New York State Department of Health

Wadsworth Center

Clinical Laboratory Evaluation Program

Clinical Laboratory Standards of Practice

Part 1 – General Systems

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Quality Management System

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Quality Management System Fundamental Standard of Practice 1 (QMS F1) The laboratory director and owner are jointly and separately responsible for laboratory operations and shall exercise authority for the design, implementation, maintenance and improvement of a quality management system. The quality system must be designed to assess and continuously improve the delivery of services to meet the needs of patients. Key system practices shall include periodic audits of laboratory operations for compliance with stated requirements, management review of audit findings and authorization for implementation of plans for operations improvement that were developed in concert with stakeholders. **Statutory Authority: Article 5, Title V Public Health Law Section 575 (2) and (3)**	Laboratory compliance with the Quality Management System Fundamental Standard of Practice is evaluated by review of laboratory practices using minimum requirements specified in Sustaining Standards of Practice 1 though 5. Your laboratory should be prepared to provide documentation of quality goals, objectives, performance measures and quality improvement initiatives for each of the quality system essentials under Quality Management System Sustaining Standard of Practice 1. Quality systems are uniquely dependent on laboratory leadership and infrastructure. A laboratory permit becomes void upon a change in location, director or owner. Upon a change in the assistant director designated as a sole certificate of qualification holder for a category, the permit becomes void in the categories affected. The voiding of a permit, or portions of a permit, may be stayed upon receipt of timely notification, which shall serve as a new permit application. A stay of the voiding of a permit or portions of a permit shall be effective until the department issues a final determination with respect to the new application. In the case of a change in director, if a permanent new director has not been approved at the time the director listed on the existing permit ceases to function as director, a transition plan shall be submitted within five days nominating an individual to serve as interim director, until a permanent appointment can be made.
Quality Management System Sustaining Standard of Practice 1 (QMS S1): ***Establishment of Specifications and Requirements*** The quality management system shall **establish written specifications and requirements** for the following quality system essential elements: a) qualifications, responsibilities, authority and interrelationships of all personnel; b) adequate training and competency evaluation of all staff and supervision by competent persons conversant with the purpose,	Specifications and requirements established by laboratory management under **Quality Management System Sustaining Standard of Practice 1** shall meet or exceed minimum requirements provided under applicable parts of these Clinical Laboratory Standards of Practice. In developing specifications and requirements for effective delivery of laboratory services, management should identify and seek input from stakeholders, i.e., those who have expectations and dependencies on the quality of services provided. Specifications and requirements developed by laboratory management and stakeholders should be clearly described and presented to vendors and contractors that provide support and resources for laboratory operations. References to applicable sustaining standards of practice for the establishment of specifications and requirements may include, but not limited to:

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procedures, and assessment of results of the relevant examination procedures; c) management support of all laboratory personnel by providing them with the appropriate authority and resources to carry out their duties and by responding to their concerns and problems; d) provision and maintenance of facilities as necessary to support analytical systems and to promote safety and security practices; e) laboratory information system initial and periodic performance verification; f) development, updating, approval and implementation of standard operating procedures; g) protocols to ensure positive identification and optimum integrity of primary and subsamples from the time of collection or receipt through completion of testing and reporting of results, including written policies and procedures for test request, patient preparation, specimen type, collection, labeling, handling and processing; h) specimen acceptance and rejection criteria; i) selection of instruments and reagents; j) validation or verification, as appropriate, of examination procedures' performance characteristics; k) quality control practices that monitor the conformance of examination procedures to specified requirements; l) mechanisms to verify test results prior to release; m) timely and accurate reporting of results, including alert results; n) enrollment in a CMS-approved proficiency testing program for tests performed that are included in Subpart I (42 CFR 493), or for those tests not included in Subpart I, participate in alternative assessments of examination procedures' performance; o) evaluation of performance in proficiency testing and alternative assessments of examination procedures' performance; p) identification and resolution of nonconformities;	a) Human Resources S1, S3, S4, S5; Director S3(f) b) Human Resources S6, S7, S8 c) Director S3 d) General Facilities S1 e) Laboratory Information System S2, S4 f) Operating Procedures S2, S6 g) Requisition S3 h) Processing S4 i) Validation S1; Laboratory Equipment S1(a) j) Validation S5 k) Quality Control S1-S6 l) Process Review S2 m) Reporting S1-S6 n) Proficiency Testing S1-S8; Quality Assurance S3 o) Quality Assurance S3 (c)(d) p) Control of Non-Conformities S1 q) Complaint Resolution S1 r) Referral S1 s) t) Retention S1, Retention S3 u) Quality Assurance S1, S2 c) Appropriate authority includes the delegation of responsibility to all laboratory personnel to bring concerns about laboratory practices or behavior that places the integrity of laboratory operations and services at risk to the attention of management, or if deemed necessary by laboratory personnel, to the attention of the Clinical Laboratory Evaluation Program. t) *Document control: specimen processing & process verification* means a system whereby the entire test process can be recreated through document review for purposes of substantiating the reported test findings. Associated records include the standard operating procedures in effect at the time of

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q) complaint investigations; r) selection of referral laboratories; s) communications with patients, health professionals, referral laboratories, vendors, contractors, and any applicable accreditation and regulatory agencies; t) *document control: specimen processing & process verification*, and specimen retention; and, u) quality assessment and continuous improvement of all laboratory practices, including but not limited to the establishment of objective monitors of process performance and management review of ongoing evaluations of laboratory performance. **Regulatory authority: 10 NYCRR subdivision 58-1.2 (c) and paragraph 19.3 (c)(3)**	specimen analysis, test requisition, accession records, identification of resources (equipment, reagent and quality control lot numbers) used for the analysis, equipment maintenance and reagent and quality control material validation records, worksheets, test reports, and the identification of personnel who performed pertinent tasks in the test process. *Document control: specimen processing & process verification* should allow complete documentation of the test process in a timely manner for test requisitions selected by representatives of the Clinical Laboratory Evaluation Program.
Quality Management System Sustaining Standard of Practice 2 (QMS S2): *Quality Manual* A quality manual shall describe the quality management system and the roles and responsibilities of personnel designated to inculcate the quality systems. It shall include or make reference to the detailed supporting procedures in the laboratory's Standard Operating Procedure Manual. **Regulatory authority: 10 NYCRR subdivision 58-1.2 (c) and paragraph 19.3 (c)(3)**	The Quality Manual must minimally include documentation of quality goals, objectives, performance measures and quality improvement initiatives for each of the quality system essentials under Quality Management System Sustaining Standard of Practice 1.

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Quality Management System Sustaining Standard of Practice 3 (QMS S3): ***Quality System Audits*** The laboratory shall establish and continuously evaluate performance indicators to assess compliance with specifications and requirements that have been established under Quality Management System Sustaining Standard of Practice 1. Where indicated, non-conformance is investigated and corrective action taken. a) Audits to determine compliance with applicable regulations and standards shall be formally planned, organized, and carried out by designated qualified personnel and shall be conducted at least annually. To the extent possible, personnel shall not audit their own activities. b) The procedures for audits shall be defined and documented and include types of audits, frequencies, methodologies, and required documentation. c) When non-conformance to specifications and requirements or opportunities for improvement are noted, the laboratory shall undertake appropriate corrective or preventive actions, which shall be documented and carried out within an agreed-upon time. The risk for adverse outcomes should be assessed and any non-conformance that has the potential for adverse impact to patient care should be corrected immediately. d) There shall be evidence that the laboratory director, and where appropriate, the owner, were engaged in the development, review and approval of performance (quality) indicators and action plans for process improvement or resolution of non-conformance. **Regulatory authority: 10 NYCRR subdivision 58-1.2 (c) and paragraph 19.3 (c)(3)**	Laboratories should continuously monitor and evaluate the effectiveness of its policies and procedures, and compliance with its process specifications and requirements. When effectiveness and/or compliance are assessed to be lacking, the laboratory should react immediately and appropriately. 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 the course of a survey cycle (i.e., two years).

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Quality Management System Sustaining Standard of Practice 4 (QMS S4): ***Management Review*** The quality management system shall include a **management review** to verify the effectiveness of corrective action and to ensure the continuing suitability and effectiveness of laboratory policies, procedures and capabilities in support of patient care. Management review shall take account of but not be limited to: a) follow-up of previous management reviews; b) status of corrective actions taken and required preventive action; c) reports from managerial and supervisory personnel; d) the outcome of recent quality system audits; e) the outcome of Department of Health inspection reports, proficiency testing, and other forms of interlaboratory comparison; f) any changes in the volume and type of work undertaken; g) feedback, including complaints and other relevant factors, from clinicians, patients, laboratory personnel and other parties; h) quality indicators for monitoring the laboratory's contribution to patient care; i) nonconformities; j) monitoring of turnaround time; and, k) results of continuous improvement processes. **Regulatory authority: 10 NYCRR subdivision 58-1.2 (c) and paragraph 19.3 (c)(3)**	Management includes the laboratory owner, administrator, laboratory director and assistant directors, and laboratory manager(s).

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Quality Management System Sustaining Standard of Practice 5 (QMS S5): ***Documentation of Review Outcomes*** Findings and the actions that arise from quality system audits and management reviews shall be recorded, and laboratory staff informed of these findings and the decisions made as a result of the review. Laboratory management shall ensure that these actions are discharged within an appropriate and agreed-upon time. Quality systems assessment records shall be retained for at least two years. **Regulatory authority: 10 NYCRR subdivision 58-1.2 (c) and paragraph 19.3 (c)(3)**	Reports of management review should be retained for two years, and must be made available for review by representatives of the Clinical Laboratory Evaluation Program, either at time of inspection or by *ad-hoc* request.

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Director Fundamental Standard of Practice1 (DIR F1): Director and Assistant Director Oversight The laboratory shall provide effective leadership for the delivery of clinically useful laboratory services. The director and/or assistant director(s) is responsible for designing, validating, and maintaining the technical accuracy and medical reliability of laboratory tests in the categories where the individual has been designated responsible as attested to in the application materials submitted to the Clinical Laboratory Evaluation Program. **Statutory authority: Article 5, Title V Public Health Law Section 577**	As required in Section 58-1.1 of 10 NYCRR, when a director does not hold a certificate of qualification in all categories in which the laboratory tests, an assistant director with a certificate of qualification in the category must be designated in the laboratory permit or category addition application materials. In this instance the assistant director is considered the 'sole director' for that category and assumes all responsibilities and liabilities as if he or she were the director of the laboratory. The fulfillment of director and/or assistant director oversight stands alone as a **fundamental** standard of practice, and if the standard is not met, places laboratory permit and director/assistant director's Certification of Qualification approvals at risk. Compliance with this Fundamental Standard of Practice is evaluated through assessment of director and assistant director fulfillment of responsibilities specified under the Director Sustaining Standard of Practice 1 and Director Sustaining Standard of Practice 3. The regulatory framework for director credentials and responsibilities is as specified at 10NYCRR Part 19. A person should not be designated as an assistant director if they do not hold responsibilities as described in 10NYCRR Part 19, 10NYCRR Subpart 58-1 or these standards. The Clinical Laboratory Evaluation Program should be contacted by the director or assistant director or owner whenever they find themselves in a position where they are unable to fulfill their duties.

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Director Sustaining Standard of Practice 1 (DIR S1): Director and Assistant Director Involvement and Time Commitment The director and designated assistant director(s) shall spend an adequate amount of time on-site, in the laboratory, to direct and supervise the technical performance of the staff and be readily available for personal or telephone (or electronic) consultation to the laboratory's staff and clients. The amount of time a director/assistant director spends on site must be specified in their job description and shall be consistent with responsibilities described in Director Sustaining Standard of Practice 3. **Regulatory authority: 10 NYCRR subdivision 58-1.2(a)**	Designated assistant director is defined in **Director Fundamental Standard of Practice1.** The director must spend sufficient time on-site to effectively discharge the responsibilities described in Director Sustaining Standard of Practice 3. Section 58-1.2 of 10 NYCRR describes full-time or regular part-time hours are required. Regular part-time hours are defined as a minimum of 20 hours per week. Time commitments of less than 20 hours per week will be considered based on the number of categories the director and assistant director is responsible for, the volume and complexity of testing performed at the laboratory, the laboratory's performance as demonstrated by proficiency testing and on-site survey, the qualifications of other personnel on site, and time commitments at other laboratories. The circumstances requiring the director/assistant director(s) presence and the amount of time each are to spend on site must be specified in the job description required in Director Sustaining Standard of Practice 3. There must be documented evidence that the director/assistant director is actively involved in laboratory operations. Measures used to evaluate the effectiveness of the director/assistant director's oversight include, but are not limited to, active participation in the quality management system as described in Quality Management System Fundamental Standard of Practice 1, management of adverse outcomes and non-conformities; participation in the on-site survey; appropriate management of the results of the on-site survey, and performance in proficiency testing. Previous approvals for time commitments of less than full-time may be rescinded if the evaluation of director or assistant director effectiveness demonstrates that his or her involvement is not acceptable. Notifications submitted to add a director or assistant director that list hours 'as needed' or having overlapping hours between positions, will not be accepted.

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Director Sustaining Standard of Practice 2 (DIR S2): Director Affiliations The director shall serve a laboratory full time, or on a regular part-time basis, to perform the duties listed in these Standards, and in 10NYCRR Part 58 and 10NYCRR Part 19. Regular part-time basis shall mean assumption of full responsibility for direction, technical operation and the quality management system of the laboratory. An individual shall serve as director or sole Certificate of Qualification holder for a permit category for no more than two clinical laboratories or blood banks, except that a clinical laboratory and blood bank on the same premises shall count as one affiliation, and An individual may be authorized to serve as laboratory director or sole certificate of qualification holder for one or more permit categories for more than two but no more than five laboratories or blood banks, provided: a) the immediate patient care needs of an area can be met only by allowing an individual to exceed the number of directorships allowed; b) the total volume and types of laboratory services provided by the several laboratories are not such as to require the services of more than one director; c) laboratories under the director's oversight are operated in compliance with department requirements. Such authorizations must be renewed biennially. **Regulatory authority: 10 NYCRR subdivisions 58-1.2 (a) and (b)**	A sole director is an assistant director who is the only Certificate Qualification holder designated as responsible for a specific laboratory permit category. Regular part-time is considered 20 hours per week of on-site presence. Other arrangements for minimum on-site presence may be considered based on the complexity and volume of testing at the laboratory. Please refer to the guidance provided in Director Sustaining Standard of Practice 1: Director and Assistant Director Involvement and Time Commitment.

Director Sustaining Standard of Practice 3 (DIR S3): Director Responsibilities A determination as to whether the director has adequately fulfilled the responsibilities indicated in a-n of this standard will be based on an assessment of laboratory compliance with department requirements. While certain of these responsibilities may be delegated to qualified individuals, such delegation must be in writing. Notwithstanding such delegation, the director remains ultimately responsible for monitoring that these responsibilities have been met and for the oversight of all laboratory operations. The director shall: a) provide oversight of all aspects of the laboratory's quality management system to ensure conformance to requirements described in the Quality Management System chapter of these Clinical Laboratory Practice Standards; b) provide effective and efficient administrative direction of the laboratory, including budget planning and controls in conjunction with the individual(s) responsible for financial management of the laboratory; c) ensure that qualified personnel are employed including, where applicable that staff are not engaged in practices limited by license or beyond the scope of licensure; and by defining the qualifications and responsibilities of all laboratory technical staff and documenting training and/or competency; d) provide continuing educational to laboratory technical staff that is relevant to laboratory medicine; e) ensure that policies and procedures are established for monitoring staff to assess competency, and whenever necessary, provide remedial training or continuing education to improve skills; f) specify in writing the technical and administrative responsibilities and duties of all laboratory personnel, including assistant directors designated in the permit application(s) materials submitted to the Clinical Laboratory Evaluation Program. The director is responsible for competency assessment of assistant directors and direct-report supervisors. Documentation of assessments must be performed	The director remains responsible for all delegated activities and must provide evidence of ongoing monitors for the competent management of those delegations. The director may **not** delegate the following quality management system activities: definition of quality goals and process objectives for each of the quality system essentials listed under Quality Management System Sustaining Standard of Practice 1; approval of specifications and requirements established to achieve stated goals and objectives; review of quality assessment reports; and, approval of process improvement initiatives. Directors who also function as supervisors must also follow Human Resources Sustaining Standard of Practice 3. d) Education can be provided by a variety of methods including attendance at outside venues, even at other laboratories. The laboratory management needs to have documentation on-site for each technical staff member. f) Permit application materials include the initial and annual permit application as well as entries submitted through the online eCLEP system. The description of the responsibilities and tasks for the assistant directors should include the specific technical and administrative areas of responsibility noted on these forms. f) the technical supervisor for cytopathology should perform workload assessment of cytotechnologists twice per year, according to Cytopathology Sustaining Standard of Practice 9 (CY S9): Establishing a Workload Limit.

annually and whenever new systems are introduced. Remedial steps must be documented when staff do not perform as expected;

g) promote a safe laboratory environment for personnel and the public;

h) ensure that an approved procedure manual is available to all personnel;

i) monitor all work performed in the laboratory to ensure that medically reliable data are generated;

j) assure that the laboratory participates in monitoring and evaluating the quality and appropriateness of services rendered, within the context of the Quality Management System, regardless of where the testing is performed;

k) provide advice to referring physicians regarding the significance of laboratory findings and ensure that reports of test results include pertinent information required for specific patient interpretation;

l) ensure that the laboratory is enrolled in CMS- approved proficiency testing programs for all testing performed by the laboratory that are included in Subpart I (42 CFR 493 Subpart I). For all tests performed by the laboratory that are not included in Subpart I, ensure that the laboratory adopts an alternate method to verify test accuracy and reliability;

m) ensure that the laboratory adheres to the Department's administrative and technical requirements for proficiency testing;

n) select all reference laboratories;

o) maintain an effective working relationship with applicable accrediting and regulatory agencies, administrative officials, and the medical community; and

p) effectively implement a plan of correction to deficiencies identified.

Regulatory authority: 10 NYCRR Section 58-1.2 and subdivision 19.3 (c)

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Human Resources Fundamental Standard of Practice 1 (HR F1): Staff Qualifications The laboratory shall have effective leadership and personnel with education, training and experience commensurate with the complexity of services provided and as necessary for the design, validation and delivery of clinically useful laboratory services. **Statutory authority: Public Health Law Article 5, Title V Sections 575 (2) and (3)**	Compliance with this Fundamental Standard of Practice is through an assessment of conformance to minimum requirements under Human Resources Sustaining Standards of Practice 1 through 12~~11~~. The regulatory framework for technical personnel credentials, duties and responsibilities are specified in 10NYCRR Part 19 and in the following subparts of 10NYCRR Part 58: 58-1.2 Laboratory director. 58-1.3 Clinical laboratory supervision. 58-1.4 Qualifications of laboratory supervisor. 58-1.5 Duties and qualifications of clinical laboratory technical personnel.
Human Resources Sustaining Standard of Practice 1 (HR S1): Organizational Plan Laboratory management shall have an organizational plan which consists of an organization chart, personnel policies, and job descriptions that define qualifications and duties for all personnel, including specimen collection staff, technical staff, supervisors, laboratory managers, administrators, assistant directors and the laboratory director. If the laboratory employs consultants, the duties for these individuals must be specified in writing. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(6) and subdivision 58-1.2(d)**	Competency assessments should correspond to the responsibilities described in the job description. The organizational chart should identify all staff that report directly and indirectly to the director, including assistant director(s) and technical staff.

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Human Resources Sustaining Standard of Practice 2 (HR S2): Personnel Records Laboratory management shall maintain records of the relevant licensure, educational and professional qualifications, training and experience, continuing education, dates of employment, and competence of all personnel for the duration of employment and six years thereafter. **Regulatory authority: 10 NYCRR Subdivision 58-1.2(d)**	Duties and qualifications for laboratory supervisors and cytology supervisors are described 10NYCRR Part 58. Requirements for licensure through the New York State Education Department are available at www.op.nysed.gov. Licensure is not required for individuals performing testing for non-medical purposes, such as parentage/identity testing or forensic toxicology, or for individuals employed as technicians, technologists or cytotechnologists in out-of-state laboratories; however, these individuals must continue to meet the education and experience requirements in 10NYCRR Subpart 58-1. Laboratories located in New York State must maintain copies of the license or limited license issued by the New York State Education Department for all technical personnel. Documentation required for directors and assistant directors is a copy of their New York State Certificate of Qualification. For out-of-state laboratories, diplomas, resumes, and/or transcripts; 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 evaluation policies.
Human Resources Sustaining Standard of Practice 3 (HR S3): Supervisor Responsibilities A qualified individual, under the general direction of the laboratory director, shall supervise technical personnel and the reporting of findings, perform tests requiring special scientific skills, and, in the absence of the director, be responsible for the proper performance of all laboratory procedures. An individual who qualifies as a cytology supervisor shall supervise technical personnel in the specialty of cytopathology. Responsibilities of a laboratory supervisor include: a) day-to-day supervision of test performance by testing personnel; b) monitoring laboratory processes to ensure that acceptable levels of analytic performance are maintained, to include review of quality	Qualifications for laboratory supervisors and cytology supervisors are described 10NYCRR Part 58. The requirement for the laboratory experience necessary to qualify as a supervisor must be gained subsequent to qualifying as a technologist or cytotechnologist. 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 technical 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. An individual functioning as a supervisor may delegate, in writing, responsibilities such as quality control review and quality assurance activities to other competent and trained supervisor – qualified (as defined in section 58-1.4 in Chapter 10 of NYCRR) technical staff, provided supervisory review of these activities is

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control, instrument and equipment maintenance, and other quality assurance activities; c) assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; d) in the event of non-conformances, ensuring that results of test examinations are not reported until all corrective actions have been taken and the test system is properly functioning; e) verifying that staff are trained and competent prior to performing testing on patient specimens independently; and, f) verifying that testing personnel are evaluated semiannually during the first year of hire, and thereafter annually, as being competent for assigned tasks and that remedial action is performed when staff do not perform as expected. **Regulatory authority: 10 NYCRR Section 58-1.3**	documented (e.g., periodic communications, summary reports, etc.) and non-conforming events are brought to the attention of the supervisor. f) Semiannual is used to describe an event that takes place two times during the first year of hire, 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.
Human Resources Sustaining Standard of Practice 4 (HR S4): Technical Personnel Responsibilities Technical personnel must: a) follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of test examinations; b) maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens; c) adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed; d) follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;	

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e) be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the supervisor or director; and, f) document 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 Sustaining Standard of Practice 5 (HR S5): Quality Systems Manager The laboratory director shall designate a quality systems manager who has the training, experience and authority to provide effective leadership for activities necessary to ensure communication, training, competency assessment and ongoing compliance monitoring with requirements under the laboratory's quality management system. **Regulatory authority: 10 NYCRR subdivision 58-1.2(c)**	There must be a designated position for a Quality Systems Manager and a job description. The individual designated as Quality Systems Manager 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 Quality Systems Manager is expected to be a resource person to the Department when there is a need for document review and compliance assessment. Persons who limit their scope of activity to oversight of quality system activities do not require licensure by the State Education Department.

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Human Resources Sustaining Standard of Practice 6 (HR S6): Training Laboratory management shall have procedures for the training for all staff. Training must be documented for all individuals, 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, as well as supervisory and management staff. Personnel must be trained and their competence assessed in the performance of all tasks for which they are responsible. Training by test system manufacturers or through industry sponsored workshops, while a valuable component of a laboratory training program, cannot be substituted for training programs based on an assessment of the individual's duties, background and skills. Training programs should include the following elements: • objectives for the training; • identification of the methods to be used in training; • identification of the materials to be used in the training; • criteria to assess the effectiveness of training. **Regulatory authority: 10 NYCRR subdivision 58-1.2(d)**	Training on safety protocols as required under Facility Design and Resource Management, Safety Standards, should include use of a biosafety cabinet, when present in the laboratory. Laboratories are encouraged to include a training video prepared by the Wadsworth Center's Laboratory Response Network entitled, Essentials in Biosafety, in its training program for use of biosafety cabinets. Training should also be provided on ensuring data ethics and integrity. Data integrity is defined as: generating, transforming, maintaining and assuring the accuracy, completeness and consistency of data for a specimen over its entire life cycle (i.e., from collection to reporting and including quality assessment and improvement) in compliance with applicable regulations. Data, in this instance, is meant to encompass all manner of data generated to produce a test result.

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Human Resources Sustaining Standard of Practice 7 (HR S7): Competency Assessment - Supervisory Staff Laboratory management shall have procedures to evaluate the competence of supervisory staff through annual performance reviews that include, but are not limited to, an assessment of the ability of the supervisory to fulfill the responsibilities described under Human Resources Sustaining Standard of Practice 3 and: a) compliance with policies and procedures; b) communication, including bringing problems and non-conformities to the attention of laboratory management; c) leadership and problem-solving capabilities; d) allocation of resources; and e) personnel management. **Regulatory authority: 10 NYCRR subdivision 58-1.2(d)**	If a supervisor or director/assistant director also functions as technical staff, he or she must also be competency assessed for those technical functions as outlined in Human Resources Sustaining Standard of Practice 8 (HR S8): Competency Assessment – Technical Staff. Technical staff that have been delegated to perform supervisory functions must also be competency assessed for those supervisory functions.
Human Resources Sustaining Standard of Practice 8 (HR S8): Competency Assessment – Technical Staff Laboratory management shall: a) have written procedures for performing and documenting competency assessment for all staff to include, at a minimum: i. direct observation of employee's duties by supervisory staff; ii. observation of compliance with safety protocols; iii. review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records; iv. monitoring the recording and reporting of test results;	Competency assessment must be documented for all individuals who perform technical functions, including healthcare providers performing testing at the point of care, and supervisory and management staff performing testing.

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v. direct observation of performance of instrument maintenance and function checks; vi. assessment of test performance through testing of previously analyzed specimens, internal blind, or external proficiency testing samples; and vii. assessment of problem solving skills; viii. assessment of competency of any delegated supervisory functions; b) document the actual date of observation or be able to recreate the test performance event as applicable; and, c) evaluate the competency of staff for all tasks for which they are responsible at least semiannually during the first year the individual tests patient specimens and thereafter annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be re-evaluated to include the use of the new test methodology or instrumentation. **Regulatory authority: 10 NYCRR subdivision 58-1.2(d)**	Documentation of the event used for the assessment of the staff's test performance must contain enough specific detail so that the evaluation can be substantiated. For example, for external proficiency testing, the date of the event, the score and analytes that the staff member tested needs to be retrievable. Documentation of the event when using previously analyzed specimens must indicate the date and the result of both the original testing and the testing performed by the staff member. Internal samples should be aliquots of previously analyzed specimens that are reintroduced into the work load in a blinded fashion.

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Human Resources Sustaining Standard of Practice 9 (HR S9): Competency Assessment – Non-technical Staff Laboratory management shall: a) have written procedures for performing and documenting competency assessment for all staff to include, at a minimum: i. direct observation of employee's duties by supervisory staff; ii. observation of compliance with safety protocols; iii. periodic review of work product for compliance with standard operating procedures and applicable workload limits; iv. monitoring the recording and reporting of test results; v. assessment of problem solving skills; b) document the actual date of observation or be able to recreate the performance event as applicable; and, c) evaluate the competency of staff for all tasks for which they are responsible at least annually. **Regulatory authority: 10 NYCRR subdivision 58-1.2(d)**	Competency assessment must be documented for all individuals who perform supportive tasks; such as data entry, accessioning, and phlebotomy; that are not technical in nature. This includes biomedical engineering staff working on laboratory equipment and IT staff working on the laboratory information system. iv. This is applicable to clerks/customer service or other non-technical staff who provide tests results to providers or the nursing floors.
Human Resources Sustaining Standard of Practice 10 (HR S10): Continuing Education The laboratory director shall provide continuing education to laboratory technical staff commensurate with the scope of their duties and such training and continuing education shall be documented. A minimum of twelve hours of continuing education must be performed by laboratory technical staff on an annual basis and staff participation must be documented. **Regulatory authority: 10 NYCRR subdivision 58-1.2(d)**	Acceptable forms of continuing education include in-service, professional meetings or industry sponsored training/workshop programs. Cytotechnologists must follow the continuing education requirements of 10 NYCRR subdivision 58-1.12(c).

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Human Resources Sustaining Standard of Practice 11 (HR S11): Supervisor Staffing The clinical laboratory shall have a supervisor on the laboratory premises during all hours in which tests are performed. An exception to the on-premises requirement shall be considered when performance of testing is required for emergency purposes, provided the person performing the test qualifies as a clinical laboratory technologist, the results of his or her work are reviewed by the supervisor or director during his or her next duty period, and a record is maintained to reflect the actual review. **Regulatory authority: 10 NYCRR Section 58-1.12**	For testing performed without a supervisor on-site, the director should establish the maximum time period between reporting of test results and the review. This time period should consider the implications of incorrect results on patient care. The director should describe the elements of testing that need supervisor review, including quality control.
Human Resources Sustaining Standard of Practice 12 (HR S12): Staffing Levels The laboratory shall employ a sufficient number of qualified technical personnel to ensure that there are no gaps in laboratory staffing and that supervisors have sufficient time to appropriately perform their supervisory functions even if they have bench responsibilities. **Regulatory authority: 10 NYCRR Section 58-1.12**	If the laboratory is run with minimal staffing, the laboratory shall have a planned ability to expeditiously obtain additional qualified staff or consultants should the need arise. The laboratory's performance on on-site survey and proficiency testing; its ability to implement an effective plan of correction to the deficiencies identified; and its ability to sustain compliance over time will be used as an indicator that staffing is insufficient.

Facility Design and Resource Management	
Standard	***Guidance***
Facility Design and Resource Management Fundamental Standard of Practice 1 (FDRM F1) The facility design and resource management, applicable to general facilities, space, laboratory equipment, laboratory information systems, reagents and laboratory safety are the responsibility of the laboratory director and owner, and must meet specifications established by the laboratory's quality management system and shall be in compliance with the requirements of this part. Identified non-conformance should not present imminent jeopardy to the integrity of laboratory services, to employee safety, or to patient care. **Statutory authority: Article 5, Title V Public Health Law Sections 575 (2) and (3)**	Effective inventory and document control are essential to the management of resources. Records of resource procurement or manufacture with identifiers (e.g., lot number, serial number, version number), verification of suitability for use, date placed into use, and maintenance and environmental controls should be designed to facilitate the linkage of resources in use at the time of specimen analysis.

Facility Design and Resource Management	
Standard	***Guidance***
General Facilities	
General Facilities Sustaining Standard of Practice 1 (GF S1): Design and Environment The laboratory design and environment shall be suitable for the tasks performed and have: a) sufficient space allocated so that its workload can be performed without compromising the quality of work and safety of personnel; b) energy sources, lighting, ventilation, water, waste and refuse disposal, and environmental controls commensurate with task requirements; c) protection from fluctuations and interruptions in electrical current that would pose risk to the reliability of test systems; d) backup power so that critical systems can be maintained or controlled as recovery procedures are followed; e) controlled access to and use of areas affecting the quality of the examinations, safeguarding specimens and resources from unauthorized access; and f) relevant storage space and conditions, consistent with Quality Management System specifications and manufacturer's instructions, if provided, to ensure the continuing integrity of specimens, slides, histology blocks, retained micro-organisms, documents, files, manuals, equipment, reagents, laboratory supplies, records, and results as specified in the *Records and Specimen Retention* sections of these Standards. **Regulatory authority: 10 NYCRR Section 58-1.6**	Notification of changes in laboratory location that may void the laboratory permit must be made as indicated in the Quality Management System Fundamental Standard of Practice (QMS F1).

Facility Design and Resource Management

Standard	*Guidance*
General Facilities Sustaining Standard of Practice 2 (GF S2): Monitor and Control The laboratory shall monitor, control, and record environmental conditions, as required by relevant Quality Management System specifications or where they may influence the quality of the results. Attention should be paid to biological sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature, water quality, and sound and vibration levels, as appropriate, to the technical activities concerned. **Regulatory authority: 10 NYCRR Section 58-1.6**	Each laboratory is expected to use the appropriate water quality as required for each instrument, kit, or test system. Laboratories producing water should consider parameters such as pH, silicate content, particulate matter and bacterial and organic content in assessing water quality. These parameters vary by test system and should be assessed by the laboratory for appropriateness and monitoring. Laboratories purchasing water that has already been classified are not expected to evaluate these parameters unless specified by the manufacturer or by the laboratory in its procedure manual. It is acceptable to monitor temperatures with a continuous recording thermograph. It is acceptable for temperatures to be maintained and monitored internally by an instrument, provided test results are either not generated or are flagged when the acceptable temperature range is exceeded. Environmentally controlled spaces may also be monitored through an electronic on-line monitoring system. An alarming system should be initiated when temperatures exceed acceptable limits.

Facility Design and Resource Management

Standard	*Guidance*
General Facilities Sustaining Standard of Practice 3 (GF S3): Separation of Incompatible Activities There shall be effective separation between adjacent laboratory sections in which there are incompatible activities. Measures shall be taken to prevent cross-contamination. The laboratory using target amplification procedures shall establish and implement procedures to prevent nucleic acid contamination that minimally includes: a) a unidirectional workflow from pre- to postamplification; b) preamplification procedures shall be performed in a dedicated work area that excludes amplified DNA to minimize specimen contamination; c) equipment and personal protection items shall be dedicated to either the pre- or postamplification area; d) reagents used for amplification shall not be exposed to postamplification work areas; and, e) specimens shall not be exposed to postamplification work areas. **Regulatory authority: 10 NYCRR Section 58-1.6**	Examples of where separation is needed include: a) where examination procedures pose a hazard, e.g., mycobacteriology, radionuclides; b) where the work may be affected or influenced by not being separated, e.g., nucleic acid amplifications; c) where an environment conducive to quiet and uninterrupted work is required, e.g., cytopathology screening; and d) where work requires a controlled environment, e.g., large computer systems. 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. b) 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 is recommended. c) Equipment includes instruments and supplies, including, but not limited to, pipets, pipettors, bulbs, tips, pens, and cleaning supplies. Personal protection items include laboratory coats, gloves, safety glasses and other individually worn barriers.
General Facilities Sustaining Standard of Practice 4 (GF S4): Cleanliness Work areas shall be clean and well maintained. Storage and disposal of dangerous materials shall be those specified by relevant regulations. **Regulatory authority: 10 NYCRR Section 58-1.6**	

Facility Design and Resource Management	
Standard	***Guidance***
Laboratory Equipment	
Laboratory Equipment Sustaining Standard of Practice 1 (LE S1): Procurement and Installation The laboratory shall be furnished with all items of equipment required for the provision of services (including primary sample collection, sample preparation and processing, examination, and storage). Laboratory equipment shall be: a) selected and shown (upon installation and in routine use) to be capable of achieving the performance required; b) uniquely labeled, marked, or otherwise identified and properly referenced in records of maintenance, function checks and performance assessment; c) labeled or otherwise coded, to indicate the status of calibration or verification and the date when recalibration or reverification is due; and d) maintained in a safe working condition, including examination of electrical safety, emergency stop devices, and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. **Regulatory authority: 10 NYCRR Section 58-1.6**	The laboratory should establish and/or verify the performance specifications of the assay as part of the initial validation, and design systems to monitor methods and equipment to ensure that these performance specifications remain stable during the use of the assay. The performance specifications of an assay may be modified based on the quality assessment program or as required to maintain clinical validity.

Facility Design and Resource Management

Standard	*Guidance*
Laboratory Equipment Sustaining Standard of Practice 2 (LE S2): Function Checks and Preventive Maintenance Laboratory management shall establish a program that monitors and demonstrates proper calibration and function of equipment prior to initial use and annually thereafter, and maintain documentation of preventive maintenance that, at a minimum, follows the manufacturer's recommendations. **Regulatory authority: 10 NYCRR Section 58-1.6**	When manufacturer's instructions, operator's manuals, or other documentation are available, they may be used to establish requirements, but manufacturer recommendations should be verified and made more rigorous should laboratory experience require. A service contract for preventive maintenance from an outside source is acceptable provided that there is a description of the services performed for each instrument or piece of equipment. A service contract does not negate the laboratory's responsibility for performing other routine maintenance not included in the maintenance contract. Documentation of work performed during installation, preventative maintenance or repair by outside vendors must be maintained. If the laboratory deviates from the manufacturer's written recommendations for monitoring and preventive maintenance, the modification must be validated. Recommendations from manufacturers must be in writing; verbal communication from manufacturer's representatives authorizing changes to preventive maintenance or monitoring procedures is not sufficient. The laboratory may consider more frequent calibration verification of instruments and equipment, depending on use. For examples, increased frequency of pipettor calibration may be necessary based on the volumes of liquids being delivered, the volume of use, and the viscosity of the liquids being handled.
Laboratory Equipment Sustaining Standard of Practice 3 (LE S3): Use and Preventive Maintenance Instructions Up-to-date instructions on the use and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer, shall be readily available for use by laboratory personnel. **Regulatory authority: 10 NYCRR Section 58-1.6**	

Facility Design and Resource Management

Standard	*Guidance*
Laboratory Equipment Sustaining Standard of Practice 4 (LE S4): Maintenance Records Records shall be maintained for each item of equipment contributing to the performance of examinations. These records shall include at least the following: a) identity of the equipment; b) manufacturer's name and serial number or other unique identification; c) date placed into service; d) the manufacturer's instructions; e) equipment performance and function check records that confirm equipment's suitability for use; f) maintenance carried out to date and what maintenance is planned for the future; and, g) damage, malfunction, modification or repair to the equipment. **Regulatory authority: 10 NYCRR Section 58-1.6**	Performance records should include copies of reports/certificates of all calibrations and/or verifications including dates, time, and results, adjustments, the acceptance criteria, and due date of the next calibration and/or verification, together with the frequency of checks carried out between maintenance/calibration, as appropriate. These records shall be maintained and shall be readily available for the life span of the equipment and two years thereafter, including electronic records. An alternate means of documentation must be used if the instrument's internal system purges or overwrites the monitoring data. Records must be maintained under protocols for *document control: specimen processing & process verification* and made available when there is a request for the recreation of the test process for selected patient specimens.

Facility Design and Resource Management

Standard	*Guidance*
Laboratory Equipment Sustaining Standard of Practice 5 (LE S5): Managing Defective Equipment Whenever equipment is found to be defective through function checks or other monitors of performance, it shall be taken out of service, clearly labeled, and appropriately stored until it has been repaired and shown by calibration, verification, or function checks to meet specified acceptance criteria, and the laboratory shall: a) examine the effect of this defect on previous examinations; b) determine the need to initiate a non-conformance investigation and take appropriate corrective action when necessary; c) take reasonable measures to decontaminate equipment prior to service, repair, or decommissioning; d) provide to the person working on the equipment a list of the measures taken to reduce contamination; e) provide suitable space for repairs and appropriate personal protective equipment; and f) ensure that repaired or serviced equipment is checked and shown to be functioning satisfactorily before the equipment is returned to laboratory use. **Regulatory authority: 10 NYCRR Section 58-1.6**	

Facility Design and Resource Management

Standard	*Guidance*
Laboratory Equipment Sustaining Standard of Practice 6 (LE S6): CO2 Incubators The percentage of CO2 in CO2 incubators (range 5-10%) shall be monitored as follows: a) for those incubators without a CO2 monitoring system, CO2 levels must be measured daily using an outside CO2 measurement device (eg. Fyrite, electronic CO2 analyzer), or b) if the incubators have a CO2 monitoring system, it must be validated monthly by use of an additional separate monitoring system. **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 a Fyrite CO_2 Analyzer if the following conditions are met: a) using a Fyrite CO_2 Analyzer, the laboratory should test the CO_2 level daily for one week or until the level is stable; b) if the CO_2 level is within range for at least one week then the laboratory may test the CO_2 level with the Fyrite CO_2 analyzer weekly for the next month to detect long term drift while recording daily the level from the automatic readout; and, c) if the CO_2 level is in range for all weekly readings, then the laboratory may test the CO_2 level monthly with Fyrite while recording the level from the automatic readout daily. If any of these or a subsequent reading is out-of-range the laboratory shall repeat steps a-c. If the laboratory uses commercial CO_2 bags, the manufacturer's instructions should be followed.
Laboratory Equipment Sustaining Standard of Practice 7 (LE S7): UV Decontamination If ultraviolet light (UV) is used as part of the decontamination protocol, the laboratory shall: a) implement personal safety procedures; b) check the energy efficiency of the UV lights at least every six months; and, c) replace bulbs as needed to maintain the manufacturer's recommended UV levels. **Regulatory authority: 10 NYCRR Section 58-1.6**	The Centers for Disease Control (CDC) and the National Institute of Health (NIH) agree that UV lamps are not recommended nor required in biological safety cabinets (ABSA Position Paper on UV in BSCs). However, if used, it is recommended that a 10 - 15 minute UV exposure of the work area be performed at the beginning and end of the workday. It is recommended that the bulbs be cleaned weekly with 70% ethanol to optimize the light output and enhance germicidal effectiveness, taking proper precaution to prevent electric shock. Energy output should be no less than 40 microwatts per square centimeter at 254 nanometers. Plate irradiation testing may also be used to verify that the energy output is sufficient to kill microorganisms.

Facility Design and Resource Management	
Standard	***Guidance***
Laboratory Equipment Sustaining Standard of Practice 8 (LE S8): Thermal Cyclers For procedures using a thermal cycler, the laboratory shall: a) program the thermal cycler per the test kit manufacturer's instructions; b) run internal performance checks at least once a year, or more frequently if the manufacturer recommends this, on thermal cyclers that have the capability to run this check; and c) verify the uniformity of temperature across the entire sample block at inception and then periodically to ensure continued uniformity. **Regulatory authority: 10 NYCRR Section 58-1.6**	a) Deviations from manufacturer instructions must be validated. b) This should include monitoring of the rate of temperature increase where possible. c) If an electronic check for temperature homogeneity is available, then follow the manufacturer's instructions for frequency of checks. If not, then a calibrated device or weakly reactive controls to monitor a random series of wells should be run when the instrument is first used. Ongoing verification of temperature homogeneity is recommended thereafter.
Laboratory Equipment Sustaining Standard of Practice 9 (LE S9): Ancillary Equipment In those cases where the laboratory needs to use equipment outside its permanent control, laboratory management shall ensure that the Laboratory Equipment requirements of this part are met. **Regulatory authority: 10 NYCRR Section 58-1.6**	The laboratory is responsible for ensuring that all requirements for equipment such as preventive maintenance and calibration are met, regardless of whether the equipment is rented, leased or located in another part of the facility such as a research or core laboratory.
Reagents & Supplies	
Reagents Sustaining Standard of Practice 1 (REAG S1): Acquisition The laboratory shall be furnished with all reagents, kits and supplies required for the provision of services. Purchased items shall consistently meet the laboratory's quality requirements. There shall be procedures and criteria for inspection, acceptance/rejection, and storage of consumable materials. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	

Facility Design and Resource Management	
Standard	***Guidance***
Reagents Sustaining Standard of Practice 2 (REAG S2): Verification – General Requirement Purchased equipment and consumable supplies that affect the quality of the service shall not be used until they have been verified as complying with standard specifications or requirements defined for the procedures concerned. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	This 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.

Facility Design and Resource Management

Standard	*Guidance*
Reagents Sustaining Standard of Practice 3 (REAG S3): Verification of Reagents and Media For reagent, media, and supply checks, the laboratory must follow the manufacturer's specifications for using reagents, media and supplies and be responsible for the results. In addition, the laboratory must: a) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, and identification systems (systems using two or more substrates or two 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 (unless otherwise specified in these standards), 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)**	

Facility Design and Resource Management

Standard	*Guidance*
Reagents Sustaining Standard of Practice 4 (REAG S4): Inventory Control There shall be an inventory control system for supplies. This system should include the recording of lot numbers and expiration dates of all relevant reagents, control materials, and calibrators; the date of receipt in the laboratory; the date of performance verification and the date the material is placed in service. All of these quality records shall be available for laboratory management and Department review. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	Inventory control should ensure that the laboratory has sufficient reagents to verify new lots and shipments. Reagent backorders should be documented using communications from the manufacturer. Records of inventory control must be maintained under protocols for document control and made available when there is a request for the recreation of the test process for selected patient specimens
Reagents Sustaining Standard of Practice 5 (REAG S5): Labeling Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: a) identity; b) titer, strength or concentration as applicable; c) storage conditions; d) preparation date or date opened and the identity of the preparer; e) unopened and opened expiration date if pertinent to the performance of the reagent; and, f) other relevant information. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	In-house prepared microbiological media (tubed and plated) need not be labeled individually provided each storage rack or tray includes the required identifying information and each tube/plate identifier is traceable to the storage rack or tray. d) The identity of the preparer does not need to be on the reagent label but can be documented using other formats such as worksheets.

Facility Design and Resource Management	
Standard	***Guidance***
Reagents Sustaining Standard of Practice 6 (REAG S6): Kit Components Whenever kits are used, components shall not be interchanged unless otherwise specified by the manufacturer, or verified by the laboratory. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	
Reagents Sustaining Standard of Practice 7 (REAG S7): Expiration Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded the manufacturer's stated expiration date, have deteriorated, or are of substandard quality. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	Laboratories may use reagents beyond the expiration date only if the manufacturer has provided written authorization to do so. The laboratory may not conduct its own validation studies to extend the shelf life of reagents. Outdated items may be used for training or student use. They should, in this case, be stored separately from in dated reagents and be clearly labeled "Educational use only" or similar wording. For reagents provided without a manufacturer expiration date, the laboratory director shall determine the expiration date based on test development and validation data. The expiration date should be based on viability, obvious contamination or deterioration, or problems with quality control. Laboratory-determined expiration dates should be re-evaluated periodically, and revised as needed, based on historical data review, lot-to-lot verification, and/or test calibration.
Reagents Sustaining Standard of Practice 8 (REAG S8): PCR Probes, Primers Probes and primers used in PCR shall not be frozen and thawed repeatedly. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	Probes and primers should be stored in small aliquots to minimize the number of freeze /thaw cycles.

Facility Design and Resources Management	
Standard	***Guidance***

Facility Design and Resources Management

Laboratory Safety	(effective November 1, 2010, Safety S12 effective August 1, 2011, Safety S1, S3 and S6 revised and effective July 14, 2014) These safety standards apply to all laboratories regardless of location.
Safety Sustaining Standard of Practice 1 (Safety S1): Biohazard Risk Assessment and Biosafety Program The laboratory shall conduct an infectious agent risk assessment for each permit category, or designated area separate from the laboratory space, and based on this review shall develop and implement an appropriate biosafety program that identifies the laboratory's biosafety level(s) and incorporates the use of biosafety equipment, practices and procedures that shall: a) be described in the laboratory's safety manual; b) be revised as necessary and reviewed by the director at least annually; c) minimally meet biosafety level 2 (BSL-2) criteria and incorporate, as appropriate, the use of a certified class II (or higher) biological safety cabinet (BSC) and/or other containment equipment/devices and practices intended to prevent release of infectious aerosols into the work environment; and, d) incorporate the use of appropriate personal protective equipment (PPE) such as lab coats or gowns, face shields and disposable gloves intended to protect the worker from splashes, spills or other direct contact with infectious specimens/materials; and, e) when applicable, include a written plan to be implemented in the event that an agent suspected of exceeding the laboratory's biosafety level/practices is encountered. The plan shall include provisions for: i. immediate notification of the laboratory supervisor and/or director; ii. cessation of work with the material until appropriate safety practices and PPE can be put into place or the specimen referred to an appropriate laboratory; iii. implementation of the employee exposure plan, if applicable; and, f) require that the biohazard risk assessment be revised as necessary and reviewed by the director at least annually. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	A five-step approach to infectious agent risk assessment: i. Identify the biorisk characteristics (e.g. pathogenicity, route of infection) and doses (concentration/volume) of agents handled by the laboratory. ii. Identify laboratory practices that increase exposure risks such as aerosol-generating procedures (centrifuging, vortexing, etc.) and the use of sharps. iii. Determine the appropriate biosafety level (BSL) and develop a biosafety program that includes the appropriate precautions, practices, PPE, safety equipment and facility design and access. iv. Review the risk assessment process and biosafety program with biosafety professionals. v. Ensure staff knowledge and proficiency regarding the laboratory's biosafety program, including the use of PPE and safety equipment. A biosafety professional is a competent person who has a relevant qualification in the field of life sciences and additional recent working experience or training in the microbiological laboratory or in laboratory infection control procedures consistent with the type of work performed by the laboratory. Diagnostic and health care laboratories must minimally meet BSL-2 criteria. Aerosol-generating specimen/culture procedures (e.g. vortexing, centrifuging, pipetting, mixing) should incorporate the use of practices and equipment (e.g. BSC) or devices (e.g. closed centrifuge cups/carriers) intended to prevent release of aerosols. A designated area separate from the laboratory space, as intended in this standard, means a single location where testing is performed under more than one permit category,means a patient service center, a limited service laboratory, or areas designated as point of care testing sites. Biosafety in Microbiological and Biomedical Laboratories available at http://www.cdc.gov/biosafety/publications/bmbl5/index.htm is an advisory document from the CDC providing recommendations for conducting work in biomedical and clinical laboratories safely. Risk level criteria are used to define the infectiousness and transmissibility of an agent and the severity of the disease it causes. Biosafety level 1 (BSL-1) – agents do not cause disease in healthy humans, a basic level of protection is required. BSL-2 – moderate risk agents may cause varying severity of human disease if ingested or through mucuous membrane or percutaneous exposure. BSL-3 – serious and fatal infections may occur through aerosol transmission. BSL-4 –exotic agents transmitted through aerosols that pose a high risk for life threatening diseases with no available treatment.

Facility Design and Resources Management

Standard	*Guidance*
Safety Sustaining Standard of Practice 2 (Safety S2) Employee Occupational Exposure Plan The laboratory shall establish an employee infectious agent exposure control plan appropriate for the testing and procedures performed by the laboratory. The plan shall include: a) immediate notification of the laboratory director or designee of an occupational exposure or of an employee exhibiting symptoms consistent with an occupational exposure; b) medical risk assessment; c) diagnostic testing and treatment, as appropriate; d) root cause investigation; and, e) documentation of the incident and implementation of corrective action and retraining as necessary. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	The employee exposure plan should be developed based on the laboratory's infectious agent risk assessment (see Safety S1) and should take into account the specimen types received and the procedures performed. b) The plan should provide options for the employee to consult their own physician or a physician provided by the laboratory. **References**: 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 at reasonable risk of coming into contact with blood and other potentially infectious materials that may contain HIV, HBV or HCV. These requirements do not take into account exposures risks for other agents or other routes of exposure such as those that may be encountered in laboratories performing culture procedures.

Facility Design and Resources Management

Standard	*Guidance*
Safety Sustaining Standard of Practice 3 (Safety S3): Facility Design Laboratory facilities shall be designed to ensure that infectious agents cannot be transmitted to health care workers or the general public and shall include: a) a pest management plan which ensures that pests cannot act as a mechanical vector to spread infectious agents; b) sufficient space between benches, cabinets and equipment to allow adequate cleaning; c) flooring and furniture located in the testing laboratory must be impervious to liquids and capable of being easily cleaned and decontaminated. Carpets and rugs must not be used in the laboratory where specimens are processed and/or manipulated. d) work surfaces that are impervious to liquids and resistant to moderate heat and the chemicals used for cleaning and decontamination; e) adequate hand washing facilities within the laboratory work area; f) properly maintained eye wash facilities; g) emergency showers, if appropriate; and, h) doors designed to facilitate access control. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	a) The pest management plan can include mechanical barriers such as screens on the windows to prevent flies from entering the laboratory or visual inspection of the structural integrity of the facility. c) Chairs and other furniture used in the laboratory work area should be covered with a non-fabric material that can be easily decontaminated. Rugs and carpets may not be used in areas where open specimens are handled. They may be used in areas where stained, fixed and, when appropriate, coverslipped slides are examined. Rubber non-skid mats may be used in specimen processing areas provided they are easily decontaminated. e) Minimally, laboratories should be designed so that hand washing facilities are located near each exit. Additional, hand washing facilities should be located so that there is easy access for use prior to handling communal objects (e.g. phone, keyboard, etc). Chemical disinfectants are not considered an acceptable alternative to soap-and-water hand washing in the BSL-2 or higher clinical laboratory setting. Patient Service Centers are under the auspices of the laboratory and must also follow this standard including the placement of hand washing facilitates. When collecting urine specimens for chain of custody (forensic) purposes attempts should be made to provide hand washing facilities to the donor without compromising the integrity of specimen. f) Plumbed eye wash stations should be flushed weekly. Manufacturer's maintenance instructions should be followed for free standing eye wash devices and discarded when outdated or appear contaminated. g) OSHA rules for emergency showers when caustic or corrosive chemicals are used must be followed. See also Safety Sustaining Standard of Practice15. h) Preferably, self-closing doors should be used in the laboratory.

Facility Design and Resources Management

Standard	*Guidance*
Safety Sustaining Standard of Practice 4 (Safety S4): Access Access to the laboratory shall be limited or restricted as required to protect the public and/or employees. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	The laboratory director is responsible for defining and approving the levels of access and identifying the laboratory's biosecurity practices, as appropriate for the setting. See *Biosafety in Microbiological and Biomedical Laboratories*; 5th edition, CDC: http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_sect_IV.pdf
Safety Sustaining Standard of Practice 5 (Safety S5): Biohazard Labels Warning labels with the universal biohazard symbol or with the legend "Biohazard" shall be affixed: a) on or adjacent to the door or entranceway of a laboratory room or a subdivided area within a modular room where clinical specimens or other potentially infectious materials are handled, stored, processed, manipulated or tested; and, b) On each refrigerator, freezer, incubator or other equipment that is located in a hallway or other type of open access or passage area and is used for storing/holding clinical specimens or other potentially infectious materials. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(11)**	a) Applying labels to equipment within these labeled rooms/areas is optional. Clerical or data entry stations not requiring the use of PPE may be designated as such within the laboratory area at the discretion of the laboratory director. However, these areas must be clearly delineated from the technical areas and writing instruments, phones, keyboards, etc. in the clerical/data entry areas must be dedicated to those areas and must not be used by individuals wearing PPE. See Safety Sustaining Standard of Practice 8 for activities prohibited in these areas. There should be a system in place that prevents maintenance and/or repairs to be performed on "dirty" equipment without adequate use of PPE and/or decontamination.

Facility Design and Resources Management

Standard	*Guidance*
Safety Sustaining Standard of Practice 6 (Safety S6): Biological Safety Cabinets (BSC) Laboratories utilizing a BSC shall: a) decontaminate the BSC with an appropriate disinfectant before and after each use and immediately following a spill or splash; b) monitor and document the air flow prior to use; c) test and certify the BSC *in situ* at the time of installation within the laboratory, at any time the BSC is moved, and at least annually thereafter; and, d) document that all users are trained in the proper use of the BSC and are periodically observed for compliance with defined practices. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	The need for a class II or higher BSC should be determined based on the laboratory's biohazard risk assessment (see Safety Sustaining Standard of Practice 1). Airflow monitoring may be accomplished by the use of a magnehelic or similar device, or a device built into the cabinet, with or without an alarm. During installation it should be verified that fluctuations of the room supply and exhaust air do not cause the BSC to operate outside the parameters for containment. BSCs should be situated so as to avoid interference of airflow such as by opening of doors or personnel traffic. The BSC shall be certified according to the *National Sanitation Foundation (2002), Standard 49, Class II (laminar flow) Biohazard Cabinetry,* Ann Arbor, MI. References: *Biosafety in Microbiological and Biomedical Laboratorie*s (http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_appendixA.pdf). An instructional video *Essentials of Biosafety: Overview of Biosafety Principles and Use of the Biological Safety Cabinet* is available on the Wadsworth Center website and the Departments Health Commerce System. Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, 3rd edition (www.cdc.gov/od/ohs/biosfty/primary_containment_for_biohazards.pdf)

Facility Design and Resources Management	
Standard	***Guidance***
Safety Sustaining Standard of Practice 7 (Safety S7): Food Storage Food and drink shall be stored outside the work areas in cabinets or refrigerators designated for this purpose and not in refrigerators or areas where clinical specimens or other infectious or potentially infectious materials may be present. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	This includes glucose solutions stored by the laboratory.
Safety Sustaining Standard of Practice 8 (Safety S8): Personal Practices Food storage/preparation, eating, drinking, smoking, handling contact lenses, applying cosmetics or lip balm and use of personal electronic devices are prohibited in work areas that present a reasonable likelihood of occupational exposure to chemical or radiologic hazards, or infectious materials. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	Regarding exposure to infectious materials, an area where clinical specimens or other potentially infectious materials are handled, processed or tested is considered to present a reasonable likelihood of exposure to infectious materials. Personal electronic devices (e.g. cell phones, beepers) or other personal items should be handled in a manner that ensures they do not become contaminated and should not be handled at the work station. This practice applies to students, non-lab personnel and visitors who have been given access to the laboratory.

Facility Design and Resources Management

Standard	*Guidance*
Safety Sustaining Standard of Practice 9 (Safety S9): Personal Protective Equipment (PPE) Availability, Use and Maintenance The employer shall: a) provide PPE as appropriate for the type of work performed (see Safety Sustaining Standard of Practice 1) at no expense to the employee; b) ensure that PPE is accessible at the worksite, properly maintained and that used PPE is not stored in clean areas; c) provide cleaning, maintenance and/or disposal at no cost to the employee; d) ensure that employees are trained in the proper use of PPE prior to use, including donning and doffing; e) not allow employees to wear PPE outside the work area; and, f) not allow employees to remove PPE or laboratory coats from the premises. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	PPE should be worn whenever there is a risk of contact with infectious materials or hazardous materials. The type of PPE that should be utilized in a particular setting should be determined as part of the biohazard risk assessment (Safety Sustaining Standard of Practice 1) and the chemical hygiene and radiological safety plan (Safety Sustaining Standard of Practice 15). Regarding use of PPE, personnel should use disposable gloves and a protective laboratory coat or gown whenever handling or manipulating fresh, frozen or diluted patient specimens that have not been treated to eliminate risk of infection. Additionally, a splash barrier capable of protecting the face should be used whenever performing manipulations on these materials that may produce splashes (e.g. capping/uncapping containers, pipetting/dispensing, vortexing, mixing/diluting, shaking). Face protection can be accomplished by using an individual face shield, a bench-top splash shield or a BSC with proper positioning of the worker. Glasses or goggles do not provide adequate protection unless worn with a face mask that covers the mouth and nose. PPE should be removed immediately upon contamination. PPE should be removed upon completion of work and either properly discarded or decontaminated and stored if reusable. Hands should be washed immediately upon removing PPE. Chemical disinfectants are not considered an acceptable alternative to soap-and-water hand washing in the clinical laboratory setting. Laboratory coats designated for wear in public areas should not be used as PPE and should be stored in a clearly defined clean area away from potential contact with coats or smocks used as PPE. PPE such as PAPRs (Powered Air Purifying Respirators) or respirators should be examined prior to each use and should be inspected annually. A visual inspection of the hosing, bonnet, and unit as well as a battery check should be performed every time the unit is used. Annual competency assessment should include the proper use of all PPE as described in the Human Resource standard for Competency Assessment of Non-Supervisory Staff.

Facility Design and Resources Management

Standard	*Guidance*
Safety Sustaining Standard of Practice 10 (Safety S10): Disposable Gloves The laboratory's biosafety program shall include a policy regarding use of disposable gloves when handling infectious or potentially infectious materials including that gloves: (a) must be worn when handling primary specimens; (b) must be worn when handling any items for which there is a likelihood that such handling may result in direct contact with infectious or potentially infectious material; (c) must be worn when the employee has cuts, scratches or other breaks in the skin and is handling infectious or potentially infectious material, regardless of likelihood of direct exposure; (d) must be removed and discarded immediately upon contamination; (e) must be removed and discarded immediately upon task completion at each work station (e.g. BSC, bench space) followed by hand washing; and (f) must not be washed or reused. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	The laboratory's risk assessment (see Safety Sustaining Standard of Practice 1) should guide the laboratory director in tailoring a "glove use policy" that is based on the type of work performed by the laboratory. Optional glove use during activities not related to handling infectious or potentially infectious material is at the discretion of the laboratory director. e) Chemical disinfectants are not considered an acceptable alternative to soap-and-water hand washing in the BSL-2 or higher clinical laboratory setting. e) Caution should be used when removing gloves; snapping or stretching the gloves may result in aerosol formation. Removing gloves immediately upon leaving each workstation greatly reduces the likelihood for inadvertent contamination of communal and personal objects (e.g. phones, pencils, keyboards, etc). When used for phlebotomy procedures, gloves should be changed between patients.

Facility Design and Resources Management

Standard	*Guidance*
Safety Sustaining Standard of Practice 11 (Safety S11): Sharps The laboratory biosafety program shall include the following practices: a) training for the safe handling of sharps; b) needles shall not be recapped, or removed 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 (e.g., collection of blood gas specimens); and, c) used disposable needles shall not be bent, sheared, broken, removed from syringes or otherwise manipulated by hand, but shall be placed in a puncture-proof, leak-proof container used for sharps disposal. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	The safety manual should include written policies for the acceptance of specimens that include needles. Syringes that re-sheath the needle, needle-less systems, and other safety devices should be used. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) should be used for phlebotomy or the aspiration of fluids. See Safety Sustaining Standard of Practice 17 for disposal of sharps.
Safety Sustaining Standard of Practice 12 (Safety S12): Work Surface Decontamination Laboratory work surfaces shall be decontaminated with an appropriate disinfectant following spills of infectious or potentially infectious material, and at a frequency defined in the laboratory's biohazard risk assessment as described in Safety Sustaining Standard of Practice 1. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	When using household bleach (5.25% sodium hypochlorite), it is recommended that 1:10 dilutions be prepared daily. Biohazard risk assessment should consider the number of specimens and the types of manipulations when setting the frequency of decontamination. Documentation is not required except when deemed necessary by the person responsible for ensuring compliance with the laboratory's safety policy.

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Standard	***Guidance***
Safety Sustaining Standard of Practice 13 (Safety S13): Safety Breaches The laboratory safety manual shall include the procedure for decontaminating spills and splashes of infectious or potentially infectious material. Such incidents, as well as other safety breaches, shall be: a) cleaned immediately and surfaces decontaminated using an appropriate disinfectant; b) immediately reported to the laboratory director or designee and documented; c) assessed for the need to implement the employee exposure plan; d) investigated to identify cause; and, e) followed up with remedial action and retraining as necessary. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	Spill decontamination protocols should be adequate for the spill size, location (e.g. floor, inside BSC) and nature of the spilled material. Minimally, prior to cleaning the site, the spill should be confined using an absorbent material and treated with an effective disinfectant for an appropriate period of time. Procedures should include guidance for safe clean-up and disposal of broken glass and other sharps.
Safety Sustaining Standard of Practice 14 (Safety S14): Biosafety Program Training All personnel involved with handling clinical specimens and other infectious or potentially infectious material and/or medical waste shall receive training on the laboratory's biosafety program including the potential hazards associated with their work activities and the practices and procedures intended to avoid exposure to and/or dissemination of infectious material. This training shall be conducted as part of initial employee training and annually thereafter and shall be documented. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	Training should include familiarization with the laboratory's occupational exposure plan. Training and discussion should be supplemented with ongoing supervisory observation to ensure staff compliance with the laboratory's safety policies and proper use of PPE.

Facility Design and Resources Management

Standard	*Guidance*
Safety Sustaining Standard of Practice 15 (Safety S15): Chemical Hygiene and Radiological Safety Plan Laboratories shall develop and implement written chemical hygiene and radiological safety plans that shall be available to employees upon request whenever laboratory work involves the use of hazardous chemicals or radioactive materials. The plan shall: a) describe the use of fume hoods or other protective equipment whenever handling hazardous materials; b) establish procedures for exposure monitoring when permissible exposure levels of hazardous materials are exceeded; c) describe precautions for handling reagents containing toxic, hazardous or radioactive substances, including methods for their proper labeling and disposal; d) ensure proper storage of hazardous materials, including the use of a flame proof cabinets, where appropriate; e) establish a designated area for hazardous chemical and radiological material storage and disposal; f) include an action plan for dealing with laboratory accidents; and maintain eye wash and emergency shower facilities for such incidents; g) contain a protocol for managing documented exposure to chemical or radiological materials; h) contain a management protocol for maintenance of chemical and radiological exposure records on each employee; i) document that employees are provided with training regarding toxic substances and radiological materials in the workplace and use of protective equipment prior to beginning work with these materials and annually thereafter; and j) provide ready access for all employees to Material Safety Data Sheets (MSDS) for all chemicals in use by the laboratory. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	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. i) Minimally, training should be conducted as part of initial employee training and annually thereafter. f) OSHA rules for emergency showers when caustic or corrosive chemicals are used must be followed.

Facility Design and Resources Management

Standard	*Guidance*
Safety Sustaining Standard of Practice 16 (Safety S16): Radioactive Materials Clinical laboratories located in New York State that use radioactive materials shall: a) have a New York State license to store radioactive materials; and b) maintain documentation of inspection by the NYSDOH Bureau of Environmental Radiation Protection pursuant to 10 NYCRR Part 16 and ensure ongoing compliance with such regulations. **Regulatory Authority: 10 NYCRR paragraph 19.3(c)(11)**	For laboratories located in New York State, questions concerning the storage and disposal of radioactive materials should be directed to the New York State Department of Health Bureau of Environmental Radiation Protection at 518-402-7550 or berp@health.ny.gov.

Facility Design and Resources Management

Standard	*Guidance*
Safety Sustaining Standard of Practice 17 (Safety S17): Compliance with Local, State and Federal Statutes and Regulations The director shall ensure that the laboratory complies with all applicable local, state and federal laws, regulations and requirements for: a) packaging and shipping of infectious substances; b) storage, treatment and disposal of regulated medical waste; and c) storage, handling and disposal of chemicals and radiologic waste. **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 Article 13, Title XIII, Section 1389 of NYS Public Health Law and in Part 70 of NYCRR. These regulations provide specific information regarding the use, labeling, handling, packaging and disposal of sharps and containers used for disposal of RMW generated by laboratories. Packaging and shipping requirements vary based on several factors including the type of specimen; likelihood that the specimen contains a category A or Category B pathogen; and the type of carrier/shipper being used (e.g. commercial carrier; private ground carrier; air transport). The laboratory must therefore review applicable Department of Transportation (DOT) and International Air Transport Association (IATA) requirements as well as requirements that may be in place by a commercial transporter. Packaging and shipping regulations are defined in the U.S. DOT Hazardous Materials Regulations (HMR; 49CFR Parts 171-178), available at ecfr.gpoaccess.gov. DOT regulations were harmonized with United Nation (UN) recommendations in 2006. IATA guidelines are available at www.iata.org. Under IATA requirements, every person responsible for packaging and shipping category A infectious substances must be trained every 24 months and be certified to package and ship by their institution. Patient specimens fall into one of several categories including those that: a. are not subject to the provisions of the DOT dangerous goods regulation (e.g. dried blood spots; fecal occult blood); b. meet the definition of a category A (UN 2814 or UN2900) infectious substance (e.g. blood specimen known or reasonably suspected to contain Ebola virus); c. meet the definition of a category B (UN 3373) biological substance (e.g. blood specimen known or suspected to contain HBV); or, d. are eligible for “exempt” packaging and shipping provisions (e.g. routine cholesterol screening) (IATA only); *Note: As of Jan 2007, the use of the shipping names Diagnostic specimens and Clinical specimens is not permitted*.

Facility Design and Resources Management	
Standard	***Guidance***
Laboratory Information Systems (LIS)	
LIMS Sustaining Standard of Practice 1 (LIMS S1): General The laboratory shall ensure that test results generated by the LIS are reported, archived, and maintained in an accurate and reliable manner. **Regulatory authority: 10 NYCRR subdivision 58-1.2(c)**	
LIMS Sustaining Standard of Practice 2 (LIMS S2): Maintenance The laboratory shall perform and document the necessary 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 section 58-1.6**	
LIMS Sustaining Standard of Practice 3 (LIMS S3): Ancillary Device Maintenance All input/output devices such as printers, monitors, keyboards and modems shall be maintained to ensure accurate, clear and interference-free transmission of reports. **Regulatory authority: 10 NYCRR section 58-1.6**	
LIMS Sustaining Standard of Practice 4 (LIMS S4): Validation The laboratory shall validate any system changes, including new or revised software and/or hardware prior to their use for specimen testing, reporting and record keeping functions. **Regulatory authority: 10 NYCRR subdivision 58-1.2 (c)**	This should include new interfaces or printers to the system. The laboratory director and laboratory management must approve any installation and validation of new systems or changes to existing validated systems conducted by an IT Department or other entity outside the direct control of the laboratory.

Facility Design and Resources Management

Standard	*Guidance*
LIMS Sustaining Standard of Practice 5 (LIMS S5): Data Recovery The laboratory shall have a mechanism to assure that previous data is retrievable when the LIS is upgraded or replaced. Protocols for data recovery must include systems backup at a frequency that minimizes risk of data loss, and must provide for off-site storage of media with backed up records. **Regulatory authority: 10 NYCRR section 58-1.6**	
LIMS Sustaining Standard of Practice 6 (LIMS S6): LIMS Failure The laboratory shall implement procedures to ensure data integrity, timely reporting of results and retrieving data when the LIS is out of service. **Regulatory authority: 10 NYCRR subdivision 58-1.2(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.
LIMS Sustaining Standard of Practice 7 (LIMS S7): Reports The LIS shall be capable of generating a duplicate of the final test report and any preliminary or corrected report(s). If test results have been amended: a) the LIS shall have a mechanism to ensure that the initial report is not obliterated and/or changed in any way, except to indicate that an amended report has been issued, and the date(s) the report was changed; and, b) there shall be a mechanism to prevent the reporting of the initial test results again, unless clearly identified as such. **Regulatory authority: 10 NYCRR subdivision 58-1.2(c)**	The format of the original need not be duplicated as long as the information is identical and includes the name and address of the laboratory performing the test. The copy retrieved from the computer system, microfilm or microfiche record must contain the exact information sent to the individual ordering the test or using the test results. For tests requiring an authorized signature or containing personnel identifiers (e.g., pathology examinations), the duplicate must include the signatures or identifiers. If the LIS is not capable of maintaining both the original and amended copy, the laboratory may keep a hard copy of the original report and maintain the corrected report in the computer.
LIMS Sustaining Standard of Practice 8 (LIMS S8): Security LIS access codes shall be used to limit access to only those functions the personnel are authorized to use. **Regulatory authority: 10 NYCRR section 58-1.6**	The laboratory should determine the level of access for each job title. If data is accessible to other departments (e.g., nursing) the laboratory should have policies and procedures to prevent unauthorized access. Procedures should be in place to ensure that access has been removed, for individuals who have left the employment of the laboratory.

Facility Design and Resources Management	
Standard	**Guidance**
LIMS Sustaining Standard of Practice 9 (LIMS S9): Power Protection The LIS shall be adequately protected against power surge and electrical power interruptions. **Regulatory authority: 10 NYCRR section 58-1.6**	
LIMS Sustaining Standard of Practice 10 (LIMS S10): Transcription Accuracy If the laboratory manually transcribes or enters test requisitions, authorization information or test results into a LIS, the laboratory must ensure the information is 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 personnel, both technical and non-technical, into the LIS. If supervisory review is used to ensure the accuracy of the manual entry, the laboratory director must define the periodicity of such review. Personnel performing data-entry must be subject to training and competency assessment as specified under the Human Resources section of these standards. Results must be released by qualified technical personnel.

Standard Operating Procedures and Compliance

Standard	*Guidance*
Operating Procedures and Compliance Fundamental Standard of Practice 1 (SOP F1) The laboratory shall have a standard operating procedure manual (SOPM) that describes completely and accurately all procedures that have been validated and approved for use in the pre-examination, examination, and post-examination phases of laboratory services, and be in substantial compliance with requirements provided in Operating Procedures Sustaining Standards of Practice 1 through 7. **Statutory authority: Article 5, Title 5 Public Health Law Sections 575 (2) and (3)**	Deviations from laboratory practice described in the SOPM constitute practices that have not been validated or approved, thereby placing the reliability of laboratory services at risk. The SOPM should be written with sufficient detail to serve as a resource to technical personnel in all aspects of their responsibilities, and serve to ensure consistency of practices among all staff assigned common tasks.
Operating Procedures Sustaining Standard of Practice 1 (SOPM S1): Availability The laboratory shall develop and maintain a current and accurate laboratory standard operating procedure manual (SOPM): a) using a standardized format with a system of numbering and/or entitling individual procedures; b) containing references to appropriate scientific literature; and, c) which is available at all times in the immediate bench area of the personnel engaged in the collection, processing or examination of specimens and performing related work. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	Procedures may be kept in electronic format provided they are accessible to all staff and that backup systems exist in the event electronic systems are not functional.
Operating Procedures Sustaining Standard of Practice 2 (SOPM S2): Content The SOPM shall include complete descriptions of purpose and instructions for the laboratory's policies and procedures, including: a) intended use of the examination, including expected levels for the clinical condition of interest b) principle of the procedure used for examinations; c) specimen type, including container and preservative;	The SOPM must include policies and procedures for all the elements described in a-r that are relevant for a given assay.

Standard Operating Procedures and Compliance

Standard	***Guidance***
d) requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in Specimen Processing Sustaining Standard of Practice 4; e) required equipment and reagents; f) environmental requirements for reliable test performance; g) procedural steps to be followed in the performance of the examination, including, as appropriate: i. preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing; ii. microscopic examination, including the detection of inadequately prepared slides; iii. calibration and calibration verification procedures; iv. quality control procedures; v. corrective action to be taken when quality control or calibration fail to meet acceptance criteria; vi. visual interpretation or formulas used to calculate results; vii. interpretation of examination results; viii. required confirmatory testing; ix. reporting patient results, including the protocol for reporting imminently life-threatening results, or panic or alert values. h) reportable range of patient test results; i) biological reference values, therapeutic or toxic ranges, or other interpretive criteria as appropriate to the test; j) limitations of the procedures, including interfering substances; k) operational (function) checks, preventive maintenance of instruments and equipment; l) description of course of action should a test system become unavailable or not useable;	d) The referral laboratory's instructions for specimen collection, processing and storing should be documented for specimens that are being referred for testing. d) Criteria for specimen acceptability define those conditions under which a specimen will be tested within the limitations noted on the report. Specimens to be rejected should be accessioned, and a report indicating the reason for rejection should be generated. f) Where molecular diagnostics are performed, include provisions for prevention of nucleic acid contamination during specimen preparation and testing, and protocols for workspace decontamination. g), (ix) Summary lists of panic or alert values may be used but these values should also be included in the SOP for each individual assay.

Standard Operating Procedures and Compliance	
Standard	***Guidance***
m) storage of examined specimens, and time limits for requesting additional examinations. n) biosafety, chemical and radiological safety; o) any laboratory policy, service or procedure as required elsewhere in the New York State Laboratory Standards; p) performance specifications for accuracy, precision, reportable range of patient results, and analytical sensitivity and specificity; q) references to pertinent literature; and, r) implementation date. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	
Operating Procedures Sustaining Standard of Practice 3 (SOPM S3): Manufacturer Instruction Manuals Current manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of Operating Procedures Sustaining Standard of Practice 2. The laboratory must provide definitive instructions, including all the items under Operating Procedures Sustaining Standard of Practice 2, if they are not provided in the manufacturer's package insert or if the assay has been modified. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	
Operating Procedures Sustaining Standard of Practice 4 (SOPM S4): Bench Excerpts Card files or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a complete manual is available for reference. The card file or similar systems shall correspond to the complete manual. All procedure excerpts and notes used at the bench must be reviewed and approved by the director or supervisor at least annually. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	A process must be established to ensure the excerpts used as a quick reference at the workbench, including notes made by technical personnel, are updated to include all revisions to the procedure as approved by the laboratory director.

Standard Operating Procedures and Compliance	
Standard	***Guidance***
Operating Procedures Sustaining Standard of Practice 5 (SOPM S5): Archival The laboratory shall have a system of archiving earlier editions of SOPM entries, including all revisions, which documents dates of implementation and discontinuance, and archives shall be kept on file for a minimum of two years after the procedure has been discontinued unless a longer retention is required in another part of these Clinical Laboratory Standards of Practice or in regulation. **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 procedures in place at the time of specimen analysis. Transfusion and blood services regulations (10 NYCRR paragraph 58-2.8(a)(9)) require that discontinued procedures be retained for at least seven years.

Standard Operating Procedures and Compliance

Standard	*Guidance*
Operating Procedures Sustaining Standard of Practice 6 (SOPM S6): Director Approval Each policy and procedure and subsequent revisions shall be signed and dated prior to implementation by the current director or director-designated assistant director holding an appropriate certificate of qualification. **Regulatory authority: 10 NYCRR subdivisions 58-1.2(c) and 58-1.10(g)**	Director-designated means the assistant director who has been delegated in writing by the laboratory director as responsible for the approval of procedures used in the assistant director's area(s) of expertise. In the case of a change in director or assistant director, all procedures should be reviewed and signed by the new director and/or director designated 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 months. This standard is applicable to laboratory-derived procedures, as well as manufacturer instruction manuals adopted in lieu of laboratory-specific procedures and bench excerpts. Each procedure requires a signature and review date, and revisions to an approved SOPM should be provided in a prologue to the procedure to facilitate notification of changes. The director may use a cover sheet to annotate approval of SOPM provided the document contains a list of all procedures, their implementation dates, all revisions and revision dates. The SOPM should be revised immediately once there has been a change in procedure. Memos notifying staff of changes will be accepted provided the SOPM is updated as soon as possible. All procedures should be reviewed and signed by a new director and/or director designated assistant director as soon as possible, if not done immediately (or underway) laboratory should have a plan for having the review completed and documented within an appropriate timeframe, not to exceed six months. Blood banks need to follow the requirements in 10 NYCRR Section 58-2.8 concerning the annual review by the director or authorized supervisor. Electronic signature or an alternative system may be substituted for hard copy as long as the system is secure and can verify the director or assistant director's oversight.
Operating Procedures Sustaining Standard of Practice 7 (SOPM S7): Compliance All policies and procedures shall be followed by the laboratory staff. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	Verification of staff knowledge of standard operating procedures is an essential element of competency assessment. A process must be established to document revisions to SOPM that facilities notification of all affected staff and to document competency assessments for implementation of revised procedures.

Pre-Examination Procedures	
Standard	***Guidance***
Pre-Examination Procedures Fundamental Standard of Practice (PEP_F1) The laboratory shall be in substantial compliance with *Examination Requisition* and *Specimen Processing* Sustaining Standards of Practice as required for establishing and maintaining: integrity of patient and specimen identification; stability of specimens; and, completeness and accuracy of information essential to the interpretation and reporting of examination results. Identified non-conformance shall not present imminent jeopardy to the integrity of laboratory services or to patient care. **Statutory authority: Article 5, Title 5 Public Health Law Sections 575 (2) and (3)**	
Examination Requisition	
Requisition Sustaining Standard of Practice 1 (Requisition S1): Authorized Specimen Acceptance No establishment other than a clinical laboratory under permit shall accept specimens for the purpose of obtaining information for the diagnosis, prevention, or treatment of a disease, for the assessment of a health condition or for purposes of identification. A clinical laboratory shall test, examine or analyze specimens only at the request of persons authorized by law to use the findings of laboratory examinations in their practice or in the performance of their official duties. **Regulatory authority: 10 NYCRR subdivisions 58-1.7(a) and (b)**	This requirement shall not be deemed to prohibit the acceptance of specimens solely for teaching and research purposes, and does not apply to other entities specifically exempted under Article 5 Title V of the Public Health Law. A healthcare provider or clinical laboratory may request approval to refer a specimen to a clinical laboratory that does not hold a permit or specific test approval if the test or analysis is not available from a permit laboratory, by submitting a *Non-Permitted Laboratory Request* available at www.wadsworth.org/clep. An exception to the requirement for prior approval is allowed in cases of urgent need for testing and program staff is not available to process the referral request. An updated list of persons authorized to order tests is available at www.wadsworth.org/labcert/regaffairs.

Pre-Examination Procedures

Standard	*Guidance*
Requisition Sustaining Standard of Practice 2 (Requisition S2): Oral Request If the request is oral, the physician or other authorized person shall submit a written request to the laboratory within 48 hours. If the laboratory does not receive the written request within that period, it shall note that fact in the record of daily accession. **Regulatory authority: 10 NYCRR paragraph 59-1.7(b)(1)**	
Requisition Sustaining Standard of Practice 3 (Requisition S3): Instruction Manual The laboratory shall develop and maintain a current and accurate instruction manual for the proper identification, collection, handling and transporting of primary specimens as established under Quality Management System Sustaining Standard of Practice 1 and make such available to those responsible for primary specimen collection, handling and test ordering. The manual shall include: a) copies of or references to: i. lists of available laboratory examinations offered; ii. consent forms, when applicable; iii. information and instructions provided to patients in relation to their own preparation before primary specimen collection; and iv. information for users of laboratory services that includes methodology, testing algorithms and medical indications for the appropriate selection of available procedures. b) procedures for: i. identification and preparation of the patient (e.g., instructions to caregivers and phlebotomists); a. when the testing is for identification purposes (e.g., paternity), the identity of the tested individual shall be documented by the laboratory; and ii. primary specimen collection (e.g., phlebotomy, skin puncture, blood, tissue, urine and other body fluids) with descriptions of the primary specimen containers, order in which specimens are to be drawn, any necessary additives, and storage, and	b) Examples of identification are name, date of birth, or patient number.

Pre-Examination Procedures	
Standard	***Guidance***
c) instructions for: i. completion of request form or electronic request; ii. the type and amount of the primary specimen to be collected; iii. special timing of collection, if required; 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); vii. the positive identification in detail of the patient from whom a primary specimen is collected; viii. recording the identity of the person collecting the primary specimen; ix. safe disposal of materials used in collection; and x. when applicable, chain of custody requirements to include guidelines for the packaging the specimen in a tamper-evident manner. The manual shall be reviewed and updated as required. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	

Pre-Examination Procedures

Standard	*Guidance*
Requisition Sustaining Standard of Practice 4 (Requisition S4): Request Form The request form shall contain sufficient information to identify the patient and the authorized requester, as well as providing pertinent clinical data. The request form or an electronic equivalent should allow space for the inclusion of, but not be limited to: a) unique identification of the patient; b) clinical information relevant to the patient, which should include gender and age or date of birth, as a minimum, for interpretation purposes; c) name or other unique identifier of physician or other person legally authorized to request examinations or use medical information together with the destination for the report, or the name and address of the referring laboratory, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values; d) type of primary specimen and the anatomic site of origin, where appropriate; e) examinations 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. **Regulatory authority: 10 NYCRR section 58-1.10**	A patient's chart or medical record may be used as the test requisition or authorization provided it includes all the information indicated in a-i and is available for review by the Department. a) Two forms of identification i.e., name and date of birth or other identifier such as patient number, should be included.

Pre-Examination Procedures	
Standard	***Guidance***
Specimen Processing	
Specimen Processing Sustaining Standard of Practice 1 (Processing S1): Specimen Transport The laboratory shall monitor that specimens have been transported to the laboratory: a) within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned; b) within a temperature range specified in the primary specimen collection manual and with the designated preservatives to ensure the integrity of specimens; and c) in a manner that ensures safety for the carrier, the general public and the receiving laboratory. The procedure shall comply with national, regional, or local regulatory requirements. **Regulatory authority: 10 NYCRR subdivision 58-1.10(d)**	c) See Safety Sustaining Standard of Practice 17 (Safety S17).

Pre-Examination Procedures

Standard	*Guidance*
Specimen Processing Sustaining Standard of Practice 2 (Processing S2): Accession All primary specimens received shall be recorded in an accession book, worksheet, laboratory information system, or other comparable system. It shall include: a) the accession number or other identification of the specimen; b) the name or other identification of the person from whom the specimen was taken; c) the date and time the specimen was received in the laboratory; d) the examination or examinations requested for that specimen; e) if the request for the examination was oral and, contrary to the requirements that the request was not followed by a written request, a statement to that effect, provided that, in the case of a computerized accession system, such a statement may be recorded in a separate accession log; f) in the event a specimen is forwarded to another clinical laboratory for examinations, the name of such other laboratory, the date upon which the specimen was forwarded, the date it was examined or the result or results were reported, and the date the report of findings was received from such laboratory, provided that, in the case of a computerized accession system, such information may be recorded in a separate accession log; g) a brief description of the condition of unsatisfactory specimens when received, for example, broken, leaked, hemolyzed, turbid. **Regulatory authority: 10 NYCRR paragraph 58-1.11(b)(1)**	

Pre-Examination Procedures

Standard	*Guidance*
Specimen Processing Sustaining Standard of Practice 3 (Processing S3): Order Entry Verification If the laboratory transcribes or enters test requisitions or authorization information into a record system or laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. **Regulatory authority: 10 NYCRR subdivision 58-1.2(c)**	The laboratory must have an ongoing mechanism to ensure the accuracy of manual entries by personnel, both technical and non-technical, into the LIS.
Specimen Processing Sustaining Standard of Practice 4 (Processing S4): Rejection Criteria Criteria shall be developed and documented for acceptance or rejection of primary specimens. A specimen received by a laboratory shall not be tested or reported on if: a) the apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested; b) it has been collected, labeled, preserved or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen; c) it is perishable and the time lapse between the collection of the specimen and its receipt by the laboratory is of such duration that the test finding may no longer be reliable; or d) the date and, in the case of tests specified by the department, the hour when the specimen was taken by the physician or other authorized person is not furnished with the specimen; and, e) when a specimen is not tested for any of the reasons specified, the laboratory shall promptly notify the sender and give the reason therefore. **Regulatory authority: 10 NYCRR subdivision 58-1.10(e)**	Where there is uncertainty in the identification of the primary specimen or instability of the analytes in the primary specimen (e.g., cerebrospinal fluid, biopsy, blood gas, etc.) and the primary specimen is irreplaceable or critical, the laboratory may choose initially to process the specimen but not release the results until the requesting physician or person responsible for the primary specimen collection takes responsibility for identifying and accepting the specimen and/or providing proper information. In this instance, the signature of that person taking responsibility for the primary specimen identification should be recorded on or traceable to the request form. Specimens to be set aside for future examination should also be identifiable. If compromised primary specimens are accepted, the final report shall indicate the nature of the problem and, if applicable, that caution is required when interpreting the result.

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Specimen Processing Sustaining Standard of Practice 5 (Processing S5): Urgent Test Request The laboratory shall have a documented procedure for the receipt, labeling, processing, and reporting of those primary specimens received by the laboratory and specifically marked as urgent. The procedure shall include details of any special labeling of the request form and primary specimen, the mechanism of transfer of the primary specimen to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	
Specimen Processing Sustaining Standard of Practice 6 (Processing S6): Aliquot Identification and Integrity Specimen portions shall be traceable to the original primary specimen and procedures for the preparation and handling of specimen portions (aliquots) shall prevent the cross-contamination of primary and specimen portions. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	
Specimen Processing Sustaining Standard of Practice 7 (Processing S7): Specimen Temporary Storage Specimens shall be stored for a specified time, at conditions that ensure stability of specimen properties, for initial examination or to enable repetition of the examination after reporting of the result, or for additional examinations. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g) and paragraph 58-1.11(d)(1)**	
Specimen Processing Sustaining Standard of Practice 8 (Processing S8): Referral The laboratory must establish and follow procedures for specimen referral, if applicable, and refer a specimen for testing only to a New York State permitted laboratory. **Regulatory authority: 10 NYCRR section 58-1.9**	A healthcare provider or clinical laboratory may request approval to refer a specimen to a clinical laboratory that does not hold a permit or specific test approval if the test or analysis is not available from a permit laboratory, by submitting a *Non-Permitted Laboratory Request* available at www.wadsworth.org/clep.

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Specimen Processing Sustaining Standard of Practice 9 (Processing S9): Referred Testing If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in Requisition Sustaining Standard of Practice 4. **Regulatory authority: 10 NYCRR section 58-1.10**	

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Examination Procedures Fundamental Standard of Practice (EP F1) The laboratory shall be in substantial compliance with *Validation of Laboratory Procedures*, *Determination of Calibration and Calibration Verification Procedures*, *Establishment of Quality Control Procedures and Process Control* Sustaining Standards of Practice provided in this section as required to establish policies and procedures to ensure the initial and ongoing reliability of examination systems. Identified non-conformance shall not present imminent jeopardy to the integrity of laboratory services or to patient care. **Statutory authority: Article 5, Title V Public Health Law Sections 575 (2) and (3)**	
Validation of Laboratory Procedures	
Validation Sustaining Standard of Practice 1 (Validation S1): Selection of Examination Procedures The laboratory shall use examination procedures, including those for selecting/taking specimen portions appropriate for the examinations, which meet the needs of the users of laboratory services. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	
Validation Sustaining Standard of Practice 2 (Validation S2): Deviation from Manufacturer Instructions The laboratory shall follow manufacturer instructions for instrument or test system operation and control, except: a) when there is a difference between the New York State and manufacturer requirements, the laboratory shall follow the more stringent requirement; and, b) when modifications to manufacturer recommended procedure have been validated by the laboratory. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	Following the manufacturer instructions means the laboratory complies with requirements in package inserts and/or instrument operator manuals. This includes requirements such as single versus duplicate testing, required specimen type (e.g., serum, spinal fluid, oral fluid, urine), and calibration and quality control frequency.

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Validation Sustaining Standard of Practice 3 (Validation S3): Multi-systems Agreement A laboratory that performs the same test using different methods or instruments, or performs the same test at multiple test sites, shall have a system in place that evaluates and defines the relationship between test results every six months. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	The analysis of patient specimens across analytical platforms is preferred for defining the relationship between them. Patient specimens should be selected to provide full-range assessment of comparability. Where the differences in analytical results are clinically significant, the user of test findings should be informed of those differences. Test sites include any area where patient testing is performed, including point-of-care testing which may be testing under a Limited Service Laboratory Registration at the same address as the main laboratory.
Validation Sustaining Standard of Practice 4 (Validation S4): Documentation Documentation of method validation, including a validation summary, and multi-systems agreement, director's approval, and NYS approval, if applicable, shall be available for the period during which the procedure is used by the laboratory, and for two years after the method is discontinued. **Regulatory authority: 10 NYCRR subdivision 58-1.11(c)(3)**	Documentation should include the validation procedure, data, and resultant performance specifications. For a test that must be approved by NYS, a copy of the approval letter must be maintained. Documentation of director delegation to an assistant director for the approval of a validation must be maintained as part of the validation materials.

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Validation Sustaining Standard of Practice 5 (Validation S5): Performance Specifications Method validation shall be performed before a test method is used to report results; and, a) for methods cleared or approved by the FDA as safe and effective for in vitro diagnostic use and used unmodified, (i.e., in a manner and for indications so approved), the laboratory shall: i. **verify** performance specifications for accuracy, precision, reportable range of test results established by the manufacturer; and, ii. **verify** that the manufacturer's reference interval is appropriate for the laboratory's population. b) for methods not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures); for commercialized methods where performance specifications are not provided by the manufacturer (e.g., Investigational Use Only (IUO), Research Use Only (RUO), Forensic Use Only (FUO)); and for modified FDA-cleared or approved test systems, the laboratory shall: i. **establish** performance specifications for accuracy, precision, reportable range of test results, reference interval(s) (normal values), analytical sensitivity and specificity (to include interfering substances); and other applicable performance characteristics,	While the vendor may conduct initial on-site validation, active participation by the laboratory personnel should also be evident. Manufacturer verification of proper instrument operation is only one component of method validation. The laboratory may not state that a specific test is capable of identifying or detecting a substance at a certain concentration (i.e., titer) unless it has the data to substantiate these and all other claims. For many commonly performed tests there is a large body of peer-reviewed data that may be provisionally accepted for use as a laboratory reference (normal) range. Results from the population served should be periodically reviewed in light of these ranges thereby confirming that these values are appropriate. If the population served represents specific sub-sets of overall population (e.g., geriatric, pediatric, obstetric population), special care may be needed in establishing reference intervals. Analytical sensitivity is also referred to as the limit of detection (LOD).

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including the clinical sensitivity and specificity of novel assays without comparative methods; ii. assure that the established reference interval is appropriate for the laboratory's population; and, iii. submit validation data and SOPM for review in accordance with guidelines established by the New York State Department of Health. c) method validation shall be performed at the actual site where the method will be used; and, d) if the instrument will be hand-carried or otherwise transported to the location of the patient, the laboratory shall document the portability of the system. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	b)(iii) Submission Guidelines for Test Approval are available at: www.wadsworth.org/clep. c) If a laboratory relocates or changes testing sites, it should document that its established performance specifications for each test method are not affected by the relocation of the laboratory or test systems. Mobile instruments and point-of-care devices need not be validated in every possible site. d) Device function checks and quality control must be performed after transport and determined to be within specifications prior to use for patient specimen analysis.
Validation Sustaining Standard of Practice 6 (Validation S6): Qualitative Results Interpretation For qualitative tests, the laboratory shall determine or document the basis for specifying reportable results as positive, negative, or degree of reactivity. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	Method performance around a cutoff concentration or threshold response should be evaluated using characterized specimens that challenge method accuracy at or near the cutoff/threshold. Standard terminology should be used for reporting microscopic results in tests such as urine microscopy and manual differentials.

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Determination of Calibration and Calibration Verification Procedures	
Calibration Sustaining Standard of Practice 1 (Calibration S1): Procedure The laboratory must determine, perform and document the test system's calibration procedures for each applicable test system: a) at a minimum, in accordance with the manufacturer's instructions, if provided, using calibration materials provided or specified by the manufacturer; and, b) in accordance with criteria verified or established by the laboratory from activities pursuant to Validation Sustaining Standard of Practice 5, i. including the number, type and concentration of calibration materials, acceptable limits for calibration, and the frequency of calibration; and, ii. using calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value; and, c) whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	Frequency of calibration should be based on the manufacturer's recommendations and calibration verification results. If calibration proves less stable than the manufacturer's specification, more frequent calibration may be required. The frequency of calibration should be documented. If blood gas analysis is performed on an instrument that does not calibrate at least every 30 minutes, a calibrator or control should be tested each time patient specimens are tested. For hematology cell counting instruments which have been cleared or approved by the FDA and have not been modified by the laboratory, the calibration requirements are considered to be met if the laboratory follows the manufacturer's instructions for operation and at least two controls are run each day of testing.

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Calibration Sustaining Standard of Practice 2 (Calibration S2): Periodic Verification The laboratory shall perform and document calibration verification procedures, minimally, in accordance with the manufacturer's calibration verification instructions where provided, or in accordance with the criteria established by the laboratory, a) including the number, type and concentration of calibration materials, acceptable limits for calibration verification and frequency of calibration verification; and, b) using calibration material appropriate for the methodology 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 months, and when any of the following occur: i. a complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lots does not affect the reportable range, and control values are not adversely affected by reagent lot number changes; ii. major preventive maintenance or replacement of critical parts that may influence test performance; iii. controls reflect an unusual trend or shift or are outside the laboratory's acceptable limits and other means of assessing or correcting unacceptable control values have failed to identify and correct the problem; or, iv. the laboratory's established schedule for verifying the reportable range requires more frequent calibration verification. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	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 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.

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Quality Control Procedures	
Quality Control Sustaining Standard of Practice 1 (QC Design S1): Design of Individualized Quality Control Plan Unless the laboratory follows the minimum requirements set forth in **QC Design Sustaining Standard of Practice 2a,** the laboratory shall establish and maintain an individualized quality control plan for each assay in all specialties and subspecialties, excluding histopathology and cytopathology, that verifies the intended quality of results is achieved prior to reporting of patient results for each test. Such plans shall include: a) a risk assessment to identify and evaluate potential failures and sources of error in the entire testing process, as outlined in Quality Control Sustaining Standard S2b; b) a quality control plan, signed and dated by the laboratory director, to describe the procedure for performing quality control, including the number, type and frequency of testing control materials, and for determining the parameters of acceptability for the quality control results; at least in accordance with the FDA-cleared/approved test manufacturer's quality control instructions, where provided, and with applicable specialty standards. The quality control plan must: i. be supported by empirical data established by the laboratory; ii. must be able to detect errors that occur due to test system failure, adverse environmental conditions, or operator performance; c) a quality assessment plan 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.	It is important, for all types of laboratories, that the control system provides staff members with clear and easily understood information on which to base technical decisions. b) Data to support the quality control plan may include verification or establishment of performance specifications and historical (existing) QC data. Published data or data from manufacturers may be used as guidance, but may not be used as the sole basis for decision –making.

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d) a process or procedure that defines the review and revision of the quality control plan, as appropriate, when non-conformances are identified. e) testing with external quality control 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; f) the submission of quality control plans for non-FDA approved assays: 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 quality control procedure is changed for a New York State approved assay. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(3) and subdivision 58-1.10(g)**	e) 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.
Quality Control Sustaining Standard of Practice 2a (QC Design S2a): Minimum Requirements Unless an individualized quality control plan is established as described in **Quality Control Sustaining Standard of Practice 1**, at least once each day patient specimens are examined, the laboratory shall: a) for qualitative examinations, include a positive and negative control; b) for quantitative examinations, include two control materials of different concentration suitable for error detection throughout the reportable range; c) for examination procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively;	For tests, such as certain staining procedures, for which no controls are available, the laboratory should have a procedure for determining when the expected reaction is not achieved. Although a run may be defined as up to 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 24-hour period. 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.

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d) for examination procedures that include an extraction phase, include at least one control material that is subjected to the same extraction process as patient specimens; or e) for nucleic acid amplification procedures: i. include one control capable of detecting amplification inhibition by patient specimens unless the New York State-approved application/method exempts the requirement; ii. when more than one outcome is possible at a locus, include a control that represents each outcome periodically. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	d) Extraction control: A co-amplified housekeeping gene meets the intent of this standard. Housekeeping gene refers to a gene whose expression is unlikely to be altered. e) Inhibition controls may be excluded if there are sufficient data showing that the inhibition rate is less than 1% 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 10-fold above the assay detection limit. For multiplex assays, a low range control is required for each target. These may be run on a rotating basis and may include pools of 3-4 targets.

Quality Control Sustaining Standard of Practice S2b (QC Design S2b): QC Risk Assessment The laboratory shall conduct a risk assessment when implementing an individualized quality control plan that evaluates potential sources of error associated with all phases of testing, i.e., pre-analytical, analytical and post-analytical; evaluates the frequency and impact of identified failures and errors; and considers each of the following, at a minimum: a) specimen; b) test system; c) reagent, quality control materials and calibrators; d) environment; e) personnel: f) actual testing results performed by a representative sampling of personnel. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	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 QC data; proficiency testing data; historical 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 environment / location, the risk assessment must consider the change in environment and testing personnel and the need for a customized QCP for the different sites. a) The following must be considered for the specimen: patient preparation, specimen collection, labeling, storage, preservation, stability, transportation, processing, acceptability, rejection and referral. b) 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 data to the LIS or EHR, results reporting. c) to include preparation, stability, variability between lots, intermixing of reagents from different lots. d) to include temperature, ventilation, light intensity, noise and vibration, humidity, altitude, dust, water, utilities failure, adequate space. e) to include education, licensure where required, training, competency and adequate staffing levels. f) to include historical testing data or validation data performed by bona fide employees of the laboratory.

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Quality Control Sustaining Standard of Practice 3 (QC Design S3): Control Limits Acceptable limits for each lot or shipment of control material shall: a) be established over time by the laboratory, through concurrent testing with a control material having previously determined ranges, or established as fixed limits based on analytical system performance specifications around a validated target value; 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 Sustaining Standard of Practice 4 (QC Design S4): Assayed Value Verification For each lot of assayed control material, the laboratory may use the stated value provided the assayed value: a) is verified by the laboratory prior to being placed into use; b) corresponds to the methodology and instrumentation used; and c) ranges reflect generally accepted medical and analytical requirements for each analyte. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(3) and subdivision 58-1.10(g)**	a) The manufacturer's stated value can be verified by running the control materials in a minimum ten routine assay runs that meet criteria for acceptance with verified controls.

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Quality Control Sustaining Standard of Practice 5 (QC Design S5): Calibration Material Used as QC Material When using calibration material as a control material, the laboratory must use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	
Quality Control Sustaining Standard of Practice 6 (QC Design S6): Alternative Means of Quality Control Where quality control or calibration materials are not available, the laboratory shall establish an alternative process that detects immediate errors and monitors test performance over time. The performance of alternative control procedures must be documented. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(4) and subdivision 58-1.10(g)**	A laboratory must use commercially prepared controls or otherwise characterized materials if they are available.
Process Quality Control	
Process QC Sustaining Standard of Practice 1 (Process QC S1): Implementation For each test system: a) perform control procedures using the number and frequency established as described in **Quality Control Sustaining Standard of Practice 1** and any applicable specialty standard(s), or following requirements set forth in **QC Design Sustaining Standard of Practice 2a**; b) process and test quality control material in the same manner as patient specimens indicative of the laboratory's routine workload; and, c) define the parameters for acceptability of quality control results. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	

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Process QC Sustaining Standard of Practice 4 (Process QC S4): Electrophoresis 1. Each electrophoretic cell or chamber shall include at least one control sample containing fractions representative of those routinely reported in specimens. 2. Assays where the final product is assessed by product size shall, with every electrophoretic run, include molecular weight markers of known size that span the range of sizes routinely encountered by the method. Flanking size markers shall be used with sufficient frequency to perform accurate sizing. 3. A method shall be established to verify that the transfer from the gel to the membrane was complete. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	Where separation is based on both size and charge, running a normal serum sample and an abnormal serum sample may be adequate.
Process QC Sustaining Standard of Practice 5 (Process QC S5): Thin Layer Chromatography For all compounds or groups of compounds identified by thin layer chromatography, each test batch and plate or card shall include reference standards, a negative control and 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.
Process QC Sustaining Standard of Practice 6 (Process QC S6): Operators Quality control materials must be rotated on a regular basis among all operators who perform the test. **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.

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Process QC Sustaining Standard of Practice 7 (Process QC S7): Records Records shall be kept of the actual results for each control determination, including quality control charts and/or other records which identify by date and lot the controls and/or calibrators used by the laboratory. **Regulatory authority: 10 NYCRR paragraph 58-1.11(c)(3)**	Actual measurements taken, reactions and /or observations should be recorded. “Check” marks are not sufficient to appropriately record the acceptability of quality control unless the definition of the checkmark is established in writing. The laboratory is required to define the parameters of acceptability for quality control results. For tests in which results are reported in terms of graded reactions (e.g., 1+, 2+, minimally reactive), controls of graded reactivity should be used.
Process QC Sustaining Standard of Practice 8 (Process QC S8): Review The laboratory shall have a system of documented review of quality control records that permits the timely identification of shifts, trends or other indicators of assay instability. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	

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Process Review – Reporting – Records Retention Fundamental Standard of Practice (Process Review F1) The laboratory shall be in substantial compliance with *Process Review*, *Reporting, Records and Specimen Retention,* and *Confidentiality* Sustaining Standards of Practice provided in this section as required to ensure: pre-examination and examination procedures have been verified as compliant with specifications prior to release of test findings; test reports are complete, accurate and factual; *document control: specimen processing & process verification* allows the recreation of the test process as necessary to substantiate the report of test findings; specimens have been properly stored and available for re-examination; and, confidentiality of patient identified information is maintained. Identified non-conformance shall not present imminent jeopardy to the integrity of laboratory services or to patient care. **Statutory authority: Article 5, Title V Public Health Law Sections 575 (2) and (3)**	
Process Review	
Process Review Sustaining Standard of Practice 1 (Process Review S1): Authorized Release of Examination Results The director, or where authorized, supervisory staff, shall systematically review the results for conformity to the laboratory performance specifications and clinical information available regarding the patient, and authorize the release of the results of examinations, except that an individual qualified as a technologist may be authorized to release results of examinations required for emergency purposes. **Regulatory authority: 10 NYCRR section 58-1.3 and subdivision 58-1.10(g)**	The intent of this standard is to ensure that all protocols used for the review and release of results, including auto verification, have been approved by the director, and that supervisory staff verify that approved protocols are routinely followed by technologists who have been authorized to release results. Only qualified directors or assistant directors are authorized to release reports in the permit categories of cytogenetics and genetic testing. A Certificate of Qualification holder is authorized to release reports in cellular immunology, fetal defect markers, paternity / identity testing, and oncology. A licensed pathologist is authorized to release reports in pathology.

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Process Review Sustaining Standard of Practice 2 (Process Review S2): Process Review Criteria Systematic process review shall include verification that: a) required calibration and quality control materials have been processed; b) calibration and quality control data conform to requirements of acceptable performance; c) test results are determined (calculated) accurately; d) dilution and other correction factors have been applied appropriately; e) specimen identification and associated results are accurately linked and transcribed to the test report; f) reference intervals and interpretive reporting are appropriate for the test findings; g) abnormal results are flagged and alert or panic values are effectively and immediately communicated; and h) test comparison activities identify patient test results that appear inconsistent with relevant patient information such as age, sex, diagnosis, and relationship with other test findings. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(4) and subdivision 58-1.10(g)**	Auto verification and subsequent release of examination results is acceptable provided the director has approved the conditions and algorithm used for the auto verification process.
Process Review Sustaining Standard of Practice 3 (Process Review S3): Replicate Analyses When replicate testing is performed, specimens shall be retested if the differences between results are greater than the limits established by the laboratory or as per the manufacturer's instructions. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	

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Process Review Sustaining Standard of Practice 4 (Process Review S4): Non-Conformance When process review identifies non-conformance to requirements, the laboratory shall: a) investigate root cause and document the source(s) of error; b) develop and implement corrective action plans to address root cause; c) evaluate all patient test results obtained in the unacceptable test run and since the last acceptable test run to determine if patient test results have been demonstrated to be inaccurate and unreliable. Notify clients as appropriate within two weeks after such evaluation has been performed; d) retest specimens when a non-conformance has been shown to result in inaccurate and unreliable patient testing, if possible; e) release test reports only after corrective action has been taken and documented to be effective; and f) take appropriate preventive action to ensure that non-conformance does not recur. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(4) and subdivision 58-1.10(g)**	The requirements of this standard are intended to be assessed in concert with the requirements set forth in Corrective Action Sustaining Standard of Practice S2 and Corrective Action Sustaining Standard of Practice S3.
Reporting	
Reporting Sustaining Standard of Practice 1 (Reporting S1): Report Content Each clinical laboratory or blood bank shall produce a laboratory report and shall supply the original of said report to the physician or other authorized person submitting each specimen for analysis. Each report shall contain the following information: a) patient name or other identification and the name of the person or institution referring the specimen;	

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b) the name under which the laboratory has been issued a permit and its address, except that a d/b/a may be used provided it has been reported to the Department; c) the date, and hour if required, when the specimen was originally collected by the physician or other authorized person; d) the date the specimen was received in the laboratory; e) the test report date; f) specimen source, when appropriate; g) test results, and if applicable, units of measure, reference intervals, or a similar method for identifying abnormal values; h) signature of the qualified person who reviewed, approved and/or diagnosed the case, where required in specialty areas of examination; i) information regarding the condition and disposition of specimens that do not meet criteria for acceptability; j) in the event a specimen is forwarded to another clinical laboratory for examination, the name and address of such laboratory, and the date the specimen was tested or the date the result was reported; and k) any disclaimers or limitations to testing where required by laboratory validation or NYS approval of test method. **Regulatory authority: 10 NYCRR paragraph 58-1.11(b)(2)**	e) the test report date should be indicated for each test included on the report, therefore, there may be multiple test report dates if some tests are completed and reported before others included on the requisition. The test report date is the date that the test result is available to the provider.

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Reporting Sustaining Standard of Practice 2 (Reporting S2): Interpretation Information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(1) and subdivision 58-1.10(g)**	Interpretative statements made on patient 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 approved by the Department (see Validation Sustaining Standard of Practice 5). 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.
Reporting Sustaining Standard of Practice 3 (Reporting S3): Test Referral When a referring laboratory receives results from a referral laboratory: a) the referring laboratory shall not revise or alter, in any way, the result(s) or information directly related to the interpretation of the result(s) of any test provided by the testing laboratory; and b) an exact duplicate of the testing laboratory's report should be available through the testing laboratory upon request of an authorized person who ordered the examination. **Regulatory authority: 10 NYCRR section 58-1.9**	

Post-Examination Procedures

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Reporting Sustaining Standard of Practice 4 (Reporting S4): Corrected Reports When errors or inaccuracies in patient reports are detected, the laboratory shall: a) promptly notify the authorized person who ordered the test of reporting errors; 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, but not limited to: i. the original report date and ii. the corrected report date; and d) maintain documentation to demonstrate the basis for the change to the report. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	Notification may be given to an agent of the authorized person. This standard is not intended to address reports that are amended to include additional findings.
Reporting Sustaining Standard of Practice 5 (Reporting S5): Timeliness When the laboratory cannot report patient test results within its established time frames, the laboratory must 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 Sustaining Standard of Practice 6 (Reporting S6): Alert Value The laboratory must immediately alert the individual or entity 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. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	The laboratory records should document the date, time, test results and person to whom the results were reported.

Post-Examination Procedures	
Standard	***Guidance***
Records & Specimen Retention	
Records Retention Sustaining Standard of Practice 1 (Retention S1): Document Control The laboratory shall define, document, and maintain procedures to control all documents and information (from internal and external sources) that form its quality documentation. Document control procedures shall be written and adopted to ensure that: a) all policies and standard operating procedures are reviewed and approved by the director prior to issue; b) revisions to approved polices and procedures are properly documented, approved and distributed to appropriate personnel; c) only current, approved versions of policy and procedure are available for use at all relevant locations; and, d) obsolete policies and procedures are archived in a fashion that they are readily retrieved when there is a need or request to recreate the test protocols and process employed for patient specimens that were processed within the previous two years. **Regulatory authority: Subpart 58-1.10(g)**	The intent is that procedures exist to ensure version-sensitive documents - including policy statements, procedures, specifications, calibration tables, biological reference intervals and their origins – are approved and are made available for use at all relevant locations. Document control is required under the laboratory's Quality Management System as described in Quality Management System Sustaining Standard of Practice 1.

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Records Retention Sustaining Standard of Practice 2 (Retention S2): Reports All records and reports of tests performed including the original or duplicates of original reports received from another laboratory shall be kept on the premises of both laboratories and shall be exhibited to representatives of the department on request. The following types of laboratory reports shall be retained for at least the period specified; a) tissue pathology including exfoliative cytology - 20 years; b) syphilis serology - negative report - two years; c) cytogenetics - 25 years; and d) all others - 7 years. **Regulatory authority: 10 NYCRR paragraph 58-1.11(c)(5)**	Off-site or electronic storage systems are acceptable, provided the laboratory can produce duplicates within 24 hours of a request.
Records Retention Sustaining Standard of Practice 3 (Retention S3): Test Request and Process Documents The laboratory shall retain the following records for at least the period specified, except that where other New York State or Federal regulations or statutes require retention for different periods of time, the laboratory shall retain the appropriate record for the longest period applicable. a) *Test requisitions* shall be retained for the same period of time as required for the test results or seven years, whichever is less, except that referral information for cytogenetic cases shall be retained for six years. b) *Accession records* shall be retained for seven years. c) *Test procedures* shall be retained for at least two years after a procedure has been discontinued, and all test procedures must include the dates of initial use and discontinuance. d) *Analytic system* records, including worksheets containing instrument readings and/or personal observations upon which the outcome is based, the identity of personnel who performed the tests, quality control,	d) The laboratory must record the actual quality control results obtained and indicate its acceptability. “Check” marks are not sufficient to appropriately record the acceptability of quality control unless the definition of the checkmark is established in writing. The laboratory is

Post-Examination Procedures

Standard	*Guidance*
patient results, and product recalls for reagents and consumables shall be retained for at least two years. e) *Preventive maintenance*, service and repair records shall be retained for as long as the instrument remains in use, except that records of monitoring of temperature-controlled spaces shall be kept for two years. f) Records of test system *performance specifications* that the laboratory establishes or verifies under Validation Sustaining Standard of Practice 5 and product recalls for equipment parts shall be retained for the period of time the laboratory uses the test system plus two years after the system has been discontinued, but no less than two years. **Regulatory authority: 10 NYCRR paragraphs 58-1.11(c)(2),(3),(4)**	required to define the parameters of acceptability for quality control results.
Records Retention Sustaining Standard of Practice 4 (Retention S4): Specimen Retention Specimens shall be retained so as to be accessible to the laboratory within 24 hours for at least the period set forth below. a) blood film - other than routine - 1 year; b) blood film - routine - 6 months; c) bacteriology slide on which a diagnosis depends - 1 year; d) cytology slide showing any abnormality - 10 years; e) cytology slide showing no abnormality - 5 years; f) tissue block - 20 years; g) histopathology block - 20 years; h) histopathology slide - 20 years; i) bone marrow biopsy - 20 years; j) cytogenetic slide - 6 years; k) photographic slide of cytogenetic karyotype - 25 years; and l) recipient blood specimens - 1 week stoppered at 1-6 degrees Celsius. **Regulatory authority: 10 NYCRR paragraph 58-1.11(d)(1)**	(a)(b) A routine blood film is one where no abnormal cells or cell counts are observed or where a blood disorder is not indicated. (b) 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 for two years as required in Retention S3. 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. (d)(e) includes gynecological, non-gynecological, and FNA (fine needle aspirate) for Cytology

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Standard	***Guidance***
Records Retention Sustaining Standard of Practice 5 (Retention S5): Supplies Inventory There shall be an inventory control system for supplies. Appropriate quality records of external services, supplies, and purchased products shall be established and maintained for a period of time as defined in the quality management system. This system should include the recording of lot numbers of all relevant reagents, control materials, and calibrators; the date of receipt in the laboratory; and the date the material is placed in service. All of these quality records shall be available for laboratory management review and shall be retained for at least two years. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	The minimum retention period for the supplies inventory records is two years; the laboratory management may define any length of storage greater than two years.
Records Retention Sustaining Standard of Practice 6 (Retention S6): Laboratory Closure If the laboratory ceases operation, the laboratory director and owner must notify the Department, make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are retained and available for the time frames specified in this section and 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)**	
Confidentiality	
Confidentiality Sustaining Standard of Practice 1 (Confidentiality S1): General. All patient identified information received or generated in the laboratory shall be considered health related confidential information, and shall be so defined to employees and agents of the laboratory who may have knowledge that a test was performed and/or of the test results. 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.

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Confidentiality Sustaining Standard of Practice 2 (Confidentiality S2): Protocol The laboratory shall establish protocols to protect the confidentiality of patient identified information. The laboratory confidentiality protocol shall include the following: a) a prohibition of access or disclosure except as needed to perform authorized duties or as required in reporting laboratory results; 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 statutes and regulations; 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. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	Level of access should be defined for each job title. Employees who may have contact with confidential information should sign an attestation statement, which documents training on the laboratory's confidentiality policy, applicable statutes and regulations, and acknowledgment of the consequences of violation, which may include criminal prosecution.

Post-Examination Procedures	
Standard	***Guidance***
Confidentiality Sustaining Standard of Practice 3 (Confidentiality S3): Controlled Records Access The director shall be responsible for determining and approving the circumstances and duties where access to confidential information is appropriate, as well as when, how, and to whom information is to be released, subject to state and federal confidentiality statutes and regulations. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	Laws and regulations pertaining to HIV-related and genetic testing information and information on their applicability to testing performed at the laboratory should be available to employees.

Quality Assessment and Improvement

Standard	*Guidance*
Quality Assessment and Improvement Fundamental Standard of Practice (QA_F1) The laboratory shall be in substantial compliance with the Sustaining Standards of Practice provided in this section as required for ongoing processes to assess conformance of practices with specifications established by the laboratory, and for resolution of non-conformance, including monitors for the effectiveness of interventions for problem resolution. **Statutory authority: Article 5, Title V, Public Health Law Sections 575 (2) and (3)**	
Quality Assessment Sustaining Standard of Practice 1 (QA S1): Ongoing Monitors of Conformance The laboratory must follow written policies and procedures under its Quality Management System for an ongoing process to monitor and assess conformance with requirements under each of the following Fundamental Standards of Practice: a) Human Resources Management b) Facility Design and Resource Management c) Standard Operating Procedure Manual d) Pre-Examination Procedures e) Examination Procedures f) Post-Examination Procedures g) Quality Assessment and Improvement **Regulatory authority: 10 NYCRR section 19.3 and subdivision 58-1.2(c)**	

Quality Assessment and Improvement

Standard	*Guidance*
Quality Assessment Sustaining Standard of Practice 2 (QA S2): Quality Monitors Outcomes Quality assessment activities conducted under Quality Assessment Sustaining Standard of Practice 1 must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and training and competency assessment on revised procedures. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(3) and subdivision 58-1.2(c)**	This standard also applies to corrective action taken when unexpected proficiency testing results are obtained.
Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy For all tests performed by the laboratory that are not included in Subpart I, (42 CFR 493 Subpart I) the laboratory: a) shall have a system for verifying the reliability and accuracy of test results; b) shall perform this verification process at least semiannually; c) shall evaluate all accuracy verification challenges: i. to ensure that results are consistent with the laboratory's specified performance criteria when an event is not graded by the external quality assurance program; ii. to identify shifts and trends regardless of the score received; and d) shall initiate and document a review of verification results within two weeks and subsequently perform and document corrective action when: i. the score received in an external proficiency testing program is less than 100 percent, the result(s) are unacceptable or indicate review is required; ii. results do not meet the laboratory's specified performance criteria; or iii. shifts and trends are identified.	Preferably the laboratory will participate in an external quality assurance (proficiency testing) program. If a laboratory chooses to use PT samples from a CMS-approved PT program for the purpose of meeting this standard, and the laboratory intentionally refers those samples to another laboratory or engages in inter-laboratory communication, it will be subject to the same enforcement sanctions as described under Proficiency Testing Sustaining Standards of Practice S4 and S5. When no external program exists the laboratory may evaluate the accuracy of testing through an internal proficiency testing program that may include performance of split-sample comparisons (patient and/or quality control samples) with another validated method; evaluation of clinical outcomes; blind testing of specimens with known results, or other equivalent system. For microscopic tests not included in a PT program, the laboratory supervisor may retest a random sample of specimens throughout the year while assessing all testing personnel. For tests such as KOH preparations and erythrocyte sedimentation rates, the laboratory may utilize duplicate testing performed by two different testing personnel. Laboratories unable to participate in a proficiency test event as a graded participant are required to establish alternate means to verify the accuracy and precision of the test system for all un-graded analytes. b) Semiannual is used to describe an event that takes place two times per year, with the first event taking place in the first six months of the a year and the second event in the last six months of a year, and where the interval between events is at least four months and not more than eight months.

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Regulatory authority: 10 NYCRR paragraph 19.3(c)(4) and subdivision 58-1.10(g)	c) A laboratory's performance criteria should be based on established analytical specifications of the assay or clinical expectations. For example, the criteria used for evaluating quality control could be the criteria used for evaluating proficiency test results.
Proficiency Testing	
Proficiency Testing Fundamental Standard of Practice (PT F1) The laboratory must introduce proficiency test specimens into its routine workflow and process them using pre-examination and examination protocols generally applied to the processing of patient specimens. The examination process must in no manner be influenced by inter-laboratory communication; examination findings must be subjected to routine protocols for post-examination verification; and, examination findings must be reported to the Department of Health in a format prescribed by the Department. **Statutory authority: Article 5, Title V Public Health Law Section 576 (3)**	
Proficiency Testing Sustaining Standard of Practice 1 (PT S1): Participation Each laboratory shall participate in a formally evaluated CMS-approved proficiency testing program for each category, subcategory and analyte that is included in Subpart I (42 CFR 493 subpart I) for which the laboratory seeks or currently holds a permit. Each laboratory shall notify the Department of the proficiency testing program that will be utilized to fulfill these proficiency testing requirements in the manner prescribed by the Department. Laboratories are required to subscribe for an entire calendar year with the proficiency testing program of choice and must authorize the proficiency testing vendor to release proficiency testing grades and/or results to the Department. **Statutory authority: Article 5, Title V 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. Notification of proficiency testing enrollment is made annually in the fall via the eCLEP system on the Health Commerce System. For newly applying laboratories or laboratories applying for a new category, enrollment information is required at the time of application. Please reference federal regulations at 42 CFR §493.801. 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 should be assessed as outlined in Validation Sustaining Standard of Practice 3 (Validation S3): Multi-systems Agreement.

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Standard	*Guidance*
Proficiency Testing Sustaining Standard of Practice 2 (PT S2): Routine Analysis Unless instructed otherwise by the proficiency test provider, the laboratory shall handle, prepare, process, examine, test and report on the results obtained from the proficiency test samples it receives from the proficiency testing program provider in the same manner as patient specimens and using the primary method of analysis. Participation in proficiency testing must be rotated amongst all operators who perform the test. **Statutory authority: Article 5, Title V Public Health Law Section 576 (3)**	The proficiency test specimens should be accessioned within the limitations of the laboratory system. The intent of the standard is that the proficiency test material will be handled as much like a patient sample as possible, with the exception of automatic reflex testing to another laboratory. Routine method is the analytical system, assay, test kit, examination or instrument used as the primary method for routine workload testing at the time of the proficiency test event. If the laboratory operates on multiple shifts, participation in proficiency testing shall be rotated through all shifts on a regular basis.
Proficiency Testing Sustaining Standard of Practice 3 (PT S3): Repeated Analysis Repeated analysis of proficiency test samples shall not be permitted unless the laboratory performs the same repetitive analysis in the routine analysis of patient specimens. **Statutory authority: Article 5, Title V Public Health Law Section 576 (3)**	Proficiency samples may be used for other purposes such as competency testing, after the date the laboratories are required to report the PT results to the proficiency test provider**.**
Proficiency Testing Sustaining Standard of Practice 4 (PT S4): Interlaboratory Communication Laboratories that test proficiency test samples shall not engage in any interlaboratory communication or discussion pertaining to the results of testing proficiency test samples until after the date the laboratories are required to report the results to the proficiency test provider. **Statutory authority: Article 5, Title V Public Health Law Section 576 (3)**	Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency test sample results until after the date by which the laboratory must report results to the proficiency test provider. Whenever the Department finds substantial evidence that a laboratory has misrepresented its proficiency through intentional referral of proficiency test specimens to another laboratory and/or interlaboratory communication, resulting in submission of results generated elsewhere

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Proficiency Testing Sustaining Standard of Practice 5 (PT S5): Referral Laboratories shall not send proficiency test samples or share portions of samples with any other laboratory for analysis until after the date the laboratories are required to report the results to the proficiency test provider. **Statutory authority: Article 5, Title V Public Health Law Section 576 (3)**	or generated in collusion, the laboratories are subject to enforcement sanctions under Section 577 of Article 5, Title V, which include revocation of laboratory permit and director certificate of qualification. If a laboratory chooses to use proficiency test samples from a CMS-approved proficiency test provider for the purpose of meeting the Proficiency Testing Sustaining Standard of Practice 1 or Quality Assessment Sustaining Standard of Practice 3, and the laboratory intentionally refers those samples to another laboratory or engages in interlaboratory communication, it will be subject to the same enforcement sanctions as described above.
Proficiency Testing Sustaining Standard of Practice 6 (PT S6): Referral Notification Any laboratory that receives proficiency test samples from another laboratory for testing shall notify the Department within 72 hours of receipt or identification of such samples. **Statutory authority: Article 5, Title V Public Health Law Section 576 (3)**	
Proficiency Testing Sustaining Standard of Practice 7 (PT S7): Records Retention A laboratory shall maintain copies of all records generated from the processing of proficiency test materials and evaluation of performance, including copies of the proficiency test report forms used by the laboratory to record results, for a minimum of two years from the date of the proficiency test event for all categories except immunohematology, which requires retention for five years. **Statutory authority: Article 5, Title V Public Health Law Section 576 (3)**	
Proficiency Testing Sustaining Standard of Practice 8 (PT S8): Attestation The laboratory director, or the assistant director responsible for the permit category, and analyst(s) must sign the proficiency test provider's attestation statement indicating the routine integration of the samples in the patient	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.

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workload using the laboratory's routine method. The signed document must be kept on file in the laboratory for review by the clinical laboratory consultant during future on-site surveys. **Statutory authority: Article 5, Title V Public Health Law Section 576 (3)**	
Proficiency Testing Sustaining Standard of Practice 9 (PT S9): Performance Review The laboratory must initiate and document a review of proficiency testing performance evaluations within two weeks of notification of release and investigate results when: a) the score received in an external proficiency testing program is less than 100 percent or the results(s) are unacceptable or indicate review is required; b) results do not meet the laboratory's specified performance criteria; or c) shifts and trends are identified. 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 V Public Health Law Section 576 (3)**	This standard applies to all proficiency tests. This standard applies to educational analytes/events. a) This applies to both the analyte score and the overall testing event score.
Proficiency Testing Sustaining Standard of Practice 10 (PT S10): Performance Review - Unsatisfactory Performance The laboratory must investigate the problem(s) that contributed to the unsatisfactory performance and implement corrective action, noting that discontinuation of a test is not, in and of itself, a root cause analysis nor corrective action. Documentation of investigation and corrective action must be retained by the laboratory for a minimum two years - except for Immunohematology where five year retention is required - and made available to the Department when requested. **Statutory authority: Article 5, Title V Public Health Law Section 576 (3)**	Laboratories that are in application for a permit or new category of testing are required to provide documentation of the investigation and plan of correction in order to continue the application process.

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Proficiency Testing Sustaining Standard of Practice 11 (PT S11): Unsuccessful Performance – Cessation of Patient Testing The laboratory must cease testing of clinical specimens for a minimum of six months upon unsuccessful performance in proficiency testing where the Department finds that any of the following conditions exist: a) analytical errors suggestive of immediate jeopardy to patient care; b) the laboratory has demonstrated an inability to make progress toward improvement of previously identified substandard performance following a reasonable opportunity to correct deficiencies; c) the root causes of substandard performance are systemic to laboratory practices; d) the laboratory has demonstrated a history of non-compliance with standards of good laboratory practice; or e) there have been other instances of unsuccessful performance in the category within the past two years that reflect a pattern of poor performance relevant to the current event, including repeated unsuccessful performance (unsatisfactory performance over 3 of 5 contiguous test events) for the same analyte, category or subcategory. **Statutory authority: Article 5, Title V Public Health Law Section 576 (3)**	

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Proficiency Testing Sustaining Standard of Practice 12 (PT S12): Unsuccessful Performance – Remedial Action Laboratories that demonstrate unsuccessful performance are required to perform the following: a) identify the NYS-permitted laboratory to which it will refer clinical specimens when the laboratory is directed by the Department to cease or voluntarily ceases patient testing; b) evaluate patient test results obtained since the last acceptable run to determine if patient test results have been demonstrated to be inaccurate and unreliable, and notify clients and issue corrected reports as appropriate; c) identify root cause(s) of substandard performance, develop and implement a plan of corrective action; and report its findings to the Department; noting that discontinuation of a test, in and of itself, is not remediation, and, d) substantiate the effectiveness of corrective action by successful performance in two consecutive proficiency test events, one of which may be an out-of-sequence event provided by the proficiency testing program designated by the laboratory to fulfill proficiency testing requirements for the calendar year. **Statutory authority: Article 5, Title V Public Health Law Section 576 (3)**	
Proficiency Testing Sustaining Standard of Practice 13 (PT S13): 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 Sustaining Standard of Practice 11, 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 V, seeking limitation of the laboratory's permit in the area of failure for a minimum of six months. **Statutory authority: Article 5, Title V Public Health Law Section 576 (3) and**	Subsequent to enforcement for ceased patient testing for six months, reinstatement of testing approval is considered only if the laboratory is fully compliant with requirements under Proficiency Testing Sustaining Standard of Practice 12.

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Proficiency Testing Sustaining Standard of Practice 14 (PT S14): Unsuccessful Performance – Continued Patient Testing If conditions a - e under Proficiency Testing Sustaining Standard of Practice 11 do not exist, and the Department determines the cause(s) of substandard performance can be remedied in a timely manner, the laboratory is notified of the unsuccessful performance in proficiency testing and is instructed to perform the following while patient testing services continue: a) investigate immediately the cause(s) of substandard performance in proficiency and report its findings to the Department within two weeks (ten business days) of notification of unsuccessful performance; i) a cease testing directive will be issued to the laboratory if the results of the investigation and plan of correction are not reported within ten business days or when the plan of correction is deemed unacceptable. b) evaluate patient test results obtained since the last acceptable run to determine if patient test results have been demonstrated to be inaccurate and unreliable, and notify clients and issue corrected reports as appropriate; and c) substantiate the effectiveness of corrective action by successful performance in two consecutive proficiency test events, one of which may be an out-of-sequence event provided by the proficiency testing program designated by the laboratory to fulfill proficiency testing requirements for the calendar year. **Statutory authority: Article 5, Title V Public Health Law Section 576 (3) and 577**	

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Standard	*Guidance*
Referral and Contract Laboratories	
Referral Laboratories Sustaining Standard of Practice 1 (Referral S1): Performance Review The laboratory shall have an effective documented procedure for evaluating, selecting and monitoring the quality of referral laboratories, including any secondary referral laboratories used by the primary referral laboratory. The policies and procedures for these reviews leading to arrangements for examinations or contracts shall ensure that the: a) requirements, including the methods used, are adequately defined and documented; b) laboratory has the capability and resources to meet the requirements; c) appropriate procedures are selected and capable of meeting the contract and clinical requirements; and, d) the referral laboratory holds a New York State permit in the required category of testing and any required test approvals. **Regulatory authority: 10 NYCRR subdivisions 58-1.1(b) and 58-1.10(g)**	d) It is the responsibility of the referring laboratory to ensure that the reference laboratory holds a permit for the appropriate category and test.
Referral Laboratories Sustaining Standard of Practice 2 (Referral S2): Periodic Review Arrangements with referral laboratories shall be reviewed periodically to ensure that the: a) requirements, including the pre-examination and post-examination procedures, are adequately defined, documented, and understood; b) referral laboratory has the capability to meet the requirements and there are no conflicts of interest; c) selection of examination procedures is appropriate for the intended use; and d) respective responsibilities for the interpretation of examination results is clearly defined. **Regulatory authority: 10 NYCRR subdivision 58-1.10(g)**	As required under Quality Management System Sustaining Standard of Practice 1, laboratories establish specifications and requirements for the selection of referral laboratories. Selection criteria likely include arrangements for pre-examination and post-examination procedures, timeliness of reporting and access to expertise for results interpretation. Although the referral laboratory is permitted by the Department to accept and process specimens, the referring laboratory is best positioned to evaluate whether the referral laboratory is meeting stated performance requirements. A referral laboratory's performance history dictates the frequency of performance reviews: semi-annual review is suggested for good performing referral laboratories; monthly or more frequently where services to clients are potentially compromised by referral laboratory practices.

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Standard	***Guidance***
Referral Laboratories Sustaining Standard of Practice 3 (Referral S3): Registry of Referral Laboratories The laboratory shall maintain a register of all referral laboratories that it uses. A register shall be kept of all specimens that have been referred to another laboratory. The name and address of the laboratory responsible for the examination result shall be provided to the user of laboratory services. **Regulatory authority: 10 NYCRR subparagraph 58-1.11(b)(1)(vi)**	
Resolution of Complaints and Identification and Control of Nonconformities	
Complaint Resolution Sustaining Standard of Practice 1 (Complaint Resolution S1): General The laboratory shall have a policy and procedures for the resolution of complaints or other feedback received from clinicians, patients, laboratory employees or other parties. Records of complaints and of investigations and corrective actions taken by the laboratory shall be maintained for at least two years. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)**	Activities under Resolution of complaints and Control of Nonconformities must be documented fully and made available to representatives of the Clinical Laboratory Evaluation Program, either during on-site inspection or by *ad-hoc* request.

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Standard	*Guidance*
Control of Non-Conformities Sustaining Standard of Practice 1 (Control of Non-Conformities S1): Procedures Laboratory management shall have a policy and procedure to be implemented when it detects that any aspect of its examinations does not conform to its own procedures or the agreed upon requirements of its quality management system or the requesting clinician. These shall ensure that: a) personnel responsible for problem resolution are designated; b) the actions to be taken are defined; c) the medical significance of the nonconforming examinations is considered, and where appropriate, the requesting clinician informed; d) examinations are halted and reports withheld as necessary; e) corrective action is taken immediately (see Corrective Action S1); f) the results of nonconforming examinations already released are recalled or appropriately identified, if necessary; g) the responsibility for authorization of the resumption of examinations is defined; and h) each episode of non-conformity is documented, recorded and reviewed at regular specified intervals by laboratory management to detect trends and initiate preventive action. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)**	

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Standard	*Guidance*
Control of Non-conformities Sustaining Standard of Practice 2 (Control of Non-Conformities S2): Actionable events The laboratory shall define a non-conformity to include, at a minimum, the following: a. when the test system does not meet the laboratory's verified or established performance specifications, as evidenced by: i. equipment or methodologies that perform outside of established operating parameters or performance specifications; or ii. patient test values that are outside of the laboratory's reportable range of test results for the test system; or iii. reference range for a test procedure that is inappropriate for the laboratory's patient population; or b. when results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability; c. when the criteria for proper storage of reagents and specimens are not met. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)**	

Quality Assessment and Improvement	
Standard	***Guidance***
Corrective Action	
Corrective Action Sustaining Standard of Practice 1 (Corrective Action S1): Procedures The identification of a non-conformance shall lead to an investigation of the underlying cause(s) of the issue and subsequent corrective action(s). These shall, where appropriate, lead to preventive actions. Corrective action shall be appropriate to the magnitude of the problem and commensurate with the risks encountered. a) Laboratory management shall document and implement any changes required to its operational procedures resulting from non-conformance investigations. b) Laboratory management shall monitor the results of any corrective action(s) taken in order to ensure that they have been effective in overcoming the identified problems. c) When the identification of non-conformance or the subsequent investigation casts doubt on compliance with policies and procedures, or the quality management system, laboratory management shall ensure that appropriate areas of activity are audited in accordance with Quality Management System Sustaining Standard of Practice 3. The results of corrective actions shall be submitted for laboratory management review. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)**	

Quality Assessment and Improvement	
Standard	***Guidance***
Corrective Action Sustaining Standard of Practice 2 (Corrective Action S2): Systems Periodic Review All operational procedures shall be systematically reviewed by laboratory management at regular intervals, as defined in the quality management system, to identify any potential sources of non-conformance or other opportunities for improvement in the quality management system or technical practices. Action plans for improvement shall be developed, documented, and implemented, as appropriate. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)**	
Corrective Action Sustaining Standard of Practice 3 (Corrective Action S3): Systems Change Effectiveness After implementation of corrective, preventive, or improvement actions, laboratory management shall evaluate the effectiveness of the action through a focused review or audit of the area concerned. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)**	

Public Health Preparedness and Reporting	
Standard	***Guidance***
Public Health Preparedness and Reporting Fundamental Standard of Practice (PHP_F1) The laboratory must demonstrate policies, procedures and practices that integrate laboratory services with public health programs, including the reporting of examination findings of public health consequence and participation in the New York State Laboratory Response Network for preparedness and response to events that pose risks to public health. **Statutory authority: Article 5, Title 5 Public Health Law Sections 575 (2) and (3)**	

Public Health Preparedness and Reporting

Standard	*Guidance*
Public Health Sustaining Standard of Practice 1 (Public Health S1): Reporting Laboratories shall: a) designate person(s) responsible for ensuring that results and other information are reported as required by the Department; b) report to NYS DOH infectious disease as required in Title I Section 2102 for communicable disease reporting; c) report to NYS DOH cases of initial determination or diagnosis of HIV infection, HIV-related illness and AIDS as required in Subpart 63.4; d) report to NYS DOH results of all blood lead analyses with demographic data as required in Subpart 67-3; e) report to NYS DOH Heavy Metals Registry all elevated levels of reportable metal as provided in Title 10 Section 22.6 and 7; f) report to NYS DOH Cancer Registry every case of cancer, brain tumor, or other malignant disease as provided in Title I Section 2400-2404; g) report 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 clinical laboratory, as required under Part 22 of Chapter 1 of the State Sanitary Code; and h) Blood banks and transfusion services shall file a Blood Services Activity report annually with the department as required under 10NYCRR Section 58-2.10. **Regulatory authority: as noted and 10 NYCRR paragraph 19.3(c)(2)**	Laboratories wishing to report electronically to NYS DOH may call the ECLRS Help desk at 1-866-325-7743 for information. Effective July 1, 2006 laboratories must electronically report communicable disease test results for residents of NYC. a) 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. b) Copies of the Laboratory Reporting of Communicable Diseases guidelines are available at: www.wadsworth.org/clep. d & e) To report by mail, contact Childhood Lead Poisoning Prevention Program at 518-473-4602. e) Laboratories must report to NYS DOH: • blood cadmium concentrations greater than or equal to 10 ng/ml (10 µg/L) and urine cadmium concentrations greater than or equal to 5 µg/L; • blood mercury concentrations greater than or equal to 5 ng/ml (5 µg/L) and urine mercury concentrations greater than or equal to 20 ng/ml (20 µg/L); and • urine arsenic concentrations greater than or equal to 50 µg/L. f) Reportability is determined by the commissioner. At this time only abnormal histopathological findings must be reported.

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Standard	*Guidance*
Public Health Sustaining Standard of Practice 2 (Public Health S2): Preparedness The laboratory shall have a protocol in the SOPM defining laboratory operations and/or referral services, as needed, in the case of a natural, intentional, or unintentional event that impairs routine laboratory operations. The plan shall include periodic review of Health Commerce System (HCS) postings. **Regulatory authority: 10 NYCRR paragraph 19.3(c)(2) and subdivision 58-1.10(g)**	This includes internal and external situations such as electrical/heating/AC failures, natural disasters (e.g. ice storm, earthquake), and terrorist events. Such events could potentially interrupt multiple aspects of laboratory operation, including transportation (e.g. employee, supplies/reagents, specimens, service calls), equipment operation, information systems, and internal or external communication. Emergency information should include emergency contact information for key employees and others involved with lab operations. The system should be tested by periodic drills. The laboratory should have connectivity to sources of emergency information, including fax, e-mail and Health Commerce System (HCS) enrollment.