New York State Department of Health

Wadsworth Center

Clinical Laboratory Evaluation Program

Clinical Laboratory Standards of Practice

General Systems Standards

Effective February 12th, 2026

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

All laboratories and blood banks holding a New York State clinical laboratory permit must adhere to applicable Clinical Laboratory Standards of Practice, including:

- General Systems Standards; and
- Specialty Requirements by Category.

There are no category specific standards for the following permit categories:

- Clinical Chemistry
- Endocrinology
- Therapeutic Substance Monitoring/Quantitative Toxicology
- Transplant Monitoring
- Wet Mounts

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DEFINITIONS

Acceptability criteria: Laboratory or manufacturer-defined performance requirements (pass/fail) that must be met before proceeding with the next step in a process.

Alternative assessment: Assessment to verify test result accuracy and reliability when no formal proficiency testing (PT) program is available or where PT participation is not required.

Amended report: A report containing a modification from the original report, where the modification does not change the original result or interpretation (e.g., name, address, additional pathological information). The addition of information to a report (e.g., addendum) is considered an amended report.

Annual: An event that takes place once per year and where the interval between events is at least ten (10) months and not more than fourteen (14) months.

Assistant director(s): An individual holding a certificate of qualification (CQ) who is designated administrative and/or management responsibilities in eCLEP by the laboratory director for a specific permit category or permit categories. The director retains responsibility for a specific category and/or all permit categories unless there is a sole assistant director for the category(ies).

Auditing: A planned and systematic examination of some or all the laboratory's Quality Management System (QMS) to determine conformance with QMS quality goals, quality indicators and performance expectations.

Autorelease: Electronic system to release test results without intervention by laboratory staff.

Autoverification: Software-based rules to verify test results prior to release.

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

Category: An area, discipline or specialty of laboratory medicine defined by the Department. A director or assistant director must hold a certificate of qualification (CQ) for each category for which a New York State clinical laboratory permit is sought or held.

Certificate of qualification (CQ): A credential issued by the Department to applicants who meet the minimum laboratory director qualifications set forth in Part 19 of 10NYCRR.

DEFINITIONS

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 as described in Article 5, Title 5, Section 571 (1).

Corrected report: A report containing a change in a previously reported result and/or interpretation.

Corrective action: Action(s) taken to remedy a nonconformity, or other unwanted event, that does not comply with the laboratory's quality goals, performance expectations, established procedures and policies, and/or performance specifications.

Data integrity: Generating, transforming, maintaining and assuring the accuracy, completeness and consistency of data for a specimen. Data encompass all information collected, and data generated, to produce a test result.

Delegate: To authorize another individual to perform duties for which you are responsible.

Director (Clinical Laboratory 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 Public Health Law. Such person shall possess a certificate of qualification (CQ) issued pursuant to Part 19 of 10 NYCRR. An individual cannot be director, or sole assistant director, for more than two (2) clinical laboratories and/or blood banks as set forth in SubPart58-1 of 10NYCRR.

Document control: Refers to a system to manage the creation, review, revision, distribution, accessibility and storage of documents. Documents subject to document control include, but are not limited to, standard operating procedures, policies, instructions, programs, plans and manuals, and as indicated in any part of the New York State Clinical Laboratory Standards of Practice.

Equipment: Articles or implements that are used for a specific purpose or activity but that do not directly analyze specimens or samples. Examples of equipment include, but are not limited to, centrifuges, thermometers, balances, incubators, refrigerators, freezers, biological safety cabinets, fume hoods and pipettes.

Function check: Process performed at prescribed intervals to confirm that an instrument or equipment is operating according to manufacturer or laboratory performance specifications.

Health Commerce System (HCS): A secure New York State Department of Health website that houses eCLEP. Clinical laboratories must use eCLEP as prescribed by the Department to complete the annual permit reapplication, submit gross annual receipts figures for fee calculation and report the laboratory's chosen proficiency testing (PT) provider for each calendar year.

DEFINITIONS

Instrument: A device used to determine or analyze the components of samples or specimens.

Laboratory developed test (LDT): Laboratory developed tests are non-FDA cleared or approved assays, or modified FDA tests, that are by the laboratory offering the test. Laboratories must receive approval from the Department to perform any LDT on specimens that originate from New York State (https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval).

Laboratory management: Includes the laboratory owner(s), administrator(s), manager(s), director and assistant director(s).

Monitoring: A planned and systematic process performed at established intervals (e.g. daily, weekly, monthly, etc.) to observe, verify, and document that a process is compliant with minimum quality goals and performance expectations as established in the laboratory's Quality Management System (QMS).

Nonconformance: An event or process that does not comply with the laboratory's quality goals, performance expectations, established procedures and policies, and/or performance specifications.

Patient: Any individual that has biological material derived from their body for testing.

Performance expectations: Minimally acceptable criteria, thresholds or benchmarks that are established by the laboratory's Quality Management System (QMS).

Performance specification: Criteria defined by the manufacturer and/or laboratory to demonstrate that any instrument, equipment, test system, process and/or other system is performing as expected.

Performance verification: Processes intended to demonstrate that an instrument, equipment, test system, device, reagent and/or media meet requirements to produce accurate and reliable test results.

Preventive action: Action(s) taken to prevent recurrence of a nonconformance or to correct a defect or deficit that has not yet caused a nonconformance, but that may contribute to one in the future.

Process audit: A focused audit of an individual process against established policies and procedures, often performed in response to evidence or identification of nonconformities. Process audits detect inefficiencies, problematic steps in the process and other areas where improvement is needed.

DEFINITIONS

Proficiency testing participation: All laboratories applying for or holding a New York State clinical laboratory permit must participate in proficiency testing (PT) as prescribed by the Department. PT is required for the tests/analytes offered by the laboratory that are listed in CMS 42 CFR 493 subpart I (CLIA subpart I) or required by the Department. New York State requirements for PT are available in our PT Guide and website at https://www.wadsworth.org/regulatory/clep/pt.

Quality indicator (QI): Data identified/chosen by the laboratory as part of the Quality Management System (QMS) to monitor conformance with laboratory performance expectations.

Quality goals: Outcomes of systems or processes identified by the laboratory for improvement.

Reagents: Any substance required in the test process, including support solvents, required by the manufacturer or laboratory to achieve a reportable test result.

Reference laboratory: A New York State permitted laboratory that receives clinical specimens from another New York State permitted laboratory to perform any part of the testing process.

Root cause analysis: Analysis performed to identify the source of a nonconformance.

Semiannual: An event that takes place two times during the year, with the first event taking place in the first six months of the year and the second event in the last six months of the year, and where the interval between events is at least four months and not more than eight months.

Sole assistant director: When a laboratory director does not hold a certificate of qualification (CQ) for a category or categories, an assistant director must be designated in eCLEP as responsible for the category(ies). In instances where there is only one assistant director that holds a CQ, the assistant director serves as the director for the category(ies) and is referred to as the sole assistant director. An individual cannot be director, or sole assistant director, for more than two (2) clinical laboratories and/or blood banks as set forth in SubPart58-1 of 10NYCRR.

Supervisor: An individual, under the direction of the laboratory director, that oversees testing personnel and the reporting of test results.

System audit: An audit of the entire laboratory or a part of the laboratory that is designed to reveal either conformity or nonconformity with requirements (e.g., regulations, standards, laboratory policies and procedures, etc.).

Test process: Pre-analytic, analytic, and post-analytic steps required to produce one or more test results.

Quality Management System

Quality Management System	
Standard	***Guidance***
Quality Management System Fundamental Standard of Practice (QMS FS) The laboratory must have a Quality Management System (QMS) that continuously assesses and improves the quality of laboratory services and ensures compliance with regulatory requirements. The laboratory director, and where appropriate, the owner, must be involved in designing and implementing the QMS. The QMS must: a) set quality goals, quality indicators, and performance expectations and/or thresholds; b) ensure quality goals are reviewed on a scheduled basis, and performance expectations are met; c) continuously monitor for deviations from quality goals or performance expectations; d) include scheduled system and process audits, at least annually; and e) have a system for correcting and documenting problems uncovered by monitoring or audits. ***Statutory authority: Article 5, Title 5 Public Health Law Section 575(2) and (3)***	

Quality Management System

Standard	*Guidance*
Quality Management System Standard of Practice 1 (QMS S1): Quality Goals and Performance Expectations The laboratory's Quality Management System (QMS) must define quality goals and performance expectations that ensure the quality and timeliness of laboratory services. The QMS must meet New York State Clinical Laboratory Standards of Practice and any other applicable requirements for all laboratory processes. The laboratory's QMS must be documented and address the following: a) quality indicators (QI); b) director responsibilities; c) human resources; d) facility design; e) laboratory safety; f) laboratory information systems (LIS); g) resource management; h) document control; i) pre-analytic systems; j) analytic systems; k) post-analytic systems; l) document and specimen retention; m) proficiency testing; and n) investigations and corrective actions.	The Quality Management System (QMS) must include documents to describe personnel roles and responsibilities, and the processes they must use to meet quality goals and performance expectations. The laboratory should document how QMS requirements for (a) through (n) are met. Documentation may be in the form of a quality manual, master index or cross reference system. Examples of QMS documents include, but are not be limited to: • standard operating procedures, policies, plans, etc.; • maintenance procedures; and • forms, instructions, and client information. Please see additional information related to quality indicators at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/on-site-survey.

Quality Management System	
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Statutory authority: Article 5, Title 5 Public Health Law Section 575(2) and (3), ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c) and paragraph 19.3(c)(3)***	
Quality Management System Standard of Practice 2 (QMS S2): Quality Systems Manager The laboratory director must designate a quality systems manager or quality assurance officer who has the experience and authority to ensure communication, training, competency assessment and ongoing compliance monitoring with all requirements of the laboratory's Quality Management System (QMS). ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c)***	There must be a designated position for a quality systems manager or quality assurance officer and a job description. The designated individual must have the education, experience and authority to discharge the responsibilities of the position and must have access to personnel at all levels of the laboratory organization as required. The designated individual is expected to be a resource person to the Department when there is a need for document review and compliance assessment. The laboratory director may serve as the quality systems manager. Persons who limit their scope of activity to oversight of quality system activities do not require licensure by the New York State Education Department.
Quality Management System Standard of Practice 3 (QMS S3): Quality Indicators The laboratory must establish quality indicators (QI) that assess the quality of laboratory services and identify processes that do not meet Quality Management System (QMS) requirements for quality goals and performance expectations. The laboratory must establish QI for the following, at a minimum: a) monitoring specimen submissions, including compliance with test request requirements and the laboratory's specimen submission instructions;	Additional examples of areas where QI are valuable in assessing performance include acceptable specimen transport and storage, acceptable performance by contract and reference laboratories, verification of materials, quality control records and review, temperature and humidity records and comparability of test results. a) Examples include specimens with missing information (e.g., time of collection when required) or incorrect labels, etc.

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b) timeliness and completeness for personnel training and competency; c) performance on proficiency testing and alternative assessments of test accuracy and reliability; d) corrected test reports; e) turnaround times for urgent or STAT tests; f) complaint investigations; and g) nonconformances. ***Statutory authority: Article 5, Title 5 Public Health Law Section 575(2) and (3)***	d) Examples include numbers of corrected test reports and timeliness of client notification. e) The laboratory must select a representative sampling of STAT or urgent tests for turnaround time monitoring.
Quality Management System Standard of Practice 4 (QMS S4): Quality Indicator Monitoring The laboratory must have standard operating procedures and/or policies describing the process for monitoring quality indicators (QI). For QI, the laboratory director is responsible for establishing: a) the frequency for monitoring, which must be at least annually; b) how data will be collected, analyzed and documented; c) acceptable performance and/or threshold(s) for each indicator; and d) actions to be taken for QI that do not meet defined performance expectations and/or threshold(s), including notifications to appropriate parties, if applicable.	Examples of documentation may include: (1) continued acceptable performance expectations (e.g., measured against a threshold or benchmark); (2) areas in need of improvement; and/or (3) non-conforming events as indicated when performance expectations are not met. Actions may include notifying clients or other appropriate parties when requirements for the laboratory are not met (e.g., specimen collection instructions or test request requirements).

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Statutory authority: Article 5, Title 5 Public Health Law Section 575(2) and (3)	
Quality Management System Standard of Practice 5 (QMS S5): System and Process Audits The laboratory must perform internal audits designed to identify systems and processes that do not meet quality goals and performance expectations as defined by the laboratory's Quality Management System (QMS). Standard operating procedures and/or policies must define the audit processes, including, but not limited to: a) audit methods; b) audit frequency, which must be at least annually; c) preventive and/or corrective action of problems and nonconformances identified during the audit process; and d) designation of staff responsible for audits that, to the extent possible, limit personnel from auditing their own activities. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c) and paragraph 19.3(c)(3)***	The laboratory must perform internal audits. Audits or "mock inspections" that are performed to assess the laboratory's compliance with the requirements of regulatory or accreditation programs may not be used as the only means to meet this requirement. Audits must be performed annually; however, these audits may be performed for specific areas of the laboratory such that the entire laboratory is audited over a two (2) year period.

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Quality Management System Standard of Practice 6 (QMS S6): Quality Management System Documentation All Quality Management System (QMS) activities must be documented, including: a) quality indicator (QI) identification and monitoring; and b) findings and the actions taken from all audits and inspections. ***Statutory authority: Article 5, Title 5 Public Health Law Section 575(2) and (3)*** ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c) and paragraph 19.3(c)(3)***	
Quality Management System Standard of Practice 7 (QMS S7): Management Review Laboratory management must review and document outcomes of findings related to Quality Management System (QMS) activities. The director must set a review schedule. Documentation of laboratory director review must be at least annual. Laboratory staff must be informed of management review findings and the resulting decisions. Areas of mandatory management review include: a) quality indicators (QI); b) internal system and process audits; c) external inspection reports; d) changes in workload or test menu;	Director review of summarized QMS activities from delegated individuals may be documented through signature and date, or documented attendance at a meeting where the information is discussed. Password protected electronic signatures are acceptable to demonstrate required review.

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e) proficiency testing (PT) and alternatives to PT to assess test accuracy and reliability; f) nonconformances, including QI that do not meet laboratory performance expectations, and any resulting actions; and g) feedback or suggestions from any source, including complaints. Reports of management review must be retained according to Document and Specimen Retention Standard of Practice 1 and must be available to the Department upon request. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c) and paragraph 19.3(c)(3)***	

Director Responsibilities

Director Responsibilities	
Standard	***Guidance***
Director Fundamental Standard of Practice (DR FS) The laboratory director is responsible for all aspects of laboratory services. The laboratory director may delegate, in writing, responsibility for a category to an assistant director holding a CQ in a relevant category; however, the laboratory director retains ultimate responsibility. ***Statutory authority: Article 5, Title 5 Public Health Law Section 577*** **Guidance –** Information on responsibilities of directors of clinical laboratories and blood banks is available at: https://www.wadsworth.org/regulatory/clep/laws. Regulatory information for Section 58-1.1, Permit, and instruction on applying for a certificate of qualification are available at: https://www.wadsworth.org/regulatory/clep.	
Director Standard of Practice 1 (DR S1): Compliance with Local, State and Federal Statutes and Regulations The laboratory director and owner are jointly and separately responsible for ensuring that the laboratory complies with all applicable local, state and federal laws, regulations and requirements. ***Statutory authority: Article 5, Title 5 Public Health Law Section 575(3)*** ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	

Director Responsibilities	
Standard	***Guidance***
Director Standard of Practice 2 (DR S2): Health Commerce System The laboratory director must: a) obtain and affiliate a Health Commerce System (HCS) account as part of the requirements for a clinical laboratory permit; b) assign an HCS coordinator, either themselves or another person; c) have a standard operating procedure and/or polices for the HCS, including a schedule for maintaining the currency and accuracy of all HCS user accounts for their facility; and d) ensure that all personnel with HCS access agree to comply with the terms of the HCS security and use policies. ***Statutory authority: Public Health Law Article 5, Title 5 Sections 575(1)***	Information on obtaining an HCS account is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce. The HCS coordinator is responsible for requesting additional HCS accounts and assigning personnel roles in the HCS Communications Directory.
Director Standard of Practice 3 (DR S3): Director and Assistant Director Involvement and Time Commitment The laboratory director and assistant director(s) must: a) spend time on-site in the laboratory to direct and supervise personnel; and	Section 58-1.2 of 10 NYCRR describes full-time or regular part-time hours required for laboratory directors at: https://www.wadsworth.org/regulatory/clep/laws.

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b) be available in person, by telephone and/or through electronic consultation to the laboratory's personnel and clients. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(a)***	
Director Standard of Practice 4 (DR S4): Director Responsibilities The laboratory director and sole assistant director(s) must ensure compliance with all New York State Clinical Laboratory Standards of Practice. Responsibilities may be delegated in writing by the director. The director remains responsible for all delegated responsibilities and must provide evidence of ongoing evaluation for those delegated duties. The director is responsible for: a) compliance, evaluation and monitoring of laboratory's Quality Management System (QMS) according to New York State Clinical Laboratory Standards of Practice, including but not limited to: i. the appropriateness of laboratory services, including test procedures that meet the needs of the users of laboratory services; ii. requirements for quality indicators (QI), quality goals and performance expectations; iii. scheduled review of audits, outcomes, management reviews, and on-going monitors of conformance; and b) providing effective administrative direction, including budget planning and controls, in conjunction with the	Director responsibilities are available in Part 19 of 10 NYCRR, available at: https://www.wadsworth.org/regulatory/clep/laws. Director responsibilities related to testing must be delegated to personnel that are an assistant director or individual that qualifies as a supervisor.

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individual(s) responsible for the financial management of the laboratory; c) providing advice to clients regarding the significance of laboratory findings and ensuring that test reports include information required for interpretation; d) monitoring all work performed in the laboratory to ensure that analytically and clinically valid data are generated; e) selecting all reference laboratories; f) ensuring that sufficient and qualified personnel are employed including: i. defining the qualifications and responsibilities of all laboratory testing personnel and documenting training and/or competency; ii. where applicable, personnel are not engaged in practices limited by license or beyond the scope of licensure; and g) ensuring that supervisors have sufficient time to perform their supervisory functions even if they have testing/bench responsibilities; h) competency assessment of assistant directors and direct-report personnel; i) specifying in writing the technical and administrative responsibilities and duties of all laboratory personnel and comply with all Human Resource Standards of Practice;	g) Ability to perform supervisory functions are determined by compliance with requirements in Human Resources Standard of Practice 4.

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j) ensuring that all delegated duties are performed by staff at defined intervals, and as needed; k) promoting a safe laboratory environment to protect the public and personnel, including, as required, limited or restricted access; l) providing continuing education to laboratory testing personnel that is relevant to laboratory practices; m) ensuring that current and approved test procedures are available and accessible to all personnel; n) effectively implementing a plan of correction to deficiencies identified; o) ensuring that the laboratory complies with all proficiency testing requirements within the New York State Clinical Laboratory Standards of Practice; p) maintaining an effective working relationship with applicable accrediting and regulatory agencies, administrative officials, and the medical community; and q) directors who also function as supervisors must also meet the requirements under Human Resources Standard of Practice 4. ***Regulatory authority: 10 NYCRR section 58-1.2 and subdivision 19.3(c)***	m) Approval of new and revised test procedures may not be delegated by the laboratory director or sole assistant director.

Director Responsibilities	
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Director Standard of Practice 5 (DR S5): Document and Records Accessibility The laboratory director and owner are jointly and separately responsible for ensuring that all standard operating procedures, policies, manuals, plans, corrective actions, investigations and any other associated documents are: a) available for the recreation of the test process for reported specimens; b) available to the Department for review within twenty-four (24) hours of the Department's request; c) provided for the Department's records when requested; and d) compliant with Document and Specimen Retention Standards of Practice or according to other applicable state and federal requirements, whichever is longer. ***Statutory authority: Article 5, Title 5 Public Health Law Section 577*** ***Regulatory authority: 10 NYCRR subdivisions 58-1.10(c) and 58-1.11(c)***	Off-site or electronic storage systems are acceptable, provided the laboratory can produce duplicates within twenty-four (24) hours of a request from the Department.

Human Resources

Human Resources	
Standard	***Guidance***
Human Resources Fundamental Standard of Practice (HR FS) The laboratory must have effective leadership and personnel with the education, training and experience necessary for the delivery of laboratory services. ***Statutory authority: Public Health Law Article 5, Title 5 Sections 575(2) and (3)***	Testing personnel credentials, duties and responsibilities are specified in 10 NYCRR Part 19 and in the following subdivisions of 10 NYCRR Part 58: 58-1.2 Laboratory director, 58-1.3 Clinical laboratory supervision, 58-1.4 Qualifications of laboratory supervisor, and 58-1.5 Duties and qualifications of clinical laboratory technical personnel. 10 NYCRR Parts 19 and 58 are available at: https://www.wadsworth.org/regulatory/clep.
Human Resources Standard of Practice 1 (HR S1): Organization Charts and Job Descriptions Laboratory management must have an organizational chart(s) and job descriptions for all personnel. Job descriptions must be: a) consistent with responsibilities and duties described in the New York State Clinical Laboratory Standards of Practice; b) specified in writing for all positions and titles within the laboratory, including positions/titles held by consultants; and c) describe qualifications. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(6) and subdivision 58-1.2(d)***	Job descriptions should include, but are not limited to: specimen collection personnel; testing personnel; supervisors; laboratory managers; administrators; assistant director(s); and laboratory director(s).

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Human Resources Standard of Practice 2 (HR S2): Personnel Records The laboratory must document dates of employment for testing personnel and verify the following: a) relevant licensure when required by state law; and b) educational and professional qualifications. Personnel records must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	Duties and qualifications for laboratory supervisors and cytology supervisors are described 10 NYCRR subpart 58-1, available at www.wadsworth.org/regulatory/clep. Requirements for licensure through the New York State Education Department are available at: www.op.nysed.gov. For out-of-state laboratories: diplomas, transcripts, curriculum vitae, and/or work history; letters from former employers; or other records should be maintained to establish that education and experience requirements have been met. If the diploma does not state the specific academic major, then transcripts are required. Individuals educated in a college or university outside the United States should refer to the CLEP Program Guide for a description of acceptable credentials and evaluation policies, available at: https://www.wadsworth.org/regulatory/clep.
Human Resources Standard of Practice 3 (HR S3): Supervisor Staffing The laboratory must have a supervisor or supervisor-qualified individual, as delegated by the laboratory director in writing, that is on the laboratory premises during all hours in which tests are performed. This requirement does not apply to testing for emergency purposes, provided: a) the person performing the test qualifies as a clinical laboratory technologist;	For emergency testing performed without a supervisor on-site, the director should establish the maximum time period between reporting of test results and the review.

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b) the director has defined requirements for supervisory review of test results, including quality control; c) the results are reviewed by the supervisor or director during his or her next duty period; and d) a record is maintained to reflect review by the supervisor or director. ***Regulatory authority: 10 NYCRR subdivision 58-1.3(d)***	
Human Resources Standard of Practice 4 (HR S4): Supervisor Responsibilities Laboratory supervisors must fulfill the requirements of this Standard. Responsibilities may be delegated in writing to an individual that qualifies as a laboratory supervisor but does not hold the title of laboratory supervisor. Supervisors remain responsible for all delegated activities and must provide evidence of ongoing evaluation for those duties at regular intervals, as defined by the laboratory director. Laboratory supervisor responsibilities include: a) supervising testing personnel; b) monitoring and ensuring that acceptable performance specifications are maintained, including: i. review of quality control; ii. scheduled instrument and equipment maintenance; iii. other quality assurance activities as assigned; and	Qualifications for laboratory supervisors and cytology supervisors are described 10 NYCRR Part 58, available at: https://www.wadsworth.org/regulatory/clep/laws. For individuals not previously qualified under 10 NYCRR Part 58 to serve as a technologist or cytotechnologist, the experience requirement must be met subsequent to obtaining a license issued by the New York State Education Department. Personnel assigned testing supervisory duties must meet the education and experience requirements of a supervisor regardless of the title (i.e., lead tech) the laboratory uses for the position.

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c) ensuring test system performance: i. by initiating preventive and/or remedial actions when test procedures deviate from the laboratory's established performance specifications; ii. in the event of nonconformances, ensuring that test results are not reported until corrective action has been taken and the test is performing according to laboratory established performance specifications; and d) verifying that personnel are trained and deemed proficient prior to performing testing on patient specimens independently; e) ensuring that staff have competency assessments as needed; and f) ensuring action is taken when personnel do not perform as expected on competency assessments. ***Regulatory authority: 10 NYCRR sections 58-1.3 and 58-1.4***	
Human Resources Standard of Practice 5 (HR S5): Testing Personnel Responsibilities Testing personnel must fulfill the requirements of this Standard. Testing personnel responsibilities include: a) following the laboratory's pre-analytic and analytic procedures and maintaining records of tests;	

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b) maintaining records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens; c) adhering to the laboratory's quality assurance procedures, including documenting all: i. quality control activities; ii. instrument and equipment verifications; iii. maintenance and preventive maintenance; and d) following the laboratory's policies and procedures whenever test systems are not within the laboratory's established performance specifications; e) identifying and documenting problems that may adversely affect test performance and notifying the supervisor, assistant director(s) or director; and f) documenting all corrective actions taken when test systems deviate from the laboratory's established performance specifications. ***Regulatory authority: 10 NYCRR section 58-1.5***	
Human Resources Standard of Practice 6 (HR S6): Training for Testing and Non-testing Personnel Laboratory management must have standard operating procedures for the training and documentation of training for all testing and non-testing staff.	See specialty standards for additional training requirements, including blood and transfusion services. Off -site testing training, for example by test system manufacturers, super user, train the trainers, training at other networks/affiliates/health care systems or through industry-sponsored workshops can be used in addition to documentation of on-site specific training. Following off-site

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Personnel must be trained and deemed proficient in all tasks for which they are responsible. Training of testing personnel must be performed at the site where they perform their job, and re-training must be performed anytime that the test method or instrument changes. Training must be documented for all personnel, including healthcare providers performing testing at the point of care, staff engaged in the performance of supportive tasks such as data entry, accessioning and reporting, and supervisory and management staff. Training, and documentation of such, must include the following: a) date of training and date deemed proficient to perform tasks; b) objectives of training; c) methods to be used in training; d) materials to be used in the training; e) data integrity; and f) criteria to assess the effectiveness of training and personnel proficiency prior to clearing them to perform tasks independently. Documentation of training must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	training, staff must still demonstrate testing capabilities (e.g., calibration, quality control and maintenance training and demonstration of testing proficiency) at the site where testing is performed through the documentation required to meet this standard.

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Human Resources Standard of Practice 7 (HR S7): Competency Assessment – Supervisory Personnel Supervisors must be assessed in their responsibilities according to Human Resources Standard of Practice 4 and their competency documented. Competency assessments must be performed annually for all tasks for which the supervisor is responsible and include, as applicable: a) the date of the assessment; b) compliance with policies and procedures; c) communication, including bringing problems and non-conformities to the attention of laboratory management; d) leadership and problem-solving capabilities; e) allocation of assets for effective daily laboratory operations; and f) personnel management. Competency assessments must be performed by delegated supervisor qualified staff or the director or assistant director(s). For direct report supervisors and assistant directors, the laboratory director must approve these competencies. Documentation of competency must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	If a supervisor or director/assistant director also functions as testing personnel, he or she must also be competency assessed for those functions as required in Human Resources Standard of Practice 8. Testing personnel performing delegated supervisory functions must also be competency assessed for those supervisory functions.

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Human Resources Standard of Practice 8 (HR S8): Competency Assessment – Testing Personnel Testing personnel must be assessed in their responsibilities according to Human Resources Standard of Practice 5, and their competency documented. Competency assessments must be performed at least semiannually during the first year the individual tests patient specimens and annually thereafter. If there is a change to the test method or instrument, that causes testing personnel to alter their test process, competency must be reevaluated and documented prior to reporting patient test results and include use of the new test method or instrument. Competency assessments of testing personnel must be performed at the site where personnel perform their job. Competency assessments must be performed for all tasks for which the testing personnel are responsible and include, as applicable: a) the date of the assessment and the ability to recreate the test process used for the competency; b) assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; c) direct observation of employee's duties by supervisor qualified staff for compliance with each test procedure performed; d) direct observation of compliance with safe practices required to perform specimen testing;	Documentation of the personnel's test performance on the competency assessment must contain enough specific detail so that the evaluation can be substantiated. When using previously analyzed specimens or samples, such as quality controls or previously reported proficiency testing samples, documentation must include both the original testing and competency assessment test results. Competency assessment must be performed and documented for all laboratory personnel, including healthcare providers performing testing at the point of care.

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e) direct observation of compliance with procedures for instrument maintenance and function checks and/or preventive maintenance and proper documentation, as applicable; f) review of intermediate test results or worksheets, quality control records and proficiency testing results; g) recording and reporting of test results; h) assessment of problem-solving skills; and i) assessment of competency of any delegated supervisory functions. Competency assessments must be performed by delegated supervisor qualified staff, the laboratory director or assistant director(s). For direct report supervisors and assistant directors, the laboratory director must approve these competencies. Documentation of competency must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	
Human Resources Standard of Practice 9 (HR S9): Competency Assessment – Non-testing Personnel Non-testing personnel must be competency assessed if they perform pre-analytic or post-analytic laboratory practices. Competency assessments must be performed annually for all tasks for which non-testing individuals are responsible, and include, as applicable:	Competency assessment is required for personnel under the authority of the laboratory director, including contract employees. Competency assessment must be documented for all non-testing individuals who perform support tasks that are not related to testing, such as data entry, accessioning, and phlebotomy.

Human Resources	
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a) direct observation of safe practices required to perform their duties; b) periodic review of work product for compliance with standard operating procedures and applicable workload limits; and c) assessment of problem-solving skills. Documentation of competency must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	
Human Resources Standard of Practice 10 (HR S10): Continuing Education Continuing education must be provided to testing personnel by the laboratory director and owner, as applicable, and must be appropriately documented. A minimum of twelve (12) hours of continuing education must be performed by laboratory testing personnel per calendar year. Documentation of continuing education must be maintained in accordance with Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	Acceptable forms of continuing education include professional meetings or industry-sponsored training/workshops. Continuing education hours for part time or per diem staff may not be prorated. Cytotechnologists must follow the continuing education requirements of 10 NYCRR subdivision 58-1.12(c).

Facility Design

Facility Design	
Standard	***Guidance***
Facility Design Fundamental Standard of Practice (FD FS) The laboratory's facility design must meet its own applicable Quality Management System (QMS) specifications and comply with the requirements of this part. The laboratory director and owner are jointly and separately responsible for requirements in the New York State Clinical Laboratory Standards of Practice and any other applicable local, state and federal requirements. ***Statutory authority: Article 5, Title 5 Public Health Law Sections 575(2) and (3)***	
Facility Design Standard of Practice 1 (FD S1): Design and Environment The laboratory design and environment must be suitable for the tasks performed, including but not limited to, adequate: a) equipment, instruments, reagents, kits, supplies, and any other materials required to provide clinical testing service; b) space, such that the workload can be performed without compromising the quality of work or safety of personnel; c) furnishings and technology infrastructure, including communication and data processing systems; d) energy sources that mitigate fluctuations and interruptions, including applicable backup power; e) lighting, ventilation, water, waste and refuse disposal, and environmental controls;	Environmental conditions include, but are not limited to biological sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature, water quality, and sound and vibration levels. Appropriate water quality, as required for each instrument, kit, or test process, must be used for all testing. Laboratories must consider water quality parameters, including but not limited to: pH, silicate content, particulate matter, and bacterial and organic content where applicable. Laboratories purchasing water that has already been certified are not expected to evaluate these parameters unless required by the manufacturer or by the laboratory in its procedure manual. Temperatures may be monitored with a continuous recording thermograph. Temperatures may also be maintained and monitored internally by an instrument, when required for testing, provided test results are either not generated or are flagged when temperatures are out of the acceptable range.

Facility Design	
Standard	***Guidance***
f) safeguards, including controlled access, to protect people, specimens, laboratory resources, data, and patient information; g) precautions to protect the integrity of specimens, equipment, instruments, reagents, materials, and supplies; and h) space and conditions to store all records and materials for the length of time specified in the Document and Specimen Retention Standards of Practice. ***Regulatory authority: 10 NYCRR section 58-1.6***	Environmentally controlled spaces may also be monitored through an electronic monitoring system. This should include a process to notify staff when temperatures are outside acceptable ranges.
Facility Design Standard of Practice 2 (FD S2): Cleanliness, Monitoring and Controlling the Laboratory Environment The laboratory must: a) monitor, control, and record environmental conditions that may influence the quality of test results; b) ensure documents used to record environmental conditions are consistent with manufacturer requirements and/or laboratory standard operating procedures, if applicable; and c) ensure that the laboratory and work areas are clean and well maintained. ***Regulatory authority: 10 NYCRR section 58-1.6***	Environmental conditions include, but are not limited to biological sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature, water quality, and sound and vibration levels. Appropriate water quality, as required for each instrument, kit, or test process, must be used for all testing. Laboratories must consider water quality parameters, including but not limited to: pH, silicate content, particulate matter, and bacterial and organic content where applicable. Laboratories purchasing water that has already been certified are not expected to evaluate these parameters unless required by the manufacturer or by the laboratory in its procedure manual. Temperatures may be monitored with a continuous recording thermograph. Temperatures may also be maintained and monitored internally by an instrument, when required for testing, provided test results are either not generated or are flagged when temperatures are out of the acceptable range.

Facility Design	
Standard	***Guidance***
	Environmentally controlled spaces may also be monitored through an electronic monitoring system. This should include a process to notify staff when temperatures are outside acceptable ranges.
Facility Design Standard of Practice 3 (FD S3): Separation of Incompatible Activities The laboratory must use separate spaces for incompatible testing activities and have processes to prevent contamination. Laboratories conducting target amplification must have procedures to prevent nucleic acid contamination that include: a) unidirectional workflow from pre- to post-amplification, if needed; b) work area(s), personal protective equipment, and testing materials dedicated to pre-amplification procedures; c) work area(s), personal protective equipment, and testing materials dedicated to post-amplification procedures; and d) processes to prevent exposing specimens and pre-amplification samples to amplification products. ***Regulatory authority: 10 NYCRR section 58-1.6***	Additional examples of where separation of laboratory activities may be needed include, but are not limited to: • where testing poses a biological, chemical or radiological hazard; • where the work may be affected or influenced by not being separated (e.g., nucleic acid amplification); and • where an environment conducive to uninterrupted work/enhanced attention to detail is required (e.g., cytopathology screening). NOTE: General contamination prevention protocols are expected to be in place for all procedures. Specific requirements, which involve dedicated equipment and/or areas, are applicable to target amplification methods. Closed system amplification test (CSAT) instruments should be segregated from areas in which specimens are routinely processed to avoid cross-contamination. a) Separate rooms are recommended for pre-amplification and post-amplification procedures. If performed in the same room, dedicated areas should be defined for each phase of the work, e.g., reagent preparation, specimen preparation, amplification and detection. Plugged (aerosol barrier) tips or positive displacement pipets are recommended for pre-amplification procedures. Use of disposable, powder-free gloves are recommended.

Laboratory Safety

Laboratory Safety	
Standard	***Guidance***
Laboratory Safety Fundamental Standard of Practice (LS FS) The laboratory director and owner are jointly and separately responsible for ensuring that the laboratory is designed and operated in a safe manner to protect laboratory staff and the general public according to the New York State Clinical Laboratory Standards of Practice and applicable local, state and federal requirements. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	
Laboratory Safety Standard of Practice 1 (LS S1): Safety Policy and Procedure Approval The laboratory director, or individual delegated in writing by the director, must review and approve all new and revised safety standard operating procedures and/or policies before implementation. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	
Laboratory Safety Standard of Practice 2 (LS S2): Safety Policy and Procedure Training The laboratory must have records of initial and annual safety training for all laboratory personnel in applicable safety standard operating procedures and/or policies.	

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Records of training must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	
Laboratory Safety Standard of Practice 3 (LS S3): Occupational Injuries The laboratory must have standard operating procedures and/or policies for documenting and reporting occupational injuries or illnesses. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	
Laboratory Safety Standard of Practice 4 (LS S4): Occupational Injury Evaluation To avoid recurrence, the laboratory's Quality Management System (QMS) must require documented evaluation of occupational injury, illness and/or exposure reports. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	
Laboratory Safety Standard of Practice 5 (LS S5): Occupational Exposure Response Procedures The laboratory must have standard operating procedures for responding to potential exposures to biohazardous agents or specimens. Procedure(s) must include, but not be limited to: a) the person to notify in the event of a potential exposure and/or known exposure;	The OSHA website (www.osha.gov/SLTC/bloodbornepathogens/index.html) provides information regarding OSHA's Bloodborne Pathogens standard (Title 29 of the Code of Federal Regulations 1910.1030) and details what employers must do to protect workers following occupational exposures to blood and other potentially infectious materials that may contain HIV, HBV or HCV. Laboratories are encouraged to contact their local public health laboratory following exposure to high-risk pathogens listed as

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b) requirements to cease work immediately in the laboratory area/section where the incident occurred; c) appropriate first aid measures following an exposure incident; d) provisions for confidential medical evaluation and follow-up, including consideration of post-exposure prophylaxis when medically indicated; and e) criteria for reevaluation of the laboratory's relevant biohazard risk assessment under Laboratory Safety Standard of Practice 7. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	HHS Select Agents or Overlap Select Agents in the Federal Select Agent Regulations (42 CFR Part 73 – Public Health) or any other infectious agents that meet the definition of Risk Group 3 or 4 as defined by the World Health Organization (WHO). Procedures should provide options for the employee to confidentially consult their own physician or a physician provided by the laboratory. For high-risk pathogens, the laboratory should consider identifying in advance medical experts for consultation.
Laboratory Safety Standard of Practice 6 (LS S6): Chemical Hygiene Plan The laboratory must develop, where required, a Chemical Hygiene Plan (CHP) that defines the safety policies and procedures for all chemicals used in the laboratory according to the Occupational Safety and Health Administration's (OSHA) Laboratory Standard. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	For additional information on developing a chemical hygiene plan, see OSHA's standard on Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450) and the National Research Council's 2011 publication titled *Prudent Practices in the Laboratory – Handling and Management of Chemical Hazards*. Chemical Hygiene Plan(s) may be implemented at an institutional level by a Safety Office.
Laboratory Safety Standard of Practice 7 (LS S7): Biohazard Risk Assessment The laboratory must conduct and document a biohazard risk assessment for all sections and areas of the laboratory processing biohazardous agents or specimens that must include:	This Standard is not restricted to bloodborne pathogens and includes any potentially infectious specimen or sample (e.g., urine, stool, cultures, isolates, etc.). Guidance for conducting biohazard risk assessments can be found in the reference titled *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), available from the Centers for Disease Control and Prevention (CDC).

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a) identification of biohazardous agents and specimen types handled by the laboratory; b) identification of exposure risks associated with laboratory procedures, such as aerosol-generating procedures (e.g., centrifuging, vortexing, etc.) and the use of sharps; c) determination of the appropriate biosafety level and any additional or enhanced precautions needed as indicated by the risk assessment for each section and areas of the laboratory processing biohazardous agents or specimens; and d) documentation of review, initially, after revisions and annually, by the director or director designee, as delegated in writing by the director. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	
Laboratory Safety Standard of Practice 8 (LS S8): Biohazard Risk Management The laboratory must have standard operating procedures and/or policies for controlling biohazard risk for all areas with affected test processes. The procedures must be consistent with the biohazard risk assessment required under Laboratory Safety Standard of Practice 7. These policies and procedures must describe appropriate safe work practices, personal protective equipment (PPE), and safety equipment necessary to control exposure risks and to comply with local, state and federal regulations on occupational exposure to biohazardous	A written Exposure Control Plan (ECP) is required, where applicable, under OSHA's bloodborne pathogen standard (29CFR 1910.1030). Exposure control plan(s) may be implemented at an institutional level. A written biosafety plan or standard operating procedures shall be developed to describe control measures for other biohazards and exposure risks not considered under the scope of the OSHA bloodborne pathogen standard, as applicable. For additional information on biosafety risk assessment and mitigation, see the Centers for Disease Control and Prevention

Laboratory Safety	
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agents and specimens, and to the institution's Exposure Control Plan (ECP) for bloodborne pathogens. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	document *Biosafety in Microbiological and Biomedical Laboratories* (BMBL).
Laboratory Safety Standard of Practice 9 (LS S9): Biohazard Warning Signs and Labels Biohazard warning labels must be affixed to containers of regulated waste, sharps disposal containers, refrigerators, freezers and other containers used to store, transport or ship biohazardous agents or specimens. Biohazard warning signs must be posted at all laboratory work areas used to store or handle biohazardous agents or specimens. Clerical or data entry stations not requiring the use of personal protective equipment (PPE) may be designated as such within posted laboratory work areas at the discretion of the laboratory director. However, these designated areas must be clearly described in plans or procedures and communicated to staff. Additionally, written procedures must be in place to prevent accidental cross-contamination of writing instruments, phones, keyboards, etc. in these clerical/data entry areas. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	For additional information, see the OSHA Bloodborne Pathogens (29 CFR 1910.1030) standard and the Centers for Disease Control and Prevention document *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). Biohazard warning signs and labels must be designed to meet the requirements of the bloodborne pathogen standard where applicable.
Laboratory Safety Standard of Practice 10 (LS S10): Personal Protective Equipment for Biohazards The laboratory director and owner must: a) provide appropriate personal protective equipment (PPE), consistent with the laboratory's biohazard risk assessment according to Laboratory Safety Standard of	PPE should be worn whenever there is a risk of contact with biohazardous agents or specimens. The type of PPE that should be utilized in a particular laboratory work area or for a particular procedure should be determined as part of the biohazard risk assessment required under Laboratory Safety Standard of Practice 7.

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Practice 7 and at no expense to the employee; b) ensure that PPE is accessible at the worksite, properly maintained and that potentially contaminated PPE is not stored in clean areas; c) provide cleaning, maintenance and/or disposal of PPE at no cost to the employee; d) ensure that PPE is removed before leaving for non-laboratory areas (e.g., restrooms, cafeteria or administrative offices); and e) ensure that respirators are used and maintained in accordance with all OSHA's Respiratory Protection standard (29 CFR 1910.134). ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	For additional information, see the OSHA Bloodborne Pathogens (29 CFR 1910.1030) standard, Personal Protective Equipment Standard (1910.132), and the Centers for Disease Control and Prevention document *Biosafety in Microbiological and Biomedical Laboratories* (BMBL).
Laboratory Safety Standard of Practice 11 (LS S11): Biological Safety Cabinets Laboratories utilizing a biological safety cabinet (BSC) must: a) test and certify the BSC functions according to manufacturer specifications*:* i. at the time of installation within the laboratory; ii. any time the BSC is moved; iii. at least annually thereafter; and b) have a standard operating procedure to verify and document the BSC is functioning properly prior to each day of use; c) have a documented procedure for decontamination of	Biological Safety Cabinet selection and installation should be determined based on the laboratory's biohazard risk assessment required under Laboratory Safety Standard of Practice 7.

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the BSC with an appropriate disinfectant: i. before and after each use; ii. immediately following contamination (e.g., spill or splash of a biological material or hazardous chemical); and d) train and document the training of staff in the use of a BSC, as applicable, as part of initial employee training and annually thereafter. Training records must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	
Laboratory Safety Standard of Practice 12 (LS S12): Sharps The laboratory must have standard operating procedures and/or policies for the safe handling of sharps. The procedure or policy must include, but not be limited to: a) the laboratory's criteria for accepting or rejecting specimens that include needles; b) prohibiting recapping of needles or removing needles from syringes or other devices, unless it can be demonstrated that no alternative is feasible or that such action is required by a specific procedure; c) prohibiting disposable needles from being bent, sheared, broken or otherwise manipulated by hand; d) requirements that sharps are placed in a puncture-proof, leak-proof container for disposal;	The sharps procedure may be included in the Exposure Control Plan (ECP), as required by OSHA's Blood Borne Pathogens standard. The laboratory should annually evaluate their use of safe needle devices and adopt newer technologies, when applicable, according to the Needlestick Safety and Prevention Act.

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e) provisions for adopting improved engineering and work practice controls that reduce the risk of sharps injuries whenever practical; and f) provisions to ensure that training is conducted and documented on the use of sharps, as applicable, as part of initial employee training and annually thereafter. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	
Laboratory Safety Standard of Practice 13 (LS S13): Decontamination Procedures The laboratory must have standard operating procedures and/or policies for the cleaning and/or decontamination of work surfaces, instruments and/or equipment. The procedures must include: a) the frequency of cleaning and decontamination; b) appropriate cleaning products and/or disinfectants; and c) provisions for cleaning/decontamination and warning labels, as needed, prior to servicing and/or shipping. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	When using household bleach (5.25% sodium hypochlorite), it is recommended that 1:10 dilutions be prepared daily.
Laboratory Safety Standard of Practice 14 (LS S14): Food Storage Food and drink must be stored outside of laboratory work areas. Areas where food and drink are stored must be designated for this purpose. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	

Laboratory Safety	
Standard	***Guidance***
Laboratory Safety Standard of Practice 15 (LS S15): Laboratory Facilities – Biohazards and Chemical Hazards Laboratory facilities must be appropriately designed for biohazards and chemical hazards. The laboratory design must include: a) for biohazards, a design consistent with biosafety level(s) assigned and documented in the biohazard risk assessment under Laboratory Safety Standard of Practice 7, including: i. a sink for handwashing located in the laboratory that may be manually, hands-free, or automatically operated or other adequate hand washing facilities; ii. flooring and furniture that can be cleaned and decontaminated; iii. work surfaces that are impervious to liquids and resistant to moderate heat and the chemicals used for cleaning and decontamination; and iv. emergency eyewash equipment that is readily available and routinely tested in accordance with institutional policies, where required. b) for chemical hazards, a design and ventilation necessary for minimizing the potential for employee exposure to hazardous chemicals and as described in the Chemical Hygiene Plan required under Laboratory Safety Standard of Practice 6, including:	a) The OSHA website (www.osha.gov/SLTC/bloodbornepathogens/index.html) provides information regarding OSHA's Bloodborne Pathogens standard (Title 29 of the Code of Federal Regulations 1910.1030) and details what employers must do to protect workers with occupational exposure to blood and other potentially infectious materials that may contain HIV, HBV or HCV. a) For additional information on laboratory design for biohazards, see the Centers for Disease Control and Prevention document *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). b) The laboratory should have proper ventilation systems to rid the area of fumes created from hazardous material. OSHA limits for any hazardous chemicals, such as formaldehyde or xylene, should not be exceeded. b) For additional information on laboratory design and ventilation for working with hazardous chemicals, see the

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i. a sink for handwashing located in the laboratory that may be manual, hands-free, or automatically operated or other adequate hand washing facilities; ii. chemically resistant and impermeable flooring; iii. work surfaces that are chemically resistant, smooth, and can be cleaned; iv. emergency eyewash equipment or shower, that is properly functioning and routinely tested according to institutional policies, within the work area for immediate use when an employee could be exposed to injurious corrosive chemicals; and v. local exhaust ventilation devices (e.g., chemical fume hoods) appropriate to the materials and operations in the laboratory. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	National Research Council's 2011 publication titled *Prudent Practices in the Laboratory – Handling and Management of Chemical Hazards*. For additional information on recommended testing and maintenance of emergency eyewashes and safety showers, see the American National Standards Institute's (ANSI) consensus standard Z358.1 – 2014 *Emergency Eyewash and Shower Equipment*.
Laboratory Safety Standard of Practice 16 (LS S16): Packaging and Shipping Requirements The laboratory director must have policies that ensure compliance with all applicable local, state and federal laws, regulations and requirements for the packaging and shipping of hazardous chemicals and/or infectious substances. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	The laboratory must review applicable Department of Transportation (DOT), United States Postal Service (USPS), and International Air Transport Association (IATA) requirements, as well as requirements that may be in place by a commercial transporter. U.S. Federal regulations require training for the transport of hazardous materials every three (3) years, regardless of the mode of transportation. For transport of hazardous materials by air, both domestic and international, aviation transport associations and international regulations require training every two (2) years.

Laboratory Safety	
Standard	***Guidance***
Laboratory Safety Standard of Practice 17 (LS S17): Regulated Medical Waste Management The laboratory director and owner must ensure compliance with all applicable local, state and federal laws, regulations and requirements for the disposal of regulated medical waste. All laboratories must develop, document and implement standard operating procedures and/or policies specific to the management of regulated medical waste (RMW) generated on-site and/or treated at the facility. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(11)***	Laboratories located in New York State must comply with statutory requirements for storage, treatment and disposal of Regulated Medical Waste (RMW) as cited in 6 NYCRR IV.B.360,365 (DEC) and 10 NYCRR II.I.70 (DOH).

Laboratory Information Systems

Laboratory Information Systems	
Standard	***Guidance***
Laboratory Information Systems Fundamental Standard of Practice (LIS FS) The laboratory must have a system that manages information necessary to receive and track specimens, and report results. The information must be accurate, complete, and readily accessible. The system(s) may be manual, electronic, or a combination. All information must be retained as described in Document and Specimen Retention Standards of Practice. ***Statutory authority: Article 5, Title 5 Public Health Law Sections 575(2) and (3)***	
Laboratory Information Systems Standard of Practice 1 (LIS S1): Information System Accuracy and Reliability The laboratory must have adequate manual or electronic systems in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry, whether interfaced or entered manually, to final report destination, in a timely manner. Test results and other applicable laboratory information system (LIS) information must be archived and retained according to Document and Specimen Retention Standard of Practice 4. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c)***	

Laboratory Information Systems	
Standard	***Guidance***
Laboratory Information Systems Standard of Practice 2 (LIS S2): Laboratory Information Systems Standard Operating Procedure The laboratory must have standard operating procedures for laboratory information systems (LIS) that include: a) quality goals and performance expectations for the LIS, as described in the laboratory's Quality Management System (QMS); b) protection of personally identifiable information and protected health information; c) facility design requirements for proper system function, such as power protection; d) approval of procedures and LIS changes, as delegated in writing by the laboratory director; e) authorization for staff access and protection from unauthorized access; f) initial validation of system components and as required for changes; g) documentation of verification; h) requirements and documentation for maintenance; i) mechanism to ensure that previous data is retrievable when the LIS is upgraded or replaced; j) requirements for tracking and audit trails; and k) steps to be followed if the system is not functioning. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c)***	Explicit written policies that specify staff access, by job title, to the laboratory computer systems must be described and include how the access is obtained, maintained and inactivated. a) Examples of quality goals and performance expectations for an LIS may include accurate recording and transmission of data, protections against the loss of data and back-up systems for data, protection of confidential information, and timely reporting.

Laboratory Information Systems	
Standard	***Guidance***
Laboratory Information Systems Standard of Practice 3 (LIS S3): Laboratory Information System Training The laboratory must have standard operating procedures that instruct staff on the use of laboratory information systems (LIS) as it relates to laboratory services. All appropriate staff must be trained on use of the LIS, including necessary retraining as determined by the director, after any LIS modification. Training documentation must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c)***	
Laboratory Information Systems Standard of Practice 4 (LIS S4): Transcription Accuracy The laboratory must have a system to ensure that any manually transcribed information, including test request information and/or test results, or electronically interfaced request information and/or results, are accurately transcribed. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c)***	The laboratory must have ongoing mechanisms, such as double-keying or supervisory review, to ensure the accuracy of manual entries by testing and non-testing personnel into the LIS. The laboratory director must define the periodicity of any supervisory review. Data-entry personnel must be trained and competency assessed as specified under the Human Resources section of these standards.
Laboratory Information Systems Standard of Practice 5 (LIS S5): Calculation and Algorithm Verification Calculations, analyses and algorithms used for testing and reporting, and any changes to them, must be verified before initial use for specimen reporting, including: a) calculations performed during the test process; b) autoverification and/or autorelease;	Algorithms capable of learning should be verified using independent training and test data sets and should not be altered other than through a formal change and verification process. Autoverification should include an acceptable range of outcomes.

Laboratory Information Systems	
Standard	***Guidance***
c) analysis of large and/or complex data sets (e.g., next generation sequencing (NGS)); d) algorithms that incorporate results from multiple tests or data types to determine a risk score or other interpretation; and e) algorithms capable of learning. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c)***	
Laboratory Information Systems Standard of Practice 6 (LIS S6): Systems Failure The laboratory must have policies to ensure that: a) electronic data are backed up at a frequency that minimizes the risk of data loss; b) systems are in place to ensure data integrity and timely reporting of results if the laboratory information system (LIS) is out of service; and c) data are retrievable within twenty-four (24) hours. ***Regulatory authority: 10 NYCRR subdivisions 58-1.2(c) and 58-1.11(c)***	Timely reporting should be appropriate to the clinical need of the test results. Hospitals that offer emergency room or acute care should have a manual system that can be in place within minutes. This standard applies to on-site and remote data storage.

Resource Management

Resource Management	
Standard	***Guidance***
Resource Management Fundamental Standard of Practice (RM FS) The laboratory director and owner are jointly and separately responsible for resource management. Specifications established by the laboratory's Quality Management System (QMS) for resources and resource management must be met and comply with the New York State Clinical Laboratory Standards of Practice. The laboratory must have facilities, materials, equipment and instruments to provide appropriate services as required under Facility Design Standard of Practice 1. The laboratory must have a continuity of operations plan to describe laboratory testing services or alternative arrangements during a disaster or other emergency. ***Statutory authority: Article 5, Title 5 Public Health Law Sections 575(2) and (3)***	
General Resource Management	
General Resource Management Standard of Practice 1 (GRM S1): Continuity of Operations Plan The laboratory must have standard operating procedures and/or policies to provide services in the event of a natural, intentional, or unintentional event that impairs operations. The standard operating procedures and/or policies must include:	A plan for continuity of operations may address internal and external events, such as electrical/heating/AC failures, fire, natural disasters (e.g. ice storm, earthquake), and terrorist events.

Resource Management	
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a) contact numbers for key staff and their roles in an emergency/unexpected event; b) arrangements for communication with clients regarding the status of laboratory services; and c) pre-established arrangements for long-term storage of specimens and/or use of reference and contract laboratories to test critical specimens. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(2) and subdivision 58-1.10(g)***	
General Resource Management Standard of Practice 2 (GRM S2): Testing Supplies The laboratory must have systems to ensure that supplies required for generating test results are available. Failure to have testing supplies available when needed must be regarded as a nonconforming event according to Investigation and Corrective Action Standard of Practice 3 and investigated according to Investigation and Corrective Action Standard of Practice 4. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Testing supplies includes all materials and supplies used in the test process (e.g., pipettes, gloves, etc.).
General Resource Management Standard of Practice 3 (GRM S3): Manufacturer Requirements The laboratory must use all physical resources in the laboratory according to manufacturer instructions and/or requirements. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	This standard applies to physical resources and assets including biological safety cabinets (BSC), fume hoods, etc.

Resource Management	
Standard	***Guidance***
General Resource Management Standard of Practice 4 (GRM S4): Verification – General Requirement The laboratory must verify and document the suitability of consumable materials, including acceptance and rejection criteria, that affect the quality and/or timeliness of test results. The laboratory must: a) document prior to use for patient testing, that all consumable materials used in testing meet manufacturer or laboratory specifications; b) maintain documents that include manufacturer instructions and communications related to material quality (e.g., manufacturer or vendor recall); and c) discontinue use of any material that fails to meet specifications and document actions taken. Performance verification requirements for equipment and instruments are provided in Laboratory Equipment and Instrument Standard of Practice 3. Verification of reagents and media must comply with Reagents and Media Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g) and section 58-1.6***	Documentation must include the signature of the person determining acceptability and date that acceptability was determined. Acceptability may be accomplished by examining quality control samples and verifying that results are acceptable, provided the quality control challenge is designed appropriately to be sensitive to substandard equipment or supplies quality.

Resource Management	
Standard	***Guidance***
General Resource Management Standard of Practice 5 (GRM S5): Support Material Verification Laboratories that use testing materials and/or equipment and instruments outside of their control must ensure that initial and ongoing verifications are performed. ***Regulatory authority: 10 NYCRR section 58-1.6***	The laboratory is responsible for ensuring that all requirements for equipment and instruments, such as preventive maintenance and calibration, are met. Examples include borrowed, shared, rented or leased items or use of items used in another part of the facility.
General Resource Management Standard of Practice 6 (GRM S6): Expired Supplies The laboratory must: a) not use expired materials for testing unless the manufacturer has provided written authorization to do so; and b) not conduct its own validation studies to extend the shelf life of purchased reagents or other materials that have a manufacturer-stated expiration date. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Performance verification requirements for equipment that can be reverified (e.g., thermometers, pipettes, timers, hygrometer etc.) are provided in Laboratory Equipment and Instrument Standard of Practice 3. For consumables provided without a manufacturer expiration date, the laboratory director must determine the expiration date with empirical data, when possible. Manufacturers may recommend expiration dates that are adopted by the laboratory following director approval. Expired items may be used for training, research or student use. These materials must be clearly labeled as for "Educational use only" or similar wording and be stored separately from materials used and verified for clinical testing. For panel cells, follow manufacture instructions.

Resource Management	
Standard	***Guidance***
General Resource Management Standard of Practice 7 (GRM S7): Computer Systems Security The laboratory must have systems and protocols to ensure the integrity of computer systems from internal and external threats. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Laboratory Equipment and Instrument	
Laboratory Equipment and Instrument Standard of Practice 1 (LEI S1): Hardware and Software Settings The laboratory must have policies to ensure that unintended modifications are not made to laboratory equipment and/or instruments, both hardware and software, that would invalidate test results. After maintenance, the laboratory must ensure that hardware and software settings are returned to testing conditions. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Laboratory Equipment and Instrument Standard of Practice 2 (LEI S2): Instrument and Equipment Records For equipment and instruments, laboratories must maintain documentation of: a) the serial number or unique identifier and, if applicable, version number; and b) date(s) of:	Records related to testing equipment and instruments must be made available to the Department upon request.

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Standard	***Guidance***
i. initial calibration, certification and/or performance verifications; ii. placement into service; and iii. required recertification or performance verifications, as applicable. The laboratory must have a system to trace reported results to the instruments used to produce a specific test result. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Laboratory Equipment and Instrument Standard of Practice 3 (LEI S3): Function Checks and Performance Verification of Instruments, Equipment and Test Systems The laboratory must have standard operating procedures and/or policies to perform function checks and to verify performance of equipment, instruments and/or test systems. The laboratory must document or retain electronic records of function checks and performance verification results. Function checks and performance verifications must: a) meet manufacturer and laboratory established performance specifications; and b) be performed: i. prior to specimen testing and at least annually; ii. following service, repairs and/or updates; and iii. at a frequency defined by the manufacturer instructions; or iv. in the absence of manufacturer instructions, at a	The laboratory may have the manufacturer perform function checks and/or performance verifications. The laboratory must establish and/or verify performance specifications prior to use for reporting patient specimens and ensure that performance specifications are maintained. The laboratory may use manufacturer's instructions, operator's manuals, or other recommendations or may establish more rigorous criteria. For example, increased frequency of pipettor performance verification may be necessary based on the volumes of liquids being delivered, the frequency of use, and/or the viscosity of the liquids being handled. For a laboratory developed test (LDT), function check and performance verification criteria and frequency may be established according to Test Performance Specification Standard of Practice 2. For immunohematology, quarterly performance verification of revolutions per minute (RPM) and timer checks of centrifuges is required under Immunohematology Standard of Practice 6. For additional requirements in the category of immunohematology,

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frequency established by the laboratory to provide accurate and reliable test results. ***Regulatory authority: 10 NYCRR section 58-1.6***	please see section 10 NYCRR 58-2 at: https://www.wadsworth.org/regulatory/clep/laws.
Laboratory Equipment and Instrument Standard of Practice 4 (LEI S4): Performance Verification After Relocation After moving equipment and/or instruments that are not intended to be portable, the laboratory must document acceptable performance verification, function checks and/or analysis of quality control materials prior to specimen testing. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Laboratory Equipment and Instrument Standard of Practice 5 (LEI S5): Instruction for Maintenance and Preventive Maintenance The laboratory must have standard operating procedures and/or policies for the maintenance and preventive maintenance of equipment and instruments that are readily available to laboratory staff. ***Regulatory authority: 10 NYCRR section 58-1.6***	The standard operating procedures and/or policies may refer to the use of up-to-date relevant manufacturer provided manuals and directions for instructions on the maintenance and use of equipment/instruments.
Laboratory Equipment and Instrument Standard of Practice 6 (LEI S6): Maintenance and Preventive Maintenance Records The laboratory must perform and document maintenance for all equipment and instruments used for specimen testing and reporting.	Records must include copies of reports/certificates of all calibrations and/or verifications including dates, times, and results, adjustments, the acceptance criteria, and due date of the next calibration and/or verification.

Resource Management	
Standard	***Guidance***
Documentation must include: a) all scheduled maintenance and preventive maintenance records; b) instances and outcomes of damage, malfunctions, modifications and/or repairs; and c) dates of maintenance. ***Regulatory authority: 10 NYCRR section 58-1.6***	
Laboratory Equipment and Instrument Standard of Practice 7 (LEI S7): Managing Defective Equipment and Instruments For defective equipment and/or instruments, the laboratory must: a) clearly label the equipment or instrument as being out of service; b) document and investigate the nonconformance according to Investigation and Corrective Action Standards of Practice 3 and 4; c) examine and document the effect on specimen test results; and d) ensure that repaired or serviced equipment and instruments meet manufacturer or laboratory defined performance specifications through calibration, performance verification and/or function checks, as applicable, before being used for reporting test results. ***Regulatory authority: 10 NYCRR section 58-1.6***	

Resource Management	
Standard	***Guidance***
Laboratory Equipment and Instrument Standard of Practice 8 (LEI S8): Carbon Dioxide Incubators The laboratory must measure and document carbon dioxide (CO2) in CO2 incubators to be within a range that is appropriate for the testing performed. For incubators without a measurement system: • measure levels daily using an outside CO_2 measurement device (e.g., electronic CO_2 analyzer); or For incubators with a measurement system: • validate CO_2 levels monthly using a separate measurement device. ***Regulatory authority: 10 NYCRR section 58-1.6***	If the CO_2 incubators have an automatic CO_2 readout, the CO_2 level does not need to be tested daily with an electronic CO_2 analyzer.
Laboratory Equipment and Instrument Standard of Practice 9 (LEI S9): Thermal Cyclers and Polymerase Chain Reaction For procedures using a thermal cycler, the laboratory must: a) operate the thermal cycler per the test kit manufacturer's instructions; and b) verify the uniformity of temperature across all sample chambers at inception, annually, and after servicing. ***Regulatory authority: 10 NYCRR section 58-1.6***	b) Verification should include monitoring of temperature ramping rates where applicable. Verification may be performed indirectly by following manufacturer instructions or rotating a low positive control across every well, over time, or an electronic check for temperature homogeneity.

Resource Management	
Standard	***Guidance***
Reagents and Media	
Reagent and Media Standard of Practice 1 (RGM S1): Reagent and Media Records The laboratory must have an inventory control system for reagents and media that documents, at a minimum, the: a) lot number; b) date of receipt in the laboratory; c) date of acceptable performance verification(s); d) date(s): i. for reagents, when they are placed into service; or ii. for media, a mechanism that can identify specimens affected should the media be contaminated; and e) expiration date. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Reagent and media documentation must be made available to the Department upon request. Inventory control should ensure that the laboratory has sufficient reagents to verify new lots and shipments.
Reagents and Media Standard of Practice 2 (RGM S2): Verification of Reagents and Media – Control Procedures The laboratory must follow the manufacturer instructions for using reagents, media and supplies. In addition, unless more stringent requirements are specified elsewhere in the New York State Clinical Laboratory Standard of Practice, the laboratory must:	The laboratory must establish and/or verify performance specifications prior to use for reporting patient specimens and ensure that performance specifications are maintained. Verification may be accomplished by examining quality control samples and verifying that results are acceptable, provided the quality control challenge is designed appropriately to be sensitive to substandard equipment or supplies quality.

Resource Management	
Standard	***Guidance***
a) check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, and identification systems (systems using two (2) or more substrates or two (2) or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable; b) each day of use, test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate; c) check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use; d) before, or concurrent with the initial use: i. check each batch of media for sterility if sterility is required for testing; ii. check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and iii. document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Antibody identification cell panels must be used according to manufacturer instruction.

Resource Management	
Standard	***Guidance***
Reagents and Media Standard of Practice 3 (RGM S3): Labeling The laboratory must label all reagents and media, as applicable, with the: a) identity; b) titer, strength or concentration; c) storage conditions; d) in-house preparation date or date opened; e) identity of the person who prepared or opened the material; f) expiration date and expiration after opening, if pertinent to the performance of the reagent; and g) any additional relevant information. If a container cannot be directly labeled due limitations of the container (e.g., for tubed or plated in-house prepared microbiological media), the required information may be recorded in a manual or electronic tracking system, provided that each container is traceable to an individual entry in the tracking system. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Reagents and Media Standard of Practice 4 (RGM S4): Kit Components The laboratory must not interchange components of reagent kits of different lot numbers unless: a) specified by the manufacturer; or	

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Standard	***Guidance***
b) established and documented by the laboratory to meet test performance specifications according to Test Performance Specification Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Reagents and Media Standard of Practice 5 (RGM S5): Reagent and Media Storage For labile reagents and media that are required for testing and that do not have manufacturer storage instructions, the laboratory must establish and document storage conditions that lead to acceptable test performance. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	For temperature sensitive reagents and media, the laboratory must follow manufacturer instructions for freeze-thaw cycles or establish its own criteria. Freeze-thaw cycles must be documented where applicable.

Document Control

Document Control	
Standard	***Guidance***
Document Control Fundamental Standard of Practice (DC FS) All standard operating procedures, policies, instructions, programs, plans and manuals, and any other documents as indicated in any part of the New York State Clinical Laboratory Standards of Practice, must be maintained by the laboratory under conditions of document control. ***Statutory authority: Article 5, Title 5 Public Health Law Sections 575(2) and (3)***	
Document Control Standard of Practice 1 (DC S1): Availability All standard operating procedures, policies, instructions, programs, plans and manuals, and any other documents as indicated in any part of the New York State Clinical Laboratory Standards of Practice must be: a) under document control; b) in a standardized format with a system of numbering and/or titling of each procedure; c) current and accurate; and d) available and accessible at all times in applicable work area(s). ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Electronic procedures must be accessible to all relevant staff at all times. Backup systems are required to ensure accessibility if electronic procedures are not available.

Document Control	
Standard	***Guidance***
Document Control Standard of Practice 2 (DC S2): Compliance Laboratory staff must follow all standard operating procedures and other laboratory documents that are under document control. The laboratory must have systems established to: a) notify relevant staff of revisions; and b) provide and document training for staff on procedures and other applicable documents. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Document Control Standard of Practice 3 (DC S3): Manufacturer Instruction Manuals Current manufacturer's instructions, operator manuals, package inserts, or textbooks may be used in total or in part to meet Test Procedure Content Standards of Practice 1 and 2 or other document content requirements, provided that all relevant content requirements in any part of the New York State Clinical Laboratory Standards of Practice are fulfilled. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	All Document Control Standards of Practice apply to manufacturer instructions, operator manuals, package inserts, and/or or textbooks, etc., used in total or in part of the Test Procedure, including director approval.
Document Control Standard of Practice 4 (DC S4): Procedure Excerpts In addition to complete standard operating procedures, policies, instructions, programs, plans and/or manuals, excerpts that summarize key information may be used by laboratory staff, provided:	Procedure excerpts may also be referred to as job aides, training notes, and/or procedural subsections.

Document Control	
Standard	***Guidance***
a) the director, assistant director(s) or supervisor qualified staff reviews the excerpts at least every two (2) years and this review is documented; and b) the content provided by the excerpt does not contradict the corresponding document. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Document Control Standard of Practice 5 (DC S5): Director Approval The director or sole assistant director designated for a category must sign and date each new or revised test procedure before it is used for reporting patient test results. Approval of new and revised test procedures, as indicated by signature and date, may not be delegated by the director or sole assistant director. Test procedure review, at a minimum every two (2) years, is required by the director. This duty may be delegated in writing to an assistant director holding an appropriate certificate of qualification or an individual qualified as a laboratory supervisor. For controlled documents not related to testing, an individual may be delegated by the laboratory director, as specified in writing, to approve, sign and review documents as indicated in the New York State Clinical Laboratory Standards of Practice. ***Regulatory authority: 10 NYCRR subdivisions 58-1.2(c) and 58-1.10(g)***	Non-testing documents may include safety policies and procedures, computer system specifications and/or maintenance instructions. This standard is applicable to laboratory developed tests (LDTs), as well as manufacturer instruction manuals adopted in lieu of laboratory-specific test procedures, standard operating procedures and/or excerpts. In the case of a change in the laboratory director or sole assistant director, all test procedures should be reviewed and signed by the new director and/or sole assistant director as soon as possible. If not done immediately, the laboratory should have a plan for having the review completed and documented within an appropriate timeframe, not to exceed six (6) months. Electronic signature, or an alternative system, may be substituted for hard copy, as long as it is a password protected signature. Blood banks are required to follow the requirements in 10 NYCRR section 58-2.8 for annual review by the director or authorized supervisor.

Document Control	
Standard	***Guidance***
Document Control Standard of Practice 6 (DC S6): Controlled Document Archival The laboratory must have a system to: a) maintain and archive a copy of each revised document under document control, with the dates of use and discontinuation; and b) retain these records, if required, according to Document and Specimen Retention Standards of Practice. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	This activity is a critical element of document control whereby test reports can be readily associated with test procedures in place at the time a specific specimen was analyzed.

Pre-Analytic Systems

Pre-Analytic Systems	
Standard	***Guidance***
Pre-Analytic Systems Fundamental Standard of Practice (PRS FS) The laboratory is responsible for establishing and maintaining the: a) integrity of specimen identification; b) stability of specimens; and c) completeness and accuracy of information essential to the interpretation and reporting of test results. ***Statutory authority: Article 5, Title 5 Public Health Law Sections 575(2) and (3)***	
Test Request	
Test Request Standard of Practice 1 (TR S1): Specimen Testing All specimens must be received with a test request form or electronic equivalent from persons authorized by law to order testing. Only a New York State permitted clinical laboratory can accept specimens for testing. ***Regulatory authority: 10 NYCRR subdivisions 58-1.7(a) and (b)***	This Standard does not prohibit the acceptance of specimens for teaching or research purposes and does not apply to other entities specifically exempted under Article 5, Title 5 of the Public Health Law.

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Standard	***Guidance***
Test Request Standard of Practice 2 (TR S2): Verbal Test Request Following a verbal test request, persons authorized by law must submit a written or electronic request within forty-eight (48) hours. The laboratory must document efforts to obtain the test request. ***Regulatory authority: 10 NYCRR paragraph 58-1.7(b)(1)***	
Test Request Standard of Practice 3 (TR S3): Test Request Form The test request form, or an electronic equivalent, must have space for the following information, including but not limited to: a) patient's name or unique identifier; b) gender and age or date of birth of the patient; c) ordering and report release information, including: i. name or unique identifier of the physician or authorized ordering source; or ii. if appropriate, the individual responsible for using the test results; or iii. the name and address of the laboratory submitting the specimen for testing; and iv. as applicable, a contact person to enable the reporting of imminently life-threatening results or panic or alert values; and d) type of primary specimen and the anatomic site of origin, where appropriate;	

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Standard	***Guidance***
e) test(s) requested; f) date and, when required, time of primary specimen collection; g) date and time of receipt of specimens by the laboratory; h) for Pap smears, the patient's date of onset of last menstrual period, age, previous abnormal cytology, and previous significant history; and i) any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. A patient's chart or medical record may be used as the test request or authorization, provided it includes all the information indicated above and is available for review by the Department. Test request records must be maintained in accordance with Document and Specimen Retention Standard of Practice 7. ***Regulatory authority: 10 NYCRR section 58-1.10***	
Test Request Standard of Practice 4 (TR S4): Urgent Test Request The laboratory must have standard operating procedures and/or policies for the receipt, labeling, processing, and reporting of specimens that are marked as urgent or STAT. The procedure must include instructions for reporting critical and alert values. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	

Pre-Analytic Systems	
Standard	***Guidance***
Specimen Processing	
Specimen Processing Standard of Practice 1 (SP S1): Specimen Submission Instructions The laboratory must have current and accurate instructions for specimen identification, collection, handling and transportation for all tests offered by the laboratory. The laboratory must make the instructions available to those responsible for test ordering, and specimen collection and handling. The specimen submission instructions must include, if applicable to the test(s) offered: a) copies of or references to: i. lists of available laboratory tests offered; ii. consent forms; iii. information and instructions provided to patients for preparations before specimen collection; iv. information for users of laboratory services that includes the test method, testing algorithms and medical indications for the selection of available tests; and b) requirements for: i. identification and preparation of the patient for specimen collection (e.g., instructions to caregivers and phlebotomists); ii. primary specimen collection with descriptions of the specimen containers, order in which blood specimens are to be drawn, any necessary	For blood bank specimen requirements see 10 NYCRR section 58-2.

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Standard	***Guidance***
additives, and storage; and c) instructions for: i. completion of test request form or electronic request; ii. the type and amount of specimen to be collected; iii. special timing of collection; iv. any special handling needs between time of collection and time received by the laboratory (e.g., transport requirements, refrigeration, warming, immediate delivery, etc.); v. labeling of primary specimens with at least two unique identifiers, and where appropriate, specimen source; vi. requirements for clinical information (e.g., history of administration of drugs, gestational age, etc.); vii. the positive identification of the patient by the specimen collector; viii. specimen processing at the collection site (e.g., centrifugation, serum separation, aliquoting, freezing, etc.); ix. recording the identity of the person collecting the primary specimen; x. safe disposal of materials used in collection; and xi. chain of custody requirements including guidelines for the packaging of specimens in a	

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Standard	***Guidance***
tamper-evident manner. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Specimen Processing Standard of Practice 2 (SP S2): Monitoring Specimen Submissions The laboratory director, or individual that is delegated in writing by the director, must monitor, document and take appropriate action when specimens received do not comply with the laboratory's specimen submission instructions. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Examples of actions to be taken by the laboratory may include notification to submitters detailing problems observed, clarification of submission instructions, and/or training for submitters.
Specimen Processing Standard of Practice 3 (SP S3): Client Requests for Test Information The laboratory must make available to clients a list of test methods used by the laboratory and, as applicable, the performance specifications of these methods. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. The laboratory must update this information with any changes that affect test results or their interpretation. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(1) and subdivision 58-1.10(g)***	Interpretative statements made on reports that recommend therapeutic intervention or provide a clinical characterization of the patient must be supported by the intended use as indicated in the package insert (for FDA cleared methods) or must be supported by validation studies and receive approval for a laboratory developed test (LDT) from the Department (see Test Performance Specifications Standard of Practice 2). Information on Departmental approval of a laboratory developed test (LDT) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval. Literature references alone are not sufficient to document clinical validity. Laboratories that use FDA-cleared kits and reagents and report interpretative statements that are not supported by the intended use of the assay will be considered to have modified the assay and will be required to submit validation data that supports the interpretation.

Pre-Analytic Systems	
Standard	***Guidance***
Specimen Processing Standard of Practice 4 (SP S4): Acceptance and Rejection Procedure The laboratory must have a standard operating procedure for the acceptance and rejection of specimens. The laboratory must document the reason(s) for rejecting a specimen and notify the specimen submitter. The procedure must describe criteria for rejecting specimens, including: a) evidence that the specimen is unsatisfactory for testing or that it is inappropriate for the test requested; b) evidence of improper collection, labeling, preservation, handling or other conditions that make the specimen unsatisfactory or unreliable for testing; c) rejection of a specimen if the time between collection and receipt in the laboratory has exceeded requirements; and d) the date and, when required, the time of collection is not recorded on the test request. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(e)***	The laboratory may elect to analyze irreplaceable or critical specimens. If information is missing for irreplaceable or critical specimens, the laboratory may choose to hold results until the requesting physician, or person responsible for specimen collection, provides the proper information. For corrections, the submitter must attest to the accuracy of the changes, and documentation of the change must be recorded by the laboratory. Documentation of the change must be traceable to the specimen. If compromised specimens are tested, the final report must indicate the nature of the problem and, if applicable, that caution is required when interpreting the result, according to Reporting Standard of Practice 2.
Specimen Processing Standard of Practice 5 (SP S5): Accession Procedure and Documentation The laboratory must have a standard operating procedure to receive and document all specimens in an accession book, worksheet, electronic or other comparable system.	

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Standard	***Guidance***
Documentation must include: a) the unique accession number or other unique identifier for the specimen; b) the name or other identifier for the patient; c) the date and time the specimen was received in the laboratory; d) the test(s) requested; e) written or electronic documentation of verbal test requests and communication with the authorized ordering source to obtain a written test request; f) in the event a specimen is forwarded to a reference laboratory for testing: i. the name of the laboratory; ii. the date the specimen was sent to a reference laboratory for testing; iii. the date the specimen result(s) were reported; and g) a brief description of the condition in which unsatisfactory specimens were received (e.g., broken, leaked, hemolyzed, turbid, etc.). ***Regulatory authority: 10 NYCRR paragraph 58-1.11(b)(1)***	

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Standard	***Guidance***
Specimen Processing Standard of Practice 6 (SP S6): Specimen Transport The laboratory must monitor that specimens have been transported to the laboratory: a) within the time frame required to achieve reliable test result; b) within a temperature range specified in the specimen submission instructions and, where applicable, appropriate preservatives or protections (e.g., protected from light); and c) in a manner that ensures safety and complies with all local, state and federal transport requirements. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(d)***	
Specimen Processing Standard of Practice 7 (SP S7): Portion or Aliquot Identification and Integrity Specimen portions or aliquots must be traceable to the original specimen. Standard operating procedures for the preparation and handling of specimen portions or aliquots must describe measures to prevent the cross-contamination of primary and specimen portions as required under Test Procedure Content Standard of Practice 1. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	

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Standard	***Guidance***
Specimen Processing Standard of Practice 8 (SP S8): Specimen Storage Specimens must be stored at conditions that ensure stability. Appropriate conditions must be maintained, even during temporary storage, and allow for additional testing. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g) and paragraph 58-1.11(d)(1)***	
Reference and Contract Laboratories	
Reference and Contract Laboratory Standard of Practice 1 (RCL S1): Reference Laboratory Selection and Use The laboratory must have a standard operating procedure for selecting and using reference and/or contract laboratories, including any secondary reference laboratories used by a primary reference laboratory. It is the responsibility of the director and owner to select and use only reference and/or contract laboratories that: a) hold valid New York State permit(s) in the category of testing and any required test approvals; b) use appropriate methods for the requested testing; and c) have the capacity and resources to meet clinical and/or contractual requirements. ***Regulatory authority: 10 NYCRR subdivisions 58-1.1(b) and 58-1.10(g)***	

Pre-Analytic Systems	
Standard	***Guidance***
Reference and Contract Laboratory Standard of Practice 2 (RCL S2): Registry of Reference and Contract Laboratories The laboratory must maintain a list of all: a) reference and/or contracted laboratories that it uses; and b) specimens that have been sent to another laboratory. The name and address of the laboratory responsible for the testing and result must be provided to users of laboratory services. ***Regulatory authority: 10 NYCRR subparagraph 58-1.11(b)(1)(vi)***	Documentation that the reference or contract laboratory is permitted should be included with the list.
Reference and Contract Laboratory Standard of Practice 3 (RCL S3): Performance Assessment of Reference and Contract Laboratories Laboratories must have a standard operating procedure to evaluate and document the performance of reference and/or contract laboratories at regularly defined intervals. Laboratories must monitor, document and take appropriate action when reference and/or contract laboratories fail to meet specified criteria. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Action taken by the director for a reference and/or contract laboratory that does not perform acceptably includes written notification of problems encountered or cancelation of the contract.

Analytic Systems

Analytic Systems	
Standard	***Guidance***
Analytic Systems Fundamental Standard of Practice (AS FS) The laboratory must comply with Standards of Practice for Test Procedure Content, Test Performance Specifications, Calibration and Calibration Verification and Quality Control. The laboratory must have testing and supporting standard operating procedures. All procedures must accurately and completely describe all activities required for the test process and be in full compliance with requirements in the New York State Clinical Laboratory Standards of Practice. ***Statutory authority: Article 5, Title 5 Public Health Law Sections 575(2) and (3)***	
Test Procedure Content	
Test Procedure Content Standard of Practice 1 (TPC S1): Test Procedure Content For test procedures, required standard operating procedure content must include: a) implementation date for the current version of the test procedure; b) test purpose and intended use; c) analytic principle of the test;	

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d) biological, chemical and/or radiological safety; e) specimen type, acceptable container(s), and if applicable, minimum specimen quantity or volume and/or required preservative; f) requirements for patient preparation, specimen collection, labeling, storage, preservation, transportation, processing, and/or sending to a reference or contract laboratory; g) criteria for specimen acceptance and rejection that is consistent with requirements in Specimen Processing Standard of Practice 4; h) storage of residual specimens and time limits for requesting additional testing; i) required equipment, instruments and reagents; j) instrument and equipment function checks and preventive maintenance; k) test performance specifications for accuracy, precision, reportable range, and analytical sensitivity and specificity; l) environmental requirements, including as needed, the separation of incompatible activities and/or precautions to mitigate specimen contamination; m) actions to be taken if the laboratory is unable to perform any part of the testing procedure; n) steps required for testing, including, as appropriate: i. preparation of slides, solutions, calibrators, controls, reagents, stains and other materials	m) The test procedure may refer to separate policy documents.

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Standard	***Guidance***
used in testing; ii. microscopic examination, including the detection of inadequately prepared slides; iii. calibration and calibration verification procedures; iv. quality control procedures that specify acceptance and rejection criteria; v. corrective action to be taken when quality control or calibration verification fail to meet acceptability criteria; vi. calculations or evaluation criteria used to determine test results; vii. interpretation of test results; viii. confirmatory, supplemental or additional testing, if required; ix. reporting results, including imminently life-threatening results, or panic or alert values; and o) reportable range for quantitative tests; p) reference ranges, therapeutic or toxic concentrations, or other interpretive criteria as appropriate to the test; q) limitations of the test, including interfering substances when applicable; r) references to pertinent literature; and s) any laboratory policy, service or additional requirements as indicated in the New York State Clinical Laboratory Standards of Practice.	n) ix. Panic or alert value summary lists may be posted if under document control and where these values are referenced in the clinical test procedure. For results that are communicated verbally, a read back requirement should be implemented to verify results.

Analytic Systems	
Standard	***Guidance***
Testing procedures must be retained according to Document and Specimen Retention Standard of Practice 3. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Test Procedure Content Standard of Practice 2 (TPC S2): Test Procedures for Unidirectional Workflow In addition to the requirements in Test Procedure Content Standard of Practice 1, laboratories conducting target amplification must have procedures to prevent nucleic acid contamination that include: a) unidirectional workflow from pre- to postamplification; b) work area(s), personal protective equipment, and testing materials dedicated to preamplification procedures; c) work area(s), personal protective equipment, and testing materials dedicated to postamplification procedures; d) processes to prevent exposing specimens and preamplification samples to amplification products; and e) a decontamination and remediation plan to be implemented in the event of contamination. Testing procedures must be retained according to Document and Specimen Retention Standard of Practice 3. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Three (3) separate rooms are recommended for nucleic acid amplification assays. An alternative arrangement may be developed within a room where reagent preparations (e.g. mastermix set-up and template addition) are performed in distinct areas. a) does not apply to FDA-approved Closed System Amplification Tests (CSATs). Individuals performing CSATs may return to pre-amplification areas. e) the remediation plan should: define the decontamination procedure(s) to be employed; include root cause investigation, corrective action, competency assessment with retraining if necessary, and evidence supporting the adequacy of the remediation/decontamination procedures (e.g. environmental monitoring, increasing the number of negative controls per run).

Analytic Systems	
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Test Performance Specifications	
Test Performance Specification Standard of Practice 1 (TPS S1): Manufacturer Instructions The laboratory must follow manufacturer instructions for FDA approved, cleared or exempt instrument or test system operation and control. For FDA cleared, approved, or exempted methods used in accordance with package inserts, at a minimum, the laboratory must: a) **verify** performance specifications for accuracy, precision, and reportable range of test results established by the manufacturer; and, b) **establish** reference ranges, therapeutic or toxic concentrations, or other interpretive criteria as appropriate to the test. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Test Performance Specification Standard of Practice 2 (TPS S2): Laboratory Developed Tests The laboratory must establish method performance specifications before a test method is used to report specimen results. For laboratory developed tests (LDTs), modified FDA cleared, approved, or exempted tests, and modifications to standard methods (e.g., textbook methods), the laboratory must:	Information on Departmental approval of a laboratory developed test (LDT) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.

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a) **establish** performance specifications for accuracy, precision, reportable range, reference range(s), analytical sensitivity and specificity (to include interfering substances); clinical sensitivity and specificity; and other applicable performance characteristics; b) determine the acceptability of the established performance specification; and c) adhere to LDT guidelines established by the Department and submit required documents to the Department for approval. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Test Performance Specification Standard of Practice 3 (TPS S3): Documentation Method performance documentation must be available and accessible and include: a) the conclusion of the outcome of the performance specification studies, including: i. summary(ies) of data and performance specifications as determined for Test Performance Specification Standards of Practice 1 or 2; ii. an attestation that the director or individual delegated in writing by the director, has approved the test, including a signature and the approval date; and	Information on Departmental approval of a laboratory developed test (LDT) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.

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b) a letter of Department approval, if required. Documentation must be retained according to Document and Specimen Retention Standard of Practice 8. ***Regulatory authority: 10 NYCRR subdivision 58-1.11(c)(3)***	
Test Performance Specification Standard of Practice 4 (TPS S4): On-site Performance Specification Requirements The laboratory must verify that results meet performance specifications: a) at the site where testing is performed, and must be conducted by the laboratory's test staff, in addition to any on-site verification by the vendor; b) after an instrument is moved or changes testing sites; and c) if the instrument will be hand-carried or otherwise transported to the location of the specimen, the laboratory must document the portability of the system. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Mobile instruments and point-of-care devices need not be verified in every possible site under the same New York State permit.
Test Performance Specification Standard of Practice 5 (TPS S5): Comparability of Test Results A laboratory that performs the same test using different methods or instruments, and/or performs the same test at multiple test sites under the same Permanent Facility Identifier (PFI) must:	Analysis of samples from patient specimens is preferred for defining the relationship between test results. Specimens should be selected to provide full-range assessment of comparability.

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a) perform comparability studies as specified as part of the Quality Management System (QMS); b) establish acceptability criteria for comparing test results and document the outcome of the comparison; and c) compare test results semiannually at a minimum. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	a) The comparability study acceptability criteria may be detailed in the QMS or standard operating procedures.
Calibration and Calibration Verification	
Calibration Standard of Practice 1 (CAL S1): Calibration Process and Documentation The laboratory must determine, perform and document each system's calibration process for each test. The calibration process must be included in the test procedure according to Test Procedure Content Standard of Practice 1. Unless otherwise indicated in the New York State Clinical Laboratory Standards of Practice, the laboratory must perform calibration: a) according to manufacturer instructions, at a minimum, using calibration materials provided or specified by the manufacturer; or b) according to laboratory developed test (LDT) criteria as established for Test Performance Specification Standard of Practice 2: i. including the number, type and concentration of calibration materials, acceptable limits for calibration, and the frequency of calibration; and	Information on Departmental approval of a laboratory developed test (LDT) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval. Data must be provided for the Department upon request, including statistical analysis of the calibration and instrument read outs. If calibration proves less stable than the manufacturer's specification, more frequent calibration may be required. NOTE: If reagents are obtained from a manufacturer and all of the reagents for a test are packaged together, the laboratory is not required to perform calibration for each package of reagents, provided the packages of reagents are received in the same shipment and contain the same lot. For hematology cell counting instruments which have been cleared or approved by the FDA and have not been modified by the laboratory, the calibration verification requirements are considered to be met if the laboratory follows the

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ii. using calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	manufacturer's instructions for operation and runs at least two controls each day of testing.
Calibration Standard of Practice 2 (CAL S2): Periodic Calibration Verification The laboratory must periodically perform and document calibration verification procedures, minimally, according to manufacturer's instructions where provided, or according to laboratory developed test (LDT) criteria established for Test Performance Specification Standard of Practice 2, including: a) the number, type and concentration of calibration materials, acceptable limits for calibration verification and frequency; b) using calibration material appropriate for the method and, if possible, traceable to a reference method or reference material of known value; and verifying the laboratory's established reportable range of test results, which shall include at least a minimal (or zero) value, a mid-point value, and a maximum value at the upper limit of that range; and, c) at least every six (6) months, and when any of the following occur: i. a complete change of reagents for a procedure, unless the laboratory can demonstrate that the change does not affect the reportable range, and control values are not adversely affected by	Information on Departmental approval of a laboratory developed test (LDT) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval. For each quantitative test method or analytical system, the laboratory should evaluate the stability of calibration and other operating characteristics in establishing the calibration verification schedule. Additional calibration materials should be tested as unknowns to verify reportable range (upper, lower and mid-range) of test results. If the calibration is performed more frequently than six (6) months using calibrators that span the reportable range, the calibration verification requirements are met. NOTE: If reagents are obtained from a manufacturer and all of the reagents for a test are packaged together, the laboratory is not required to perform calibration verification for each package of reagents, provided the packages of reagents are received in the same shipment and contain the same lot. For hematology cell counting instruments which have been cleared or approved by the FDA and have not been modified by the laboratory, the calibration verification requirements are considered to be met if the laboratory follows the manufacturer's instructions for operation and at least two

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reagent lot number changes; ii. major preventive maintenance or replacement of parts that may influence test performance; iii. controls reflect an unusual trend or shift or are outside the laboratory's acceptable limits and no other action can correct the problem; or iv. the laboratory's procedures require more frequent calibration verification. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	controls are run each day of testing.
Quality Control	
Quality Control Standard of Practice 1 (QC S1): Minimum Quality Control Requirements Quality controls must be analyzed according to manufacturer instructions or as described below, whichever is more stringent, unless an Individualized Quality Control Plan (IQCP) is established as described in Quality Control Standards of Practice 2, 3 and 4. Category specific New York State Clinical Laboratory Standards of Practice for quality controls that are more stringent than manufacturer instructions or the requirements below must be followed and are not eligible for an IQCP. At least once each day specimens are tested, the laboratory must test quality controls as follows: a) for qualitative tests, include a positive and negative control;	Information on Departmental approval of a laboratory developed test (LDT) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval. For tests, such as certain staining procedures, for which no controls are available, the laboratory should describe in their standard operating procedure how to determine when the expected reaction is not achieved. Although a run may be defined as up to twenty-four (24) hours, a laboratory that elects to perform all quality control at a fixed time (e.g., start of the day shift) should demonstrate that the system is stable throughout the twenty-four (24) hour period.

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b) for quantitative tests, include two (2) control materials of different concentration suitable for error detection throughout the reportable range; c) for tests producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively; d) for tests that include an extraction phase, include at least one (1) control sample or material that is subjected to the same extraction process as specimens and that is capable of detecting errors in the extraction process; or e) for nucleic acid amplification methods: i. include one (1) control capable of detecting amplification inhibition by patient specimens unless the Department approved laboratory developed test (LDT) exempts the requirement; and ii. when more than one (1) outcome is possible at a locus, include a control that represents each outcome periodically. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	c) For semiquantitative tests: anti-streptolysin O titer and antihyaluronidase titer tests do not require a negative control; cold agglutination tests do not require a positive control; radial immuno-diffusion tests require one control or standard on each plate. e) Inhibition controls may be excluded if there are sufficient data showing that the inhibition rate is less than one (1) percent for a specimen type for the assay. It is possible to extend inhibition data to other analytes when applying the same extraction procedure and specimen matrix and utilizing the same amplification methodology. Inhibition controls are not required if the run includes isolates only and not patient specimens. Negative controls, including template-free mastermix controls, not only serve to identify technical and/or reagent issues, but also help identify amplicon contamination. The negative controls may include a reagent processing control that serves as both a template-free mastermix reagent control as well as a processing/extraction negative control. For laboratories preparing mastermix to be used on multiple instruments, the template-free mastermix control should be utilized for each run of each instrument. For infectious diseases molecular amplification procedures, the positive control should be of a low but detectable amount. A low-range positive is defined as having a value of not more than ten (10) fold above the assay detection limit. For multiplex

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	assays, a low range control is required for each target. These may be run on a rotating basis and may include pools of three (3) to four (4) targets.
Quality Control Standard of Practice 2 (QC S2): Individualized Quality Control Risk Assessment If the laboratory does not follow minimum quality control requirements in Quality Control Standard of Practice 1, then a risk assessment must be performed to determine if an Individualized Quality Control Plan (IQCP) may be implemented. The documented risk assessment must, at a minimum: a) identify and evaluate potential sources of error associated with the test process based on testing performed by a representative sampling of staff; b) evaluate the frequency and impact of identified errors; c) consider the potential errors that might be attributable to the following components of the test process: i. specimen (e.g., labeling, transportation, storage, etc.); ii. test system (e.g., interfering substances, equipment failure/errors, etc.); iii. reagent, quality control materials and calibrators (e.g., shipment, storage, expired materials, etc.); iv. environment (e.g., temperature, ventilation, dust, etc.); and	Additional information on IQCP requirements is available on the CMS website. The laboratory should refer to the following to conduct the risk assessment: regulatory requirements; manufacturer package insert, operator's manual, troubleshooting guide, and bulletins; laboratory-performed verification and establishment of performance specifications data; testing personnel qualifications, training and competency records; historical quality control (QC) data; proficiency testing data; historical quality assurance (QA) data; and scientific publications. In laboratories with multiple numbers of identical devices (same make and model), a single risk assessment may be performed for the test system. When identical devices are utilized in different environments/locations, the risk assessment must consider this factor and the potential need for a customized IQCP for the different sites. a) to include historical testing data or validation data performed by bona fide employees of the laboratory. c) i. the following must be considered for the specimen: patient preparation, specimen collection, labeling, storage, preservation, stability, transportation, processing, acceptability, rejection and referral. c) ii. to include function and maintenance checks, inadequate sampling, detection of interfering substances, mechanical or electronic failures, system control and function checks failures, software and/or hardware issues, transmission of

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v. staff (e.g., training, competency, staffing levels, etc.). ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	data to electronic systems including the laboratory information system (LIS) or electronic health records (EHR), and results reporting. c) iii. to include preparation, stability, variability between lots, intermixing of reagents from different lots. c) iv. to include temperature, ventilation, light intensity, noise and vibration, humidity, altitude, dust, water, utilities failure, and adequate space. c) v. to include education, licensure where required, training, competency and adequate staffing levels.
Quality Control Standard of Practice 3 (QC S3): Design of an Individualized Quality Control Plan If the laboratory chooses to perform quality control (QC) less frequently than specified in Quality Control Standard of Practice 1, the laboratory must implement an Individualized Quality Control Plan (IQCP) based on the risk assessment performed according to Quality Control Standard of Practice 2. The laboratory must establish and maintain an IQCP, as described below, for any assay chosen by the laboratory in all categories, excluding histopathology and cytopathology, that verifies the intended quality of results is achieved prior to reporting results. The IQCP must include: a) approval, including signature and date, by the laboratory director or individual delegated in writing by the director before implementation and following any revisions;	Additional information on IQCP requirements is available on the CMS website. Information on Departmental approval of a laboratory developed test (LDT) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.

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b) the process for performing QC, including: i. the number, type and frequency of control materials that must at least meet manufacturer's quality control instructions, when provided; ii. the criteria for acceptable control results and reporting of specimen data; and c) data from the laboratory to support the process for testing QC in (b) above; d) requirements for testing external QC materials with each: i. change of reagent lot number; ii. new shipment; iii. change in storage conditions; iv. replacement of a critical part; or v. following any major preventive maintenance; and e) for a laboratory developed test (LDT), the laboratory must submit quality control plans to the Department for approval: i. as part of a validation package for the addition of a non-FDA-approved assay to the laboratory's test menu; or ii. when the QC procedure is changed for an LDT already approved by the Department; and f) a process that ensures annual review and documentation of review for effectiveness by the	d) External QC refers to the use of control materials that are not integrated into the design of the assay. This would include control material purchased from a commercial vendor or derived in-house. This is distinct from internal QC, such as would be encountered in a single-use device like an immunochromatographic cassette.

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director or an individual delegated in writing by the director. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(3) and subdivision 58-1.10(g)***	
Quality Control Standard of Practice 4 (QC S4): Quality Assessment Plan for Individualized Quality Control Plan If an Individualized Quality Control Plan (IQCP) is developed according to Quality Control Standard of Practice 3, the laboratory must establish and maintain an IQCP Quality Assessment Plan. The IQCP Quality Assessment Plan must include: a) approval, including signature and date, by the laboratory director or individual delegated in writing by the director before implementation and following any revisions; b) a system to monitor overall quality performance, to include an assessment of the accuracy and precision of test performance that may be influenced by changes in test system stability, environmental conditions, or variance in operator performance; c) a process that defines the review and revision of the quality control plan, as appropriate, when nonconformances are identified; and d) a process that ensures annual review and documentation of review for effectiveness by the director or an individual delegated in writing by the director.	Additional information on IQCP requirements is available on the CMS website.

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Regulatory authority: 10 NYCRR paragraph 19.3(c)(3) and subdivision 58-1.10(g)	
Quality Control Standard of Practice 5 (QC S5): Control Limits Acceptability criteria for each lot or shipment of unassayed control material must: a) be established over time by the laboratory through: i. concurrent testing with a control material having previously determined ranges; or ii. established as fixed limits based on analytical system performance specifications around a validated target value; and b) reflect generally accepted medical and analytical requirements for each analyte; and c) be established prior to being placed into use. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(3) and subdivision 58-1.10(g)***	
Quality Control Standard of Practice 6 (QC S6): Assayed Value Verification For each lot of assayed control material, the laboratory must verify the: a) assayed value prior to and/or concurrent with being placed into use; b) assayed value corresponds to the method and instrument used; and	The control material(s) may be verified concurrent with testing of specimens, but results must not be reported until the performance criteria have been verified.

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c) ranges reflect accepted medical and analytical requirements for each analyte. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(3) and subdivision 58-1.10(g)***	
Quality Control Standard of Practice 7 (QC S7): Calibration Material Used as a Quality Control Laboratories using a calibration material as a control must use a calibration material from a different lot number than that used to establish a cut-off value or used as calibration standards for the test system. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(3) and subdivision 58-1.10(g)***	
Quality Control Standard of Practice 8 (QC S8): Alternative Means of Quality Control A laboratory must use commercially prepared controls or otherwise characterized materials if they are available. Where quality control (QC) or calibration materials are not available, the laboratory must describe in their test procedure, according to Test Procedure Content Standard of Practice 1, the QC process used to detect immediate errors and monitor test performance over time. The acceptability criteria of alternative control procedures must be documented in the test procedure. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(4) and subdivision 58-1.10(g)***	

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Quality Control Standard of Practice 9 (QC S9): Control Implementation Laboratories must: a) analyze controls using the number and frequency: i. established under Quality Control Standard of Practice 1; ii. as required in any applicable category specific New York State Clinical Laboratory Standard of Practice; or iii. following requirements established according to Quality Control Standard of Practice 2, 3 and 4; and b) define and document the acceptability criteria of quality control results. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Quality Control Standard of Practice 10 (QC S10): Control Routine Analysis Quality control materials must be rotated among all testing personnel, and to the extent possible, tested in the same manner as patient specimens. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	If a laboratory operates on multiple shifts, quality control material shall be incorporated on other shifts on a regular basis. Rotation among testing personnel may be conducted, for example, during annual competency assessments or after calibration, or with the verification of new lots of materials.
Quality Control Standard of Practice 11 (QC S11): Electrophoresis For laboratories performing electrophoresis:	Where separation is based on both size and charge, running a normal serum sample and an abnormal serum sample may be adequate.

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a) each electrophoretic cell or chamber must include at least one (1) control sample containing fractions representative of those routinely reported in specimens; b) assays where the final product is assessed by product size must, with every analysis: i. include molecular weight markers of known size that span the range of sizes routinely encountered by the method; ii. flanking size markers must be used with sufficient frequency to perform accurate sizing; and c) a method must be established to verify that the transfer from the gel to the membrane was complete. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Quality Control Standard of Practice 12 (QC S12): Thin Layer Chromatography For all compounds or groups of compounds identified by thin layer chromatography, the laboratory must include for each test batch and plate or card: a) reference standards; b) a negative control; and c) a control with analyte concentration near the limit of detection where control materials are processed through the extraction phase of the analysis. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	A threshold control contains a concentration of the analyte(s) of interest that approximates the limit of detection or cut-off.

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Quality Control Standard of Practice 13 (QC S13): Control Records Records of actual results for each quality control must be maintained by the laboratory, including: a) quality control charts; and/or b) other records which identify the controls by date and lot. Actual measurements taken, reactions and /or observations must be recorded, including if the results are acceptable. "Check" marks are not sufficient to record acceptability unless the definition of the checkmark is established in writing. For tests in which results are reported in terms of graded reactions (e.g., 1+, 2+, minimally reactive), the reaction grade must be recorded. Control records must be available for recreation of the test process and when requested by the Department. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(c)(3)***	
Quality Control Standard of Practice 14 (QC S14): Control Review The laboratory must have a system for documented review of quality control records that identifies shifts, trends or other indicators of test instability. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	

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Post-Analytic Systems Fundamental Standard of Practice (PAS FS) The laboratory must comply with Result Review, Reporting, Public Health Reporting, and Confidentiality Standards of Practice. Compliance is required to ensure: a) appropriate data review prior to release of test reports; b) test reports are accurate; c) that the laboratory complies with New York State public health requirements, if applicable; and d) confidentiality of patient information. ***Statutory authority: Article 5, Title 5 Public Health Law Sections 575(2) and (3)***	
Result Review	
Result Review Standard of Practice 1 (RR S1): Result Review Criteria The laboratory must have standard operating procedures for the review of test results for accuracy and reliability. Staff that are responsible for result review must be specified in writing. The laboratory must document the review of test results and testing adherence to acceptability criteria. Autoverification and subsequent release of examination results is acceptable, provided the conditions and algorithms used	

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have been approved and signed by the director or an individual delegated in writing by the director. Review of all test results must verify that: a) test results were produced with the required calibration and/or quality control materials; b) calibration and/or quality control data are acceptable based on manufacturer requirements or laboratory developed acceptability criteria; c) test results are determined and/or calculated correctly; d) dilution and other correction factors have been applied, if needed; e) specimen identification and associated results are accurately linked and transcribed to the test report; f) patient test results that are consistent with relevant patient information such as age, gender, diagnosis, and relationship are identified; g) reference ranges are appropriate; h) reporting interpretations are appropriate for the test results; and i) abnormal results are flagged, and alert or panic values are communicated according to the laboratory's established standard operating procedures, protocols or policies. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(4) and subdivision 58-1.10(g)***	

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Result Review Standard of Practice 2 (RR S2): Acceptable Differences for Replicate Analyses The laboratory must have a policy to establish acceptable differences when replicate analyses are performed on a specimen, including: a) requirements for retesting if the difference between results is greater than the limits established by the manufacturer's instructions or the laboratory's defined acceptability criteria; b) reporting policies (e.g., first value reported if differences are acceptable, report the mean of two (2) values, etc.); and c) notification of clients if a value cannot be reported due to unacceptable differences in results. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Acceptable differences or allowable discrepancies for specimen test results may be determined based on the precision observed for a control material at a similar analyte concentration.
Result Review Standard of Practice 3 (RR S3): Nonconformance Identification During result review, any nonconformities identified as not following the laboratory's established standard operating procedures or policies must be investigated. Actions taken by the laboratory must include, but are not limited to: a) performing root cause analysis when a nonconformance in the test process is identified and implement corrective action(s), if required;	The requirements of this standard are intended to be assessed in concert with Investigation and Corrective Action Standards of Practice 3, 4 and 5.

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b) evaluating test results obtained since the last acceptable testing to determine if results are inaccurate or unreliable; c) retesting specimens and notifying clients for any reported results that are determined to be inaccurate or unreliable; d) releasing test reports only after corrective action has been taken and documented to be effective; and e) taking appropriate preventive action to ensure that nonconformance does not recur. The laboratory director or individual delegated in writing by the director must document review of the investigation and approval of any corrective action taken. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(4) and subdivision 58-1.10(g)***	
Reporting	
Reporting Standard of Practice 1 (REP S1): Authorized Release of Test Results The requirements to authorize release of test results must be described in a standard operating procedure. The procedure must define staff that are authorized to release test results, as delegated in writing by the director. Standard operating procedures for automated verification and release of results must be approved by the director or individual delegated as responsible in writing by the director. In the categories of cytopathology and histopathology, only a licensed pathologist, practicing in the state where they are	Supervisor qualified staff must verify that approved protocols are routinely followed by testing personnel who have been authorized to release results. Electronic signatures must be password protected. Personnel working remotely, in accordance with the current CLEP Remote Activities Policy, must be licensed in both the state where they are performing such work and in the state where the laboratory is located, where licensure is required.

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licensed, is authorized to release pathology reports, with the exception of negative gynecological cytopathology reports which may be released by a cytotechnologist. ***Regulatory authority: 10 NYCRR section 58-1.3 and subdivision 58-1.10(b) and (g)***	Remote review of cytology digital slides is not permitted.
Reporting Standard of Practice 2 (REP S2): Test Report Content Test results must be available in a timely manner to the authorized ordering source or client. Laboratories must be capable of producing a copy of a laboratory report that meets the below requirements. Test results, whether transmitted electronically or by hard copy, must include all required report information, including: a) patient name or other identification; b) the name and address under which the reporting laboratory has been issued a permit, unless the laboratory has reported to the Department an alternative name (e.g., "doing business as"); c) the date, and hour if required, when the specimen was collected; d) the test report date; e) specimen type and/or source (i.e., anatomic location), when appropriate; f) the test(s) performed g) test results, and if applicable, units of measure, reference ranges, or a similar method for identifying abnormal values;	"a copy" of a laboratory report may be either electronic or hardcopy.

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i. Alternative mechanisms other than reporting these values on the report may be approved by the d(D)epartment; h) signature of the qualified person who reviewed, approved and/or diagnosed the case, as required under Reporting Standard of Practice 1; or i. a record of the cytotechnologist releasing the report is required for negative gynecological cytopathology reports; and i) a statement on the report if compromised specimens are tested, the nature of the problem and, if applicable, any impact on result interpretation; j) if applicable, the name and address of the reference or contract laboratory and the date the specimen was tested or the date the result was reported; k) any disclaimers or limitations to testing where required by the Department for an approved laboratory developed test (LDT); l) any additional information required for the interpretation of results; and m) any other information as required in any part of the New York State Clinical Laboratory Standards of Practice. Report information, whether required or discretionary, must be accurate. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(b)(2)***	j) The address of a remote location performing review of digital results under a laboratory's permit may be indicated on the final report by a code. The testing laboratory is responsible for maintaining a 'key' to correlate codes to addresses. l) Examples include: disclosure of the specific equation used for estimated Glomerular Filtration Rate (eGFR) for clinician awareness, limitations stated by the manufacturer prohibiting testing, or limitations stated by the manufacturer affecting results in certain patient populations.

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Reporting Standard of Practice 3 (REP S3): Reference and Contract Laboratory Test Reports Test results from a reference or contract laboratory must not be revised or altered, including information related to the interpretation of the result(s) provided by the testing laboratory. Upon request of the authorized ordering source or client, a reference or contract laboratory must make an exact duplicate of their report available. ***Regulatory authority: 10 NYCRR section 58-1.9***	
Reporting Standard of Practice 4 (REP S4): Corrected Reports When errors or inaccuracies in test reports are detected, the laboratory must: a) promptly notify the authorized ordering source or client of the reporting error(s); b) promptly issue a report that identifies the corrected information and clearly indicates the report as corrected; c) maintain the ability to generate the information contained in the original report as well as the corrected report to include: i. the original report date; ii. the corrected report date; and	Notification may be given to an agent of the authorized ordering source. This standard is not intended to address reports that are amended to include additional findings.

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d) maintain documentation to demonstrate the basis for the change to the test report. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Reporting Standard of Practice 5 (REP S5): Timeliness When the laboratory cannot report patient test results within its established time frames, the laboratory must establish and follow a policy to determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	
Reporting Standard of Practice 6 (REP S6): Alert Value The laboratory must immediately alert the authorized ordering source or client requesting the test and, if applicable, the individual responsible for using the test results, when any test result indicates an imminently life-threatening condition, or panic or alert values, according to protocols established in Test Procedure Content Standard of Practice 1. The laboratory must document the date, time, test results and recipient to whom the results were reported. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	

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Public Health Reporting	
Public Health Reporting Standard of Practice 1 (PHR S1): Required Public Health Reporting Laboratories must designate staff responsible for reporting results on specimens originating from New York State that are determined to meet any of the following: a) infectious diseases as required in Title I Section 2102 for communicable disease reporting, including all SARS-CoV-2 test results; b) cases of initial determination or diagnosis of HIV infection, HIV-related illness and AIDS as required in Subpart 63.4; c) results of all blood lead analyses with demographic data as required in Subpart 67-3; d) all elevated levels of reportable metal as provided in Title 10 sections 22.6 and 22.7; e) every case of cancer, brain tumor, or other malignant disease as provided in Title I sections 2400-2404; and f) test results indicative of pesticide exposure, such as blood cholinesterase levels and levels of pesticides in human tissue specimens which exceed the normal range established by the laboratory, as required under Part 22 of Chapter 1 of the State Sanitary Code. In addition, an annual Blood Services Activity report is required from blood banks and transfusion services as required under 10 NYCRR section 58-2.10.	Additional information on reporting requirements are available at: https://www.wadsworth.org/regulatory/clep/laws. The testing laboratory is responsible for reporting except for lead testing where the referring laboratory and the testing laboratory may agree on which laboratory will report. Both laboratories are accountable to ensure that a report is made. Laboratories must electronically report communicable disease test results though the ECLRS module in the Health Commerce System (HCS). Heavy Metals Registry reporting may be done electronically through ECLRS or by paper. For additional information, see Department websites for Communicable Disease Reporting, the Heavy Metals Registry and the Cancer Registry.

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Regulatory authority: as noted and 10 NYCRR paragraph 19.3(c)(2)	
Public Health Reporting Standard of Practice 2 (PHR S2): Communicable Disease Confirmation New York State Public Health Law Section 576-c (4) and Article 11 of the New York City Health Code require confirmatory testing of isolates for communicable diseases. For specimens that are suspected or reported as confirmed positive for communicable diseases, the testing laboratory must submit isolates for confirmatory testing in accordance with the Communicable Disease Reporting Guidelines. ***Statutory authority: as noted***	For specific communicable diseases and additional information, see Communicable Disease Reporting Guidelines at: https://www.wadsworth.org/regulatory/clep/laws.
Confidentiality	
Confidentiality Standard of Practice 1 (CON S1): Confidentiality Training The laboratory must ensure that protected health information regarding patients is kept confidential throughout all phases of the total testing process that are under the laboratory's control. The laboratory must have a policy to educate staff on protected health information. At a minimum, confidentiality training must be done as part of initial employee training, and annually thereafter. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Special attention should be given to confidentiality training of employees of patient service centers and other patient contact areas of the laboratory.
Confidentiality Standard of Practice 2 (CON S2): Confidentiality Protocol	Employees who may have contact with confidential information should sign an attestation statement, which documents training

Post-Analytic Systems	
Standard	***Guidance***
The laboratory must establish policies and protocols to ensure that protected health information remains confidential. The policies and protocols must include: a) a prohibition of access or disclosure unless approved by the director to perform duties; and b) responsibilities of all employees and agents to ensure that: i. confidential information is accessible only to authorized persons; ii. confidential information, if stored, is secure; iii. only information necessary to fulfill authorized functions is maintained in the laboratory units; iv. confidential information is secured from casual observation; v. confidential information is released or transferred only as authorized by the director, subject to New York State and federal confidentiality requirements; vi. obsolete information is purged or destroyed in an appropriate manner; and vii. proper behavior is exhibited showing no discrimination, abuse or other adverse actions directed at any patient or client. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	on the laboratory's confidentiality policy, applicable statutes and regulations, and acknowledgment of the consequences of violation, which may include criminal prosecution.
Confidentiality Standard of Practice 3 (CON S3): Controlled Records Access	Laws and regulations pertaining to HIV-related and genetic testing information and information on their applicability to

Post-Analytic Systems	
Standard	***Guidance***
The director is responsible for determining and approving: a) the circumstances and duties where access to confidential information is appropriate for staff; and b) how, and to whom, information is to be released, subject to state and federal confidentiality requirements. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	testing performed at the laboratory should be available to employees.

Document and Specimen Retention

Document and Specimen Retention	
Standard	***Guidance***
Document and Specimen Retention Fundamental Standard of Practice (DSR FS) The laboratory must comply with Document and Specimen Retention requirements as indicated in any part of the New York State Clinical Laboratory Standards of Practice. Documents must be retained for recreation of the test process and to substantiate test report findings. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576***	
Document and Specimen Retention Standard of Practice 1 (DSR S1): Quality Assurance Records All manuals, standard operating procedures, policies and documents related to the laboratory's Quality Management	

Document and Specimen Retention	
Standard	***Guidance***
System (QMS) and quality assurance activities must be retained for a minimum of two (2) years, unless otherwise indicated below. Documentation that must be retained includes, but is not limited to: a) internal systems and process audits, and external inspection documents, including: i. who conducted the audit; ii. the dates of the audit; iii. audit findings and any actions taken; iv. for the category of forensic identity, all audit records must be retained for three (3) years and according to Forensic Identity Standard of Practice 29; and b) complaints, investigations related to complaints and, if applicable, corrective action(s) associated with Investigation and Corrective Action Standards of Practice 1; c) nonconformances and related documents associated with Investigation and Corrective Action Standard of Practice 2; d) corrective action documents associated with Investigation and Corrective Action Standard of Practice 4: i. for the category of forensic identity, laboratories must retain corrective action records for three	

Document and Specimen Retention	
Standard	***Guidance***
(3) years and according to Forensic Identity Standard of Practice 28; and e) review of the effectiveness of corrective actions associated with Investigation and Corrective Action Standard of Practice 5. ***Regulatory authority:10 NYCRR subdivision 58-1.2(c)***	
Document and Specimen Retention Standard of Practice 2 (DSR S2): Human Resources, Training and Competency Records The laboratory must retain human resources, training and competency records for the duration of employment and six (6) years thereafter, unless otherwise indicated below, including: a) relevant licensure; b) educational and professional qualifications; c) dates of employment; d) job descriptions; e) training: i. with the exception of safety training which must be retained for three (3) years. f) competency assessments; and g) continuing education. ***Regulatory authority: 10 NYCRR Subdivision 58-1.2(d)***	

Document and Specimen Retention	
Standard	***Guidance***
Document and Specimen Retention Standard of Practice 3 (DSR S3): Controlled Document Retention Unless a longer retention time is required in another part of the New York State Clinical Laboratory Standards of Practice or elsewhere in regulation, the laboratory must retain controlled documents, including test procedures developed according to Test Procedure Content Standards of Practice 1 and 2, for the duration of use and two (2) years after discontinuation or archival. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Transfusion and blood services regulations (10 NYCRR paragraph 58-2.8(a)(9)) require that discontinued procedures be retained for at least seven (7) years.
Document and Specimen Retention Standard of Practice 4 (DSR S4): Laboratory Information System Records Retention The laboratory must retain laboratory information system (LIS) records for two (2) years including records related to: a) validation of system changes, including new or revised software and/or hardware prior to their use for specimen testing, reporting and record keeping functions; and b) system maintenance required by the LIS manufacturer, or established and validated by the laboratory, including the environmental and operating conditions necessary to maintain the integrity of data. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c)***	

Document and Specimen Retention	
Standard	***Guidance***
Document and Specimen Retention Standard of Practice 5 (DSR S5): Verification Records The laboratory must retain records on verification of supplies, equipment and instruments, and reagents and media for the duration of use and two (2) years after discontinuation. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	The minimum retention period for the supplies inventory records is two (2) years; the laboratory management may define any length of storage greater than two (2) years.
Document and Specimen Retention Standard of Practice 6 (DSR S6): Monitoring, Maintenance and Preventive Maintenance Records The laboratory must retain records for: a) environmental monitoring performed according to Facility Design Standard of Practice 2, including monitoring of temperature-controlled spaces, for two (2) years; and b) maintenance and preventive maintenance records generated according to Laboratory Equipment and Instrument Standard of Practice 3, including service and repair records, for as long as the instrument remains in use and two (2) years following discontinuation of use. ***Regulatory authority: 10 NYCRR paragraphs 58-1.11(c)(2),(3),(4)***	

Document and Specimen Retention	
Standard	***Guidance***
Document and Specimen Retention Standard of Practice 7 (DSR S7): Test Request and Specimen Processing Documents The following records must be retained for at least the period specified, except where other New York State or federal regulations or statutes require retention for different periods of time, the laboratory must retain the appropriate record for the longest period applicable. The laboratory must retain: a) test request documentation associated with Test Request Standards of Practice for the same period of time as required for the test report for a specific category or seven (7) years, whichever is less, with the exception of information for cytogenetic cases that must be retained for six (6) years; and b) accession records associated with Specimen Processing Standards of Practice for seven (7) years. ***Regulatory authority: 10 NYCRR paragraphs 58-1.11(c)(1) and (2)***	
Document and Specimen Retention Standard of Practice 8 (DSR S8): Analytic System Records Retention Analytic system records must be retained by the laboratory, as follows: a) performance specification data and records of acceptability criteria that the laboratory establishes or	

Document and Specimen Retention	
Standard	***Guidance***
verifies under Test Performance Specification Standards of Practice 1 and 2 must be retained for as long as the laboratory uses the test process, plus two (2) years after discontinuation: b) testing records, including but not limited to worksheets containing instrument readings, the identity of staff who performed the test(s), and raw patient results, must be retained for two (2) years; Next Generation Sequencing (NGS) FASTQ files or equivalent; and in the category of cellular immunology, electronic flow cytometer data in listmode or equivalent format, must be retained for two (2) years; c) result review records, including acceptability of quality control and calibration materials for two (2) years: d) histogram of an automated differential result for two (2) years; and e) a record of the purity of all drug standard(s) for the period they are in use, and for two years thereafter for forensic toxicology. ***Regulatory authority: 10 NYCRR paragraphs 58-1.11(c)(2),(3),(4)***	
Document and Specimen Retention Standard of Practice 9 (DSR S9): Report Retention All reports of tests performed, including the original or duplicates of original reports received from another laboratory, must be kept on the premises of both laboratories.	Off-site or electronic storage systems are acceptable, provided the laboratory can produce records within twenty-four (24) hours of a request. Original electronic data must be maintained as long as the case file and must be protected from loss or modification.

Document and Specimen Retention	
Standard	***Guidance***
Reports must be produced for the Department upon request and be retained by the laboratory for: a) tissue pathology including exfoliative cytology for twenty (20) years; b) syphilis serology negative report for two (2) years; c) cytogenetics for twenty-five (25) years and according to Cytogenetics Standard of Practice 14; d) case files for forensic identity investigations and electronic data for fifteen (15) years and according to Forensic Identity Standard of Practice 19; and e) all others for seven (7) years. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(c)(5)***	
Document and Specimen Retention Standard of Practice 10 (DSR S10): Specimen Retention Laboratories must be able to retrieve specimens within twenty-four (24) hours. Specimens must be retained, as follows: a) blood films: i. routine, for six (6) months; ii. other than routine, for one (1) year; b) bacteriology slide on which a diagnosis depends, for one (1) year;	For specimens not addressed in this Standard, the laboratory director may determine an appropriate retention time. a) i and ii. A routine blood film is one where no abnormal cells or cell counts are observed, or where a blood disorder is not indicated. a) A routine histogram of an automated differential is one that results as “normal” or “negative” and does not imply the need for further analysis. Histograms are considered to be an instrument printout and must therefore be retained, electronically or as hard copy, for two (2) years as required in Document and Specimen Retention Standard of Practice

Document and Specimen Retention	
Standard	***Guidance***
c) cytology slide showing: i. no abnormality, for five (5) years; ii. any abnormality, for ten (10) years; d) tissue block for twenty (20) years; e) pathology tissue remnants, until a diagnosis is made; f) histopathology: i. block, for twenty (20) years; ii. slide, for twenty (20) years; g) bone marrow biopsy, for twenty (20) years; h) cytogenetic slide, for six (6) years; i) recipient blood specimens, for one (1) week stoppered at one (1) to six (6) degrees Celsius; j) samples of each unit of transfused blood, for seven (7) days for further testing in the event of a transfusion reaction; k) forensic toxicology specimens that were reported as positive, adulterated, substituted or invalid for a minimum of one (1) year and according to Forensic Toxicology Standard of Practice 34; and l) mycobacteriology: i. all original and subsequent *M. tuberculosis* complex isolates from all patients, for one (1) year and according to Mycobacteriology Standard of Practice 13; and ii. stained slides of direct smears from primary	8. It is not required for a laboratory to create or maintain routine blood films if such films are not routinely generated in accordance with the laboratory's approved procedures. c) i. and ii. include gynecological, non-gynecological, and fine needle aspirate (FNA) for cytopathology. f) i. and ii. Slides or electronic images that allow re-evaluation of the entire slide(s) used for reported results. i) Recipient refers to any person receiving blood or blood components.

Document and Specimen Retention	
Standard	***Guidance***
specimens, until the final culture report has been issued and according to Mycobacteriology Standard of Practice 9. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(d)(1)***	
Document and Specimen Retention Standard of Practice 11 (DSR S11): Proficiency Testing Records Retention A laboratory must maintain all records generated during the test process for proficiency testing samples, including test reports. All documentation of review, investigation, corrective action, nonconformance, or other documentation related to proficiency testing, must also be retained. Records must be retained for a minimum of two (2) years from the date of the proficiency test for all categories except: a) forensic identity, which requires three (3) years and according to Forensic Identity Standard of Practice 26; and b) immunohematology, which requires five (5) years. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	
Document and Specimen Retention Standard of Practice 12 (DSR S12): Laboratory Closure The laboratory director and owner are jointly responsible for notifying the Department if the laboratory ceases operation. The laboratory director and owner are jointly and separately responsible for ensuring that all records and, as applicable,	

Document and Specimen Retention	
Standard	***Guidance***
slides, blocks, and tissue, are retained and available for the time frames specified in this section. The laboratory must inform the Department and former clients as to where such records and specimens are maintained. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	

Proficiency Testing

Proficiency Testing	
Standard	***Guidance***
Proficiency Testing Fundamental Standard of Practice (PT FS) All permitted laboratories must meet New York State and federal proficiency test requirements. Failure to comply with New York State Standards and federal regulation may result in	

Proficiency Testing	
Standard	***Guidance***
sanctions being brought against laboratories under state and federal regulations. For each analyte performed, in all categories held on the permit, the laboratory is responsible for establishing, monitoring and maintaining the: a) accuracy and reliability of test results through participation in proficiency testing; and/or b) alternative assessment of test performance. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	
Proficiency Testing Standard of Practice 1 (PT S1): Enrollment, Department Notification and Participation For each category, subcategory and analyte designated as New York State mandated in the Clinical Laboratory Evaluation Program Proficiency Testing Guide, laboratories must: a) enroll in a New York State approved and mandated proficiency testing program; b) notify the Department on an annual basis, in a manner prescribed by the Department, of proficiency testing program(s) to be used to fulfill these requirements; c) successfully participate in proficiency testing using their primary method of analysis. Once enrolled with a proficiency testing program to fulfil this requirement, the laboratory must participate with the same program until the end of the calendar year.	Please see 42 CFR §493.801 for federal Proficiency Testing regulations. Information on Department notification and annual Proficiency Testing enrollment is available in the PT Guide and on our website and available at: https://www.wadsworth.org/regulatory/clep/pt. Participation in proficiency testing is recommended for all tests not included in Subpart I, if a formally evaluated program is available. When laboratories use more than one method to determine results for a given analyte, only the primary method should be evaluated using proficiency testing. Secondary methods must be assessed as outlined in Test Performance Specification Standard of Practice 5.

Proficiency Testing	
Standard	***Guidance***
Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)	
Proficiency Testing Standard of Practice 2 (PT S2): Authorized Release of Proficiency Testing Results The laboratory must authorize the proficiency test provider to release all proficiency testing grades and/or results to the Department, in a manner prescribed by the Department. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	Participation in proficiency testing is recommended for all tests not included in Subpart I, if a formally evaluated program is available.
Proficiency Testing Standard of Practice 3 (PT S3): Alternative to Proficiency Testing Laboratories must have standard operating procedures to verify the reliability and accuracy of test results for: a) New York State mandated analytes for which there is no commercially-available proficiency testing; and b) tests/analytes that are not listed in 42 CFR 493 subpart I for which: i. the laboratory does not participate in commercially-available proficiency testing; or ii. proficiency testing is not available. Test reliability and accuracy assessment must be conducted at least semiannually and according to Proficiency Testing Standard of Practice 10. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(4) and subdivision 58-1.10(g)***	Information on New York State PT requirements is available at: https://www.wadsworth.org/regulatory/clep/pt. The laboratory may evaluate the accuracy of testing through testing of: split-samples (specimens and/or quality control samples) with another validated method; blind testing of specimens with known results; or other equivalent system. Participation in proficiency testing is recommended for all tests not included in Subpart I, if a formally evaluated program is available. When laboratories use more than one method to determine results for a given analyte, only the primary method is required to be assessed twice per year per this standard. Secondary methods must be assessed against the primary method as outlined in Test Performance Specification Standard of Practice 5.

Proficiency Testing	
Standard	***Guidance***
Proficiency Testing Standard of Practice 4 (PT S4): Routine Analysis Unless instructed otherwise by the proficiency testing provider, laboratories must use the same test process for proficiency testing samples that is used for patient specimens. Proficiency testing samples must be: a) incorporated into the laboratory's routine workflow; and b) rotated among all operators that perform testing; c) in microbiology, reported to the highest level of organism identification performed by the laboratory. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	Proficiency test samples must be accessioned and handled as much like patient specimens as possible, with the exception of automatic reflex testing to another laboratory. The highest level of organism identification means the highest level of identification performed and resulted by the laboratory for patient specimens for the organism identified.
Proficiency Testing Standard of Practice 5 (PT S5): Repeated Analysis Laboratories must not repeatedly analyze proficiency testing samples unless patient specimens are routinely tested this way. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	Proficiency test samples must not be used for other purposes (e.g., competency testing) until after the date the laboratory is required to report the proficiency test results to the proficiency test provider**.**
Proficiency Testing Standard of Practice 6 (PT S6): Interlaboratory Communication Laboratories, including laboratories with multiple testing sites or separate locations, must not engage in interlaboratory communication or discussions related to the results of proficiency testing samples until after the date the laboratories	Whenever the Department finds evidence that a laboratory has misrepresented its proficiency through referral of proficiency test samples and/or interlaboratory communication, resulting in submission of results generated elsewhere or generated in collusion, the laboratories are subject to enforcement sanctions

Proficiency Testing	
Standard	***Guidance***
are required to report the results to the proficiency test provider. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	under Section 577 of Article 5, Title 5, which include revocation of laboratory permit and director certificate of qualification.
Proficiency Testing Standard of Practice 7 (PT S7): Proficiency Testing Sample Referral Laboratories must not send proficiency test samples or share portions or aliquots of proficiency testing samples with any other laboratory until after the date the laboratories are required to report the results to the proficiency test provider. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	Whenever the Department finds evidence that a laboratory has misrepresented its proficiency through referral of proficiency test samples and/or interlaboratory communication, resulting in submission of results generated elsewhere or generated in collusion, the laboratories are subject to enforcement sanctions under Section 577 of Article 5, Title 5, which include revocation of laboratory permit and director certificate of qualification.
Proficiency Testing Standard of Practice 8 (PT S8): Proficiency Testing Referral Notification The laboratory must have a standard operating procedure or policy that prohibits proficiency testing sample referral to, and acceptance from, other laboratories. Laboratories must notify the Department within seventy-two (72) hours if samples are received or identified as proficiency testing samples from another laboratory. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	
Proficiency Testing Standard of Practice 9 (PT S9): Attestation The proficiency test provider's attestation statement must be	The summary page(s) generated by online results submission, signed by the required personnel, fulfills this requirement. These documents will be reviewed during the on-site survey.

Proficiency Testing	
Standard	***Guidance***
signed by the: a) laboratory director or individual delegated in writing by the director as responsible; and b) analyst(s) performing the test. The signed document must be kept on file in the laboratory for review by the Department during on-site survey. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	
Proficiency Testing Standard of Practice 10 (PT S10): Performance Review – All Results The laboratory director or staff delegated in writing by the director, must review and document evaluation: a) of all proficiency testing results; b) of any results produced as an alternative to proficiency testing to fulfill the requirements of Proficiency Testing Standard of Practice 3; and c) within two (2) weeks of proficiency testing results becoming available from the provider or completing the alternative assessment. For proficiency testing, an individual analyte score and, when applicable, overall event testing score, must be reviewed. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	This standard applies to all proficiency tests, alternatives to proficiency testing, and educational analytes/events.
Proficiency Testing Standard of Practice 11 (PT S11):	This standard applies to all proficiency tests and alternatives to

Proficiency Testing	
Standard	***Guidance***
Result Investigation The laboratory must perform root cause analysis for all proficiency testing results and any results produced as an alternative to proficiency testing when: a) the score received in a proficiency testing program is less than one hundred (100) percent; b) results do not meet the laboratory's specified performance criteria; and/or c) shifts and trends are identified. The laboratory director or assistant director responsible for the category must document review of the investigation. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	PT.
Proficiency Testing Standard of Practice 12 (PT S12): Unsatisfactory and Unacceptable Performance – Remedial Action The laboratory must implement and document corrective action(s), if needed, when an unsatisfactory or unacceptable proficiency testing (PT) or alternative assessment result is identified. Laboratories that demonstrate unsatisfactory or unacceptable performance must: a) identify impacted patient results based on the root cause analysis of the unsuccessful or unsatisfactory PT performance investigation performed according to Proficiency Testing Standard of Practice 11; and	

Proficiency Testing	
Standard	***Guidance***
b) notify clients and issue corrected reports for reported results that are determined to be inaccurate or unreliable. The laboratory director or staff delegated as responsible in writing by the director must document review and approval of any corrective action taken. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	
Proficiency Testing Standard of Practice 13 (PT S13): Unsuccessful Performance – Remedial Action and Continued Specimen Testing Laboratories that are notified by the Department of unsuccessful performance in proficiency testing must: a) identify a New York State permitted laboratory to refer patient specimens to for testing, in the event that patient testing is voluntarily stopped; b) immediately perform root cause analysis to identify the root or contributing cause(s) of the deficiency to include what happened, why and how the nonconformity occurred, when it began and who was involved; c) describe the impact of the nonconformity on results; d) notify clients and issue corrected reports for reported results that are determined to be inaccurate or unreliable; e) report findings to the Department within the specified time period of notification of unsuccessful performance:	Laboratories may perform one (1) out of sequence event per year if the out of sequence event is supplied by the PT provider designated by the laboratory.

Proficiency Testing	
Standard	***Guidance***
i. failure to report the results of the investigation and plan of correction to the Department within ten (10) business days, or when the plan of correction is deemed unacceptable by the Department, will result in a cease testing directive being issued by the Department; and f) demonstrate the effectiveness of the corrective action through successful performance in two (2) consecutive proficiency test events. The laboratory director or assistant director responsible for the category must document review of the investigation and approval of any corrective action taken. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	
Proficiency Testing Standard of Practice 14 (PT S14): Unsuccessful Performance – Cessation of Specimen Testing The laboratory must cease testing of clinical specimens for a minimum of six (6) months upon unsuccessful performance in proficiency testing and in the event that the Department determines that any of the following conditions exist: a) immediate jeopardy to patient health or safety; b) the laboratory fails to provide satisfactory evidence that it has taken steps to correct the problem(s) identified during remedial action of the unsuccessful proficiency testing performance, according to the requirements for Proficiency Testing Standard of Practice 13;	

Proficiency Testing	
Standard	***Guidance***
c) the root cause(s) of unsatisfactory performance are systemic to laboratory practices; d) the laboratory has demonstrated a history of non-compliance with standards of good laboratory practice; or e) the Department determines that the laboratory has demonstrated a pattern of poor performance, including unsatisfactory performance over three (3) of five (5) consecutive test events for the same analyte, category or subcategory. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	
Proficiency Testing Standard of Practice 15 (PT S15): Unsuccessful Performance – Department Enforcement Where performance in proficiency testing provides evidence of risk for patient harm as judged by criteria a-e under Proficiency Testing Standard of Practice 14, and the laboratory does not comply with the Department's directive to cease testing, the Department will take enforcement action as authorized by Sections 576(3) and 577 of Public Health Law, Article 5, Title 5, seeking limitation of the laboratory's permit in the area of failure for a minimum of six (6) months. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3) and 577***	Subsequent to enforcement for ceased patient testing for six (6) months, reinstatement of testing approval is considered only if the laboratory is fully compliant with requirements under Proficiency Testing Standard of Practice 13.
Proficiency Testing Standard of Practice 16 (PT S16): Proficiency Testing Documentation	

Proficiency Testing	
Standard	***Guidance***
Laboratories must maintain the following documentation of the processing and reporting of proficiency testing samples: a) steps taken in handling, preparing, processing, examining, testing and reporting all results in the proficiency test event; b) the proficiency testing provider's attestation form completed in accordance with the provider's instructions and requirements; and c) copies of all testing records, including copies of the proficiency test report forms that must be retained according to Document and Specimen Retention Standard of Practice 11. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	

Investigation and Corrective Action

Investigation and Corrective Action	
Standard	***Guidance***
Investigation and Corrective Action Fundamental Standard of Practice (ICA FS) The laboratory must comply with the Standards of Practice provided in this section. The laboratory must follow established procedures, address nonconformances when appropriate, and evaluate the effectiveness of corrective actions. ***Statutory authority: Article 5, Title 5, Public Health Law Sections 575(2) and (3)***	
Investigation and Corrective Action Standard of Practice 1 (ICA S1): Complaint Investigation and Resolution The laboratory must have a standard operating procedure to address and resolve complaints or other communications received from staff, clients, and/or any outside sources or entities. The procedure must describe requirements for: a) documentation: b) criteria for complaint investigation; and c) actionable events requiring nonconformance investigation and corrective action. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)***	
Investigation and Corrective Action Standard of Practice 2 (ICA S2): Procedure and Documentation for Control of Nonconformities	

Investigation and Corrective Action	
Standard	***Guidance***
The laboratory must have a standard operating procedure describing actions taken when laboratory services do not follow an established policy and/or standard operating procedure, requirements of the Quality Management System (QMS) or client specifications. All nonconformities must be documented and ensure that: a) personnel responsible for problem resolution are designated; b) appropriate steps to be followed are defined; c) the clinical significance of the nonconforming laboratory service is considered, and where appropriate, the authorized ordering source or client is informed; d) testing is suspended, and reports withheld as necessary; e) corrective action and root cause analysis are initiated at the time the nonconformance is identified; f) any released test results associated with nonconforming laboratory services are identified and recalled or corrected, if necessary; g) steps to be taken to resume testing and authorization for resumed testing are defined; and h) each episode of nonconformity is documented, recorded and reviewed at regular specified intervals as defined in the standard operating procedures to detect trends and initiate preventive action(s). ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)***	

Investigation and Corrective Action	
Standard	***Guidance***
Investigation and Corrective Action Standard of Practice 3 (ICA S3): Actionable Events The laboratory must define a nonconformity to include any aspect of the test process that does not follow the laboratory's established standard operating procedure and/or policies, requirements of the Quality Management System (QMS) or client specifications including: a) when the criteria for proper storage of reagents and specimens are not met; or b) supplies are insufficient or not available for testing; or c) equipment, instruments or testing that perform outside of established operating parameters or performance specifications, as evidenced by: i. unacceptable results or performance; ii. unacceptable differences in test results between different instruments or with the same test performed at multiple testing sites; or d) when results of quality control and/or or calibration materials fail to meet the laboratory's established acceptability criteria; or e) specimen results outside of the laboratory's reportable range for the test procedure indicate that the test is not performing according to the laboratory's defined performance specifications; or f) reference ranges for a test procedure are inappropriate for the laboratory's test population.	

Investigation and Corrective Action	
Standard	***Guidance***
Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)	
Investigation and Corrective Action Standard of Practice 4 (ICA S4): Corrective Action Procedure and Documentation The laboratory must have a standard operating procedure describing the process for initiating corrective actions that are appropriate to the magnitude of the problem and commensurate with the risks encountered. For corrective actions, the laboratory must: a) perform root cause analysis to identify underlying cause(s) of a nonconformance; b) initiate and document corrective actions and, where appropriate, preventive actions; c) document and implement any policy and/or standard operating procedure changes required for corrective actions, if applicable; d) assess the results of any corrective actions taken to ensure that they have been effective; e) ensure that noncompliant practices are not occurring in other sections/categories of the laboratory; and f) submit the results of corrective actions to the laboratory director or individual designated in writing by the director for documentation of review. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)***	

Investigation and Corrective Action	
Standard	***Guidance***
Investigation and Corrective Action Standard of Practice 5 (ICA S5): Corrective Action Effectiveness After implementation of a corrective action, preventive action, or improvement, the laboratory must evaluate and document an assessment of effectiveness. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)***	

APPENDIX

Table 1. Test Procedure content requirements in General Systems Standards and Specialty Requirements by Category

Section or Category	Abbreviation	Standard title
General Systems	TPC S1	Test Procedure Content
General Systems	TPC S2	Test Procedures for Unidirectional Workflow
Laboratory Blood Services	LBS S2	Procedure
Cellular Immunology	CI S9	Antibody Fluorochrome Stability
Cellular Immunology	CI S13	Event Collection Procedure
Cellular Immunology – Leukocyte Function	LF S6	Function Quality Control – Negative, Positive, and Multi-level Controls
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping	NM S1	Single Platform Requirements
Genetic Testing	GT S3	Test Procedure
Histocompatibility	HC S1	Test Procedure
Immunohematology	IH S4	Standard Operating Procedure
Microbiology	MB S7	Laboratory Response Network
Microbiology – Bacteriology	BT S5	Defining Antibiotic Panels
Microbiology – Mycology	MY S8	Antifungal Susceptibility Testing Quality Control
Microbiology – Parasitology	PS S5	Examination of Blood Smears
Microbiology – Virology	VR S2	Cell Culture Records
Microbiology – Virology	VR S3	Cell Culture Shelf Life and Condition
Microbiology – Virology	VR S7	Viral Culture Criteria and Timepoints
Parentage/Identity Testing	PIT S6	Test Procedure Content

Table 2. Reporting content requirements in General Systems Standards and Specialty Requirements by Category

Section or Category	Abbreviation	Standard title
General Systems	REP S2	Test Report Content
Blood Lead	BL S8	Reporting Potential Contamination
Blood Lead	BL S9	Reporting Potential for Fingerstick Contamination
Blood Lead	BL S11	Reporting
Blood Lead ASV Sensor	BLS S4	Repeat Analysis
Blood Lead ASV Sensor	BLS S5	Potential for Fingerstick Contamination
Cellular Immunology	CI S5	Viability Reporting
Cellular Immunology – Leukocyte Function	LF S13	Proliferation Reporting
Cellular Immunology – Leukocyte Function	LF S14	Reporting Flow Cytometric Results for Functional Analysis
Cellular Immunology - Non-Malignant Leukocyte Immunophenotyping	NM S13	CD34 Stem Cell Enumeration – Reporting Requirements
Cellular Immunology - Non-Malignant Leukocyte Immunophenotyping	NM S17	Paroxysmal Nocturnal Hemoglobinuria Diagnosis – Review Criteria and Reporting
Cellular Immunology - Non-Malignant Leukocyte Immunophenotyping	NM S19	Leukocyte Adhesion Deficiency (unstimulated expression) – Report Requirements
Cellular Immunology – Malignant Leukocyte Immunophenotyping	ML S4	Report Requirements
Clinical Toxicology	CT S2	Qualitative Testing
Clinical Toxicology	CT S3	Reports
Cytogenetics	CG S12	Reporting
Diagnostic Immunology	DI S1	Syphilis Screening Algorithm Using Nontreponemal Tests
Diagnostic Immunology	DI S2	Syphilis Screening Algorithm Using Treponemal Tests
Diagnostic Immunology	DI S5	Reporting Preliminary Positive HIV Test Results
Forensic Identity	FI 20	Reports and Case Files

Section or Category	Abbreviation	Standard title
Forensic Toxicology	FT S30	Authorized Reporting – Initial Testing Only Laboratories
Forensic Toxicology	FT S32	Confirmation Testing Report Content
Genetic Testing	GT S6	Report Content
Microbiology	MB S6	Reports
Microbiology Nucleic Acid Amplification Assay	MNA S3	Reports for Laboratory Developed Sequence-based Assays
Microbiology – Mycobacteriology	TB S5	Reporting Smear Results
Microbiology – Parasitology	PS S7	Report Content
Microbiology – Parasitology	PS S8	Single-Use Antigen Assays
Microbiology – Parasitology	PS S9	Reporting Negative Results
Oncology – Soluble Tumor Markers	OC S1	Soluble Tumor Marker Report Requirements
Oncology – Molecular and Cellular Tumor Markers	OC S2	Molecular and Cellular Tumor Markers Report Requirements
Parentage/Identity Testing	PIT S8	Report Content
Cytopathology	CY S15	Reporting
Histopathology	HT S2	Report Nomenclature
Trace Elements	TE S9	Reporting Potential Contamination