



Department
of Health

Wadsworth
Center

Clinical Laboratory Evaluation Program



A Guide to Program Requirements and Services

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

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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 proficiency testing and accreditation requirements, as documented by a valid New York State permit, which includes a CLIA number. Laboratories in other states may enroll in New York State's CLIA-approved proficiency testing program to meet CLIA proficiency test requirements. However, eligibility for CLIA certification remains the responsibility of each state's regional CMS office. 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.

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, proficiency testing, 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 <http://www.wadsworth.org/labcert/lep/lep.html> 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/clep. 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.

Clinical laboratory permits are valid for one year, commencing on July 1 of each year (initial permits can be issued at anytime 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 and permit reapplications and the Electronic Proficiency Testing Reporting System (EPTRS) for reporting of proficiency testing results and viewing the status of validation packages. Other Wadsworth Center applications located on the HCS include: the Electronic Clinical Laboratory Report System (ECLRS); and the Clinical Laboratory Information Management System (CLIMS).

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](#), available on our website www.wadsworth.org/clep under Applications and Forms. 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. 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.

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.

Definitions with respect to the HCS:

Director - This is the individual who can bind the organization with the Department. 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.

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.

Proficiency Testing

Once all administrative requirements for the completion of the clinical laboratory permit application have been met and Certificates of Qualification have been issued to the director and any assistant directors (see the section on [Laboratory Director Requirements](#)) the laboratory will be placed in "Applied Pending" status and will receive regularly scheduled New York State proficiency test samples for all testing specialty categories (hereinafter; permit categories) and tests/analytes for which proficiency testing is available. Proficiency test requirements are met for the permit categories of Toxicology - Blood Lead Screening Tests Only and Toxicology – Blood Lead Comprehensive upon satisfactory performance in all components of two proficiency test events. Proficiency test requirements are met for all other permit categories upon satisfactory performance in all components of the initial 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. The annual proficiency testing schedule is posted at www.wadsworth.org/labcert/clep/PT/PTschedule.htm. Out-of-sequence proficiency test events may be offered if samples are available and the regularly scheduled proficiency test event is more than four weeks away.

All laboratories applying for or holding a New York state clinical laboratory permit must participate in the state proficiency testing program for each category, subcategory and analyte for which proficiency testing is offered. Participation in the New York state proficiency testing program fulfills federal proficiency testing requirements

for laboratories located in New York State and proficiency testing results for these laboratories will be released to the federal Centers for Medicaid and Medicare Services (CMS). Laboratories located outside New York state must authorize the release of New York state proficiency test results to fulfill federal proficiency test requirements. Those laboratories must disclose to the Department the federally approved proficiency test provider that is being utilized to fulfill federal proficiency testing requirements.

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 and areas of laboratory medicine for which New York state proficiency testing is not available, the laboratory is required to have an alternate system for verifying the reliability and accuracy of their test results at least twice a year through participation in other external proficiency testing programs or through the implementation of an internal proficiency testing program. Detailed information on the available New York state proficiency tests can be found in the section of this guide titled [Category Descriptions and Proficiency Testing Requirements](#).

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 Comprehensive Test Approval Policy and Submission Guidelines available at www.wadsworth.org/clep under 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 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/clep under On-Site Survey 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. A Quality Management Systems (QMS) approach is used to conduct surveys, including a sampling of patient reports known as a Document Control review. This approach ensures laboratories are measured consistently and objectively by requiring the same documentation across testing methods. The Document Control review is designed to recreate the entire path of testing for specific patient results. An Example Document Control form used by surveyors is available at www.wadsworth.org/clep under On-Site Survey Standards / Survey and Standards Educational Materials.

The *entrance conference* allows the surveyor to explain the survey and Document Control processes 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 QMS 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 laboratory's table of organization will be reviewed and the laboratory must provide orientation to lines of authority. The surveyor and laboratory staff will agree on the tests to be used for the Document Control survey tool.

For the *laboratory orientation* the surveyor will tour the facility while the laboratory assembles the Document Control 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 Document Control 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: evaluation of proficiency test performance, whether from New York State, an external program or developed in-house.
- 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 Department has prepared specific guidance to laboratories on implementing a QMS, available at www.wadsworth.org/clep under Program Guide. The Specialty Standards of Practice will be surveyed for compliance using Document Control packages. This may be done only for selected specialties, based on the samples selected. Audit documentation will also be reviewed.

Employees involved in the processing of samples selected for the Document Control 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/clep under Statute and Regulations. During the survey the laboratory will be expected to complete forms to document reporting for the following programs: Communicable Disease, Blood Lead, Cancer Registry, and Heavy Metals. 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/clep under On-site Survey Standards / Survey and Standards Educational Materials. 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/clep under Applications and Forms. 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/clep. To add or delete a test/analyte, the processes outlined in the [Comprehensive Test Approval Policy and Submission Guidelines](#), available at www.wadsworth.org/clep under Test Approval, must be followed depending on the nature of the test.

To add a new permit category, payment of applicable fees and, if applicable, an on-site survey, successful completion of proficiency testing requirements and test approval through method validation review must occur before testing can begin and an amended permit will be issued. In addition, a director must be identified who holds, or qualifies for, a Certificate of Qualification in the appropriate permit category. The laboratory will not be eligible to receive proficiency test samples and 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. The notification to add testing must be received two weeks prior to the shipment of the proficiency test event to ensure samples are available to send to the laboratory.

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/clep under Test Approval.

On February 27, 2012, the Department adopted a policy governing the performance of tests that are under review by the Department. Laboratories that submit method validation for a test that is categorized under a permit category for which the laboratory is approved will be conditionally approved to begin testing pending the outcome of the validation review. This conditional approval may be revoked if the laboratory fails to respond in the appropriate timeframe to requests for additional information. Laboratories that submit validation for a test

that is categorized under a permit category for which the laboratory is not approved cannot begin testing until all requirements for the addition of the category have been fulfilled. This may include the following: successful participation in proficiency testing, if applicable; participation in an on-site survey and successful remediation of any deficiencies identified; and completion of the method review process to include a letter of approval to perform the test from the Department. Laboratories that do not currently hold a New York State clinical laboratory permit may not begin testing until they have completed all permit requirements.

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/clep under Applications and Forms.

Deleting a Category: Requests to delete a category should be made through eCLEP. If a category or test is subject to proficiency testing, the laboratory must inform the Department no later than two weeks prior to the shipment of the next proficiency test event in the area of testing being deleted, either by submitting the appropriate forms or by written notification. Failure to do so may result in a failing grade for non-participation in the proficiency test event.

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.

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 March. 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 May. Partial payments may be made on or before June 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 of 10 NYCRR, available at our website at www.wadsworth.org/clep under Statute and 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 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/clep under Applications and Forms. 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 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) or the Association of International Credential Evaluators, Inc. (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 directors or other individuals 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 you have 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/clep under Applications and Forms. 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 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 their experience in the form of one or more letters from a current or previous laboratory directors or other individuals with whom the post-degree training and/or experience was acquired in the each Certificate of Qualification category. 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 you have 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 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. 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/clep under On-site Survey Standards / Survey and Standards Educational 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. Respiratory therapists may act as supervisors for blood gas and related testing after they have completed two

years of experience. 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) or the Association of International Credential Evaluators, Inc. (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

Formal acknowledgment of the Department's exempt status under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) was published in the August 28, 1995 edition of the Federal Register. Participation in the Department's accreditation and proficiency testing programs fulfills all state and federal requirements for permit-holding laboratories and blood banks located in the state. Permit-holding clinical laboratories and blood banks located outside the state may use the Department's proficiency testing program for CLIA regulatory purposes. However, holding a New York State clinical laboratory permit will not, in itself, exempt an out-of-state laboratory from federal certification or accreditation requirements.

Proficiency test events in each permit category are designed and administered by a scientific staff member of the Wadsworth Center who holds a New York State Certificate of Qualification in the corresponding permit category. The test samples are verified through stringent in-house quality control testing and, when appropriate, analysis by referee laboratories. Detailed information concerning the preparation and grading of each test event is included in the section of this guide titled Category Descriptions and Proficiency Testing Requirements. Distinction is made in the individual category descriptions between those tests and procedures that are proficiency tested by New York State regulations and those that are tested under federal requirements.

A list of common tests/analytes and procedures, cross-referenced with the Department's testing categories, can be found on www.wadsworth.org/clep under Category and Test/Analyte Index. Please note that not all analytes and procedures currently tested or employed by clinical laboratories are proficiency tested by New York State. In those areas of laboratory medicine for which New York State proficiency testing is not available, laboratories are expected to implement alternate monitoring systems for verifying the reliability and accuracy of their test results at least twice a year. This can be accomplished through participation in other external proficiency testing programs or through the implementation of an internal proficiency-testing program. In addition to alternative monitoring, the laboratory may be required to submit procedure manuals or validation data for review and approval by the Department. Please refer to the [Comprehensive Test Approval and Submission Guidelines](#) available at www.wadsworth.org/clep under Test Approval.

Documenting the Proficiency Testing Process

Participating 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 Electronic Proficiency Test Reporting System (EPTRS) Summary Page which includes the attestation statement printed and signed by the laboratory director or responsible assistant director, the delegated submitter and the analyst.
4. For proficiency test events that are not reportable through EPTRS, the test attestation statements signed by the director or the authorized assistant director (certificate of qualification holder for the permit category) and the analyst(s) performing the testing.

Proficiency Testing Frequency

Proficiency testing samples for each permit category and test required by federal and state regulations are sent to participating laboratories three times per year, except Mycobacteriology which is sent to participating laboratories twice per year. Proficiency tests for each permit category that are not federally required but are

required by state regulations are sent to participating laboratories twice per year, except for the categories of Fetal Defect Markers and Trace Elements which occur three times per year. The glass-slide component of the Cytohematology event is scheduled annually. Most test events consist of five samples, for a total of fifteen samples per year in each category or test, unless noted otherwise in the section of this guide titled Category Descriptions and Proficiency Testing Requirements. Laboratories performing gynecologic Cytopathology testing must document enrollment in a federally-approved proficiency testing program. Laboratories performing Forensic Identity Testing 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.

Requirements for Participation

All laboratories applying for or holding a clinical laboratory permit must participate in the New York State proficiency testing program 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.

1. The laboratory shall participate in the New York State proficiency testing program for each permit category and tests for which the laboratory seeks or currently holds a permit, and for which graded as well as educational proficiency testing is offered.
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 Department. 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 Department.
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.

Ungradeable Proficiency Testing Samples

Occasionally a sample is found to be "ungradeable" due to the lack of consensus among participating, reference or referee laboratories. In such instances, laboratories will not be penalized. Information concerning "ungradeable" samples will be provided as part of the critique and/or report distributed to all participating laboratories at the conclusion of each testing event.

Proficiency Testing Program Administrative Policies

The following are the Department's policies concerning the reporting and grading of proficiency testing results submitted by laboratories applying for or holding a New York State clinical laboratory permit. Please note that the Department has implemented a web-based Electronic Proficiency Testing Reporting System (EPTRS) and electronic submission is mandatory for all challenges currently available on-line. Information on enrollment can be obtained at www.wadsworth.org/labcert/clep/PT/epters.htm.

*Non-Participation - Failure to submit test results will result in a score of zero. Laboratories are responsible for using the Department's proficiency testing schedule to track shipment dates for test events in which they participate. However, the proficiency testing technical section may excuse participation in a test event if the laboratory has:

1. Performed successfully in the two previous test events;
2. Patient testing has been suspended over the timeframe for the test event; and
3. The Department has been notified of the temporary suspension of testing prior to the closure of the proficiency test event.

'Saved, Not Submitted Results' – Laboratories that enter and save results via EPTRS but do not click the 'Submit/Attest' Button will receive a score of zero.

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.

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 [Comprehensive Test Approval Policy and Submission Guidelines](#), available at www.wadsworth.org/clep under Test Approval, for the appropriate course of action based on nature of the test.

Notification of Non-Receipt or Damaged Samples - Laboratories must notify the contact person in the appropriate technical section as indicated in the [Clinical Laboratory Reference System Staff list](#), available at www.wadsworth.org/clep under Proficiency Testing, if the test samples are not received within five days of the shipment date, or if the samples are received in unsatisfactory condition. Replacement samples may be provided if the technical section is notified within this time frame. Please note: replacement samples are not available for the category of Toxicology - Blood Lead Screening Only. Please refer to the Mycobacteriology and Toxicology - Blood Lead Screening Tests Only proficiency testing technical section descriptions for their specific requirements regarding notification of non-receipt or damaged samples.

Replacement Samples - The laboratory may request replacement samples under circumstances where, in routine laboratory practice, the recourse in clinical testing is to collect additional specimens (e.g., laboratory accident or instrument failure). Replacement samples are available as specified in the section of this guide titled Category Descriptions and Proficiency Testing Requirements.

Signatures - Reports of proficiency test findings must be signed to attest that the proficiency samples were handled in the same manner as patient specimens.

For those laboratories submitting electronically, the EPTRS Summary Page, which includes the attestation statement, must be printed and signed by the laboratory director or responsible assistant director, the delegated submitter and the analyst **prior to submission** of the proficiency test results. The signed document must be kept on file in the laboratory for review by a Department surveyor during the next on-site survey.

Laboratories must continue to mail result forms for any category for which electronic proficiency testing is not yet available. If the laboratory director or responsible assistant director is unavailable to review the test results and sign the results prior to the submission deadline, the laboratory should retain a copy of the results report form and transmit the unsigned original, with a note of explanation, to the proficiency test technical section. The copy of the document should be signed by the director or responsible assistant director and forwarded to the proficiency test technical section within two working days of their return.

A responsible assistant director is an individual holding a New York State certificate of qualification who the laboratory director has designated in writing to the Department as responsible for any of the director's duties, as specified in Part 19 of 10NYCRR, for any or all permit categories. In order to sign off on proficiency testing, the assistant director must hold a Certificate of Qualification in that category and be designated as responsible for the category.

Grading Method - The grading method and passing score used for each category and/or test for which proficiency testing is offered is described in the Category Descriptions and Proficiency Testing Requirements section of this Guide.

Sample Validation - Proficiency testing samples not validated by eighty (80) percent of participating and/or referee laboratories will not be graded, and participating laboratories will be notified of such action at the conclusion of each test event.

Review - Any request for reconsideration of grading must be submitted to the Department in writing, with supporting documentation, within thirty days of the submission of the graded proficiency test results. An event can be re-graded only if it is determined that an error was made on the part of the Department, e.g., data entry error. Results are graded based on the information submitted. Changes will not be accepted after the postmark deadline.

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 to use as part of the remediation. Remedial samples for investigation will be provided if available and the regularly scheduled proficiency test event is more than four weeks away. The investigation and any subsequent remediation conducted by the laboratory may be reviewed during on-site survey or the proficiency testing technical section may request that documentation be submitted for review.

New laboratories or laboratories that are pending for a permit category, are required to investigate the problem(s) that contributed to the unsatisfactory performance and implement corrective action. The documentation of the investigation and the laboratory's plan of correction must be submitted electronically clepeptrs@health.ny.gov within 2 weeks of receipt of evaluation report indicating the unsatisfactory performance. Failure to submit an acceptable plan of correction or failure to implement the plan of correction can result in administrative action and 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 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 proficiency testing technical section, the laboratory must demonstrate satisfactory performance in two consecutive proficiency test events.

The decision as to whether a laboratory should 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**)

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 Public Health Law, Article 5, Title V.

If the response to each of questions 1 - 5 above is **no**, and if the director of the proficiency testing section 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 proficiency section 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, only one of which can be an off-schedule 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, one of which may be conducted on-site. 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, 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 judged 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 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. Laboratory directors 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/labcert/limited.

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/polep or by contacting POLEP at 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 and a list of waived tests by specific kit and manufacturer is available at FDA Waived Tests.

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 or (518) 485-5341. Information is also available at their website www.wadsworth.org/labcert/blood_tissue.

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. 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. Application forms are available at www.wadsworth.org/clep under Applications and Forms. 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 in writing. 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 available at www.wadsworth.org/clep under Applications and Forms.

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 to a current approved patient service center must be notified to the Department. A location change requires the submission of a new Patient Service Center application. Changes in owner, parent laboratory or a closure can be documented on the Patient Service Center change form. Forms are available at www.wadsworth.org/clep under Applications and Forms.

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/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 or in writing to the address below. Information and application materials may also be obtained at www.wadsworth.org/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/clep under Proficiency Testing. 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.

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.

Challenge: For quantitative tests, an assessment of the amount of substance or analyte present or measured in a proficiency-testing sample. For qualitative tests, a challenge refers to the determination of the presence or the absence of an analyte, organism, or substance in a proficiency-testing sample.

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: A component of the laboratory reference system operated by the Wadsworth Center, and administered by the Clinical Laboratory Reference System. As part of this program, clinical laboratories analyze test samples or evaluate test materials prepared by the Department's technical section staff and report the results, which are graded in accord with established criteria.

Referee laboratory: A term referring to a laboratory currently in compliance with New York State requirements that has a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific category or analyte and has been designated by the proficiency testing section as a referee laboratory. Referee laboratories analyze proficiency testing samples for the purpose of determining the correct response in a testing event for specific category or analyte.

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.

Sample: A material contained in a vial, test tube, on a slide, or other storage container that contains material to be tested by the proficiency testing program participants.

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, medical technologists, cytotechnologists, histotechnologists, histotechnicians, respiratory therapy technologists and technicians and medical 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 and Proficiency Testing Requirements

Please refer below to obtain descriptions about the various permit categories and proficiency testing materials available from the Department. 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/clep under Statute and Regulations.

Andrology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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 Urinalysis. 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.

PROFICIENCY TESTING OFFERED

No proficiency testing is offered at this time.

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

Bacteriology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

COMPREHENSIVE:

This category is for laboratories that examine any type of clinical specimen for aerobic and/or anaerobic bacteria. These laboratories identify organisms to the genus and/or species level and may also perform antimicrobial susceptibility testing, molecular assays and direct detection techniques. Laboratories holding this category may also perform testing as described under the Restricted category listed below.

RESTRICTED:

This category is for laboratories that restrict their testing to one or more of the following:

- Gram stains: for laboratories that prepare and examine gram-stained smears for the presence of bacterial organisms.
- Gonorrhea and Chlamydia: for laboratories testing specimens for *Neisseria gonorrhoeae* and/or *Chlamydia trachomatis*. This includes testing by culture, direct detection (including molecular methods).
- Throat culture: for laboratories that perform throat cultures for Group A *Streptococcus* only.
- Urine culture: for laboratories that isolate and identify bacteria from urine by culture. Identification may range from gram stain reactions to full genus and species identification, as well as antimicrobial susceptibility testing.
- Antigen detection: for laboratories that use antigen detection techniques to examine specimens for one or more bacterial antigens.
- Molecular methods: for laboratories that perform molecular assays for identification of bacterial species except *Neisseria gonorrhoeae* and/or *Chlamydia trachomatis*.

PROFICIENCY TESTING OFFERED

(CMS regulated analytes or tests are indicated with an asterisk)

Comprehensive

- Culture and Identification* Susceptibility testing*
- Direct Detection of Group A *Streptococcus* and/or *Chlamydia**

Restricted

- **Gram Stains**
- **Gonorrhea and Chlamydia**
 - Direct Detection of *N. gonorrhoeae* and *C. trachomatis**
 - *N. gonorrhoeae* culture*
- **Throat Culture**
 - Culture and Identification*
- **Urine Culture**
 - Culture and Identification*
 - Susceptibility testing*
- **Antigen Detection**
 - Antigen detection of Group A *Streptococcus**
- **Molecular Methods**
 - No proficiency testing is offered

Proficiency test samples may include, but are not limited to, the following list of organisms:

<i>Acinetobacter</i>	<i>Eikenella</i>	<i>Oligella</i>
<i>Actinobacillus</i>	<i>Enterobacter</i>	<i>Pasteurella</i> (excluding <i>Pasteurella multocida</i> type B)
<i>Actinomyces</i>	<i>Enterococcus</i>	<i>Pediococcus</i>
<i>Aerococcus</i>	<i>Erysipelothrix</i>	<i>Peptococcus</i>
<i>Aeromonas</i>	<i>Escherichia</i>	<i>Peptostreptococcus</i>
<i>Agrobacterium</i>	<i>Eubacterium</i>	<i>Plesiomonas</i>
<i>Alcaligenes</i>	<i>Flavobacterium</i>	<i>Prevotella</i>
<i>Alteromonas</i>	<i>Fusobacterium</i>	<i>Propionibacterium</i>
<i>Arcanobacterium</i>	<i>Haemophilus</i>	<i>Proteus</i>
<i>Bacillus</i> (excluding <i>Bacillus anthracis</i>)	<i>Hafnia</i>	<i>Providencia</i>
<i>Bacteroides</i>	<i>Kingella</i>	<i>Pseudomonas</i>
<i>Bifidobacterium</i>	<i>Klebsiella</i>	<i>Salmonella</i>
<i>Bordetella</i>	<i>Kluyvera</i>	<i>Serratia</i>
<i>Burkholderia</i> (excluding <i>B. mallei</i>)	<i>Lactobacillus</i>	<i>Shigella</i>
<i>Campylobacter</i>	<i>Legionella</i>	<i>Staphylococcus aureus</i>
<i>Capnocytophaga</i>	<i>Listeria</i>	<i>Stenotrophomonas</i>
<i>Cardiobacterium</i>	<i>Micrococcus</i>	<i>Stomatococcus</i>
<i>Cedecea</i>	<i>Moraxella</i>	<i>Streptococcus</i>
<i>Citrobacter</i>	<i>Morganella</i>	<i>Veillonella</i>
<i>Clostridium</i>	<i>Neisseria</i>	<i>Vibrio</i>
<i>Comamonas</i>	<i>Nocardia</i>	<i>Yersinia</i> (excluding <i>Yersinia pestis</i>)
<i>Corynebacterium</i>	<i>Ochrobacterium</i>	Other genera of clinically significant bacteria
<i>Edwardsiella</i>	<i>Oerskovia</i>	

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Comprehensive

Proficiency test kits consist of at least five specimens for identification. Laboratories will be instructed to perform susceptibility testing on one of the specimens used for identification. One sample for Group A Streptococcus antigen detection, and/or one sample for Chlamydia direct detection are also included if the laboratory offers this testing. This PT kit is mailed three times per year.

Restricted

- Gram Stain - the proficiency test event consists of five slides and is mailed three times per year.
- Gonorrhea and Chlamydia - the proficiency test event consists of five samples for Gonorrhea and Chlamydia direct detection or molecular identification and five samples for Gonorrhea culture and is mailed three times per year.
- Throat Culture - the proficiency test event consists of five swabs and is mailed three times per year.
- Urine Culture - the proficiency test event consists of five lyophilized samples and is mailed three times per year. Laboratories will be instructed to perform susceptibility testing on one of the specimens used for identification.
- Antigen Detection - the proficiency test event consists of five samples for detection of Group A Streptococcus antigen and is mailed three times per year.

SOURCE OF SAMPLES

The proficiency test samples are commercially prepared.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUATION

Acceptable responses must be authenticated by 80% or more of the referee or participating laboratories. Referee laboratory performance is re-evaluated after each proficiency testing year and a new list of referee laboratories is prepared.

GRADING

Scored results are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

Grades are determined as follows:

$$\text{Sample Score} = \frac{(a + b)}{(c + d + e)} \times 100$$

- a= number of correct responses
- b= number of correct antibiotic susceptibility results (if applicable)
- c= number of possible responses
- d= number of possible antibiotic susceptibility results (if applicable)
- e= number of additional incorrect responses reported

Grades for each sample are averaged to determine the final grade for each testing event. Failure to attain an overall testing event score of at least 80% is unsatisfactory performance. The Department reserves the right to order the cessation of testing for a particular method or sample type (e.g., Gram Stains or stool culture) when continued substandard proficiency test performance is demonstrated for that method or sample type.

Qualitative Antigen Tests

Presence or Absence of the bacterial antigen

$$\text{Event Score} = \frac{\text{Number of acceptable responses}}{\text{Total number of samples tested}} \times 100$$

Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to five business days from the shipment date. Replacement is dependent on circumstances.

Blood pH and Gases

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

This category is for laboratories performing measurements of blood pH, pCO₂ and/or pO₂. 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.

PROFICIENCY TESTING OFFERED

(CMS regulated analytes or tests are indicated with an asterisk)

pH*	Chloride
pCO ₂ *	Glucose
pO ₂ *	Ionized Calcium
	Lactate
	Potassium
	Sodium

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard o Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Proficiency test kits consist of five samples and are mailed three times each year.

SOURCE OF SAMPLES

The proficiency test samples are commercially prepared. Aqueous based samples are used.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUATION

Target values for all quantitative tests are calculated by the mean of all participant responses after removal of outliers (those responses > ± 3 S.D. from the original mean). Comparative method or "peer group" targets are used when it is shown that specific methods demonstrate a bias with proficiency samples not observed with patient specimens.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte	Acceptable performance
pH	Target value ± 0.04
Blood gas pCO ₂	Target value ± 5mm Hg or ± 8% (whichever is greater)
Blood gas pO ₂	Target value ± 3 S.D.
Chloride	Educational (will be graded beginning 2016)
Glucose	Educational (will be graded beginning 2016)
Ionized Calcium	Educational (will be graded beginning 2016)

Lactate	Educational (will be graded beginning 2016)
Potassium	Educational (will be graded beginning 2016)
Sodium	Educational (will be graded beginning 2016)

GRADING

Scored results are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/epters.htm.

Grades are determined as follows:

$$\begin{aligned} \text{Analyte Score} &= \frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 \\ \text{Event Score} &= \frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of challenges for all analytes}} \times 100 \end{aligned}$$

Failure to attain an overall testing score of at least 80% is unsatisfactory performance.

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to the published submission deadline.

Blood Services

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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 – Restricted (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 (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.

PROFICIENCY TESTING OFFERED

Proficiency testing requirements are met by successful participation in the categories of Immunohematology, Diagnostic Immunology – Donor Services Serology, Clinical Chemistry, Bacteriology – Restricted, and Hematology.

Cellular Immunology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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. 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.

PROFICIENCY TESTING OFFERED

No proficiency testing is offered at this time.

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

Clinical Chemistry

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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.

PROFICIENCY TESTING OFFERED (CMS regulated analytes or tests are indicated with an asterisk)

Alanine aminotransferase *	Cholesterol, LDL	Magnesium*
Albumin *	Creatine kinase *	Phosphorus
Alkaline phosphatase *	Creatine kinase-MB *	Potassium *
Amylase *	Creatinine *	Sodium *
Aspartate aminotransferase *	Gamma glutamyltransferase	Total protein *
Bilirubin, total *	Glucose *	Triglycerides *
Calcium, total *	Homocysteine	Troponin I
Chloride *	Iron *	Troponin T
Cholesterol, Total *	Lactate dehydrogenase*	Urea nitrogen *
Cholesterol, HDL *	Lactate dehydrogenase isoenzyme 1 *	Uric acid *

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Proficiency test kits consist of five samples and are mailed three times per year.

SOURCE OF SAMPLES

The proficiency test samples are prepared by Wadsworth Center staff. The base matrix consists of normal processed human serum supplemented with the test analytes.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUATION

Target values utilized are derived from all-participant mean values calculated by robust statistical technique. In some cases, however, it is recognized that method, reagent and/or instrument specific targets may be required. All data are reviewed prior to the establishment of acceptable limits and "peer group" specific targets are used where appropriate.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Test/Analyte	Acceptable performance
Alanine aminotransferase	Target value \pm 20%
Albumin	Target value \pm 10%
Alkaline phosphatase	Target value \pm 30%
Amylase	Target value \pm 30%
Aspartate aminotransferase	Target value \pm 20%
Bilirubin, total	Target value \pm 0.4 mg/dL or \pm 20% *
Calcium, total	Target value \pm 1.0 mg/dL
Chloride	Target value \pm 5%
Cholesterol, total	Target value \pm 10%
Cholesterol, HDL	Target value \pm 30%
Cholesterol, LDL	Target value \pm 25%
Creatine kinase	Target value \pm 30%
Creatine kinase-MB	Target value \pm 3 S.D.
Creatinine	Target value \pm 0.3 mg/dL or \pm 15% *
Gamma glutamyltransferase	Target value \pm 30%
Glucose	Target value \pm 6 mg/dL or \pm 10% *
Homocysteine	Target value \pm 20% or \pm 2 μ mol/L
Iron	Target value \pm 20%
Lactate dehydrogenase	Target value \pm 20%
Lactate dehydrogenase isoenzyme 1	Target value \pm 30%
Magnesium	Target value \pm 25%
Phosphorus	Target value \pm 0.45 mg/dL or 13% *
Potassium	Target value \pm 0.5 mmol/L
Sodium	Target value \pm 4 mmol/L
Total protein	Target value \pm 10%
Triglycerides	Target value \pm 25%
Troponin I	Educational (will be graded beginning 2016)
Troponin T	Educational (will be graded beginning 2016)
Urea nitrogen	Target value \pm 2 mg/dL or \pm 9% *
Uric acid	Target value \pm 17%

whichever is greater*

GRADING

Scored results are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

Grades are determined as follows:

$$\text{Analyte Score} = \frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100$$

$$\text{Event Score} = \frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of challenges for all analytes}} \times 100$$

Failure to attain an overall analyte score of 80% is unsatisfactory performance.

Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to the published submission deadline.

Cytogenetics

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

Cytogenetics is the analysis of the chromosome complement of human cells for changes in chromosome number or structure. Methods use include metaphase chromosome analysis by standard methods (e.g., G-banding), metaphase and interphase fluorescence in situ hybridization (FISH), and chromosome microarray (CMA) testing, including array comparative genomic hybridization (aCGH).

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).

PROFICIENCY TESTING OFFERED

No proficiency testing is offered at this time.

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

Cytokines

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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.

PROFICIENCY TESTING OFFERED

No proficiency testing is offered at this time.

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

Cytopathology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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.

PROFICIENCY TESTING OFFERED

No proficiency testing is offered at this time. Laboratories performing gynecologic cytopathology testing must be enrolled in a federally approved proficiency testing program and submit documentation of enrollment annually as part of the annual permit reapplication. All pathologists at the laboratory must document a passing score on the federally-approved proficiency test before an initial laboratory permit may be issued.

For all tests with no available New York State proficiency test (PT), the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

Diagnostic Immunology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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.

PROFICIENCY TESTING OFFERED

CMS regulated analytes or tests are indicated with an asterisk

Diagnostic Services

Alpha-1-antitrypsin *	Immunoglobulin A (IgA) *
Antinuclear Antibody *	Immunoglobulin E (IgE) *
Antistreptolysin O *	Immunoglobulin G (IgG) *
Complement C3 *	Immunoglobulin M (IgM) *
Complement C4 *	Lyme Disease Borrelia burgdorferi Antibody
Anti-CMV	Lyme Disease Western blot IgG
Anti-HBc *	Lyme Disease Western blot IgM
HBe Ag *	Rheumatoid Factor *
HBs Ag *	Rubella Antibody Total IgG *
Anti-HCV	Rubella IgM
Anti-HIV *	Syphilis RPR*
Anti-HTLV	Syphilis Treponemal Antibody *
Heterophile (Infectious Mononucleosis) *	

Donor Services

Anti-CMV	Anti-HIV *
Anti-HBc *	Anti-HTLV
HBs Ag *	Syphilis RPR*
Anti-HCV	Syphilis Treponemal Antibody *

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Proficiency test kits consist of five samples of each analyte and are mailed three times per year.

SOURCE OF SAMPLES

The proficiency test samples are commercially prepared.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUTION

Acceptable responses must be authenticated by 80% or more of the referee or participating laboratories.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte	Acceptable performance
Alpha-1-antitrypsin	± 3 S.D.
Antinuclear Antibody	Positive or Negative or ± 2 dilutions
Antistreptolysin O	Positive or Negative or ± 2 dilutions
Complement	C3 ± 3 S.D.
Complement	C4 ± 3 S.D.
Anti-CMV	Positive or Negative
Hepatitis	Reactive (Positive) or Nonreactive (Negative)
Anti-HBc	Reactive (Positive) or Nonreactive (Negative)
HBe Ag	Reactive (Positive) or Nonreactive (Negative)
HBs Ag	Reactive (Positive) or Nonreactive (Negative)
Anti-HCV	Reactive (Positive) or Nonreactive (Negative)
Anti-HIV	Reactive or Nonreactive
Anti-HTLV	Reactive (Positive) or Nonreactive (Negative)
Heterophile	Positive or Negative
IgA	± 3 S.D.
IgE	± 3 S.D.
IgM	± 3 S.D.
IgG	± 25%
Lyme Disease Borrelia burgdorferi	Positive or Negative

Lyme Disease Western blot IgG	Positive or Negative
Lyme Disease Western blot IgM	Positive or Negative
Rheumatoid Factor	Positive or Negative or ± 2 dilutions
Rubella IgG Antibody	Total Immune or Nonimmune or Positive or Negative
Rubella IgM Antibody	Total Immune or Nonimmune or Positive or Negative
Syphilis RPR	Reactive or Nonreactive or ± 1 dilution

GRADING

Scored results are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

Grades are determined as follows:

$$\text{Analyte Score} = \frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100$$

$$\text{Event Score} = \frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of challenges for all analytes}} \times 100$$

Diagnostic Services Serology

Failure to attain an overall analyte score of at least 80% is unsatisfactory performance.
 Failure to attain an overall testing score of at least 80% is unsatisfactory performance.

Donor Services Serology

Failure to attain an overall testing score of 100% is unsatisfactory performance.

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to five business days from the shipment date.

Endocrinology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

This category is for laboratories evaluating endocrine function and vitamin status in the body by measuring hormones, vitamins and related analytes in body fluids. Examples of analytes in this category are: insulin, a peptide hormone; testosterone, a steroid hormone; thyroxin (T4) and catecholamines, hormones and neurotransmitters derived from amino acids; and vitamin B12 and folic acid, as vitamins.

PROFICIENCY TESTING OFFERED

(CMS regulated analytes or tests are indicated with an asterisk)

25-OH Vitamin D2	Intact Parathyrin (PTH)
25-OH Vitamin D3	Lutropin (LH)
25-OH Vitamin D, total	Progesterone
Cortisol *	Prolactin
Dehydroepiandrosterone sulfate (DHEA-S)	Testosterone
Estradiol	Thyrotropin (TSH) *
Estriol, Free	Thyroxin (T4) *
Folic Acid	T3, Free
Follitropin (FSH)	T4, Free *
Human Chorionic Gonadotropin (hCG), Intact *	Triiodothyronine (T3), Total *
hCG, Qualitative*	T3 Uptake *
hCG, Total Beta *	T Uptake *
Insulin	Vitamin B-12
DHEA	17 hydroxy progesterone

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Proficiency test kits consist of five samples and are mailed three times each year.

SOURCE OF SAMPLES

The proficiency test samples are prepared by Wadsworth Center staff. The base matrix consists of normal processed human serum supplemented with the test analytes.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUATION

Target values for quantitative tests are calculated from all-participant mean values by a robust statistical technique. Where available, target values are established or verified by reference methods or weighed-in values. Comparative method or "peer group" targets are used when it is shown that specific methods demonstrate a bias with proficiency samples not observed with patient specimens.

For qualitative tests, acceptable responses must be authenticated by 80% or more of the participating laboratories.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte	Acceptable performance
25-OH Vitamin D2	Target value \pm 25%
25-OH Vitamin D3	Target value \pm 25% or 3 ng/mL*
25-OH Vitamin D, total	Target value \pm 25% or 3 ng/mL*
Cortisol	Target value \pm 25%
DHEA-S	Target value \pm 25% or 15 μ g/dL*
Estradiol	Target value \pm 25% or \pm 30 pg/mL *
Estriol, Free	Target value \pm 25% or \pm 3.0 ng/mL *
Folic Acid	Target value \pm 30% or \pm 2.0 ng/mL *
FSH	Target value \pm 25%
hCG, Intact	Target value \pm 3 S.D.
hCG, Qualitative	Positive or Negative
hCG, Total Beta	Target value \pm 3 S.D.
Insulin	Target value \pm 25% or \pm 3.0 μ U/mL *
Intact PTH	Target value \pm 30% or 10.0 pg/mL*
LH	Target value \pm 25% or \pm 1.5 mIU/mL*
Progesterone	Target value \pm 25% or \pm 1.0 ng/mL *
Prolactin	Target value \pm 25% or \pm 1.0 μ g/L *
Testosterone	Target value \pm 25% or \pm 20.0 ng/dL*
TSH	Target value \pm 3 S.D.
T4	Target value \pm 20% or \pm 1 μ g/dL *
T3, Free	Target value \pm 25%
T4, Free	Target value \pm 3 S.D.
T3, Total	Target value \pm 3 S.D.
T3 Uptake	Target value \pm 3 S.D.
Vitamin B12	Target value \pm 25%
DHEA	Educational (will be graded beginning 2016)
17 hydroxy progesterone	Educational (will be graded beginning 2016)
* whichever is greater	

GRADING

Scored results are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9

(PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/lep/PT/eptrs.htm.

Grades are determined as follows:

Analyte Score =	$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}}$	X 100
Event Score =	$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of challenges for all analytes}}$	X 100

Failure to attain an overall analyte score of 80% is unsatisfactory performance.

Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to the published submission deadline.

Fetal Defect Markers

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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 using plasma-derived DNA or RNA amplification and sequencing techniques is performed under the category of Genetic Testing - Molecular.

PROFICIENCY TESTING OFFERED

Maternal Sera (First and Second Trimesters)

- alpha-fetoprotein (AFP)
- unconjugated estriol (uE3)
- dimeric inhibin A (DIA)
- human chorionic gonadotropin (hCG-all forms)
- pregnancy associated plasma protein A (PAPP-A)

Amniotic Fluid

- alpha-fetoprotein (AFP)

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Proficiency test kits consist of up to fifteen samples (five second trimester maternal sera, up to five first trimester maternal sera and five amniotic fluids) and are mailed three times per year.

SOURCE OF SAMPLES

The proficiency test samples are prepared by Wadsworth Center staff. Maternal sera samples are prepared in 6% bovine serum albumin solution in Tris-buffered saline supplemented with the test analytes. Amniotic fluid is prepared from non-diluted normal or pathologic specimens from known dated pregnancies.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/epters.htm.

SAMPLE EVALUATION

Comparative method or "peer group" target values for quantitative tests are calculated by the mean of all participant responses, using the respective method, after the removal of outliers (those responses $> \pm 3$ S.D. from the original mean). Where available, target values are established or verified by reference methods or weighed-in values.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte	Acceptable performance
AFP (Maternal Sera)	± 3 S.D.
uE3 (Maternal Sera)	± 3 S.D.
DIA (Maternal Sera)	± 3 S.D.
hCG (Maternal Sera)	± 3 S.D.
AFP (Amniotic Fluid)	± 3 S.D.
PAPP-A (First Trimester)	± 3 S.D.

GRADING

Proficiency test grades are reported to the laboratory via postal service. The results should be reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9).

Grades are determined as follows: Failure to attain an overall testing score of at least 80% is unsatisfactory performance.

$$\text{Analyte Score} = \frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100$$

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to the published submission deadline.

Forensic Identity

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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 http://www.wadsworth.org/labcert/lep/ls_standards_current.htm. 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.

PROFICIENCY TESTING OFFERED

No proficiency testing is offered at this time. 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.

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

Genetic Testing

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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 performing SNP-based comparative genomic hybridization and using molecular methods to confirm results.

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.

PROFICIENCY TESTING OFFERED

No proficiency testing is offered at this time.

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

Hematology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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.

PROFICIENCY TESTING OFFERED

(CMS regulated analytes or tests are indicated with an asterisk)

Cellular Hematology

Leukocyte Count*
Erythrocyte Count*
Hemoglobin*
Hematocrit*
Platelet Count*

Coagulation

Prothrombin Time*
International Normalized Ratio
Activated Partial Thromboplastin Time*
Fibrinogen*

Cytohematology

Cytohematology / Cell Identification (Photographic Images) *
Cytohematology / Cell Identification (Glass Slide Program)

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Cellular Hematology (Blood Cell Counts)

Proficiency test kits consist of five blood samples and are mailed three times per year.

Coagulation

Proficiency test kits consist of five lyophilized plasma samples for prothrombin time, INR, APTT and fibrinogen and are mailed three times per year.

Cytohematology (Cell Identification)

Proficiency test kits consist of five photographic images that are electronically distributed three times per year and five glass slides that are mailed once a year.

SOURCE OF SAMPLES

The proficiency test samples for blood cell counts and coagulation are commercially prepared. Photographic images and glass slides are prepared by Wadsworth Center staff.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUATION

When possible, targets utilized are derived from all-participant mean values calculated by a robust statistical technique. However, it is recognized that method, reagent and/or instrument specific targets may be required and "peer group" specific targets are used where appropriate. For qualitative descriptive tests, acceptable responses must be authenticated by 80% or more of the participating laboratories.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte	Acceptable performance
Leukocyte Count	Target Value \pm 15%
Erythrocyte Count	Target Value \pm 6%
Hemoglobin	Target Value \pm 7%
Hematocrit	Target Value \pm 6%
Platelet Count	Target Value \pm 25%
Prothrombin Time	Target Value \pm 15%
International Normalized Ratio	Target Value \pm 20%
Activated Partial Thromboplastin Time	Target Value \pm 15%
Fibrinogen	Target Value \pm 20%
Cell Identification (Photographic Images)	Correct Identification
Cell Identification – Cytohematology (Glass Slide Program)	Correct identification of cellular elements and morphology; enumeration within 95% confidence limits

GRADING

Scored results are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

Grades are determined as follows:

$$\text{Analyte Score} = \frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100$$

$$\text{Event Score} = \frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of challenges for all analytes}} \times 100$$

Failure to attain an overall analyte score of at least 80% is unsatisfactory performance.
 Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

Glass slide evaluation

For differential cell counts, results are evaluated using 0.95 and 0.99 confidence limits based on overall participant performance for each cell type or feature. Error points are assigned for any result falling outside these limits, with a larger number of error points assigned for results outside 0.99.

For example the range for basophil:
 7-15 cells/100 = 0.95 range
 4-20 cells/100 = 0.99 range

A result of 10 basophils would have 0 error points; a result of 6 basophils would have 3 error points; a result of 2 basophils would have 6 error points. Default error points are assigned as follows, though are adjusted on the specific nature of cells present and their enumeration:

Error points outside 95%	Error points outside 99%	Cell type
10	20	Blast cell not classified
10	20	Myeloblast/Promyelocyte
10	20	Lymphoblast/Prolymphocyte
10	20	Monoblast/Promonocyte
10	20	Erythroblast
10	20	Lymphoma/Sezary cell
10	20	Hairy cell
3	6	Myelocyte
3	6	Metamyelocyte
3	6	Band neutrophil
2	4	Segmented neutrophil
3	6	Eosinophil
3	6	Basophil
2	4	Lymphocyte
3	6	Atypical lymphocyte
3	6	Monocyte
10	20	Plasma cell
3	6	NRBC / 100 WBC

Other features such as anisocytosis, presence of sickle cells, presence of Howell-Jolly bodies, etc are assigned error points based on false positive/negative results. A false positive identification of sickle cells would result in 10 error points; a false negative identification of sickle cells would result in 25 error points. Default error points are assigned as follows, though are adjusted on the specific nature of the case and participant consensus:

Error points for a false negative result	Error points for a false positive result	Feature or cell
1	1	Anisocytosis
1	1	Poikilocytosis
1	1	Macrocytosis
1	1	Microcytosis
2	1	Hypochromia
2	1	Polychromasia
2	1	Reduced number of platelets
2	1	Increased number of platelets
3	2	Phagocytosis of platelet(s)
2	2	Bizarre or irregular platelets
2	2	Clumped platelets
2	2	Giant platelets
2	2	Platelet satellitosis
4	2	Auer rods
2	2	Dohle bodies
2	2	Hypersegmentation
2	2	Pelger Huet anomaly
4	2	Smudge / Basket cells
3	2	Toxic granulation
2	2	Acanthocytes
3	2	Basophilic stippling
2	2	Blister cells (pre keratocytes)
1	2	Cabot rings
2	2	Echinocytes (crenated/burr cells)
2	2	Elliptocytes (ovalocytes)
3	2	Howell-Jolly bodies
3	2	Pappenheimer bodies
2	2	Red cell agglutinates
2	2	Rouleaux
2	2	Schistocytes
2	2	Schuffner's granules
25	10	Sickle cells (drepanocytes)
3	2	Spherocytes
3	2	Stomatocytes
3	2	Target cells (codocytes)
3	2	Tear drop cells (dacrocytes)
25	10	Bacteria
25	10	Fungi/yeast
25	10	Malaria/Babesiosis
0	0	Stain precipitate
3	2	Phagocytosis of red cell(s)

All error points are deducted from a starting score of 100. A score of <80% is considered unsatisfactory performance for that slide.

Failure on two consecutive Cytohematology Diagnostic proficiency tests could result in sanctions being taken against a laboratory. The laboratory may be required to seek more extensive retraining, preferably at a school of medical technology.

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to the published submission deadline.

Histocompatibility

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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 testing to monitor the status of a patient following an organ or tissue transplant must hold the category of Transplant Monitoring.

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.

PROFICIENCY TESTING OFFERED

No proficiency testing is offered at this time.

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

Histopathology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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:

Testing includes all tissue. Testing for human papillomavirus (HPV) in tissue is performed under this category. All other HPV testing is performed under Oncology – Human Papillomavirus Testing.

ORAL PATHOLOGY:

Testing is limited to the oral cavity.

DERMATOPATHOLOGY:

Testing is limited to skin.

PROFICIENCY TESTING OFFERED

No proficiency testing is offered at this time.

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

Immunoematology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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‡
(‡No New York State proficiency test is offered for these tests at this time.)

PROFICIENCY TESTING OFFERED

(CMS regulated analytes or tests are indicated with an asterisk)

ABO group*
Subgroups of A
Rh group*
Rh phenotype (C, E, c and e antigens)
Direct Antiglobulin test
Unexpected antibody detection*
Antibody identification*
Compatibility testing*

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Each proficiency test kit includes five whole blood specimens for ABO, Rh, Rh phenotype, direct antiglobulin test, unexpected antibody detection, and antibody identification. One donor specimen to mimic a segment is included for compatibility testing. Test kits are mailed three times per year.

SOURCE OF SAMPLES

The proficiency test samples are commercially prepared.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/lep/PT/epters.htm.

SAMPLE EVALUATION

For ABO group, Rh group, and compatibility testing, acceptable responses must be authenticated by 100% of the referee laboratories or 95% or more of all participating laboratories. For all other analytes, acceptable responses must be authenticated by 95% or more of the referee or participating laboratories.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte	Acceptable
<i>ABO group</i>	100%
<i>Rh group</i>	100%
<i>Rh phenotype</i>	80%
<i>Unexpected antibody detection</i>	100%
<i>Antibody identification</i>	90%
<i>Compatibility testing</i>	100%
<i>Subgroups of A</i>	80%
<i>Direct Antiglobulin test</i>	80%

GRADING

Scored results are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

Grades are determined as follows:

$$\text{Analyte Score} = \frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100$$

$$\text{Event Score} = \frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of challenges for all challenges}} \times 100$$

Satisfactory performance: 100% score achieved for ABO/Rh group, unexpected antibody detection, and compatibility testing; $\geq 90\%$ score achieved for antibody identification, AND $\geq 80\%$ for Rh phenotype, if performed.

Unsatisfactory performance: $<100\%$ score achieved for ABO/Rh group, unexpected antibody detection, and/or compatibility testing; $<90\%$ score achieved for antibody identification, AND/OR $<80\%$ score achieved for Direct Antiglobulin Testing, Subgroups of A and Rh phenotype, if performed.

NOTIFICATION

If samples have not arrived or are unacceptable for testing, the laboratory is required to notify the section within five business days of the announced shipment date. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances in which the routine laboratory practice for patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to the published submission date.

Mycobacteriology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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.

PROFICIENCY TESTING OFFERED

(CMS-regulated analytes or tests are indicated with an asterisk)

*Acid Fast smears (microscopy)**
*Mycobacterium culture/identification**
*Mycobacterium susceptibility testing**

Proficiency test samples may include, but are not limited to, the following list of organisms:

<i>Mycobacterium abscessus</i>	<i>Mycobacterium intracellulare</i>
<i>Mycobacterium asiaticum</i>	<i>Mycobacterium kansasii</i>
<i>Mycobacterium avium</i>	<i>Mycobacterium malmoeense</i>
<i>complex</i>	
<i>Mycobacterium bovis</i>	<i>Mycobacterium scrofulaceum</i>
<i>Mycobacterium chelonae</i>	<i>Mycobacterium shimoidei</i>
<i>Mycobacterium flavescens</i>	<i>Mycobacterium szulgai</i>
<i>Mycobacterium fortuitum</i>	<i>Mycobacterium terrae</i>
	<i>complex</i>
<i>Mycobacterium gastri</i>	<i>Mycobacterium tuberculosis</i>
	<i>complex</i>
<i>Mycobacterium gordonae</i>	

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Acid Fast smears (microscopy): Proficiency test kits consist of five slides for microscopy and are mailed via next day United Parcel Service (UPS) twice per year.

Mycobacterium culture/identification with or without susceptibility testing: Proficiency test kits consist of five slides for microscopy and five samples for identification and susceptibility. These samples are mailed via Federal Express (FEDEX) overnight delivery twice per year.

SOURCE OF SAMPLES

Samples are prepared by Wadsworth Center staff from well-characterized clinical specimens. A suspension of hog gastric mucin is seeded with live strains of *Mycobacterium* sp. and/or normal flora.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUATION

Acceptable responses must be authenticated by 90% of the laboratories holding a New York State permit.

GRADING

Scored results are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

Grades are determined as follows:

Microscopy - Presence or Absence of the acid-fast organisms

$$\text{Event Score} = \frac{\text{Number of acceptable responses}}{\text{Total number of samples tested}} \times 100$$

Failure to attain a score of at least 80% is unsatisfactory performance.

Identification

$$\text{Identification} = \frac{\text{Number of correct responses}}{\text{Number of organisms} + \text{Number of incorrect responses}} \times 100$$

Failure to attain a score of at least 80% is unsatisfactory performance.

Susceptibility Testing

$$\text{Susceptibility Testing} = \frac{\text{Number of correct susceptibility test responses}}{\text{Number of susceptibility test responses}} \times 100$$

Failure to attain a score of at least 80% is unsatisfactory performance.

The score for a testing event in mycobacteriology is the average of the microscopy, identification and susceptibility scores. Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

NOTIFICATION

The laboratory is required to notify the section within two days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS) and Federal Express (FEDEX).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to two business days from the shipment date.

Mycology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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.

PROFICIENCY TESTING OFFERED

(CMS regulated analytes or tests are indicated with an asterisk)

Culture and Identification*

Susceptibility testing of mold and yeast

Antigen Detection of *Cryptococcus neoformans*

Molecular Methods - No proficiency testing offered at this time.

Yeast proficiency test samples may include, but are not limited to, the following list of organisms:

Blastoschizomyces capitatus	Candida viswanathii	Pichia ohmeri
Candida albicans	Candida zeylanoides	Prototheca sp
Candida ciferrii	Cryptococcus albidus	Prototheca wickerhamii
Candida dubliniensis	Cryptococcus gattii	Prototheca zopfii
Candida famata	Cryptococcus laurentii	Rhodotorula glutinis
Candida glabrata	Cryptococcus neoformans	Rhodotorula minuta
Candida guilliermondii	Cryptococcus sp.	Rhodotorula mucilaginosa
Candida kefyr	Cryptococcus terreus	Rhodotorula sp.
Candida krusei	Cryptococcus uniguttulatus	Saccharomyces cerevisiae
Candida lipolytica	Geotrichum candidum	Saccharomyces sp
Candida lusitanae	Geotrichum sp	Sporobolomyces salmonicolor
Candida norvegensis	Hansenula anomala	Trichosporon asahii
Candida parapsilosis	Malassezia furfur	Trichosporon inkin
Candida rugosa	Malassezia pachydermatis	Trichosporon mucoides
Candida sp.	Malassezia sp.	Trichosporon sp
Candida tropicalis		

Mold proficiency test samples may include, but are not limited to, the following list of organisms:

Absidia corymbifera	Emmonsia sp.	Phialophora verrucosa
Absidia sp.	Epidermophyton floccosum	Phoma sp.
Acremonium sp.	Epidermophyton sp.	Pithomyces sp.
Alternaria sp.	Epicoccum sp.	Pseudallescheria boydii
Arthrographis sp.	Exophiala dermatitidis	Pseudallescheria sp.
Aspergillus clavatus	Exophiala jeanselmei	Rhizomucor pusillus
Aspergillus flavus	Exophiala sp	Rhizomucor sp.
Aspergillus fumigates	Exserohilum sp.	Rhizopus oryzae
Aspergillus glaucus	Fonsecaea sp.	Rhizopus sp.
Aspergillus nidulans	Fusarium oxysporum	Scedosporium apiospermum
Aspergillus niger	Fusarium solani	Scedosporium prolificans
Aspergillus sp	Fusarium sp.	Scedosporium sp.
Aspergillus terreus	Gliocladium sp.	Scopulariopsis brevicaulis
Aspergillus versicolor	Helminthosporium sp.	Scopulariopsis brumptii

Athrinium sp.	Histoplasma capsulatum	Scopulariopsis sp.
Aureobasidium pullulans	Hormonema dematioides	Scytalidium hyalinum
Aureobasidium sp.	Hormonema sp.	Scytalidium sp.
Basidiobolus ranarum	Malbranchea sp.	Sepedonium sp.
Beauveria sp.	Microsporum audouinii	Sporothrix schenckii
Bipolaris sp.	Microsporum canis	Sporothrix sp.
Blastomyces dermatitidis	Microsporum cookei	Stachybotrys atra
Chaetomium globosum	Microsporum gypseum	Stachybotrys sp.
Chaetomium sp.	Microsporum nanum	Syncephalastrum racemosum
Chrysosporium sp.	Microsporum persicolor	Syncephalastrum sp.
Cladophialophora bantiana	Microsporum sp.	Trichoderma sp.
Cladophialophora boppii	Mucor circinelloides	Trichophyton ajelloi
Cladophialophora carrionii	Mucor plumbeus	Trichophyton interdigitale
Cladophialophora sp.	Mucor racemosus	Trichophyton mentagrophytes
Cladosporium sp.	Mucor sp.	Trichophyton rubrum
Coccidioides sp.	Nigrospora sp.	Trichophyton schoenleinii
Cokeromyces recurvatus	Paecilomyces lilacinus	Trichophyton sp.
Conidiobolus coronatus	Paecilomyces sp.	Trichophyton terrestre
Conidiobolus sp.	Paecilomyces variotii	Trichophyton tonsurans
Cunninghamella bertholletiae	Penicillium marneffeii	Trichophyton verrucosum
Cunninghamella sp.	Penicillium sp.	Trichophyton violaceum
Curvularia sp.	Phaeoannellomyces werneckii	Trichothecium sp.
Drechslera sp.	Phialophora richardsiae	Ulocladium sp.
Emmonsia parva	Phialophora sp.	Ustilago sp.
		Verticillium sp.

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice

TEST KIT AND FREQUENCY OF MAILING

Identification kit (Fungus): Proficiency test kits consist of five specimens for identification. Mold samples for identification are included in the first and third event of year. Yeast samples for identification are included in the second event of the year.

Identification kit (Yeast-only): Proficiency test kits consist of five yeast samples and are mailed three times per year.

Susceptibility kit: Proficiency test kits consists of one known yeast sample and are mailed three times a year. Additionally, for laboratories offering susceptibility testing for molds, one known mold sample is also included three times a year.

Direct Detection kit: Proficiency test kits consist of five samples and are mailed two times per year.

SOURCE OF SAMPLES

The proficiency test samples are prepared by Wadsworth Center staff from clinical and reference fungal strains available in the collection.

Cryptococcus neoformans antigen samples are prepared and standardized according to published methods.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUATION

Acceptable responses must be authenticated by 80% or more of the referee or participating laboratories.

GRADING

Scored results are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

Grades are determined as follows:

Identification of Molds and Yeast

Event Score =	$\frac{\text{Number of acceptable responses}}{\text{Number of fungi present} + \text{Number of incorrect responses}}$	X 100
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Antifungal Susceptibility

A maximum score of 100 is equally divided among the drugs selected by the individual laboratory. Acceptable results for antifungal susceptibility testing for yeasts are MICs with +/- 2 dilutions range and interpretation where applicable as per NCCL/CLSI guidelines. Susceptibility testing for molds is Educational.

Antigen Detection

Presence or Absence of *Cryptococcus neoformans* antigen.

Failure to attain an overall testing score of at least 80% is unsatisfactory performance.

The Department reserves the right to order the cessation of testing for a particular method or sample type (e.g., cryptococcal antigen or molds) when continued substandard proficiency test performance is demonstrated for that method or sample type.

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to five business days from the shipment date.

Oncology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

The Oncology categories includes tests used in tumor screening, diagnosis, prognosis and management, including the standard serum-based tumor markers, as well as tests for tumor cell specific acquired genotypic and/or phenotypic alterations. 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) and bead-based assays such as Luminex®.

MOLECULAR AND CELLULAR TUMOR MARKERS:

This category is for laboratories performing tests on cellular material to detect tumor-specific acquired 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 or translocations, mutations, altered gene/protein expression, and *ex vivo* determination of chemotherapeutic drug sensitivity. Methodologies used are generally, though not exclusively, molecular biology-based, and results can be qualitative or quantitative.

Array comparative genomic hybridization (aCGH) assays for acquired chromosomal aberrations (gain or loss) may be performed under this category. However, if the confirmatory test is by FISH, then the provisions below for FISH testing apply.

Laboratories that want to perform diagnostic evaluations of blood dyscrasias and acquired cytogenetic changes of neoplasias in non-dividing cells or tissue by interphase FISH may do so under the following provisions:

1. The Oncology laboratory has a documented collaborative arrangement with a permitted cytogenetics laboratory and/or a qualified cytogeneticist to assist in performing validations and to provide ongoing consultation. Alternatively, these tests may be offered under the Cytogenetics – Cancer permit.
2. Laboratories that offer interphase FISH testing for hematological neoplasias under the Oncology – Molecular and Cellular Tumor Markers permit category are expected to participate in that category's proficiency testing.
3. A limited number of interphase FISH test may also be performed under the categories of Histopathology - General and Cytopathology Non-gynecological Testing (refer to those category descriptions for details).

HUMAN PAPILLOMAVIRUS (HPV) TESTING:

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

PROFICIENCY TESTING OFFERED (CMS regulated analytes or tests are indicated with an asterisk)

Soluble Tumor Markers

Alpha-fetoprotein tumor markers (AFPTM)*
CA125
CA15-3
CA19-9
CA27.29
Carcinoembryonic antigen (CEA)
Prostate Specific Antigen (PSA)

Complexed PSA (cPSA)
Free PSA (fPSA)

Molecular and Cellular Tumor Markers

Gene rearrangements, chromosome translocations, and gene mutations associated with leukemia/lymphoma

Human Papillomavirus (HPV)

HPV testing in gynecological samples; screening and genotyping

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Soluble Tumor Markers

Proficiency test kits consist of five samples and are mailed three times per year.

Molecular and Cellular Tumor Markers

Proficiency test kits consist of three samples and are mailed two times per year.

Human Papillomavirus (HPV)

Proficiency test kits consist of five samples and are mailed two times per year.

SOURCE OF SAMPLES

Soluble Tumor Markers The proficiency test samples are prepared by Wadsworth Center staff. The base matrix consists of human serum supplemented with the test analytes.

Molecular and Cellular Tumor Markers The proficiency test samples are prepared by Wadsworth Center staff from fresh whole blood.

Human Papillomavirus (HPV) The proficiency test specimens contain cell suspensions in PreservCyt™ solution.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUATION

Soluble Tumor Markers

Results are quantitative. Determination of the correct result for each test sample will be based on the statistical evaluation of the peer group; that is, results from the laboratories are grouped based on the use of the same method (instrument and/or reagents). Specifically, where there are at least three participating laboratories, the mean, median, standard deviation and acceptable range are determined from those results. Where available, a target value will be assigned based on international reference standards.

Molecular and Cellular Tumor Markers

Results are qualitative for the most part. The correct results generally will be determined from the method specific consensus from all labs. For quantitative assays, such as Q-RT PCR, the correct result will be determined from the consensus from all labs.

Human Papillomavirus (HPV)

Results are qualitative. The correct results generally will be determined from the method specific consensus from all labs.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Soluble Tumor Markers

Analyte	Acceptable performance
AFPTM	± 3 S.D.*
CA125	± 3 S.D.
CA15-3	± 3 S.D.
CA19-9	± 3 S.D.
CA27.29	± 3 S.D.
CEA	± 3 S.D.
PSA	± 3 S.D.
cPSA	± 3 S.D.
fPSA	± 3 S.D.

Molecular and Cellular Tumor Markers

Currently educational only; for qualitative tests, does or does not correspond to the lab consensus; for quantitative tests, what constitutes an acceptable performance has not yet been decided.

Human Papillomavirus (HPV)

Analyte	Acceptable performance
HPV Screening	Does or does not correspond to the lab consensus
HPV Genotyping	Currently educational only

*Peer group specific or average may be used to determine acceptable range.

GRADING

Scored results for soluble tumor markers are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/lep/PT/epters.htm.

Proficiency test grades for Oncology – HPV Testing are reported to the laboratory via postal service. The results should be reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9).

Grades for soluble tumor markers and HPV screening are determined as follows:

$$\text{Analyte Score} = \frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100$$

Failure to attain an overall testing score of at least 80% is unsatisfactory performance.

Proficiency test grades for molecular and cellular tumor markers are reported to the laboratory via postal service. The results should be reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9).

NOTIFICATION

The laboratory is required to notify the section within five days of shipment if samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to the published submission deadline, subject to availability and/or sample stability.

Parasitology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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.

PROFICIENCY TESTING OFFERED

(CMS regulated analytes or tests are indicated with an asterisk)

- Blood Smear*
- Ova and Parasites*
- Wet mount
- Antigen detection of *Cryptosporidium* and/or *Giardia*

Proficiency test samples may include, but are not limited to, the following list of organisms:

PROTOZOA

Amoebae	Ciliates & Flagellates
Blastocystis hominis	Balantidium coli
Endolimax nana	Chilomastix mesnili
Entamoeba coli	Dientamoeba fragilis
Entamoeba hartmanni	Giardia intestinalis/lamblia
Entamoeba histolytica/dispar	Trypanosoma cruzi
Iodamoeba butschlii	Trypanosoma brucei

Apicomplexa

Babesia sp.	Plasmodium falciparum
Cryptosporidium sp.	Plasmodium malariae
Cyclospora cayetanensis	Plasmodium ovale
Elimera sp.	Plasmodium vivax
Isospora belli	Toxoplasma gondii

Grades are determined as follows:

Sample Score =	$\frac{\text{Number of acceptable responses}}{\text{Number of parasites present} + \text{Number of incorrect responses}}$	X 100
Event Score =	$\frac{\text{Sum of sample scores}}{\text{Number of samples tested}}$	X 100

Failure to attain an overall testing score of at least 80% is unsatisfactory performance. The Department reserves the right to order the cessation of testing for a particular method or sample type (e.g., Giardia antigen or blood smear) when continued substandard proficiency test performance is demonstrated for that method or sample type.

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided for a period of up to five business days from the shipment date.

Parentage / Identity

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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.

PROFICIENCY TESTING OFFERED

No proficiency testing is offered at this time.

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

Therapeutic Substance Monitoring / Quantitative Toxicology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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.

PROFICIENCY TESTING OFFERED

(CMS regulated analytes or tests are indicated with an asterisk)

Alcohol, blood (ethanol)*	Phenytoin*
Acetaminophen	Primidone*
Carbamazepine*	Procainamide*
Diogoxin*	Quinidine*
Ethosuximide*	Salicylate
Gentamicin*	Theophylline*
Lithium*	Tobramycin*
N-acetyl procainamide*	Valproic acid*
Phenobarbital*	Vancomycin

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Proficiency test kits consist of five serum samples and are mailed three times each year.

SOURCE OF SAMPLES

The proficiency test samples are prepared by Wadsworth Center staff. The base matrix consists of normal processed serum supplemented with the test analytes

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUATION

Target values for quantitative tests are calculated from all-participant mean values by a robust statistical technique. Where available, target values are established or verified by reference methods or weighed-in values. Comparative method or "peer group" targets are used when it is shown that specific methods demonstrate a bias with proficiency samples not observed with patient specimens.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte	Acceptable performance
Acetaminophen	Target value ± 20% or 3.0 mg/L*
Carbamazepine	Target value ± 25%
Digoxin	Target value ± 20% or ± 0.2 ng/mL ***
Ethanol	Target value ± 25%
Ethosuximide	Target value ± 20%
Gentamicin	Target value ± 25%
Lithium	Target value ± 20% or ± 0.3 mmol/L ***
Phenobarbital	Target value ± 20%
Phenytoin	Target value ± 25%
Free Phenytoin	Target value ± 25%
Primidone	Target value ± 25%
Procainamide	Target value ± 25%
NAPA	Target value ± 25%
Quinidine	Target value ± 25%
Salicylate	Target value ± 20% or ± 3.0 mg/dL*
Theophylline	Target value ± 25%
Tobramycin	Target value ± 25%
Valproic acid	Target value ± 25%
Vancomycin	Target value ± 20% or ± 3.0 mg/L*

* whichever is greater

GRADING

Scored results are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/epters.htm.

Grades are determined as follows:

Analyte Score =	$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}}$	X 100
Event Score =	$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of challenges for all analytes}}$	X 100

Failure to attain an overall analyte score of 80% is unsatisfactory performance.

Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to the published submission deadline.

Toxicology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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 qualitative toxicology testing, including ethanol, the results of which are intended to assist medical professionals in patient management.

CLINICAL TOXICOLOGY - INITIAL TESTING ONLY:

This category is for laboratories providing clinical toxicology services that are limited to initial (screening) tests. When requested by the health care provider, laboratories must refer presumptive positive specimens to a laboratory holding a Clinical Toxicology – Comprehensive permit for confirmatory testing.

CLINICAL TOXICOLOGY - COMPREHENSIVE:

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

PROFICIENCY TESTING OFFERED

Amphetamines	Methadone
Barbiturates	Opiates
Benzodiazepine	Phencyclidine
Benzoylcegonine	Propoxyphene
Ethanol	THC-cannabinoids
Fentanyl	Tricyclic Antidepressants

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Proficiency test kits consist of four to six samples and are mailed two times each year. A hand-carried proficiency test event may be required at the time of the on-site survey.

SOURCE OF SAMPLES

The proficiency test samples are prepared by Wadsworth Center staff. The base matrix consists of human urine supplemented with the test analytes.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/epters.htm.

SAMPLE EVALUATION

Comparative method or "peer group" targets are used when it is shown that specific methods demonstrate a bias with proficiency samples not observed with patient specimens.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte	Acceptable performance
Amphetamines	Presence or Absence
Barbiturates	Presence or Absence
Benzodiazepine	Presence or Absence
Benzoylcegonine	Presence or Absence
Ethanol	Presence or Absence
Methadone	Presence or Absence
Opiates	Presence or Absence
Phencyclidine	Presence or Absence
Propoxyphene	Presence or Absence
THC-cannabinoids	Presence or Absence
Tricyclic Antidepressants	Presence or Absence

GRADING

Presence or absence of the drug, relative to reported cutoff concentrations.

Proficiency test grades are reported to the laboratory via postal service. The results should be reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9).

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to the published submission deadline.

Toxicology – Blood Lead

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

BLOOD LEAD – COMPREHENSIVE:

This category is for laboratories that perform blood lead measurements using reference systems based on atomic absorption spectrometry (AAS) and/or induction coupled plasma mass spectrometry (ICP-MS); or bench-top anodic stripping voltammetry (ASV; i.e. Model 3010B by Magellan Diagnostics, Inc.). Laboratories holding this category may also perform testing using point-of-care lead analyzers 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 - SCREENING TESTS ONLY:

This category is for laboratories using point-of-care lead analyzers such as the LeadCare® II (Magellan Diagnostics, Inc.) that are based on single-use, disposable sensors, i.e., screen printed electrode technology. This category is also applicable to laboratories using the Lead Care Ultra™ system from Magellan Diagnostics, Inc. Laboratories using Lead Care Ultra™ may submit a complete validation that demonstrates traceability to SI units and analytical performance that would justify classification under Blood Lead – Comprehensive.

Laboratories holding this category must either refer presumptive positive specimens (i.e., 5 µg/dL) 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 reference method.

PROFICIENCY TESTING OFFERED

(CMS regulated analytes or tests are indicated with an asterisk)

Blood Lead (BPb) * (to include both screening tests only and comprehensive categories)

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Proficiency test kits consist of five samples and are mailed three times each year.

SOURCE OF SAMPLES

The proficiency test samples are prepared by Wadsworth Center staff from whole blood collected from lead-dosed goats.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUATION

Target values for blood lead are established as the all-method mean by +>+80% consensus of the referee laboratories.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte	Acceptable performance
BPb	Target Value ± 4 g/dL (values < 40 g/dL) or ± 10% (values > 40 g/dL)

GRADING

Scored results are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

Analyte Score =	$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}}$	X 100
Event Score =	$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of challenges for all analytes}}$	X 100

Failure to attain an overall testing score of at least 80% is unsatisfactory performance.

NOTIFICATION

Blood Lead Screening Tests Only - The laboratory is required to notify the section by 12:00 pm (EST) the day after the PT is shipped that samples have not arrived or are unacceptable for testing. Failure to notify the section by 12:00 pm (EST) the day after the PT is shipped will result in a score of zero. Proficiency test samples are shipped using United Parcel Service (UPS) Next Day Air Service.

Blood Lead Comprehensive - The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

Blood Lead Screening Tests Only - Replacement samples are not available due to the requirements of the screening technology.

Blood Lead Comprehensive - The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to the published submission deadline.

Trace Elements

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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.

PROFICIENCY TESTING OFFERED

Whole Blood

Arsenic, cadmium, mercury

Urine

Arsenic, cadmium, mercury, lead plus selected trace elements from the National Health and Nutrition Examination Survey (NHANES).

Serum

Aluminum, copper, selenium, zinc

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Proficiency test kits consist of five samples and are mailed three times per year.

SOURCE OF SAMPLES

The proficiency test samples are prepared by Wadsworth Center staff from whole blood, urine and serum.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/lep/PT/eptrs.htm.

SAMPLE EVALUATION

Target values for trace elements are established as the robust mean of the results reported by all participants in the event. The robust statistics are obtained by utilizing algorithms based on those presented in ISO 13258_2005E Statistical Methods for use in proficiency testing by interlaboratory comparison.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Matrix	Analyte	Acceptable performance
Whole blood		
	Arsenic	$\pm 6 \mu\text{g/L}$ (values = $30 \mu\text{g/L}$) or $\pm 20\%$ (values > $30 \mu\text{g/L}$)
	Cadmium	$\pm 1 \mu\text{g/L}$ (values = $6.6 \mu\text{g/L}$) or $\pm 15\%$ (values > $6.6 \mu\text{g/L}$)

	Mercury	± 3 µg/L (values = 10 µg/L) or ± 30% (values > 10 µg/L)
Urine		
	Arsenic	± 6 µg/L (values = 30 µg/L) or ± 20% (values > 30 µg/L)
	Cadmium	± 1 µg/L (values = 6.6 µg/L) or ± 15% (values > 6.6 µg/L)
	Lead	± 40 µg/L (values = 400 µg/L) or ± 10% (values > 400 µg/L)
	Mercury	± 3 µg/L (values = 10 µg/L) or ± 20% (values > 10 µg/L)
Serum		
	Aluminum	± 5 µg/L (values = 25 µg/L) or ± 20% (values > 25 µg/L)
	Copper	± 95 µg/L (values = 635 µg/L) or ± 15% (values > 635 µg/L)
	Selenium	± 2 µg/L (values = 10 µg/L) or ± 20% (values > 10 µg/L)
	Zinc	± 15 µg/L (values = 100 µg/L) or ± 15% (values > 100 µg/L)

GRADING

Scored results are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

Analyte Score =	$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}}$	X 100
Event Score =	$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of challenges for all analytes}}$	X 100

Failure to attain an overall testing score of at least 80% is unsatisfactory performance.

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to the published submission deadline.

Transplant Monitoring

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

This category is for laboratories performing testing to monitor the status of a patient following an organ or tissue transplant. This includes engraftment monitoring, molecular assays that monitor for rejection and the FDA-cleared Cylex™ ImmunKnow® assay for monitoring immune function following transplant.

PROFICIENCY TESTING OFFERED

No proficiency testing is offered at this time.

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

Urinalysis

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

This category is for laboratories that perform a qualitative or semi-quantitative analysis of urinary glucose, protein, ketones, pH, hemoglobin, bilirubin, specific gravity, and a microscopic evaluation of urine for cellular and formed elements such as casts, crystals, white blood cells, and red blood cells. Laboratories holding this category may also report the presence of bacteria, yeast, and *Trichomonas vaginalis*. However, the culture or identification of these elements may only be performed under the appropriate microbiology category. Quantitative urine testing is performed under appropriate categories of Clinical Chemistry or Toxicology. Testing for presence of sperm in urine may be performed under the categories of either Andrology or Urinalysis.

PROFICIENCY TESTING OFFERED

- Glucose
- Protein
- Ketones
- pH
- Hemoglobin
- Bilirubin
- Specific Gravity

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Proficiency test kits consist of five samples and are mailed two times each year.

SOURCE OF SAMPLES

The proficiency test samples are prepared by Wadsworth Center staff. The base matrix consists of synthetic urine supplemented with the test analytes.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUATION

Target values for quantitative tests are calculated by the mean of all participant responses after removal of outliers (those responses $> \pm 3$ S.D. from the original mean). Where available, target values are established or verified by reference methods or weighed-in values. Comparative method or "peer group" targets are used when it is shown that specific methods demonstrate a bias with proficiency samples not observed with patient specimens.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte	Acceptable performance
glucose	The acceptable range is based on the consensus of participating laboratories and comparison to the weighed in target value.
protein	
ketones	
hemoglobin	
bilirubin	
pH	Acceptable range is based on participating laboratory means \pm 2 S.D. or \pm 0.5 (whichever is greater).
specific gravity	

GRADING

Proficiency test grades are reported to the laboratory via postal service. The results should be reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9).

Analyte Score =	$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100$
Event Score =	$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of challenges for all analytes}} \times 100$

Failure to attain an overall testing score of at least 80% is unsatisfactory performance.

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to the published submission deadline.

Urine Pregnancy

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

This category is for laboratories performing urine pregnancy tests. Serum pregnancy tests (serum *beta*-hCG determinations) for the purpose of assessing pregnancy are performed under the category of Endocrinology.

PROFICIENCY TESTING OFFERED

Human Chorionic Gonadotropin (hCG)

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Proficiency test kits consist of five samples and are mailed two times each year.

SOURCE OF SAMPLES

The proficiency test samples are prepared by Wadsworth Center staff. The base matrix consists of synthetic urine supplemented with the test analyte.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUATION

Acceptable responses must be authenticated by 80% or more of the participating laboratories.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Analyte	Acceptable performance
Human Chorionic Gonadotropin (hCG)	Positive or Negative

GRADING

Proficiency test grades are reported to the laboratory via postal service. The results should be reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9).

Grades are determined as follows:

Analyte Score =	$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}}$	X 100
Event Score =	$\frac{\text{Number of acceptable responses for all analytes}}{\text{Total number of challenges for all analytes}}$	X 100

Failure to attain an overall testing score of at least 80% is unsatisfactory performance.

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS).

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to the published submission deadline.

Virology

Contact Information for CLRS Staff

CATEGORY DESCRIPTION

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.

PROFICIENCY TESTING OFFERED

(CMS regulated analytes or tests are indicated with an asterisk)

- Virus isolation and identification* (all viral agents)
- Direct antigen testing for Influenza A* and B*
- Direct antigen testing for Respiratory Syncytial Virus (RSV)*
- Direct antigen testing for Rotavirus (ROTA)*
- Molecular Testing for Influenza

Please note that proficiency testing materials for virus culture and identification are not designed for molecular techniques, and those for direct antigen testing are not designed for direct immunofluorescent detection; they should not be used for the proficiency testing of these methods.

Proficiency test samples may include, but are not limited to, the following list of viruses:

Adenovirus	Measles virus
Coxsackie virus A	Mumps virus
Coxsackie virus B	Parainfluenza 1
Cytomegalovirus	Parainfluenza 2
Echovirus	Parainfluenza 4
Enterovirus	Respiratory syncytial virus
Herpes simplex virus I	Rhinovirus
Herpes simplex virus II	Rotavirus
Influenza A virus	Varicella virus
Influenza B virus	

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.

TEST KIT AND FREQUENCY OF MAILING

Proficiency test kits consist of five samples and are mailed three times per year.

SOURCE OF SAMPLES

The proficiency test samples are prepared by Wadsworth Center staff.

REPORTING OF RESULTS

Proficiency testing results are required to be reported through the Electronic Proficiency Testing Reporting System (EPTRS). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

SAMPLE EVALUATION

Acceptable responses must be authenticated by 80% or more of the referee or participating laboratories.

CRITERIA FOR ACCEPTABLE PERFORMANCE

Procedure	Acceptable performance
Virus isolation and Identification	80%
Direct Antigen Testing Influenza A and B*	80%
Direct Antigen Testing RSV	80%
Direct Antigen Testing ROTA	80%
Molecular Testing for Influenza	80%

Please note, for laboratories performing influenza rapid testing with kits that only detect influenza virus type A, their results will be scored solely on the basis of their detection of influenza A.

GRADING

Scored results are posted to the Electronic Proficiency Test Reporting System (EPTRS) on the Health Commerce System and an email notification is sent to the laboratory informing them the results are available. Hard-copies of the result are not mailed to the laboratory director. The results should be downloaded and reviewed by the appropriate individual(s) as required by Proficiency Testing Sustaining Standard of Practice 9 (PTS9). Information on enrollment in EPTRS and the Health Commerce System can be obtained at www.wadsworth.org/labcert/clep/PT/eptrs.htm.

Grades are determined as follows:

Isolation/Identification

$$\text{Sample Score} = \frac{\text{Number of acceptable responses}}{\text{Number of viruses present} + \text{Number of Incorrect Responses}} \times 100$$

$$\text{Event Score} = \frac{\text{Sum of sample scores}}{\text{Total number of sample scores}} \times 100$$

Qualitative Antigen Tests

Presence or Absence of the viral antigen

$$\text{Event Score} = \frac{\text{Number of acceptable responses}}{\text{Total number of samples tested}} \times 100$$

Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

The Department reserves the right to order the cessation of testing for a particular method or sample type (e.g.,ROTA antigen or respiratory sample) when continued substandard proficiency test performance is demonstrated for that method or sample type.

NOTIFICATION

The laboratory is required to notify the section within five days of shipment that samples have not arrived or are unacceptable for testing. Proficiency test samples are shipped using United Parcel Service (UPS) Next Day Air Service.

REPLACEMENT SAMPLES

The laboratory may request replacement samples under circumstances where in routine laboratory practice the recourse in patient testing is to collect additional specimens, e.g., laboratory accident or instrument failure. Replacement samples will be provided up to five business days from the shipment date.

Wet Mounts

CATEGORY DESCRIPTION

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

PROFICIENCY TESTING OFFERED

No proficiency testing is offered at this time.

For all tests with no available New York State proficiency test (PT) the laboratory shall have a system for verifying the reliability and accuracy of test results and shall perform this verification process at least twice each year. Please refer to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy in the Clinical Laboratory Standards of Practice.