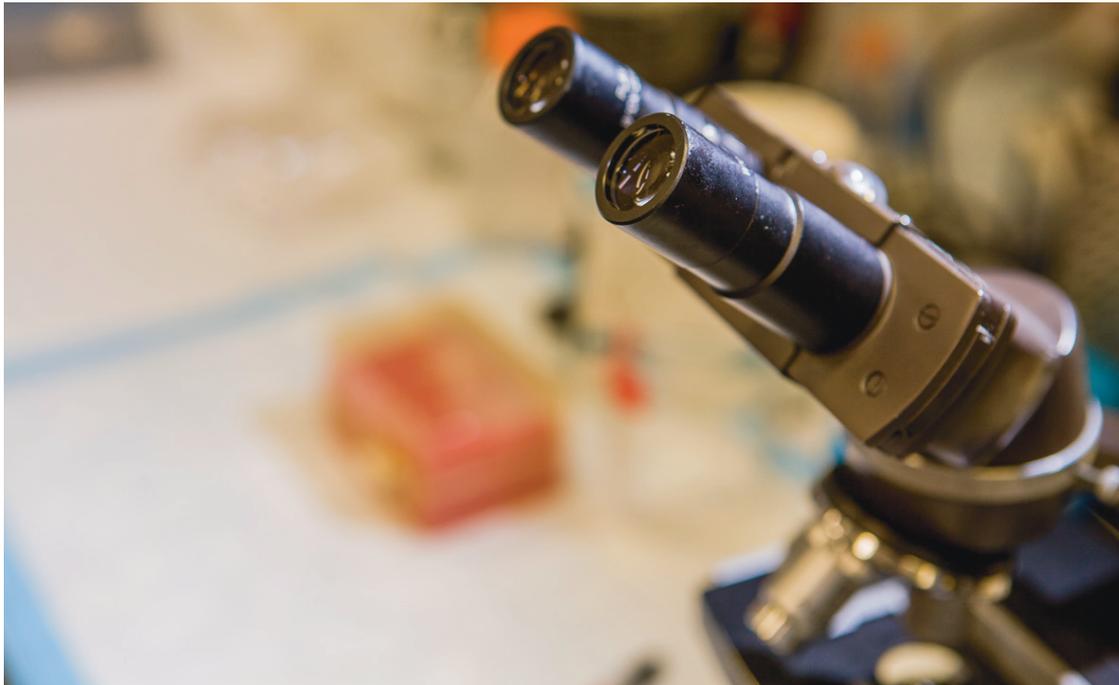




Department  
of Health

Wadsworth  
Center

# Clinical Laboratory Evaluation Program



## A Guide to Program Requirements and Services

**Application Procedures • Personnel Requirements  
Laboratory Surveys • Proficiency Testing**

*Revised July 2017*

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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, and inspection and proficiency testing 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. 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, and evaluation of the qualifications of personnel of state permit-holding clinical laboratories and blood banks. 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](http://www.wadsworth.org/regulatory/clep) or contact us at (518) 485-5378.

## 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 Title V, Section 574 of the New York State Public Health Law. Research testing is considered clinical in nature 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, however tests for these purposes that are referred 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 (518) 485-5352. 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.

### 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](http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit). An initial application for a clinical laboratory permit must be submitted with the required application and reference fees of \$1,100. Laboratories located out-of-state must also pay any travel costs associated with the on-site inspection. Requirements for a clinical laboratory permit include certification of a director and/or assistant director(s) for each testing specialty category; an on-site inspection and correction of any deficiencies identified; successful performance in proficiency testing or alternate requirements for each permit category; and departmental review and approval of any in-house developed or non-FDA approved methods. A complete application must be received before the laboratory is eligible for on-site survey. This includes the receipt of method validation review and proficiency test enrollment information, as applicable.

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. Applications for permit reapplication are available via 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.

### 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 Program applications located on the HCS are eCLEP for changes to laboratory operations, permit reapplications and viewing the status of validation packages and the Electronic Proficiency Testing Reporting

System (EPTRS) for reviewing proficiency testing results previously administered by the Department. Other Wadsworth Center applications located on the HCS include: the Electronic Clinical Laboratory Report System (ECLRS); and the Clinical Laboratory Information Management System (CLIMS).

### **Definitions with respect to the HCS:**

**Director** – The individual responsible for the ensuring the laboratory and all staff at the laboratory who hold HCS accounts comply with the terms of the Health Commerce System Organization Security and Use Policy and User Security and Use Policy.

**Coordinator** – The HCS Coordinator is the individual who has the responsibility and authority to request and manage HCS accounts for additional staff in the laboratory and manage roles in the Communications Directory.

Laboratory directors are required to obtain an HCS account as part of the requirements for a clinical laboratory permit. The laboratory director should designate a HCS Coordinator for the laboratory. To begin this process, the laboratory director and a laboratory-designated HCS coordinator must complete and submit the [Laboratory/HCS Affiliation Request form](http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit), available on our website [www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit](http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit). Once this has been received by the Program, the director and HCS Coordinator will receive, via email, additional forms which must be completed, notarized and returned to the Commerce Account Management Unit (CAMU). Upon receipt, CAMU will process and activate the HCS account(s). **Laboratory Directors with an existing HCS account must affiliate that account with each laboratory they direct.**

All other users of the HCS at a laboratory must have an individual account which can be requested once the director and coordinator accounts have been activated. The HCS Coordinator is responsible for requesting user accounts for the additional staff.

For all personnel other than the laboratory director and assistant director(s) who require access to eCLEP and/or EPTRS, a completed Delegated Submitter Form signed by the laboratory director must be submitted to the Program. This form should be submitted after the HCS Coordinator has activated the users HCS account.

When a new director is appointed at a New York State permitted laboratory, the laboratory is required to submit this change via eCLEP and submit a Laboratory/HCS Affiliation form separately. If eCLEP is in Read-Only Mode, please contact CLEP at 518-485-5378 to request that eCLEP be flipped back to OPEN mode for your facility. Please note: electronic request for a change in director through the HCS portal does not constitute notification of a change in director to the department for purposes of the New York State clinical laboratory permit.

Note that sharing of an account user id and password is a violation of the security user agreement, which will result in the temporary suspension of your account privileges until required remedial action is taken by executives at your facility.

## **Proficiency Testing**

All laboratories applying for or holding a New York State clinical laboratory permit must participate in proficiency testing with a federal Centers for Medicaid and Medicare Services (CMS)-approved provider for tests/analytes offered by the laboratory that are included in CLIA subpart I (42 CFR 493 subpart I) and adhere to the following testing procedures. Failure to comply with these procedures may result in sanctions being brought against participating laboratories under state and federal regulations. All laboratories must disclose to the Department the CMS – approved proficiency test provider that is being utilized to fulfill federal proficiency testing requirements.

Proficiency test requirements are considered met for an initial permit application upon satisfactory performance in all components for a proficiency test event. However, continued participation and satisfactory performance

must be achieved to maintain fulfillment of proficiency testing requirements until all other permit requirements are met. Laboratories must demonstrate successful participation in a proficiency testing event that occurs after the initial application is received by CLEP.

Should a laboratory perform unsatisfactorily for the entire permit category or for a test/analyte, the laboratory must investigate the cause of unsatisfactory performance and document the corrective action for review by the Department. The corrective action must be acceptable to the Department and performance in the subsequent test event must be satisfactory to meet proficiency requirements for the permit category. Unsatisfactory performance in two out of three test events will result in unsuccessful performance. Unsuccessful performance under any category for which the laboratory is currently applied, but not approved, may result in the removal of said category from applied status. Laboratories that are approved in the category for which an unsuccessful performance is received are subject to requirements outlined in the sections titled [Unsuccessful Proficiency Testing Performance](#) and [Reinstatement after Unsuccessful Performance](#).

For tests/analytes that are not included in CLIA subpart I, 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. Refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the New York State Clinical Laboratory Standards of Practice (put a link to the web page). When external proficiency testing is used to satisfy QA S3, New York State Clinical Laboratory Standards of Practice for proficiency testing also apply.

## Test Approval

New York State Public Health Law requires that the Department evaluate testing methods and procedures to assess compliance with state requirements. Laboratories are required to submit notification to the Department of their intention to add or delete tests/analytes to their list of tests offered to New York State patients. Please see the [Adding or Deleting Permit Categories or Tests/Analytes](#) section below for specific details about appropriate notification. Laboratories may also be required to submit standard operating procedure manuals (SOPMs) and validation data for proposed test methods and procedures for review and approval by the Department. This additional submission requirement applies to a FDA-approved test that has been modified by the laboratory; a non-FDA approved test, or a laboratory-developed test (LDT). A full overview of the requirements for test addition notification and/or approval is available in the Test Approval page available on our website at [www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval](http://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 patient testing can be performed. A surveyor from the Department will contact the laboratory to schedule an initial on-site survey. Subsequent routine surveys in laboratories located within the state are unannounced. All out-of-state new permit and routine 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](http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/on-site-survey/laboratory-standards). Standards undergoing revision are subject to a public comment period. Announcement of the comment period, instructions for submitting comments, responses to comments received and final outcome of the revision are posted on the website and are also sent to laboratory directors and laboratory contact persons via email.

New York State Public Health Law requires that out-of-state laboratories seeking or reapplying for a clinical laboratory permit 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. Survey expenses for in-state laboratories are included in the annual permit fees.

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](http://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 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:

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 of quality control and patient reporting
Review:	

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 for the probes of 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, distribution of blood products from the pharmacy, 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. An important role of the laboratory survey is verifying 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](http://www.wadsworth.org/regulatory/clep) 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 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 a survey report to the Program. Once reviewed, a laboratory evaluation report (LER) will be sent to the laboratory. Laboratories must respond to deficiencies identified in the LER with a Plan of Correction (POC) within ten days of receipt of the LER. A template to assist laboratories in preparing and submitting a POC is available at [www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/on-site-survey](http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/on-site-survey). The laboratory will be notified if there are any concerns with the POC or requested to submit a revised POC if the plan is found unacceptable.

## Issuing the Laboratory Permit

Once the laboratory director and any assistant directors have been issued Certificates of Qualification; the facility has been inspected and any deficiencies have been corrected; the laboratory has successfully met method approval and proficiency testing or alternate requirements for all permit categories for which it has applied; and all applicable fees have been paid, a New York State clinical laboratory permit will be issued.

## Changes in Laboratory Status

**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/application-materials](http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/application-materials).

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 his or her 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 or Tests/Analytes

Requests to add or delete permit categories must be submitted using eCLEP. A list of common tests and analytes, cross-referenced with the Department's permit categories, is available in the Category and Test/Analyte Index posted on [www.wadsworth.org/regulatory/clep/clinical-labs/change-permit](http://www.wadsworth.org/regulatory/clep/clinical-labs/change-permit). To add or delete a test/analyte, the processes outlined on the Test Approval page of our website available at [www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval](http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval), must be followed depending on the nature of the test.

To add a new permit category, a director or assistant director must be identified as the responsible individual who holds, or qualifies 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. The laboratory will not be scheduled for an on-site survey until the director responsible for the category holds the appropriate Certificate of Qualification.

Laboratories seeking to add new FDA - approved, cleared or exempt tests under an existing, approved permit category are not required to meet proficiency test requirements or undergo an on-site survey prior to initiating testing; provided the laboratory maintains current, successful participation in the proficiency testing program for other tests using a similar methodology within the permit category and notifies the Department of the addition. Laboratories seeking to add new FDA - approved, cleared or exempt tests under an approved permit category that have not previously participated in proficiency testing in that category or have performed unsatisfactorily, must notify the Department of the addition and meet proficiency test requirements, if applicable, prior to initiating testing. Validation data for the new test(s) will be reviewed by a surveyor during the next on-site survey of the laboratory. If a laboratory is requesting to add a test which introduces an entirely new methodology into the laboratory, an on-site survey may be required before the laboratory will be allowed to commence testing. Laboratories will be notified in writing via email or letter if an on - site survey is required.

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](http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval).

Deleting a Test: Only tests that were previously entered via the eCLEP application may be deleted via eCLEP. To delete tests from your test menu that were added via a Notification to Add/Delete FDA-Approved Test(s) or predecessor form, please delete via the Notification to Delete FDA-Approved Test(s) form, available at our website [www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval](http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval).

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

## Permit Reapplication

Laboratories holding a permit or applying for a permit must complete a reapplication annually. Permit reapplication is accomplished via a web-based portal called eCLEP. This web-based program is available

through the New York State Department of Health's Health Commerce System (HCS). Laboratories are notified via email in early 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. Laboratories are mailed GAR reporting forms in April. 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 [www.wadsworth.org/regulatory/clep](http://www.wadsworth.org/regulatory/clep) under Laws & Regulations. 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, or can qualify for, 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 actual hours they will serve on-site, and 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 director) for a permit category for no more than two 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 two-site limit. An individual may be authorized by the Department to exceed the two-site limit if he or she submits justification of need. For example, if due to the geographic limitations or economic needs of an area it is difficult to obtain the services of a laboratory director, or due to common ownership and oversight arrangements a single directorship would benefit laboratory operations, authorization to serve as director or sole certificate holder for more than two facilities may be granted. Authorizations to exceed the two-site limit are granted for a two-year period, expiring biennially on June 30, and will be granted and renewed only if the laboratories under the direction of the individual remain in compliance with New York State requirements.

Temporary absences of the laboratory director, or sole director for a category, of greater than or equal to three weeks must be reported to the Program and an individual with a Certificate of Qualification in the appropriate categories to cover all categories included on the permit must be identified to provide coverage.

### Applying for a Certificate of Qualification

A Certificate of Qualification application may be obtained from our website at [www.wadsworth.org/regulatory/clep](http://www.wadsworth.org/regulatory/clep) under Certificate of Qualification & Laboratory Director Requirements. The initial application fee is \$40.00. 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, physical, 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, 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](http://www.naces.org)) or the Association of International Credential Evaluators, Inc. ([www.aice-eval.org](http://www.aice-eval.org)).

## 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 one or more letters from a current or previous laboratory director or other individual with whom the post-degree training and/or experience was acquired or from a recognized expert in the categories requested. 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.

## 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 permit 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](http://www.wadsworth.org/regulatory/clep) under Certificate of Qualification & Laboratory Director 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 \$40.00 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, he/she must provide documentation of experience in the form of one or more letters from a current or previous laboratory director or other individual 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, 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](mailto:CLINLABD@mail.nysed.gov) or by telephone at (518) 474-3817, ext. 150.

### Duties and Qualifications of Laboratory Personnel

Information on the requirements for certification through SED as a clinical laboratory technician or histological technician, licensure as a clinical laboratory technologist or cytotechnologist, and restricted licensure in the specialties of Cytogenetics, Flow Cytometry/Cellular Immunology, Histocompatibility, Molecular Diagnosis, and Stem Cell Process are available [www.op.nysed.gov](http://www.op.nysed.gov). 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 technologists, cytotechnologists, and supervisors. Additional duties and qualifications for laboratory supervisors and cytology supervisors are described in regulations 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/survey-materials](http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/on-site-survey/survey-materials), 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.

All cytotechnologists must register with the Department and maintain a list of current sites of employment for the purposes of workload monitoring, in addition to holding licensure, or, for those employed out-of-state, meeting equivalent requirements. If the cytotechnologist is not registered at the time of hiring, the laboratory must submit an application for registration within one week of commencing employment. In addition, cytotechnologists are required to notify the Department within thirty days of any changes to their name, address and/or employers. The laboratory must also notify the Department when a cytotechnologist is hired, resigns or otherwise is separated from the laboratory.

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 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 in order 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](http://www.naces.org)) or the Association of International Credential Evaluators, Inc. ([www.aice-eval.org](http://www.aice-eval.org)).

## 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 PROGRAMS

### Documenting the Proficiency Testing Process

Laboratories must maintain the following documentation of the processing of proficiency testing materials for review by Department staff as required. Review of this documentation may occur during the on-site survey.

1. Each step taken in preparing, processing, examining, testing and reporting all results in the proficiency test event.
2. Copies of all testing records, including copies of the proficiency test report forms, for a minimum of two (2) years from the date of the test event for all categories, except Forensic Identity, which requires retention for three (3) years, and Immunohematology, which requires retention for five (5) years.
3. The proficiency testing provider's attestation form completed in accordance with the provider's instructions and requirements.

### Requirements for Participation

1. All laboratories applying for or holding a clinical laboratory permit must successfully participate in proficiency testing for tests/analytes offered by the laboratory that are described in CLIA subparts H and I (42 CFR 493 subpart H and 42 CFR 493 subpart I) and adhere to the following testing procedures. Failure to comply with these procedures may result in sanctions being brought against participating laboratories under state and federal regulations. The laboratory shall participate in proficiency testing from a federal Centers for Medicaid and Medicare Services (CMS)-approved provider defined by the Department as equivalent to New York State proficiency testing for each permit category and tests for which the laboratory seeks or currently holds a permit.
2. The laboratory shall examine, test, or analyze the proficiency samples in the same manner as clinical specimens, consistent with its routine workload.
3. The proficiency samples shall be examined or tested with the laboratory's routine workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods, unless otherwise instructed by the proficiency testing program.
4. Repeated testing or analysis of proficiency samples is not permitted unless the laboratory performs the same repetitive testing or analysis on patient, donor, insurance applicant or other client samples.
5. Laboratories that test proficiency samples shall not engage in any inter-laboratory communication or discussion pertaining to the results of test samples until after the date the laboratories are required to report the results to the PT provider. Laboratories with multiple testing sites or separate locations cannot participate in any communication or discussion between or among sites/locations concerning test results until after the date the laboratories are required to report the results to the PT provider.
6. Laboratories shall not send proficiency samples or portions of samples to any other laboratory or location for testing, analysis or review.
7. Any laboratory that has referred its proficiency samples to another laboratory for analysis and/or submitted the other laboratory's results as its own will face administrative sanctions and may have its permit revoked and/or denied for at least one year.
8. Any laboratory that receives proficiency samples from another laboratory for testing must notify the Department within seventy-two hours of receipt or identification of such samples.

### Temporary Suspension of Testing

Some circumstances require that a laboratory may not be able to offer a particular test or suite of tests due to backlog of reagents, loss of key personnel, etc. In these instances, laboratories may elect to temporarily suspend the offering of these test to their client and their participation in proficiency testing.

**Temporary Suspension of Testing at the Test Level** - If the laboratory temporarily suspends testing for an individual test on two or more consecutive proficiency test events, the individual test will be removed from the laboratory's test menu. To request the reinstatement of the deleted test, the laboratory should refer to the Test Approval page, available on the website at <http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval>, for the appropriate course of action based on nature of the test.

**Temporary Suspension of Testing at the Category Level** - If the laboratory is unable to participate in two or more consecutive proficiency events for all tests included in a permit category, the category will be deleted from the laboratory permit. To reapply for the category, the laboratory must submit a request to add the category via eCLEP. The laboratory will be required to successfully participate in one proficiency test event and have an on-site survey, if applicable.

## PROFICIENCY TESTING EVENT FAILURES

### Unsatisfactory Proficiency Testing Performance

Unsatisfactory performance is the failure to attain the minimum satisfactory score for the category or test/analyte for a testing event, including events that are failed for non-technical reasons such as late submission or failure to participate. Please note, removal of the category or test/analyte from the laboratory's test menu, in and of itself, is not acceptable remedial action. Laboratories that are approved for a category are required to investigate the problem(s) that contributed to the unsatisfactory performance and implement corrective action. Laboratories may request additional test samples from their proficiency test provider to use as part of the remediation. The investigation and any subsequent remediation conducted by the laboratory may be reviewed during on-site survey or the Department may request that documentation be submitted for review.

Laboratories that are applying for permit in a category or are approved for a category are required to investigate the problem(s) that contributed to the unsatisfactory performance and implement corrective action. Laboratories may request additional test samples from their proficiency testing provider to use as part of the remediation. A summary of the investigation and corrective actions must be submitted to the Department for review. The Department may request additional information. The documentation of the investigation and the laboratory's plan of corrections must be submitted electronically within 2 weeks of receipt of evaluation report indicating unsatisfactory performance. Failure to submit an acceptable plan of correction or failure to implement the plan of correction can result in administrative action or may lead to delays in issuing the laboratory permit.

### Unsuccessful Proficiency Testing Performance

Unsuccessful proficiency testing performance is unsatisfactory performance for the category or test/analyte in two consecutive or two out of three consecutive testing events, including events that are failed for non-technical reasons such as a late submission or failure to participate. The Department notifies laboratories following unsuccessful performance via a Laboratory Evaluation Report (LER) similar to the survey process described above. Please note, removal of the category or test/analyte from the laboratory's test menu, in and of itself, is not acceptable remedial action. Laboratories are required to investigate and document the problem(s) that contributed to the unsuccessful performance and implement corrective action. Laboratories may request additional test samples from their proficiency test provider to use as part of the remediation. The findings of the laboratory investigation and a description of the corrective action that is implemented must be submitted to the Department as part of the Plan of Correction to the Laboratory Evaluation Report.

Remediation programs are designed based on the nature of the unsatisfactory performances and the area of clinical laboratory medicine involved. An on-site inspection of the laboratory may be conducted. Once the laboratory's remediation is acceptable to the Department, the laboratory must demonstrate satisfactory performance in two consecutive proficiency test events.

The decision as to whether a laboratory will be ordered to cease testing of clinical specimens upon a first unsuccessful performance in proficiency testing is based on responses to the following questions: (see **Proficiency Testing Sustaining Standard of Practice 11 (PT S11): Unsuccessful Performance – Cessation of Patient Testing**) in the **Clinical Laboratory Standards of Practice**.

1. Are the analytical errors suggestive of immediate jeopardy to patient care?
2. Has the laboratory demonstrated an inability to make progress toward improvement of previously identified substandard performance following a reasonable opportunity to correct deficiencies?
3. Are the root causes of substandard performance systemic to laboratory practices?
4. Has the laboratory demonstrated a history of non-compliance with standards of good laboratory practice?
5. Have there been other instances of unsuccessful performance in the category within the past two years that reflect a pattern of poor performance relevant to the current event?

If the response is **yes** to any one of the questions 1 - 5 above and the validity of the proficiency event is substantiated, the Department is obligated to instruct the laboratory to cease testing clinical specimens and to require the laboratory to perform the following:

1. Identify the permit laboratory to which it will refer clinical specimens;
2. Investigate the cause(s) of substandard performance in the proficiency program; and
3. Conduct a retrospective review of patient results to ascertain whether similar error(s) existed in reports of test findings and to assess the need for notification of the ordering physician.

Laboratories that comply with a directive to cease testing clinical specimens due to a first unsuccessful PT performance will be reinstated after documentation of corrective action has been determined to be acceptable, the laboratory demonstrates satisfactory performance in two consecutive test events, and at least six months has elapsed since the cease testing order.

Where performance in proficiency testing provides evidence of risk for patient harm and the laboratory does not cease testing as directed, the Department will take enforcement action as authorized by Sections 576(3) and 577 of New York State Public Health Law, Article 5, Title V.

If the response to each of questions 1 - 5 above is **no**, and if the department judges that the cause(s) of the substandard performance is not systemic, can be remedied in a timely manner, and the level of performance does not compromise the clinical utility of results, the laboratory is allowed to continue testing of clinical specimens as test performance is investigated and monitored. The laboratory will be notified of the unsuccessful performance in proficiency and be instructed to perform the following:

1. Investigate immediately the cause(s) of substandard performance in proficiency;
2. Report its findings to the Clinical Laboratory Evaluation Program within two weeks (ten business days) of notification of unsuccessful performance; and
3. Demonstrate the effectiveness of corrective action by successful performance in two consecutive proficiency testing events from the same proficiency test provider, only one of which can be an off-schedule event. Please note, the off-schedule event must be from the same proficiency testing provider as the regularly scheduled testing event.

The documentation of cause(s) of unsuccessful performance and the effectiveness of corrective action must be provided to the Program within two weeks (10 business days) of notification of unsuccessful performance. If effective corrective action is not implemented and documented to the satisfaction of the proficiency testing technical section, the laboratory will be required to cease testing clinical specimens.

## Reinstatement after Unsuccessful Performance

The laboratory must characterize the cause(s) of substandard performance, develop and implement a plan of corrective action, and substantiate the effectiveness of corrective action by successful performance in two consecutive proficiency test events obtained from the same proficiency test provider. As a CLIA-exempt state, the Department must notify the federal Centers for Medicare and Medicaid Services (CMS) of any sanctions (e.g., orders to cease testing of clinical specimens) brought against laboratories enrolled in the proficiency testing program.

## Subsequent Unsuccessful Proficiency Testing Performance

Laboratories demonstrating a subsequent unsuccessful (three consecutive unsatisfactory performance or three unsatisfactory performances in four or five consecutive test events) will be instructed to cease testing clinical specimens. Laboratories that comply with a directive to cease testing clinical specimens due to subsequent unsuccessful PT performance will be reinstated after documentation of corrective action has been determined to be acceptable, the laboratory demonstrates satisfactory performance in two consecutive test events obtained from the same proficiency test provider, and at least six months has elapsed since the cease testing order.

Where performance in proficiency testing provides evidence of risk for patient harm as determined by criteria a-e under **Proficiency Testing Sustaining Standard of Practice 11 (PT S11): Unsuccessful Performance – Cessation of Patient Testing**, and the laboratory does not cease testing as directed, the Department will take enforcement action as authorized by Sections 576(3) and 577 of New York State Public Health Law, Article 5, Title V.

## ADDITIONAL APPLICATION REQUIREMENTS

### Limited Service Laboratories

Amendments to New York State Public Health Law (PHL) effective August 8, 2008 authorized the Department's processes for oversight and registration of Limited Service Laboratories. The designation Limited Service Laboratory (LSL) was established for facilities that perform only tests classified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as waived or provider-performed microscopy procedures (PPMP). These facilities 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 performing only waived or PPMP tests that are owned and/or operated by managed care organizations, hospitals or consulting firms are also included in this group. Limited Service Laboratories may collect specimens as indicated to perform confirmatory or supplemental testing when results from waived testing indicate such further testing is needed. Information on Limited Service Laboratory registrations is available at [www.wadsworth.org/regulatory/clep/limited-service-lab-certs](http://www.wadsworth.org/regulatory/clep/limited-service-lab-certs).

The laboratory director is responsible for the overall operation and administration of the laboratory. In order to comply with the requirements of the federal Centers for Medicare and Medicaid Services (CMS) CFR Section 493.1359 and Section 58-1.2 of the New York State Codes, Rules and Regulations (10 NYCRR), the laboratory director may provide oversight of no more than five sites performing provider-performed microscopy procedures or two sites holding New York State clinical laboratory permits or certificates of accreditation or compliance from CMS in addition to three sites performing provider-performed microscopy procedures. There is no limit on the number of certificate of waiver sites where an individual can perform the responsibilities of laboratory director.

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 may 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](http://www.wadsworth.org/regulatory/polep) or by contacting POLEP at [CLIA@health.ny.gov](mailto:CLIA@health.ny.gov) or (518) 485-5352.

This law authorizes the Department to charge a registration fee of \$200 for each biennial (i.e., every two years) renewal registration in addition to an initial registration fee of \$200. Limited Service Laboratories that are not-for-profit, state or local government operated, 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 registration fee of \$200 and single renewal fees of \$200, without regard to the number of sites covered by one registration. Test kits and devices classified as waived are all clearly labeled. The FDA assumed the responsibility for classifying the complexity status of laboratory tests in January 2000 and information on tests waived after January of 2000 can be obtained from the FDA website at [FDA Waived Analytes](http://www.fda.gov/oc/analytes/) and a list of waived tests by specific kit and manufacturer is available at [FDA Waived Tests](http://www.fda.gov/oc/analytes/).

### Limited Transfusion Service

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. 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 and Tissue Resources Program at [btraxess@health.ny.gov](mailto:btraxess@health.ny.gov) or (518) 485-5341. Information is also available at their website [www.wadsworth.org/regulatory/btrp](http://www.wadsworth.org/regulatory/btrp).

## 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 on-site 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 approval to operate the Patient Service Center for three months. An on-site survey will be conducted during this three-month period and if the Patient Service Center is found to be in compliance, 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.

## 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](http://www.wadsworth.org/regulatory/clep) under [Direct Access Testing](#).

## QUESTIONS

Clinical Laboratory Evaluation Program personnel, in consultation with the Wadsworth Center technical section staff, 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 telephone at (518) 485-5378, by email to [clep@health.ny.gov](mailto:clep@health.ny.gov) or in writing to the address below. Information and application materials may also be obtained at [www.wadsworth/regulatory/clep](http://www.wadsworth/regulatory/clep).

Technical or scientific questions should be directed to the appropriate contact personnel listed in Clinical Laboratory Reference System Staff list available at [www.wadsworth.org/regulatory-programs/regulatory-programs/clinical-laboratory-evaluation-program/contact-clep](http://www.wadsworth.org/regulatory-programs/regulatory-programs/clinical-laboratory-evaluation-program/contact-clep). The input of permit-holding laboratories is critical to maintaining the quality of our program. Your comments and suggestions are welcome and staff is available to answer your questions and resolve problems. The address for written correspondence is:

New York State Department of Health  
Clinical Laboratory Evaluation Program Wadsworth Center  
Empire State Plaza  
PO Box 509  
Albany, New York 12201-0509

## 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](mailto:LIU@health.ny.gov).

## 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 and distributed annually to all laboratories as part of the permit reapplication package.

**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 program. 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 program. The program grades the results using the CLIA grading criteria and sends the laboratory scores reflecting how accurately it performed the testing. CMS and accreditation organizations routinely monitor their laboratories' performance.

**Registration:** Registration for either a cytotechnologist or a limited service laboratory. Registration of cytotechnologists is required as authorized by Subpart 58-1 of 10NYCRR. Registration for a limited service laboratory is issued by the Clinical Laboratory Evaluation Program, as authorized by Public Health Law Article 5, Title V Section 579.

**Remediation:** The process by which a participating laboratory investigates unsatisfactory or unsuccessful performance in a proficiency test event, implements acceptable corrective action and provides documentation of such actions to the Department as required.

**Sole Director:** A sole Certificate of Qualification holder for a particular permit category. An individual cannot be director, or sole 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.

**Subsequent unsuccessful:** Unsatisfactory performance for the same category or test/analyte in three consecutive or three in four or five **proficiency testing performance** consecutive testing events.

**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.

**Testing personnel:** All technical personnel responsible for specimen collection and processing, test performance and/or reporting of test results, including, but not limited to, clinical laboratory supervisors, clinical laboratory technologists, cytotechnologists, histological technicians, respiratory therapy technologists and technicians and clinical laboratory technicians, or persons performing such duties.

**Unsatisfactory proficiency testing performance:** Failure to attain the minimum satisfactory score for a category or test/analyte in a testing event.

**Unsuccessful proficiency testing performance:** Unsatisfactory performance for the same category or test/analyte in two consecutive or two out of three testing events.

## 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](http://www.wadsworth.org/regulatory/clep) under Laws and Regulations.

### Andrology

This category is required 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- Cellular Hematology. Testing for presence of sperm in urine may be performed under the categories of either Andrology or the analyte of Urinalysis in Clinical Chemistry. 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 detection techniques.

### Blood pH and Gases

This category is for laboratories performing measurements of blood pH, pCO<sub>2</sub> and/or pO<sub>2</sub>. 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, hemoglobin, etc.

### 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:

- Immunohematology (red blood cell, granulocyte, and/or platelet-related testing for blood collection, transfusion, or pregnancy-associated purposes),
- Diagnostic Immunology – Donor Services Serology (serologic tests for specific markers of infectious disease),
- Hematology (for donor and/or unit qualification),
- Virology (nucleic acid testing for viruses), and

- Bacteriology (bacteria detection).

**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:**

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. 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 and Tissue Resources Program at [btraxess@health.ny.gov](mailto:btraxess@health.ny.gov) or (518) 485-5341.

**TRANSFUSION - STORAGE ONLY:**

This category is for permitted laboratories 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.

**PLASMA PROCESSING:**

This category is for facilities that fractionate plasma into infusable derivatives and/or perform viral reduction/inactivation of pooled plasma.

## 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 lymphocyte function by in vitro assays (e.g., antigen-induced proliferation, alloantigen-stimulated proliferation, mitogen-stimulated proliferation, cytolytic assays, and cytokine or immunoglobulin production). This category also includes testing monocytic and myeloid functions by in vitro assays (e.g., neutrophil generation of reactive oxygen species, monocyte phagocytosis, and production of cytokines).

NOTE: The determination of cytokines in serum, plasma or CSF is included in 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 or interferon-gamma expressing lymphocytes). This category also includes Non-Lymphoid Immunophenotyping. Example methodologies include quantification of viable Lin-/CD34+ stem cells, FLAER and CD59 expression for PNH, CD15s, CD11a, b, c & CD18 expression for LAD, and TLR expression(s) for innate immunity. If leukocytes are stimulated in vitro to induce a change in cell phenotype, the analysis also requires the Leukocyte Function category. Laboratories performing white blood cell counts and manual differentials for calculation of absolute numbers of lymphocyte/leukocyte subsets must also hold a Hematology - Cellular Hematology permit.

***MALIGNANT LEUKOCYTE IMMUNOPHENOTYPING:***

This category is for laboratories performing identification and characterization of leukemias or lymphomas in 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 are included in this category. 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 and/or the Genetic Testing - Biochemistry categories.

## Cytogenetics

Cytogenetics is the analysis of the chromosome complement of human cells for changes in chromosome number or structure. The Cytogenetics categories include standard methods, laboratory developed tests, and FDA approved/cleared tests. Methods include metaphase chromosome analysis by G-banding, chromosome microarray (CMA) testing, and metaphase and interphase fluorescence in situ hybridization (FISH).

CMA testing for constitutional disorders may also be performed under the Genetic Testing - Molecular category. CMA testing for acquired aberrations may also be performed under the Oncology - Molecular and Cellular Tumor Markers category. Confirmation of abnormal CMA results by methods other than FISH or standard metaphase chromosome analysis may require Genetic Testing – Molecular or Oncology - Molecular and Cellular Tumor Markers.

***PRENATAL:***

This category is for laboratories performing prenatal and preimplantation cytogenetic diagnosis. This category is limited to testing of ongoing pregnancies; testing of failed or terminated pregnancies falls under the Cytogenetics – Restricted category.

***CANCER:***

This category is for laboratories performing testing of blood dyscrasias or neoplasias for acquired cytogenetic aberrations. This category includes FISH to monitor bone marrow transplant status. Interphase FISH for cancer testing also may be performed under Oncology - Molecular and Cellular Tumor Markers. The metaphase components of validation for laboratory developed FISH tests require the involvement of a permitted Cytogenetics laboratory and/or a qualified Cytogeneticist.

***RESTRICTED:***

This category is for laboratories performing cytogenetic tests exclusive of prenatal diagnosis and cancer cytogenetics. This category includes testing of material derived from failed or terminated pregnancies (e.g. products of conception).

## Cytokines

This category is for laboratories performing the quantification of cytokines and chemokines in biological fluids, by 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. The measurement of cytokines and chemokines in leukocytes, or the measurements of cytokines in supernatants from in vitro leukocyte cultures are assays of the Cellular Immunology - Leukocyte Function category.

## Cytopathology

This category is for laboratories preparing and examining cells and tissue fragments that have exfoliated freely from tissue surfaces or that have been collected by brushing, scraping, washing, lavage or needle

aspiration. 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 as described below:

***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.

Testing of cytology specimens for HPV is performed under the category of Oncology-Human Papillomavirus testing.

## 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 (HBs Ag), hepatitis B core antibody (anti-HBc), hepatitis C antibody (anti-HCV), human T lymphotropic virus (HTLV) 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, 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 chemiluminoassay (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) the recommendations of the federal DNA Advisory Board and subsequent standards as issued by the Director of the Federal Bureau of Investigation (FBI) as the "Quality Assurance Standards for Forensic DNA Testing Laboratories" and the "Quality Assurance Standards for DNA Databasing Laboratories.

The NYS General and Forensic Identity Standards can be accessed via the Program website at <https://www.wadsworth.org/regulatory/clip/clinical-labs/obtain-permit/on-site-survey/laboratory-standards>. The FBI standards can be accessed at the FBI's CODIS website at <http://www.fbi.gov/about-us/lab/biometric-analysis/codis>.

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 ASCLD LAB-approved proficiency testing (PT) program and submit a brief summary of PT activities to the Forensic Identity Section every six months. See Forensic Identity Standard S29.

## Genetic Testing

The Genetic Testing categories are for laboratories performing procedures that provide information for the diagnosis of a genetic disease or its carrier state, risk assessment for drug metabolism, disease susceptibility, hemostasis, 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 markers to test for zygosity for pregnancy management and maternal cell contamination in the context of genetic diagnosis and tests using genetic markers to monitor disease progression.

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

### **CELLULAR HEMATOLOGY:**

This category is for laboratories performing one or more of the following cellular hematology tests: white cell count, red cell count, hemoglobin, hematocrit, automated differentials, and platelet count, with or without other tests such as red cell indices, reticulocyte count, and erythrocyte sedimentation rate. Laboratories performing manual differentials or manual confirmation of abnormal automated differentials must hold the Cytohematology Diagnostic category described below. Qualitative testing for the presence or absence of viable sperm in semen may be performed under the categories of either Andrology or Hematology – Cellular Hematology.

### **COAGULATION:**

This category is for laboratories performing routine coagulation testing including prothrombin time, activated partial thromboplastin time and quantitative fibrinogen, with or without other tests such as thrombin time, factor assays and bleeding time.

### **CYTOHEMATOLOGY DIAGNOSTIC:**

This category is for laboratories performing manual differentials, smear examinations, or automated differentials with manual confirmation performed on-site. 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 the Parasitology category.

## Histocompatibility

### **HISTOCOMPATIBILITY GENERAL:**

This category is for laboratories performing all phases of histocompatibility testing for organ/tissue transplantation. Testing includes HLA antigen typing, antibody screening, and when necessary, crossmatching. Laboratories performing engraftment monitoring, 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.

### **HISTOCOMPATIBILITY HLA TYPING ONLY:**

This category is for laboratories offering only HLA antigen typing. This category would apply to those laboratories performing histocompatibility testing for initial pre-transplant typing, bone marrow donor screenings, disease associations or pharmacogenetics.

## 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 Oncology – Human Papillomavirus Testing.

### **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, 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 techniques, and drug susceptibility testing.

## Oncology

The Oncology categories include tests used in tumor screening, diagnosis, prognosis and management, including the standard serum-based tumor markers, tests for tumor cell specific acquired genotypic and/or phenotypic alterations, and screening/detection of carcinogenic viruses. Due to the different methodologies used, there are three categories:

### ***SOLUBLE TUMOR MARKERS:***

This category is for laboratories performing 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 chemiluminoassay (CIA), as well as mass spectrometry (MS).

### ***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 - Cancer. However, method validation, result reporting, patient testing and any other procedure or operation must comply with all cytogenetics requirements.

### ***HUMAN PAPILLOMAVIRUS (HPV) TESTING:***

This category is for laboratories that perform HPV testing on cells, such as cells collected in liquid media from cervical swabs, as well as various other body locations.

## 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

The Parentage/Identity testing category is for laboratories that perform procedures for determination of parentage or relationships. 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 is for laboratories providing quantitative analysis of drugs (therapeutic or abused) in serum and/or blood. Drugs represented include, but are not limited to, digoxin, procainamide, quinidine, phenobarbital, phenytoin, gentamicin, theophylline, acetaminophen, salicylate, lithium and ethanol, including breath alcohol for non-forensic purposes.

## Toxicology

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

### 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.

#### ***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.

### Clinical Toxicology :

The Clinical Toxicology categories are for laboratories performing tests for the detection of drugs/metabolites, including ethanol.

#### ***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 and confirm with suitable quantitative tests, when available

## Toxicology – Blood Lead

### **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.

### **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 ( $\geq 5$  ug/dL) ( $\geq 40$  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.

## 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, molecular tests for organ rejection or the FDA-cleared Cylex™ ImmunKnow® assay for monitoring immune function following transplant.

## 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 that perform 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 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.