New York State Department of Health

Wadsworth Center

Clinical Laboratory Evaluation Program

Summary of Revised Standards – May 2021
Clinical Laboratory Standards of Practice

General Systems Standards

DEFINITION

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

Human Resources

Human Resources	
Former Standard and Guidance	***Revised Standard and 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; and b) specified in writing for all positions and titles within the laboratory, including positions/titles held by consultants. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(6) and subdivision 58-1.2(d)*** ***Guidance –*** 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).	**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) be consistent with responsibilities and duties described in the New York State Clinical Laboratory Standards of Practice; ~~and~~ b) be specified in writing for all positions and titles within the laboratory, including positions/titles held by consultants~~.~~; and c) describe qualifications. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(6) and subdivision 58-1.2(d)*** ***Guidance –*** Job descriptions should include, but are not limited to: specimen collection personnel; testing personnel; supervisors;

Human Resources	
Former Standard and Guidance	***Revised Standard and Guidance***
	laboratory managers; administrators; assistant director(s); and laboratory director(s).

Laboratory Safety

Laboratory Safety	
Former Standard and Guidance	***Revised Standard and Guidance***
Laboratory Safety Standard of Practice 15 (LS S15): Laboratory Facilities – Biohazards and Chemical Hazards Laboratory facilities must be appropriately designed for biohazards and chemical hazards. The laboratory design must include: a) for biohazards, a design consistent with biosafety level(s) assigned and documented in the biohazard risk assessment under Laboratory Safety Standard of Practice 7, including: i. a sink for handwashing located in the laboratory that may be manually, hands-free, or automatically operated; ii. flooring and furniture that can be cleaned and decontaminated; iii. work surfaces that are impervious to liquids and resistant to moderate heat and the chemicals used for cleaning and decontamination; and	**Laboratory Safety Standard of Practice 15 (LS S15): Laboratory Facilities – Biohazards and Chemical Hazards** Laboratory facilities must be appropriately designed for biohazards and chemical hazards. The laboratory design must include: a) for biohazards, a design consistent with biosafety level(s) assigned and documented in the biohazard risk assessment under Laboratory Safety Standard of Practice 7, including: i. a sink for handwashing located in the laboratory that may be manually, hands-free, or automatically operated or other adequate hand washing facilities; ii. flooring and furniture that can be cleaned and decontaminated;

Laboratory Safety	
Former Standard and Guidance	***Revised Standard and Guidance***
iv. emergency eyewash equipment that is readily available and routinely tested in accordance with institutional policies, where required. b) for chemical hazards, a design and ventilation necessary for minimizing the potential for employee exposure to hazardous chemicals and as described in the Chemical Hygiene Plan required under Laboratory Safety Standard of Practice 6, including: i. a sink for handwashing located in the laboratory that may be manual, hands-free, or automatically operated; ii. chemically resistant and impermeable flooring; iii. work surfaces that are chemically resistant, smooth, and can be cleaned; iv. emergency eyewash equipment or shower, that is properly functioning and routinely tested according to institutional policies, within the work area for immediate use when an employee could be exposed to injurious corrosive chemicals; and v. local exhaust ventilation devices (e.g., chemical fume hoods) appropriate to the materials and operations in the laboratory. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)*** **Guidance –** a) The OSHA website (www.osha.gov/SLTC/bloodbornepathogens/index.html) provides information regarding OSHA's Bloodborne Pathogens standard (Title 29 of the Code of Federal	iii. work surfaces that are impervious to liquids and resistant to moderate heat and the chemicals used for cleaning and decontamination; and iv. emergency eyewash equipment that is readily available and routinely tested in accordance with institutional policies, where required. b) for chemical hazards, a design and ventilation necessary for minimizing the potential for employee exposure to hazardous chemicals and as described in the Chemical Hygiene Plan required under Laboratory Safety Standard of Practice 6, including: i. a sink for handwashing located in the laboratory that may be manual, hands-free, or automatically operated or other adequate hand washing facilities; ii. chemically resistant and impermeable flooring; iii. work surfaces that are chemically resistant, smooth, and can be cleaned; iv. emergency eyewash equipment or shower, that is properly functioning and routinely tested according to institutional policies, within the work area for immediate use when an employee could be exposed to injurious corrosive chemicals; and v. local exhaust ventilation devices (e.g., chemical fume hoods) appropriate to the materials and operations in the laboratory. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***

Laboratory Safety	
Former Standard and Guidance	***Revised Standard and Guidance***
Regulations 1910.1030) and details what employers must do to protect workers with occupational exposure to blood and other potentially infectious materials that may contain HIV, HBV or HCV. a) For additional information on laboratory design for biohazards, see the Centers for Disease Control and Prevention document *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). b) The laboratory should have proper ventilation systems to rid the area of fumes created from hazardous material. OSHA limits for any hazardous chemicals, such as formaldehyde or xylene, should not be exceeded. b) For additional information on laboratory design and ventilation for working with hazardous chemicals, see the National Research Council's 2011 publication titled *Prudent Practices in the Laboratory – Handling and Management of Chemical Hazards*. For additional information on recommended testing and maintenance of emergency eyewashes and safety showers, see the American National Standards Institute's (ANSI) consensus standard Z358.1 – 2014 *Emergency Eyewash and Shower Equipment.*	**Guidance –** a) The OSHA website (www.osha.gov/SLTC/bloodbornepathogens/index.html) provides information regarding OSHA's Bloodborne Pathogens standard (Title 29 of the Code of Federal Regulations 1910.1030) and details what employers must do to protect workers with occupational exposure to blood and other potentially infectious materials that may contain HIV, HBV or HCV. a) For additional information on laboratory design for biohazards, see the Centers for Disease Control and Prevention document *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). b) The laboratory should have proper ventilation systems to rid the area of fumes created from hazardous material. OSHA limits for any hazardous chemicals, such as formaldehyde or xylene, should not be exceeded. b) For additional information on laboratory design and ventilation for working with hazardous chemicals, see the National Research Council's 2011 publication titled *Prudent Practices in the Laboratory – Handling and Management of Chemical Hazards*. For additional information on recommended testing and maintenance of emergency eyewashes and safety showers, see the American National Standards Institute's (ANSI) consensus standard Z358.1 – 2014 *Emergency Eyewash and Shower Equipment.*

Resource Management

Resource Management	
Former Standard and Guidance	***Revised Standard and Guidance***
Laboratory Equipment and Instrument Standard of Practice 8 (LEI S8): Carbon Dioxide Incubators The laboratory must measure carbon dioxide (CO2) in CO2 incubators with a range of five (5) to ten (10) percent. For incubators without a measurement system: • measure levels daily using an outside CO2 measurement device (e.g., electronic CO2 analyzer); or For incubators with a measurement system: • validate CO2 levels monthly using a separate measurement device. ***Regulatory authority: 10 NYCRR section 58-1.6*** ***Guidance –*** If the CO2 incubators have an automatic CO2 readout, the CO2 level does not need to be tested daily with an electronic CO2 analyzer.	**Laboratory Equipment and Instrument Standard of Practice 8 (LEI S8): Carbon Dioxide Incubators** The laboratory must measure and document carbon dioxide (CO2) in CO2 incubators to be within a range that is appropriate for the testing performed ~~of five (5) to ten (10) percent~~. For incubators without a measurement system: • measure levels daily using an outside CO2 measurement device (e.g., electronic CO2 analyzer); or For incubators with a measurement system: • validate CO2 levels monthly using a separate measurement device. ***Regulatory authority: 10 NYCRR section 58-1.6*** ***Guidance –*** If the CO2 incubators have an automatic CO2 readout, the CO2 level does not need to be tested daily with an electronic CO2 analyzer.

Analytic Systems

Analytic Systems	
Former Standard and Guidance	***Revised Standard and Guidance***
Quality Control	
Quality Control Standard of Practice 1 (QC S1): Minimum Quality Control Requirements Unless an Individualized Quality Control Plan (IQCP) is established as described in Quality Control Standards of Practice 2, 3 and 4, at least once each day specimens are tested, the laboratory must test quality controls as follows: a) for qualitative tests, include a positive and negative control; b) for quantitative tests, include two (2) control materials of different concentration suitable for error detection throughout the reportable range; c) for tests producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively; d) for tests that include an extraction phase, include at least one (1) control sample or material that is subjected to the same extraction process as specimens and that is capable of detecting errors in the extraction process; or e) for nucleic acid amplification methods: i. include one (1) control capable of detecting amplification inhibition by patient specimens	**Quality Control Standard of Practice 1 (QC S1): Minimum Quality Control Requirements** Quality controls must be analyzed according to manufacturer instructions or as described below, whichever is more stringent, ~~U~~unless an Individualized Quality Control Plan (IQCP) is established as described in Quality Control Standards of Practice 2, 3 and 4~~,~~. Category specific New York State Clinical Laboratory Standards of Practice for quality controls that are more stringent than manufacturer instructions or the requirements below must be followed and are not eligible for an IQCP. ~~a~~At least once each day specimens are tested, the laboratory must test quality controls as follows: a) for qualitative tests, include a positive and negative control; b) for quantitative tests, include two (2) control materials of different concentration suitable for error detection throughout the reportable range; c) for tests producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively; d) for tests that include an extraction phase, include at least one (1) control sample or material that is subjected to the same extraction process as specimens and that

unless the Department approved laboratory developed test (LDT) exempts the requirement; ii. when more than one (1) outcome is possible at a locus, include a control that represents each outcome periodically; and f) according to manufacturer instructions and all category specific New York State Clinical Laboratory Standards of Practice if more stringent than above. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)*** ***Guidance –*** Information on Departmental approval of a laboratory developed test (LDT) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval. For tests, such as certain staining procedures, for which no controls are available, the laboratory should describe in their standard operating procedure how to determine when the expected reaction is not achieved. Although a run may be defined as up to twenty-four (24) hours, a laboratory that elects to perform all quality control at a fixed time (e.g., start of the day shift) should demonstrate that the system is stable throughout the twenty-four (24) hour period. c) For semiquantitative tests: anti-streptolysin O titer and antihyaluronidase titer tests do not require a negative control; cold agglutination tests do not require a positive control; radial immuno-diffusion tests require one control or standard on each plate. e) Inhibition controls may be excluded if there are sufficient data showing that the inhibition rate is less than one (1) percent for a specimen type for the assay. It is possible to extend inhibition data to other analytes when applying the same extraction procedure and specimen matrix and	is capable of detecting errors in the extraction process; or e) for nucleic acid amplification methods: i. include one (1) control capable of detecting amplification inhibition by patient specimens unless the Department approved laboratory developed test (LDT) exempts the requirement; and ii. when more than one (1) outcome is possible at a locus, include a control that represents each outcome periodically.~~; and~~ ~~f) according to manufacturer instructions and all category specific New York State Clinical Laboratory Standards of Practice if more stringent than above.~~ ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)*** ***Guidance –*** Information on Departmental approval of a laboratory developed test (LDT) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval. For tests, such as certain staining procedures, for which no controls are available, the laboratory should describe in their standard operating procedure how to determine when the expected reaction is not achieved. Although a run may be defined as up to twenty-four (24) hours, a laboratory that elects to perform all quality control at a fixed time (e.g., start of the day shift) should demonstrate that the system is stable throughout the twenty-four (24) hour period. 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

utilizing the same amplification methodology. Inhibition controls are not required if the run includes isolates only and not patient specimens. Negative controls, including template-free mastermix controls, not only serve to identify technical and/or reagent issues, but also help identify amplicon contamination. The negative controls may include a reagent processing control that serves as both a template-free mastermix reagent control as well as a processing/extraction negative control. For laboratories preparing mastermix to be used on multiple instruments, the template-free mastermix control should be utilized for each run of each instrument. For infectious diseases molecular amplification procedures, the positive control should be of a low but detectable amount. A low-range positive is defined as having a value of not more than ten (10) fold above the assay detection limit. For multiplex assays, a low range control is required for each target. These may be run on a rotating basis and may include pools of three (3) to four (4) targets.	control; radial immuno-diffusion tests require one control or standard on each plate. e) Inhibition controls may be excluded if there are sufficient data showing that the inhibition rate is less than one (1) percent for a specimen type for the assay. It is possible to extend inhibition data to other analytes when applying the same extraction procedure and specimen matrix and utilizing the same amplification methodology. Inhibition controls are not required if the run includes isolates only and not patient specimens. Negative controls, including template-free mastermix controls, not only serve to identify technical and/or reagent issues, but also help identify amplicon contamination. The negative controls may include a reagent processing control that serves as both a template-free mastermix reagent control as well as a processing/extraction negative control. For laboratories preparing mastermix to be used on multiple instruments, the template-free mastermix control should be utilized for each run of each instrument. For infectious diseases molecular amplification procedures, the positive control should be of a low but detectable amount. A low-range positive is defined as having a value of not more than ten (10) fold above the assay detection limit. For multiplex assays, a low range control is required for each target. These may be run on a rotating basis and may include pools of three (3) to four (4) targets.

Post-Analytic Systems

Post-Analytic Systems	
Former Standard and Guidance	***Revised Standard and Guidance***
Public Health Reporting	
Public Health Reporting Standard of Practice 1 (PHR S1): Required Public Health Reporting Laboratories must designate staff responsible for reporting results on specimens originating from New York State that are determined to meet any of the following: a) infectious diseases as required in Title I Section 2102 for communicable disease reporting; b) cases of initial determination or diagnosis of HIV infection, HIV-related illness and AIDS as required in Subpart 63.4; c) results of all blood lead analyses with demographic data as required in Subpart 67-3; d) all elevated levels of reportable metal as provided in Title 10 sections 22.6 and 22.7; e) every case of cancer, brain tumor, or other malignant disease as provided in Title I sections 2400-2404; and f) test results indicative of pesticide exposure, such as blood cholinesterase levels and levels of pesticides in human tissue specimens which exceed the normal range established by the laboratory, as required under Part 22 of Chapter 1 of the State Sanitary Code.	**Public Health Reporting Standard of Practice 1 (PHR S1): Required Public Health Reporting** Laboratories must designate staff responsible for reporting results on specimens originating from New York State that are determined to meet any of the following: a) infectious diseases as required in Title I Section 2102 for communicable disease reporting, including all SARS-CoV-2 test results; b) cases of initial determination or diagnosis of HIV infection, HIV-related illness and AIDS as required in Subpart 63.4; c) results of all blood lead analyses with demographic data as required in Subpart 67-3; d) all elevated levels of reportable metal as provided in Title 10 sections 22.6 and 22.7; e) every case of cancer, brain tumor, or other malignant disease as provided in Title I sections 2400-2404; and f) test results indicative of pesticide exposure, such as blood cholinesterase levels and levels of pesticides in human tissue specimens which exceed the normal range established by the laboratory, as required under Part 22 of Chapter 1 of the State Sanitary Code.

Post-Analytic Systems	
Former Standard and Guidance	***Revised Standard and Guidance***
Public Health Reporting	
In addition, an annual Blood Services Activity report is required from blood banks and transfusion services as required under 10 NYCRR section 58-2.10. ***Regulatory authority: as noted and 10 NYCRR paragraph 19.3(c)(2)*** ***Guidance –*** Additional information on reporting requirements are available at: https://www.wadsworth.org/regulatory/clep/laws. The testing laboratory is responsible for reporting except for lead testing where the referring laboratory and the testing laboratory may agree on which laboratory will report. Both laboratories are accountable to ensure that a report is made. Laboratories must electronically report communicable disease test results though the ECLRS module in the Health Commerce System (HCS). Heavy Metals Registry reporting may be done electronically through ECLRS or by paper. For additional information, see Department websites for Communicable Disease Reporting, the Heavy Metals Registry and the Cancer Registry.	In addition, an annual Blood Services Activity report is required from blood banks and transfusion services as required under 10 NYCRR section 58-2.10. ***Regulatory authority: as noted and 10 NYCRR paragraph 19.3(c)(2)*** ***Guidance –*** Additional information on reporting requirements are available at: https://www.wadsworth.org/regulatory/clep/laws. The testing laboratory is responsible for reporting except for lead testing where the referring laboratory and the testing laboratory may agree on which laboratory will report. Both laboratories are accountable to ensure that a report is made. Laboratories must electronically report communicable disease test results though the ECLRS module in the Health Commerce System (HCS). Heavy Metals Registry reporting may be done electronically through ECLRS or by paper. For additional information, see Department websites for Communicable Disease Reporting, the Heavy Metals Registry and the Cancer Registry.

Document and Specimen Retention

Document and Specimen Retention	
Former Standard and Guidance	***Revised Standard and Guidance***
Document and Specimen Retention Standard of Practice 8 (DSR S8): Analytic System Records Retention Analytic system records must be retained by the laboratory, as follows: a) performance specification data and records of acceptability criteria that the laboratory establishes or verifies under Test Performance Specification Standards of Practice 1 and 2 must be retained for as long as the laboratory uses the test process, plus two (2) years after discontinuation: b) testing records, including but not limited to worksheets containing instrument readings, the identity of staff who performed the test(s), and raw patient results, must be retained for two (2) years; c) result review records, including acceptability of quality control and calibration materials for two (2) years: d) histogram of an automated differential result for two (2) years; e) a record of the purity of all drug standard(s) for the period they are in use, and for two years thereafter for forensic toxicology; and f) cellular immunology electronic flow cytometer data in listmode or equivalent format for one (1) year. ***Regulatory authority: 10 NYCRR paragraphs 58-1.11(c)(2),(3),(4)***	**Document and Specimen Retention Standard of Practice 8 (DSR S8): Analytic System Records Retention** Analytic system records must be retained by the laboratory, as follows: a) performance specification data and records of acceptability criteria that the laboratory establishes or verifies under Test Performance Specification Standards of Practice 1 and 2 must be retained for as long as the laboratory uses the test process, plus two (2) years after discontinuation; b) testing records, including but not limited to worksheets containing instrument readings, the identity of staff who performed the test(s), and raw patient results; Next Generation Sequencing (NGS) FASTQ files or equivalent; and electronic flow cytometer data in listmode or equivalent format, must be retained for two (2) years; c) result review records, including acceptability of quality control and calibration materials for two (2) years; d) histogram of an automated differential result for two (2) years; and e) a record of the purity of all drug standard(s) for the period they are in use, and for two years thereafter for forensic toxicology.~~; and~~

Document and Specimen Retention	
Former Standard and Guidance	***Revised Standard and Guidance***
	~~f) cellular immunology electronic flow cytometer data in listmode or equivalent format for one (1) year.~~ ***Regulatory authority: 10 NYCRR paragraphs 58-1.11(c)(2),(3),(4)***

Investigation and Corrective Action

Investigation and Corrective Action	
Former Standard and Guidance	***Revised Standard and Guidance***
Investigation and Corrective Action Standard of Practice 4 (ICA S4): Corrective Action Procedure and Documentation The laboratory must have a standard operating procedure describing the process for initiating corrective actions that are appropriate to the magnitude of the problem and commiserate with the risks encountered. For corrective actions, the laboratory must: a) perform root cause analysis to identify underlying cause(s) of a nonconformance; b) initiate and document corrective actions and, where appropriate, preventive actions; c) document and implement any policy and/or standard operating procedure changes required for corrective actions, if applicable;	**Investigation and Corrective Action Standard of Practice 4 (ICA S4): Corrective Action Procedure and Documentation** The laboratory must have a standard operating procedure describing the process for initiating corrective actions that are appropriate to the magnitude of the problem and ~~commiserate~~ commensurate with the risks encountered. For corrective actions, the laboratory must: a) perform root cause analysis to identify underlying cause(s) of a nonconformance; b) initiate and document corrective actions and, where appropriate, preventive actions; c) document and implement any policy and/or standard operating procedure changes required for corrective actions, if applicable;

Investigation and Corrective Action	
Former Standard and Guidance	***Revised Standard and Guidance***
d) assess the results of any corrective actions taken to ensure that they have been effective; e) ensure that noncompliant practices are not occurring in other sections/categories of the laboratory; and f) submit the results of corrective actions to the laboratory director or individual designated in writing by the director for documentation of review. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)***	d) assess the results of any corrective actions taken to ensure that they have been effective; e) ensure that noncompliant practices are not occurring in other sections/categories of the laboratory; and f) submit the results of corrective actions to the laboratory director or individual designated in writing by the director for documentation of review. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)***