratory Improvement Amendments of 1988.

**Clinical laboratory:** A facility for the microbiological, immunological, chemical, hematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body, for the purpose of obtaining information for the diagnosis, prevention or treatment of disease, or the assessment of a health condition, or for identification purposes. Such examinations shall include procedures to determine, measure, or otherwise describe the presence or absence of various substances, components or organisms in the human body.

**Clinical specimen:** A specimen obtained from a donor, patient, insurance applicant or other client.

**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 other duties and responsibilities specified in Section 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.

**FDA:** Acronym for the Food and Drug Administration of the United States Department of Health and Human Services.

**Foreign education:** Higher education obtained outside the United States.

**Permit:** A permit issued by the Clinical Laboratory Evaluation Program, as authorized by the Commissioner of the New York State Department of Health, to a clinical laboratory and/or blood bank.

**Permit Category:** please see definition for Category above.

**Proficiency testing program:** Proficiency testing (PT) is the testing of unknown samples sent to a laboratory by a CMS-approved PT provider. Most sets of PT samples are sent to participating laboratories three times per year. After testing the PT samples in the same manner as its patient specimens, the laboratory reports its sample results back to their PT provider. The PT provider grades the results using the CLIA grading criteria and sends the laboratory scores reflecting how accurately it performed the testing.

**Registration:** Registration for a limited service laboratory or source plasma donation center. Registrations for these two entity types are by the Clinical Laboratory Evaluation Program, as authorized by Public Health Law Article 5, Title V.

**Sole Assistant Director:** A sole Certificate of Qualification holder for a particular permit category. An individual cannot be director, or sole assistant director, for more than two clinical laboratories and/or blood banks as set forth in SubPart58-1 of 10NYCRR.

**Standard operating procedure manual (SOPM):** A manual that describes all methods, materials and other documentation required for overall operation of the laboratory, including, but not limited to, procedures necessary to perform all laboratory tests, examinations or analyses for which the laboratory holds a permit.

**Test:** A technical procedure for the examination of a specimen obtained from the human body for the purpose of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of a health condition or for identification purposes.

# CATEGORY DESCRIPTIONS

Please refer below to obtain descriptions about the various permit categories. Permit categories are based on the purpose of testing and require that the director or assistant director holds a Certificate of Qualification for each category for which a permit is sought. The individual holding the Certificate of Qualification for the category is responsible for the administration of the technical and scientific operation of the clinical laboratory or blood bank, including supervision of test procedures, the reporting of test results, providing advice to referring physicians regarding the significance of laboratory findings and interpretive data, and performing the other duties and responsibilities specified by Section 19.3 of 10NYCRR (New York State Code of Rules and Regulations). Information on the duties and qualifications for laboratory directors can be found in Parts 19 and 58 of 10NYCRR, available at our website at www.wadsworth.org/regulatory/clep under Laws and Regulations.

## Andrology

This category is for laboratories that perform tests of male fertility on patient or donor specimens. These tests include, but are not limited to, semen analysis (sperm concentration/count, sperm motility, and sperm morphology), semen biochemical tests, sperm DNA fragmentation assays, cervical mucus penetration tests, anti-sperm and anti-ovary antibody tests, sperm-egg interaction tests, and other sperm function tests.

Qualitative testing for the presence or absence of viable sperm in semen may be performed under the categories of either Andrology or Hematology. Measurements of reproductive hormones, such as testosterone, FSH or LH activity, are included in the Endocrinology category. Testing to detect genetic markers of infertility and preimplantation genetic diagnosis of embryos is included in the Genetic Testing – Molecular category.

## Bacteriology

This category is for laboratories that examine clinical specimens for the presence of bacteria. Methodologies include, but are not limited to, culture, gram stains, antimicrobial susceptibility testing, molecular assays and/or direct antigen detection techniques.

## Blood pH and Gases

This category is for laboratories performing measurements of blood pH, $pCO_2$ and/or $pO_2$. Blood gas laboratories may also perform testing for carboxyhemoglobin, oxyhemoglobin, methemoglobin and carbon monoxide under this category or they may be performed by a laboratory holding the category of Clinical Chemistry.

Additional permit categories may be needed if testing in the areas of Clinical Chemistry or Hematology are being performed on a Blood Gas analyzer. These tests may include, but are not limited to, electrolytes and hemoglobin.

## Blood Services

Blood Services categories are for blood banks that collect, process, and/or issue blood for transfusion. One or more categories may be appropriate based on the scope of services.

Additional permit categories may be needed if testing of donor specimens is performed on-site:

- Bacteriology (screening of blood components)
- Clinical Chemistry (total protein and ALT)
- Diagnostic Immunology – Donor Services Serology (serologic tests for specific markers of infectious disease),
- Hematology (for donor and/or unit qualification),
- Immunohematology (red blood cell, granulocyte, and/or platelet-related testing for blood collection, transfusion, or pregnancy-associated purposes),
- Parasitology (screening of blood components)
- Virology (screening of blood components).

***COLLECTION:***
This category is for blood banks that collect, process, store, and distribute allogeneic and/or autogeneic blood for transfusion or fractionation purposes.

***COLLECTION - AUTOGENEIC ONLY:***
This category is for blood banks that collect only blood for autogeneic (autologous) transfusion and do not cross over these units or their components for allogeneic use.

***TRANSFUSION SERVICE*:** This category is for blood banks that perform pre-transfusion testing and issue blood for transfusion. Such sites must also hold Immunohematology. A hospital's permit in Blood Services – Transfusion covers transfusions performed at any location that is owned and operated by, and physically attached to, the hospital.

***TRANSFUSION - STORAGE ONLY*:** This category is for facilities that issue blood for transfusion, but rely on a blood bank holding a permit in Blood Services – Transfusion and Immunohematology to perform pre-transfusion testing.

Non-hospital sites and satellite sites that are not otherwise required to hold a clinical laboratory or blood bank permit must be approved as a LIMITED TRANSFUSION SERVICE in order to perform transfusions. Inquiries regarding Limited Transfusion Services should be directed to the Blood Resources Program at brp@health.ny.gov.

## Cellular Immunology

Laboratories analyzing the function and/or phenotype of cells in the immune system must hold any or all of the categories below that describe the scope of their services.

***LEUKOCYTE FUNCTION:***
This category is for laboratories testing any leukocyte function with *in vitro* assays (e.g., antigen-induced proliferation, alloantigen-stimulated proliferation, mitogen-stimulated proliferation, cytolytic assays, cytokine or immunoglobulin production, neutrophil generation of reactive oxygen species, and phagocytosis). If determination of the immunophenotype of the leukocytes being assayed is included as part of the assay (e.g., *in vitro* culturing to induce cytokine synthesis with the purpose of identifying the cell type expressing a cytokine), the analysis also requires the Non-malignant Leukocyte Immunophenotyping category.
NOTE: The determination of cytokines in serum, plasma, CSF, or culture supernatants from Leukocyte Function analysis must also include the Cytokine category.

***NON-MALIGNANT LEUKOCYTE IMMUNOPHENOTYPING:***
This category is for laboratories performing Lymphoid and T-Lymphoid Immunophenotyping. This includes the identification and enumeration of non-malignant lymphocytes that bear different surface and/or intracellular markers for the purpose of assessing the immunological status of an individual (e.g., quantifying $CD4^+$ T-lymphocytes, T regulatory cells, or interferon-gamma expressing lymphocytes). NOTE: If leukocytes are stimulated *in vitro* to induce a change in cell phenotype, the analysis also requires the Leukocyte Function category.

This category also includes Non-Lymphoid Immunophenotyping. Example methodologies include quantification of viable $Lin^-/CD34^+$ stem cells, deficiency of glycophosphatidylinositol linked surface markers (e.g., CD24, CD14, CD59) for Paroxysmal Nocturnal Hemoglobinuria, deficiency of CD15s, CD11a, b, c & CD18 expression for Leukocyte Adhesion Deficiency, and TLR expression(s) for innate immunity. Laboratories performing white blood cell counts and manual differentials for

calculation of absolute numbers of lymphocyte/leukocyte subsets must also hold a Hematology permit.

***MALIGNANT LEUKOCYTE IMMUNOPHENOTYPING:***
This category is for laboratories performing identification and characterization of leukemia or lymphomas from blood and tissue specimens based on cell phenotype, including cell surface and cytoplasmic antigens, with or without ploidy analysis.

## Clinical Chemistry

This category is for laboratories performing diagnostic clinical chemistry tests including substrates, enzymes, electrolytes, and metal analyses. Laboratories issued a Clinical Chemistry permit may perform a full scope of clinical chemistry testing except in those areas defined by the Blood pH and Gases, Trace Elements, Therapeutic Substance Monitoring/Quantitative Toxicology, Endocrinology, Genetic Testing - Biochemistry and Urinalysis categories.

This category also includes tests for soluble tumor markers found in body fluids such as serum, urine, etc. Results from these tests are generally quantitative. Methodologies used include radioimmunoassay (RIA), enzyme immunoassay (EIA), or chemiluminescent immunoassays (CIA), as well as mass spectrometry (MS).

## Cytogenetics

Cytogenetics is the analysis of the chromosome complement of human cells for constitutional or acquired changes in chromosome number or structure. Laboratories may perform prenatal, preimplantation, postnatal, and cancer testing under this category. The Cytogenetics category includes standard methods, laboratory developed tests, and FDA approved/cleared tests. Methods include metaphase chromosome analysis by G-banding, chromosomal microarray (CMA) testing, array comparative genomic hybridization (aCGH), and metaphase and interphase fluorescence in situ hybridization (FISH).

CMA and aCGH testing for constitutional disorders also may be performed under the Genetic Testing – Molecular category. CMA, aCGH, or FISH testing for acquired aberrations also may be performed under the Oncology - Molecular and Cellular Tumor Markers category. Confirmation of abnormal CMA results, if performed, requires the appropriate permit category.

## Cytokines

This category is for laboratories performing the quantification of cytokines and chemokines in biological fluids or cell culture supernatants with methods such as ELISA, FIA, or RIA. Cytokines and chemokines include both immunoregulatory molecules as well as molecules that influence the activity of other organ systems.

**NOTE:** If the measurement of cytokines and chemokines produced by leukocytes is involved, the assays must also include the Cellular Immunology – Leukocyte Function category. If cytokine(s) expressed within a leukocyte population are measured, the analyses are in the Non-Malignant Leukocyte Immunophenotyping category and not Cytokines.

## Cytopathology

Cytopathology category is for laboratories preparing and examining cells and tissue fragments that have exfoliated freely from tissue surfaces, that have been collected by brushing, scraping, washing, lavage or needle aspiration including cellular material that has been embedded in paraffin for cell-block preparation. The laboratory that performs both the technical and professional components, or the laboratories that performs each component individually, must hold each appropriate subcategory for the testing being performed. Testing of cytology specimens for HPV is performed under the category of Virology.

***GYNECOLOGICAL TESTING:***
This category is for laboratories that perform gynecological cytopathology testing on patient specimens for diagnostic or prognostic purposes.

***NON-GYNECOLOGICAL TESTING:***
This category is for laboratories that perform non-gynecological cytopathology testing on patient specimens for diagnostic or prognostic purposes. Approved laboratories may offer the FDA-cleared UroVysion™ assay under this category.

## Diagnostic Immunology

The Diagnostic Immunology categories are for laboratories performing the following types of tests: serologic tests for autoantibodies (excluding tests for antibodies against blood cells performed under the categories of Hematology, Immunohematology, and Histocompatibility and excluding tests for antibodies against spermatozoa performed under the category of Andrology), serologic tests for specific markers of infectious diseases or exposure to such diseases (e.g., antibody/antigen), and tests for nonspecific indicators of infectious diseases or exposure to such diseases (e.g., immunoglobulin or complement levels).

***DIAGNOSTIC SERVICES SEROLOGY:***
This category is for laboratories that perform any diagnostic immunologic test on patient specimens for diagnostic or prognostic purposes.

***DONOR SERVICES SEROLOGY:***
This category is for donor banks, and laboratories under contract to donor banks, that perform tests on donors of human organs, tissues and/or blood for transfer, transfusion or transplantation. Mandated tests include syphilis-reagin or treponemal antibody, hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc), hepatitis C antibody (anti-HCV), human T lymphotropic virus I/II antibody and human immunodeficiency virus (HIV). However, donor banks that perform any additional serologic tests, e.g., cytomegalovirus (CMV) antibody, must also hold this category. Donor Services laboratories must also hold the category Diagnostic Services Serology if they perform tests on patient specimens for diagnostic or prognostic purposes.

## Endocrinology

This category is for laboratories evaluating endocrine function and vitamin status in the body by measuring hormones, including urine pregnancy, and vitamins and related analytes in body fluids.

## Fetal Defect Markers

This category is for laboratories performing prenatal screening for risk assessment of chromosomal abnormalities or other defects of the fetus (e.g., neural tube defects) in the first and/or second trimester. Analytes are measured in maternal serum and amniotic fluid, and methodologies used include radioimmunoassay (RIA), enzyme immunoassay (EIA) or chemiluminescent immunoassays (CIA). Mass values obtained must be compared to the individual laboratory normative data of weekly values and converted to multiple of the medians (MOM). One of several algorithms is then used to calculate an individual's risk.

Laboratories that measure gestational age-dependent alpha-fetoprotein (AFP) in amniotic fluid must confirm the result by electrophoretic identification of acetylcholinesterase.

**Please note** that prenatal screening for chromosomal abnormalities by assessing plasma-derived DNA or RNA (e.g. Non-Invasive Prenatal Testing or NIPT) is performed under the category of Genetic Testing - Molecular.

## Forensic Identity

This category is for laboratories that perform DNA-based procedures for the determination of identity, or for the determination of parentage, for forensic purposes. Also included under this category are screening procedures to determine the presence of body fluids on evidentiary materials for forensic purposes. At this time, the standards for this category are those based on 1) the New York State DOH Clinical Laboratory

Standards of Practice, 2) the New York State DOH Forensic Identity Standards; and 3) current and relevant Federal Bureau of Investigation (FBI) standards including the "Quality Assurance Standards for Forensic DNA Testing Laboratories" and the "Quality Assurance Standards for DNA Databasing Laboratories".

Documents summarizing the validation and implementation of *all* technical procedures must be submitted for approval by the Forensic Identity Section. Approval of each procedure must be obtained prior to use on New York State samples. These procedures include but are not limited to: screening assays for the presence of biological fluids; DNA extraction; DNA quantitation; DNA amplification; fragment and sequence detection platforms; and data analysis software.

Laboratories are required to participate in an ANAB-approved proficiency testing (PT) program and submit a brief summary of PT activities to the Forensic Identity Section every six months.

## Genetic Testing

The Genetic Testing categories are for laboratories performing procedures that provide information for the diagnosis of disease caused genetically and/or epigenetically, or its carrier state, risk assessment for drug metabolism, disease susceptibility, hemostasis, guiding disease treatment, and disease risk and lifestyle assessments in addition to screening tests intended broadly for asymptomatic individuals not yet presenting with disease. These categories are also for laboratories using molecular methods to confirm results generated by SNP-based comparative genomic hybridization tests.

Predisposition testing for inherited cancers, preimplantation diagnosis (including molecular analysis of cells from embryos to detect single gene disorders, haplotype analysis for complex mutations, or HLA haplotyping for a sibling match prior to implantation), non-invasive prenatal diagnosis and pharmacogenetics applications are all included in the Genetic Testing category. Also, this category includes the use of genetic or epigenetic markers to test for zygosity for pregnancy management and maternal cell contamination in the context of diagnosis and tests using these markers to monitor disease progression. This category also comprises the use of RNA, including but not limited to mRNA and microRNA, as applied to expression levels, managing disease progression, and guiding disease treatment.

Some applications of molecular methods are not included in the Genetic Testing categories. Laboratories may also need to hold the additional categories including Cytogenetics, Forensic Identity, Histocompatibility, Immunohematology, Parentage/Identity, and/or Oncology – Molecular and Cellular Tumor Markers (for somatic changes in tumor tissue), as appropriate.

> ***GENETIC TESTING – MOLECULAR*:** This category is for laboratories performing diagnostic and predictive genetic testing utilizing DNA and/or RNA-based methodologies.
>
> ***GENETIC TESTING – BIOCHEMISTRY*:** This category is for laboratories performing genetic testing utilizing biochemical procedures in laboratories where a specific genetic diagnosis or carrier status is being determined.

## Hematology

This category is for laboratories performing cellular hematology tests, such as white cell count, red cell count, hemoglobin, hematocrit, and platelet count, with or without other tests such as red cell indices, reticulocyte count, and erythrocyte sedimentation rate; manual differentials, smear examinations, or automated differentials with manual confirmation performed on-site; coagulation tests, such as prothrombin time, activated partial thromboplastin time and quantitative fibrinogen, with or without other tests such as thrombin time, and factor assays.

Qualitative testing for the presence or absence of viable sperm in semen may be performed under the categories of either Andrology or Hematology. If blood-borne parasites are observed during the routine smear examination, they may be reported as presumptive, however, the examination of blood smears specifically for parasites or the identification of parasites requires a permit in Parasitology.

## Histocompatibility

This category is for laboratories performing histocompatibility testing for organ/tissue transplantation. Testing may include HLA antigen typing, antibody screening, or crossmatching. Laboratories performing HLA antigen typing for disease associations or pharmacogenetics may perform that testing under this category or under the Genetic Testing category.

Laboratories performing chimerism analysis, gene expression analysis or the Immuknow® assay to monitor the status of a patient following an organ or tissue transplant must hold the category of Transplant Monitoring.

## Histopathology

The Histopathology categories are for laboratories performing gross and microscopic examination of tissues, including special stains and immunohistochemistry. Certain in situ hybridization tests, such as FDA-cleared fluorescence *in situ* hybridization tests (FISH) for the detection of Her-2/neu and TOP2A gene amplifications can be performed under either the Histopathology – General or the Oncology – Molecular and Cellular Tumor Markers category.

***GENERAL:***
This category is for testing of all tissue. Testing for HPV in tissue is performed under this category. All other HPV testing is performed under Virology.

***ORAL PATHOLOGY:***
This category is for testing limited to the oral cavity.

***DERMATOPATHOLOGY:***
This category is for testing limited to skin, including examining frozen sections of skin excised during Mohs surgery.

## Immunohematology

This category is for laboratories that perform red blood cell-, granulocyte- and/or platelet-related testing for blood collection, transfusion or pregnancy-associated purposes. Methodologies include serologic, molecular and flow cytometric techniques for tests such as: red blood cell antigen and antibody testing, direct antiglobulin testing, compatibility testing, granulocyte antigen and antibody testing, platelet antigen and antibody testing, and assessment of fetomaternal hemorrhage.

## Mycobacteriology

This category is for laboratories that perform any technique for the detection and identification of mycobacteria to the extent of their abilities, including examination of smears for acid-fast bacilli, culture, molecular techniques, and drug susceptibility testing on Mycobacterium tuberculosis complex organisms.

## Mycology

This category is for laboratories that perform any technique for the detection and identification of molds and yeast to the extent of their abilities, including antigen detection assays, culture, molecular and protein based assays, and antifungal drug susceptibility testing.

## Oncology- Molecular and Cellular Tumor Markers

This category is for laboratories performing tests on cellular or tumor tissue material to detect tumor-specific acquired (somatic) genetic or phenotypic alterations. It includes, but is not limited to, tests that detect gene rearrangements, chromosomal aberrations such as gain/loss of chromosome regions, translocations, mutations, altered gene/protein expression, and *ex vivo* determination of chemotherapeutic drug sensitivity. It also includes circulating tumor cell detection and cell free DNA/RNA analysis (liquid biopsy). Methodologies used are generally, though not exclusively, molecular biology-based, and results can be qualitative and/or quantitative. FISH and array comparative genomic hybridization (aCGH) assays for acquired chromosomal aberrations may be performed under this category or under Cytogenetics.

## Parasitology

This category is for laboratories that test patient specimens in order to detect and identify parasitic agents. Laboratories holding this category may perform microscopy, antigen detection, or molecular detection methods. Techniques may include wet mounts, permanent stained smears prepared from blood, stool or tissues, immunofluorescent microscopy, antigen detection with later flow devices or by EIA, or nucleic acid amplification based methods.

## Parentage / Identity

This category is for laboratories that perform procedures for the determination of parentage or relationship. Laboratories performing parentage and/or identity tests for forensic purposes must hold a permit in the Forensic Identity category.

## Therapeutic Substance Monitoring / Quantitative Toxicology

This category, also known as Ther. Sub. Mon./Quant. Tox., is for laboratories providing quantitative analysis of drugs and/or metabolites (therapeutic or abused) in serum, plasma and/or whole blood for the purpose of monitoring concentrations of active drug and/or metabolites and of quantifying subtherapeutic and/or toxic substance concentrations. Quantitative Toxicology includes quantitation of ethanol, including breath alcohol for non-forensic purposes, as well as analysis of all clinically relevant matrices for exogenous, non-drug/non-elemental compounds that may affect human health. This category also includes testing for development of antibodies against varied therapeutic compounds (e.g., monoclonal antibody-based drugs and enzyme replacement therapies).

## Toxicology

Laboratories that provide toxicology testing must hold a permit in one or more of the following categories:

### Clinical Toxicology

The Clinical Toxicology categories are for laboratories performing tests for the detection of drugs/metabolites, including ethanol. Quantitative reporting of specimen validity testing (e.g., pH, creatinine, oxidants) requires a permit in Clinical Chemistry.

***CLINICAL TOXICOLOGY – QUALITATIVE TESTING ONLY:***
This category is for laboratories providing clinical toxicology services that are limited to qualitative tests using methods including, but not limited to, immunoassays, e.g., EIA, CIA, ELISA, and EMIT.

***CLINICAL TOXICOLOGY - COMPREHENSIVE:***
This category is for laboratories performing quantitative tests suitable for confirmation of qualitative presumptive positive drug/metabolite tests. Methods typically include, but are not limited to chromatographic methods, e.g. LC-MS/MS or GC-MS. Laboratories permitted in this category may also perform qualitative tests.

## Forensic Toxicology

The Forensic Toxicology categories are for laboratories that provide the analysis of urine and alternative specimens, including hair, oral fluid, sweat and breath, for abused substances where the legal defensibility of laboratory services must be established and maintained. Such services include pre-employment screening; for cause (i.e., incident/accident-related) and return to work testing, random employment testing; any testing situation where employment, benefits or services may be terminated or denied as the result of positive finding; and postmortem toxicology testing conducted by private sector laboratories. Laboratories qualifying for these categories must have protocols for specimen chain-of-custody and laboratory security. Quantitative reporting of specimen validity testing (e.g., pH, creatinine, oxidants) requires a permit in Clinical Chemistry.

***FORENSIC TOXICOLOGY - INITIAL TESTING ONLY:***
This category is for laboratories performing forensic drug-testing limited to initial (screening) testing only. Laboratories holding this category must refer presumptive positive specimens to a laboratory holding a Forensic Toxicology-Comprehensive permit for confirmatory testing.

***FORENSIC TOXICOLOGY - COMPREHENSIVE:***
This category is for laboratories performing on-site confirmation analysis of presumptive positive drug screens using confirmatory methods acceptable to the Department.

## Toxicology – Blood Lead

***BLOOD LEAD – ASV USING SCREEN PRINTED SENSORS:***
This category is for laboratories using point-of-care lead analyzers (e.g., LeadCare® II by Magellan Biosciences, Inc. that are based on ASV with single use, disposable sensors, i.e., screen-printed electrode technology. Laboratories holding this category must either refer positive specimens (≥5 ug/dL) (≥ 40 ug/dL for LeadCare Plus or LeadCare Ultra cf. CLS 11) to a laboratory holding a Blood Lead - Comprehensive permit for confirmatory testing using a reference method or, when a confirmatory specimen is unavailable, identify on the report the method/manufacturer used and the need for confirmation by a reference method.

***BLOOD LEAD – COMPREHENSIVE:***
This category is for laboratories that perform blood lead measurements using reference methods based on atomic absorption spectrometry (AAS) and/or inductively coupled plasma mass spectrometry (ICP-MS). Laboratories holding this category may also perform testing using point-of-care lead analyzers based on anodic stripping voltammetry (ASV) with screen-printed sensors, provided they also perform reference methods. This category includes testing for erythrocyte protoporphyrin.
Testing for electrolytes such as sodium, potassium, magnesium and calcium are included under the Clinical Chemistry category. Testing for trace elements such as arsenic, cadmium, mercury, copper, zinc, selenium and aluminum are included under the Trace Elements category.

## Trace Elements

This category is for laboratories performing testing for trace elements (e.g., arsenic, cadmium, mercury, copper, zinc, selenium, aluminum) in clinical specimens, including whole blood, serum or urine. Testing for blood lead is included under the Toxicology – Blood Lead categories. Testing for electrolytes such as sodium, potassium, calcium and magnesium is performed under the Clinical Chemistry category.

## Transplant Monitoring

This category is for laboratories performing chimerism analysis following a stem cell or bone marrow transplant, gene expression analysis for organ rejection, or the FDA-cleared Cylex ImmunKnow® assay for monitoring immune function following transplant.

## Urinalysis

This category is for laboratories performing a qualitative or semi-quantitative analysis of urinary glucose, protein, ketones, pH, hemoglobin, bilirubin, specific gravity, and/or a microscopic evaluation of urine for cellular and formed elements such as casts, crystals, white blood cells, and red blood cells. Laboratories holding this category may report the presence or absence in urine of bacteria, yeast, sperm or *Trichomonas vaginalis;* noting that speciation of bacteria or yeast requires the appropriate microbiology category. Quantitative urine testing is performed under appropriate categories of Clinical Chemistry or Toxicology.

## Virology

This category is for laboratories that perform any technique for the detection and identification of any viral agents routinely encountered in a clinical virology laboratory. Laboratories holding this category may perform antigen detection, virus culture, or molecular detection methods. Techniques may include methods for the assessment of antiviral drug susceptibility, subtyping, or other virus characterization techniques.

## Wet Mounts

This category is for laboratories performing a direct, unstained examination of urogenital specimens (vaginal and urethral secretions) for the presence or absence of *Trichomonas vaginalis*, yeast, or bacteria, or to identify clue cells. It also includes tests for vaginal pH. Laboratories performing Gram stains on urogenital specimens must also hold the category of Bacteriology.

Out-of-state laboratories are not eligible for this category due to the concerns regarding viability of the specimen during/after transport.