General Systems Standards

Director Responsibilities

Director Responsibilities			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Director Fundamental Standard of Practice (DR FS) The laboratory director is responsible for all aspects of laboratory services. The laboratory director may delegate, in writing, responsibility for a category to an assistant director holding a CQ in a relevant category; however, the laboratory director retains ultimate responsibility. ***Statutory authority: Article 5, Title 5 Public Health Law*** ***Section 577*** **Guidance –** Information on responsibilities of directors of clinical laboratories and blood banks is available at:	None	**Director Fundamental Standard of Practice (DR FS)** The laboratory director is responsible for all aspects of laboratory services. The laboratory director may delegate, in writing, responsibility for a category to a~~n assistant director~~ technical director holding a CQ in a relevant category; however, the laboratory director retains ultimate responsibility. ***Statutory authority: Article 5, Title 5 Public Health Law Section ~~577~~575***	**Guidance –** Information on responsibilities of directors of clinical laboratories and blood banks is available at: www.wadsworth.org/regulatory/clep/laws Regulatory information for Section 58-1.1, Permit, and instruction on applying for a certificate of qualification are available at: www.wadsworth.org/regulatory/clep

Director Responsibilities			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
https://www.wadsworth.org/regulatory/clep/laws Regulatory information for Section 58-1.1, Permit, and instruction on applying for a certificate of qualification are available at: https://www.wadsworth.org/regulatory/clep			

Director Responsibilities			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Director Standard of Practice 3 (DR S3): Director and Assistant Director Involvement and Time Commitment The laboratory director and assistant director(s) must: a) spend time on-site in the laboratory to direct and supervise personnel; and b) be available in person, by telephone and/or through electronic consultation to the laboratory's personnel and clients. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(a)***	Section 58-1.2 of 10 NYCRR describes full-time or regular parttime hours required for laboratory directors at: https://www.wadsworth.org/regulatory/clep/laws	**Director Standard of Practice 3 (DR S3): Director and ~~Assistant~~ Technical Director Involvement and Time Commitment** The laboratory director and ~~assistant~~ technical director(s) must: a) spend time on-site in the laboratory to direct and supervise personnel; and b) be available in person, by telephone and/or through electronic consultation to the laboratory's personnel and clients. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(a)***	Section 58-1.2 of 10 NYCRR describes full-time or regular parttime hours required for laboratory directors at: https://www.wadsworth.org/regulatory/clep/laws

Director Responsibilities			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
New Standard	New Standard	**Director Standard of Practice 6 (DR S6): Technical Director Responsibilities** The technical director(s) must ensure compliance with all New York State Clinical Laboratory Standards of Practice. The technical director is responsible for: a) selecting and verifying test methodology and device(s) provide accurate and reliable results; b) defining, implementing, and monitoring of the performance characteristics of all testing procedures; c) enrolling and ensuring participation in a proficiency testing program acceptable to the Department for the testing performed; d) establishing a quality program appropriate for the testing performed;	b) While a technical director can define the performance characteristics in all testing procedures, the laboratory director remains responsible for approving new test procedures.

Director Responsibilities			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
		e) ensuring appropriate corrective actions are taken prior to the release of patient test results whenever test systems do not meet established performance specifications; f) providing training and continuing education to laboratory staff; g) ensuring that competency of testing personnel is assessed as defined by Human Resources Standard of Practice 8 (HR S8) h) selecting all reference laboratories for services not offered by the laboratory i) adhere to the requirements as defined by the Cytopathology Standards of Practice ***Regulatory authority: 10 NYCRR section 58-1.2 and 58-6.4 and 58-6.5***	

Human Resources

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Human Resources Fundamental Standard of Practice (HR FS) The laboratory must have effective leadership and personnel with the education, training and experience necessary for the delivery of laboratory services. ***Statutory authority: Public Health Law Article 5, Title 5 Sections 575(2) and (3)***	Testing personnel credentials, duties and responsibilities are specified in 10 NYCRR Part 19 and in the following subdivisions of 10 NYCRR Part 58: 58-1.2 Laboratory director, 58-1.3 Clinical laboratory supervision, 58-1.4 Qualifications of laboratory supervisor, and 58-1.5 Duties and qualifications of clinical laboratory technical personnel. 10 NYCRR Parts 19 and 58 are available at: https://www.wadsworth.org/regulatory/clep.	Same	Testing personnel credentials, duties and responsibilities are specified in 10 NYCRR ~~Part 19~~ Subpart 58-6 and in the following ~~subdivisions~~ sections of 10 NYCRR Part 58: 58-1.2 Laboratory director and technical director, 58-1.3 Clinical laboratory supervision, 58-1.4 Qualifications of laboratory supervisor, and 58-1.5 Duties and qualifications of clinical laboratory technical personnel. 10 NYCRR Part~~s 19 and~~ 58 ~~are~~ is available at: https://www.wadsworth.org/regulatory/clep.

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Human Resources Standard of Practice 1 (HR S1): Organization Charts and Job Descriptions Laboratory management must have an organizational chart(s) and job descriptions for all personnel. Job descriptions must be: a) consistent with responsibilities and duties described in the New York State Clinical Laboratory Standards of Practice; b) specified in writing for all positions and titles within the laboratory, including positions/titles held by consultants; and c) describe qualifications. ***Regulatory authority: 10 NYCRR paragraph***	Job descriptions should include, but are not limited to: specimen collection personnel; testing personnel; supervisors; laboratory managers; administrators; assistant director(s); and laboratory director(s).	Same	Job descriptions should include, but are not limited to: specimen collection personnel; testing personnel; supervisors; laboratory managers; administrators; ~~assistant~~ technical director(s); and laboratory director.~~(s).~~

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
19.3(c)(6) and subdivision 58-1.2(d)			
Human Resources Standard of Practice 3 (HR S3): Supervisor Staffing The laboratory must have a supervisor or supervisor-qualified individual, as delegated by the laboratory director in writing, that is on the laboratory premises during all hours in which tests are performed. This requirement does not apply to testing for emergency purposes, provided: a) the person performing the test qualifies as a clinical laboratory technologist; b) the director has defined requirements for supervisory review of test results, including quality control; c) the results are reviewed by the supervisor or	For emergency testing performed without a supervisor on-site, the director should establish the maximum time period between reporting of test results and the review.	**Human Resources Standard of Practice 3 (HR S3): Supervisor Staffing** The laboratory must have a supervisor or supervisor-qualified individual, as delegated by the laboratory director in writing, that is on the laboratory premises during all hours in which tests are performed. An exception to ~~T~~this requirement is allowed ~~does not apply to testing for emergency purposes,~~ provided: ~~a) the person performing the test qualifies as a clinical laboratory technologist;~~ ~~b) the director has defined requirements for supervisory review of test results, including quality control;~~ ~~c) the results are reviewed~~	~~For emergency testing performed without a supervisor on-site, the director should establish the maximum time period between reporting of test results and the review.~~

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
director during his or her next duty period; and d) a record is maintained to reflect review by the supervisor or director. ***Regulatory authority: 10 NYCRR subdivision 58-1.3(d)***		~~by the supervisor or director during his or her next duty period; and~~ ~~d) a record is maintained to reflect review by the supervisor or director.~~ a) the supervisor(s) is immediately accessible by telephone or synchronous two-way audio-visual communication to all personnel during all hours of testing; b) the supervisor(s) is assigned on-site hours by the laboratory director which must be sufficient to ensure adequate supervision for testing performed but can not be less than eight (8) hours per week; c) documentation that defines and delegates supervisory responsibilities including whether responsibilities are performed on-site	b) A minimum of eight (8) hours per week on-site is required at each PFI for which an individual is delegated supervisory responsibilities.

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
		versus off-site must be maintained; d) documentation that defines which supervisor is responsible for a specific time period is maintained; e) the supervisor responsible for a specific period may only serve in this capacity at five (5) clinical laboratories or blood banks; f) and the laboratory has not been informed by the Department they are not eligible for remote supervision. ***Regulatory authority: 10 NYCRR subdivision 58-1.3(d)***	f) Laboratories must meet the requirements in 10NYCRR Section 58-1.3 to be eligible for remote supervision.

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Human Resources Standard of Practice 5 (HR S5): Testing Personnel Responsibilities Testing personnel must fulfill the requirements of this Standard. Testing personnel responsibilities include: a) following the laboratory's pre-analytic and analytic procedures and maintaining records of tests; b) maintaining records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens; c) adhering to the laboratory's quality assurance procedures, including documenting all: i. quality control activities;	None	**Human Resources Standard of Practice 5 (HR S5): Testing Personnel Responsibilities** Testing personnel must fulfill the requirements of this Standard. Testing personnel responsibilities include: a) following the laboratory's pre-analytic and analytic procedures and maintaining records of tests; b) maintaining records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens; c) adhering to the laboratory's quality assurance procedures, including documenting all: i. quality control activities;	Same

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
ii. instrument and equipment verifications; iii. maintenance and preventive maintenance; and d) following the laboratory's policies and procedures whenever test systems are not within the laboratory's established performance specifications; e) identifying and documenting problems that may adversely affect test performance and notifying the supervisor, assistant director(s) or director; and f) documenting all corrective actions taken when test systems deviate from the laboratory's established performance specifications.		ii. instrument and equipment verifications; iii. maintenance and preventive maintenance; and d) following the laboratory's policies and procedures whenever test systems are not within the laboratory's established performance specifications; e) identifying and documenting problems that may adversely affect test performance and notifying the supervisor, ~~assistant~~ technical director(s) or director; and f) documenting all corrective actions taken when test systems deviate from the laboratory's established performance specifications.	

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Regulatory authority: 10 NYCRR section 58-1.5		***Regulatory authority: 10 NYCRR section 58-1.5***	

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Human Resources Standard of Practice 7 (HR S7): Competency Assessment - Supervisory Personnel Supervisors must be assessed in their responsibilities according to Human Resources Standard of Practice 4 and their competency documented. Competency assessments must be performed annually for all tasks for which the supervisor is responsible and include, as applicable: a) the date of the assessment; b) compliance with policies and procedures; c) communication, including bringing problems and non-conformities to the attention of laboratory management; d) leadership and problem-	If a supervisor or director/assistant director also functions as testing personnel, he or she must also be competency assessed for those functions as required in Human Resources Standard of Practice 8. Testing personnel performing delegated supervisory functions must also be competency assessed for those supervisory functions.	**Human Resources Standard of Practice 7 (HR S7): Competency Assessment - Supervisory Personnel** Supervisors must be assessed in their responsibilities according to Human Resources Standard of Practice 4 and their competency documented. Competency assessments must be performed annually for all tasks for which the supervisor is responsible and include, as applicable: a) the date of the assessment; b) compliance with policies and procedures; c) communication, including bringing problems and non-conformities to the attention of laboratory management; d) leadership and problem-	If a supervisor, technical director or director~~/assistant director~~ also functions as testing personnel, ~~he or she~~ they must also be competency assessed for those functions as required in Human Resources Standard of Practice 8. Testing personnel performing delegated supervisory functions must also be competency assessed for those supervisory functions.

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
solving capabilities; e) allocation of assets for effective daily laboratory operations; and f) personnel management. Competency assessments must be performed by delegated supervisor qualified staff or the director or assistant director(s). For direct report supervisors and assistant directors, the laboratory director must approve these competencies. Documentation of competency must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***		solving capabilities; e) allocation of assets for effective daily laboratory operations; and f) personnel management. Competency assessments must be performed by delegated supervisor qualified staff or the director or ~~assistant~~ technical director(s). For direct report supervisors and ~~assistant~~ technical directors, the laboratory director must approve these competencies. Documentation of competency must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Human Resources Standard of Practice 8 (HR S8): Competency Assessment-Testing Personnel Testing personnel must be assessed in their responsibilities according to Human Resources Standard of Practice 5, and their competency documented. Competency assessments must be performed at least semiannually during the first year the individual tests patient specimens and annually thereafter. If there is a change to the test method or instrument, that causes testing personnel to alter their test process, competency must be reevaluated and documented prior to reporting patient test results and include use of the new test method or instrument. Competency assessments of testing personnel must be	Documentation of the personnel's test performance on the competency assessment must contain enough specific detail so that the evaluation can be substantiated. When using previously analyzed specimens or samples, such as quality controls or previously reported proficiency testing samples, documentation must include both the original testing and competency assessment test results. Competency assessment must be performed and documented for all laboratory personnel, including healthcare providers performing testing at the point of care.	**Human Resources Standard of Practice 8 (HR S8): Competency Assessment-Testing Personnel** Testing personnel must be assessed in their responsibilities according to Human Resources Standard of Practice 5, and their competency documented. Competency assessments must be performed at least semiannually during the first year the individual tests patient specimens and annually thereafter. If there is a change to the test method or instrument, that causes testing personnel to alter their test process, competency must be reevaluated and documented prior to reporting patient test results and include use of the new test method or instrument. Competency assessments of testing personnel must be	Same

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
performed at the site where personnel perform their job. Competency assessments must be performed for all tasks for which the testing personnel are responsible and include, as applicable: a) the date of the assessment and the ability to recreate the test process used for the competency; b) assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; c) direct observation of employee's duties by supervisor qualified staff for compliance with each test procedure performed; d) direct observation of compliance with safe		performed at the site where personnel perform their job. Competency assessments must be performed for all tasks for which the testing personnel are responsible and include, as applicable: a) the date of the assessment and the ability to recreate the test process used for the competency; b) assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; c) direct observation of employee's duties by supervisor qualified staff for compliance with each test procedure performed; d) direct observation of compliance with safe	

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
practices required to perform specimen testing; e) direct observation of compliance with procedures for instrument maintenance and function checks and/or preventive maintenance and proper documentation, as applicable; f) review of intermediate test results or worksheets, quality control records and proficiency testing results; g) recording and reporting of test results; h) assessment of problem-solving skills; and i) assessment of competency of any delegated supervisory functions. Competency assessments must be performed by		practices required to perform specimen testing; e) direct observation of compliance with procedures for instrument maintenance and function checks and/or preventive maintenance and proper documentation, as applicable; f) review of intermediate test results or worksheets, quality control records and proficiency testing results; g) recording and reporting of test results; h) assessment of problem-solving skills; and i) assessment of competency of any delegated supervisory functions. Competency assessments must be performed by	

Human Resources			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
delegated supervisor qualified staff, the laboratory director or assistant director(s). For direct report supervisors and assistant directors, the laboratory director must approve these competencies. Documentation of competency must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***		delegated supervisor qualified staff, the laboratory director or ~~assistant~~ technical director(s). For direct report supervisors and ~~assistant~~ technical directors, the laboratory director must approve these competencies. Documentation of competency must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	

Document Control

Document Control			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Document Control Standard of Practice 4 (DC S4): **Procedure Excerpts** In addition to complete standard operating procedures, policies, instructions, programs, plans and/or manuals, excerpts that summarize key information may be used by laboratory staff, provided: a) the director, assistant director(s) or supervisor qualified staff reviews the excerpts at least every two (2) years and this review is documented; and b) the content provided by the excerpt does not contradict the corresponding document.	Procedure excerpts may also be referred to as job aides, training notes, and/or procedural subsections.	**Document Control Standard of Practice 4 (DC S4):** **Procedure Excerpts** In addition to complete standard operating procedures, policies, instructions, programs, plans and/or manuals, excerpts that summarize key information may be used by laboratory staff, provided: a) the director, ~~assistant director(s)~~, technical director(s) or supervisor qualified staff reviews the excerpts at least every two (2) years and this review is documented; and b) the content provided by the excerpt does not contradict the corresponding document.	Same

Document Control			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Regulatory authority: 10 NYCRR subdivision 58-1.10(g)		***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	

Document Control			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Document Control Standard of Practice 5 (DC S5): Director Approval The director or sole assistant director designated for a category must sign and date each new or revised test procedure before it is used for reporting patient test results. Approval of new and revised test procedures, as indicated by signature and date, may not be delegated by the director or sole assistant director. Test procedure review, at a minimum every two (2) years, is required by the director. This duty may be delegated in writing to an assistant director holding an appropriate certificate of qualification or an individual qualified as a laboratory supervisor.	Non-testing documents may include safety policies and procedures, computer system specifications and/or maintenance instructions. This standard is applicable to laboratory developed tests (LDTs), as well as manufacturer instruction manuals adopted in lieu of laboratory-specific test procedures, standard operating procedures and/or excerpts. In the case of a change in the laboratory director or sole assistant director, all test procedures should be reviewed and signed by the new director and/or sole assistant director as soon as possible. If not done immediately, the laboratory should have a plan for having the review completed and documented within an	**Document Control Standard of Practice 5 (DC S5): Director Approval** The director ~~or sole assistant director designated for a category~~ must sign and date each new or revised test procedure before it is used for reporting patient test results. Approval of new and revised test procedures, as indicated by signature and date, may not be delegated by the director. ~~or sole assistant director.~~ Test procedure review, at a minimum every two (2) years, is required by the director. This duty may be delegated in writing to an ~~assistant~~ technical director holding an appropriate certificate of qualification or an individual qualified as a laboratory supervisor. For controlled documents not related to testing, an individual may be delegated by the laboratory director, as specified	Non-testing documents may include safety policies and procedures, computer system specifications and/or maintenance instructions. This standard is applicable to laboratory developed tests (LDTs), as well as manufacturer instruction manuals adopted in lieu of laboratory-specific test procedures, standard operating procedures and/or excerpts. In the case of a change in the laboratory director ~~or sole assistant director,~~ all test procedures should be reviewed and signed by the new director ~~and/or sole assistant director~~ as soon as possible. If not done immediately, the laboratory should have a plan for having the review

Document Control			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
For controlled documents not related to testing, an individual may be delegated by the laboratory director, as specified in writing, to approve, sign and review documents as indicated in the New York State Clinical Laboratory Standards of Practice. **Regulatory authority: 10 NYCRR subdivisions 58-1.2(c) and 58-1.10(g)**	appropriate timeframe, not to exceed six (6) months. Electronic signature, or an alternative system, may be substituted for hard copy, as long as it is a password protected signature. Blood banks are required to follow the requirements in 10 NYCRR section 58-2.8 for annual review by the director or authorized supervisor.	in writing, to approve, sign and review documents as indicated in the New York State Clinical Laboratory Standards of Practice. **Regulatory authority: 10 NYCRR subdivisions 58-1.2(c) and 58-1.10(g)**	completed and documented within an appropriate timeframe, not to exceed six (6) months. Electronic signature, or an alternative system, may be substituted for hard copy, as long as it is a password protected signature. Blood banks are required to follow the requirements in 10 NYCRR section 58-2.8 for annual review by the director or authorized supervisor.

Reporting

Reporting			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Reporting Standard of Practice 2 (REP S2): Test Report Content Test results must be available in a timely manner to the authorized ordering source or client. Laboratories must be capable of producing a copy of a laboratory report that meets the below requirements. Test results, whether transmitted electronically or by hard copy, must include all required report information, including: a) patient name or other identification; b) the name and address under which the reporting laboratory has been issued a permit, unless the laboratory has reported to the Department an alternative name (e.g.,	"a copy" of a laboratory report may be either electronic or hardcopy.	**Reporting Standard of Practice 2 (REP S2): Test Report Content** Test results must be available in a timely manner to the authorized ordering source or client. Laboratories must be capable of producing a copy of a laboratory report that meets the below requirements. Test results, whether transmitted electronically or by hard copy, must include all required report information, including: a) patient name or other identification; b) the name and address under which the reporting laboratory has been issued a permit, unless the laboratory has reported to the Department an alternative name (e.g.,	Same

Reporting			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
"doing business as"); c) the date, and hour if required, when the specimen was collected; d) the test report date; e) specimen type and/or source (i.e., anatomic location), when appropriate; f) the test(s) performed g) test results, and if applicable, units of measure, reference ranges, or a similar method for identifying abnormal values; i. Alternative mechanisms other than reporting these values on the report may be approved by the d(D)epartment; h) signature of the qualified person who reviewed, approved and/or diagnosed the case, as required under		"doing business as"); c) the date, and ~~hour~~ time if required, when the specimen was collected; d) the test report date; e) specimen type and/or source (i.e., anatomic location), when appropriate; f) the test(s) performed g) test results, and if applicable, units of measure, reference ranges, or a similar method for identifying abnormal values; i. Alternative mechanisms other than reporting these values on the report may be approved by the Department; h) signature of the qualified person who reviewed, approved and/or diagnosed the case, as required under	

Reporting			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Reporting Standard of Practice 1; or i. a record of the cytotechnologist releasing the report is required for negative gynecological cytopathology reports; and i) a statement on the report if compromised specimens are tested, the nature of the problem and, if applicable, any impact on result interpretation; j) if applicable, the name and address of the reference or contract laboratory and the date the specimen was tested or the date the result was reported; k) any disclaimers or limitations to testing where required by the	j) The address of a remote location performing review of digital results under a laboratory's permit may be indicated on the final report by a code. The testing laboratory is responsible for maintaining a 'key' to correlate codes to addresses.	Reporting Standard of Practice 1; or i. a record of the cytotechnologist releasing the report is required for negative gynecological cytopathology reports; and i) a statement on the report if compromised specimens are tested, the nature of the problem and, if applicable, any impact on result interpretation; j) if applicable, the name and address of the reference or contract laboratory and the date the specimen was tested or the date the result was reported; k) any disclaimers or limitations to testing where required by the	

Reporting			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Department for an approved laboratory developed test (LDT); l) any additional information required for the interpretation of results; and m) any other information as required in any part of the New York State Clinical Laboratory Standards of Practice. Report information, whether required or discretionary, must be accurate. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(b)(2)***	l) Examples include: disclosure of the specific equation used for estimated Glomerular Filtration Rate (eGFR) for clinician awareness, limitations stated by the manufacturer prohibiting testing, or limitations stated by the manufacturer affecting results in certain patient populations.	Department for an approved laboratory developed test (LDT); l) any additional information required for the interpretation of results; and m) any other information as required in any part of the New York State Clinical Laboratory Standards of Practice. Report information, whether required or discretionary, must be accurate. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(b)(2)***	

Document and Specimen Retention

Document and Specimen Retention			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Document and Specimen Retention Standard of Practice 6 (DSR S6): Monitoring, Maintenance and Preventive Maintenance Records The laboratory must retain records for: a) environmental monitoring performed according to Facility Design Standard of Practice 2, including monitoring of temperature-controlled spaces, for two (2) years; and b) maintenance and preventive maintenance records generated according to Laboratory Equipment and Instrument Standard of Practice 3, including service and repair records, for as long as the instrument remains	None	**Document and Specimen Retention Standard of Practice 6 (DSR S6): Monitoring, Maintenance and Preventive Maintenance Records** The laboratory must retain records for: a) environmental monitoring performed according to Facility Design Standard of Practice 2, including monitoring of temperature-controlled spaces and/or humidity-controlled spaces, for two (2) years; and b) maintenance and preventive maintenance records generated according to Laboratory Equipment and Instrument Standard of Practice 3, including service and repair records, for as long as	Same

Document and Specimen Retention			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
in use and two (2) years following discontinuation of use. ***Regulatory authority: 10 NYCRR paragraphs 58-1.11(c)(2),(3),(4)***		the instrument remains in use and two (2) years following discontinuation of use. ***Regulatory authority: 10 NYCRR paragraphs 58-1.11(c)(2),(3),(4)***	

Document and Specimen Retention			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Document and Specimen Retention Standard of Practice 7 (DSR S7): Test Request and Specimen Processing Documents The following records must be retained for at least the period specified, except where other New York State or federal regulations or statutes require retention for different periods of time, the laboratory must retain the appropriate record for the longest period applicable. The laboratory must retain: a) test request documentation associated with Test Request Standards of Practice for the same period of time as required for the test report for a specific category or seven (7) years, whichever is less, with the exception of	None	**Document and Specimen Retention Standard of Practice 7 (DSR S7): Test Request and Specimen Processing Documents** The following records must be retained for at least the period specified, except where other New York State or federal regulations or statutes require retention for different periods of time, the laboratory must retain the appropriate record for the longest period applicable. The laboratory must retain: a) test request documentation associated with Test Request Standards of Practice for the same period of time as required for the test report for a specific category or ~~seven (7)~~ two (2) years, whichever is less ~~with the exception~~	Same

information for cytogenetic cases that must be retained for six (6) years; and b) accession records associated with Specimen Processing Standards of Practice for seven (7) years. ***Regulatory authority: 10 NYCRR paragraphs 58-1.11(c)(1) and (2)***		~~of information for cytogenetic cases that must be retained for six (6) years;~~ and b) accession records associated with Specimen Processing Standards of Practice for ~~seven (7)~~ two (2) years. ***Regulatory authority: 10 NYCRR paragraphs 58-1.11(c)(1) and (2)***	

Document and Specimen Retention			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Document and Specimen Retention Standard of Practice 9 (DSR S9): Report Retention All reports of tests performed, including the original or duplicates of original reports received from another laboratory, must be kept on the premises of both laboratories. Reports must be produced for the Department upon request and be retained by the laboratory for: a) tissue pathology including exfoliative cytology for twenty (20) years; b) syphilis serology negative report for two (2) years; c) cytogenetics for twenty-five (25) years and according to Cytogenetics Standard of Practice 14;	Off-site or electronic storage systems are acceptable, provided the laboratory can produce records within twenty-four (24) hours of a request. Original electronic data must be maintained as long as the case file and must be protected from loss or modification.	**Document and Specimen Retention Standard of Practice 9 (DSR S9): Report Retention** All reports of tests performed, including the original or duplicates of original reports received from another laboratory, must be kept on the premises of both laboratories. Reports must be produced for the Department upon request and be retained by the laboratory for: a) tissue pathology and ~~including exfoliative~~ cytology for ~~twenty (20)~~ ten (10) years; b) ~~syphilis serology negative report for two (2) years~~ molecular oncology for ten (10) years; c) cytogenetics for ~~twenty-five (25)~~ ten (10) years and according to Cytogenetics Standard of Practice 14;	Same

Document and Specimen Retention			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
d) case files for forensic identity investigations and electronic data for fifteen (15) years and according to Forensic Identity Standard of Practice 19; and e) all others for seven (7) years. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(c)(5)***		d) ~~case files for forensic identity investigations and electronic data for fifteen (15) years and according to Forensic Identity Standard of Practice 19;~~ and all others for two (2) years. ~~e) all others for seven (7) years.~~ ***Regulatory authority: 10 NYCRR paragraph 58-1.11(c)(5)***	

Document and Specimen Retention			
Current Standard	***Current Guidance***	***Proposed Standard***	***Proposed Guidance***
Document and Specimen Retention Standard of Practice 10 (DSR S10): Specimen Retention Laboratories must be able to retrieve specimens within twenty-four (24) hours. Specimens must be retained, as follows: a) blood films: i. routine, for six (6) months; ii. other than routine, for one (1) year; b) bacteriology slide on which a diagnosis depends, for one (1) year; c) cytology slide showing: i. no abnormality, for five (5) years; ii. any abnormality, for ten (10) years; d) tissue block for twenty (20) years; e) pathology tissue	For specimens not addressed in this Standard, the laboratory director may determine an appropriate retention time. a) i and ii. A routine blood film is one where no abnormal cells or cell counts are observed, or where a blood disorder is not indicated. a) A routine histogram of an automated differential is one that results as "normal" or "negative" and does not imply the need for further analysis. Histograms are considered to be an instrument printout and must therefore be retained, electronically or as hard copy, for two (2) years as required in Document and Specimen Retention Standard of Practice 8. It is not required for a laboratory to create or maintain routine blood	**Document and Specimen Retention Standard of Practice 10 (DSR S10): Specimen Retention** Laboratories must retain specimens until ~~be able to retrieve specimens for twenty-four (24) hours~~ release of the final report ~~within twenty-four (24) hours,~~ except the ~~S~~specimens listed below must be retained, as follows: a) ~~blood films:~~ tissue pathology permanent slides, for twenty (20) years; ~~i. routine, for six (6) months;~~ ~~ii. other than routine, for one (1) year;~~ b) ~~bacteriology slide on which a diagnosis depends~~ tissue pathology paraffin blocks, for two (2) ~~one (1)~~ years; c) tissue pathology immunohistochemical	For specimens not specifically addressed in this Standard, the laboratory director may determine an appropriate retention time which shall not be before the final report is released. ~~a) i and ii. A routine blood film is one where no abnormal cells or cell counts are observed, or where a blood disorder is not indicated.~~ ~~a) A routine histogram of an automated differential is one that results as "normal" or "negative" and does not imply the need for further analysis. Histograms are considered to be an instrument printout and must therefore be retained, electronically or as hard copy, for two (2) years as required in Document and Specimen Retention Standard of Practice 8. It is not required for a~~

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remnants, until a diagnosis is made; f) histopathology: i. block, for twenty (20) years; ii. slide, for twenty (20) years; g) bone marrow biopsy, for twenty (20) years; h) cytogenetic slide, for six (6) years; i) recipient blood specimens, for one (1) week stoppered at one (1) to six (6) degrees Celsius; j) samples of each unit of transfused blood, for seven (7) days for further testing in the event of a transfusion reaction; k) forensic toxicology specimens that were reported as positive, adulterated, substituted or invalid for a minimum of one (1) year and	films if such films are not routinely generated in accordance with the laboratory's approved procedures. c) i. and ii. include gynecological, non-gynecological, and fine needle aspirate (FNA) for cytopathology. f) i. and ii. Slides or electronic images that allow re-evaluation of the entire slide(s) used for reported results. i) Recipient refers to any person receiving blood or blood components.	and/or digital images, for ten (10) years; ~~cytology slide showing:~~ ~~i. no abnormality, for five (5) years;~~ ~~ii. any abnormality, for ten (10) years~~; d) cytopathology slides, for five (5) years; ~~tissue block for twenty (20) years;~~ e) cytopathology digital images, for five (5) years; ~~pathology tissue remnants, until a diagnosis is made;~~ f) bacteriology and mycobacteriology slides, for two (2) weeks after final confirmatory report is issued; ~~histopathology:~~ ~~i. block, for twenty (20) years;~~ ~~ii. slide, for twenty (20) years;~~ g) mycobacteriology isolates, for one (1) year;	~~laboratory to create or maintain routine blood films if such films are not routinely generated in accordance with the laboratory's approved procedures.~~ ~~c)~~ d) and e) ~~i. and ii.~~ cytopathology includes gynecological, non-gynecological, and fine needle aspirate (FNA). ~~for cytopathology.~~ ~~f) i. and ii. Slides or electronic images that allow re-evaluation of the entire slide(s) used for reported results.~~ ~~i) Recipient refers to any person receiving blood or blood components.~~

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according to Forensic Toxicology Standard of Practice 34; and l) mycobacteriology: i. all original and subsequent M. tuberculosis complex isolates from all patients, for one (1) year and according to Mycobacteriology Standard of Practice 13; and ii. stained slides of direct smears from primary specimens, until the final culture report has been issued and according to Mycobacteriology Standard of Practice 9. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(d)(1)***		~~bone marrow biopsy, for twenty (20) years;~~ h) cytogenetic permanent slides, for three (3) ~~six (6)~~ years; i) cytogenetic digital images, for ten (10) years; and ~~recipient blood specimens, for one (1) week stoppered at one (1) to six (6) degrees Celsius;~~ j) samples of each unit of transfused blood, for seven (7) days for further testing in the event of a transfusion reaction; k) forensic toxicology specimens that were reported as positive, adulterated, substituted or invalid for a minimum of one (1) year and according to Forensic Toxicology Standard of Practice 34; and l) molecular oncology immunohistochemical	

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		images or permanent slides, for ten (10) years. ~~mycobacteriology:~~ ~~i. all original and subsequent M. tuberculosis complex isolates from all patients, for one (1) year and according to Mycobacteriology Standard of Practice 13; and~~ ~~ii. stained slides of direct smears from primary specimens, until the final culture report has been issued and according to Mycobacteriology Standard of Practice 9; and~~ Specimens specifically listed above must be retrievable within twenty-four (24) hours of request. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(d)(1)***	