New York State Department of Health

Wadsworth Center

Clinical Laboratory Evaluation Program

Clinical Laboratory Standards of Practice

Part 2 – Specialty Requirements

Laboratory Specialty Standards of Practice

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Effective March 2008 except as indicated

Note**:** There are no special standards for the following permit categories. Compliance with the New York State Clinical Laboratory Standards of Practice Part 1 - General Systems is expected and required for all specialty testing categories.

Clinical Chemistry
Endocrinology
Therapeutic Substance Monitoring / Quantitative Toxicology
Wet Mounts

Andrology

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
Andrology Standard 1 (AN S1) For automated methods for sperm counts and/or motility, electronic controls should be run as instrument checks, as recommended by the manufacturer, at least once during each day of use.	Electronic controls, used in accordance with the manufacturer's recommendations, are acceptable alternatives to matrix controls if: a) A system is in place to monitor the entire analytical system; b) The laboratory first establishes, through documented studies, the stability of the instrument; and, c) Matrix controls, if available, are run at least once per week of use. Acceptable validation documentation could include matrix appropriate control data, which shows method stability over several weeks.
Andrology Standard 2 (AN S2) For manual sperm counts and concentration: a) a minimum of two levels of quality control shall be run each day of use; b) counts shall be performed, in duplicate, using two separate counting chambers, or two separate aliquots; and c) acceptable precision limits for duplicate counts shall be defined.	Quality control for sperm counts should include a normal and at least one abnormal level in the expected range of patient samples. Acceptable controls are two levels of a standardized solution measured each day of use on two different counting chambers. Patient specimens used, as controls should be verified in the same run with the assayed material. Tolerance limits should be established for the value of each control. The results of duplicate counts should be averaged. It is recommended that precision limits be determined based on an approximate 95% confidence interval for differences between the two counts. If the difference exceeds the precision limits, fresh duplicate preparations should be recounted.

Andrology

Standard	Guidance
Andrology Standard 3 (AN S3) When sperm counts, motility and concentration are performed manually: a) testing shall be performed, in duplicate from one dilution, using two separate counting chambers; b) forward progression shall be evaluated and graded as a subset of motility; and, c) acceptable precision limits for duplicate testing shall be defined.	
Andrology Standard 4 (AN S4) When sperm morphology is assessed, stains shall be used to facilitate classification of cell types.	
Andrology Standard 5 (AN S5) Cervical mucus penetration tests shall be performed in duplicate.	
Andrology Standard 6 (AN S6) Indirect anti-sperm antibody test methods shall include a positive and a negative control with each assay.	
Andrology Standard 7 (AN S7) Sperm-egg interaction tests (e.g., hamster-egg penetration assay, hemizona bioassay) shall include a positive control with each assay.	

Blood pH and Gases

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Effective August 5, 2016	
Blood pH and Gases Standard 1 (BP S1) Unless an Individualized Quality Control Plan is established in accordance with Quality Control Sustaining Standard of Practice S1 (QC Design S1): Design of Individualized Quality Control Plan, for all blood gas instruments: a) three levels of control shall be used on each day of testing, and a minimum of one control shall be run each eight hours of testing; and b) a control or calibrator shall be run with each patient unless the blood gas instrument internally verifies the calibration at a minimum of every 30 minutes.	

Blood Services

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Effective January 1, 2019	Laboratories performing non-automated tests to screen for platelet contamination may do so under their Blood Services permit. Laboratories using automated systems must hold, at a minimum, a permit in the category of Bacteriology – Other and should refer to Bacteriology Standard of Practice 1 (BT S1): Reagent QC for quality control requirements. Autogeneic (autologous) collections that are not crossed over for allogeneic use should not be included, and blood banks that perform only such collection need not file a report. All collections for allogeneic use, including those from community donors, directed donors and crossed-over autogeneic (autologous) donors, should be included.
Blood Services Standard 1 (BS S1) For donor services, the Quality Manual shall include a protocol that defines the qualifications of personnel who respond to donor reactions.	10NYCRR subdivision 58-2.6(a) requires that medical services for emergency care of the donor shall be available. As a minimum, when performing donor collection procedures, a nurse or other qualified person specially trained to recognize and treat donor reactions should be immediately available (within approximately ten seconds or audible calling distance) and a physician should be available by telephone for consultation. Persons drawing blood for transfusion should also be trained to recognize donor reactions.

Blood Services Standard 2 (BS S2) Facilities utilizing a one-person verification process for matching recipients to the blood or blood component at the time of transfusion must: a) Use an FDA-approved automated identification technology that positively identifies the recipient and matches the blood or blood component to the recipient; b) Follow the manufacturer's instructions for the proper collection and labelling of the pre-transfusion specimen, including the placement and retention of any required secondary bar-coded wristbands; i. All required bar-coded wristbands must be placed on the patient prior to the collection of the pre-transfusion specimen; c) Follow the manufacturer's instructions for the automated matching of the patient to the blood or blood component prior to transfusion; i. If automated scanning mechanisms fail, including the need to perform manual data entry, or if any bar-coded identification band is removed from the patient prior to the transfusion for any reason, the facility must use a two-person patient identification process.	(c) The 'manufacturer' in this instance includes both the vendor of the electronic ID system and the vendor of the bar-coded wristbands, if not the same.

Cellular Immunology	
Standard	**Guidance**
All laboratories shall comply with the applicable requirements contained in the Clinical Laboratory Standards of Practice- General Systems. In addition, the Cellular Immunology laboratory shall meet the applicable standards outlined below:	Assay Validation Requirements: Validation requirements, including, specimen number, are available from the Cellular Immunology Submission Guidelines for Assay Approval on our website at www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.
Leukocyte Function	
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 1 (CILF S1): Client Instructions for Specimen Collection and Transport The laboratory shall provide specimen collection and transport instructions to clients indicating: a) the anticoagulant(s) that must be used for each assay offered; b) the specimen's collection date and time must be documented; c) blood samples must be handled and transported in a manner to assist in maintenance of the specimens between 18 and 25 degrees Celsius and transported in a timely manner so that the laboratory can begin testing within the NYS-approved validated assay time frames; d) specimen collections must be performed at the same time of day when longitudinal studies of function involving serial monitoring have been requested; and e) any other information considered significant for specimen analysis.	It is recommended that a specimen from a normal donor be collected and shipped whenever possible, as a shipment control. Comparison of the shipment normal control and the in-house derived normal control should assist in controlling for possible shipment effects. e) For example, required specimen volume for testing (refer to Leukocyte Function Standard 5).

Cellular Immunology

Standard	Guidance
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 2 (CILF S2): Specimen Anticoagulant Requirements The laboratory shall only accept and analyze blood provided in the anticoagulant that has been used to establish and standardize the assay and achieve normal ranges, as previously approved by NYS.	If a specimen is received in an anticoagulant that is different than that defined in the specimen collection instructions, the specimen must be rejected unless the laboratory has data substantiating that a substitute reagent does not produce a statistically different response.
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 3 (CILF S3): Specimen Storage Length and Temperature The laboratory shall: a) test blood specimens that are 24 hours or less post-collection unless NYS-approval for testing older specimens has been obtained; b) store specimens post collection between 18 and 25 degree Celsius with minimal exposure to temperature fluctuations.	a) Some functional assessments may require shorter specimen storage length dependent on the function to be assessed. Specimen storage before assay set-up should be kept to a minimum; 8 hours or less is optimal. Validations should demonstrate that results are within 10 percent of time zero (0-4hr) analysis. b) Specimen functional performances are very sensitive to temperature, and fluctuations can cause erroneous results.
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 4 (CILF S4): Specimen Viability A viability assessment shall be performed from an aliquot of the whole blood specimen before the assay or cell culture is started. a) Specimens with cell viability less than 80 percent shall be rejected unless the specimen is deemed irreplaceable or a specimen re-draw would be harmful to the patient. b) The viability percentage shall be included in the laboratory report. c) The report shall include a disclaimer when reporting an irreplaceable specimen with a viability of less than 80 percent.	In the event that the specimen is irreplaceable or cannot be re-drawn, criteria must be included in the laboratory SOP to delineate how the patient specimen should be handled.

Cellular Immunology

Standard	Guidance
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 5 (CILF S5): Specimen Adequacy The procedure shall define the amount of specimen (volume or cell number) needed to report test results.	Client instructions should convey individual assay requirements for specimen volume or cell number required to perform testing. Adequate numbers and viability of the cell type needed for the assay should be known prior to making the requested analysis.
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 6 (CILF S6): Aseptic Reagents The laboratory shall establish and implement a procedure for ensuring use of contamination free medium and other reagents.	Laboratories that choose not to routinely use antibiotics in cultures should document that only aseptic reagents are utilized by using routine evaluation for signs of contamination. Laboratories that use commercially prepared media should retain the manufacturer's documentation that each shipment or lot of media has been subjected to appropriate quality control procedures. The user should visually examine each shipment for color and opacity as well as ability to support cell viability and growth. In-house produced media should include analysis of aseptic condition and adequate cell growth upon stimulation.
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 7 (CILF S7): Limit of Pyrogene Levels All components (media, reagents, and plastic-ware) of the assay procedure involved with the measurement of functional activity shall not exceed 0.5 endotoxin units (EU)/mL).	The laboratory may accept the manufacturer's documentation of acceptable levels of endotoxin. The laboratory must know the level that the manufacturer considers acceptable, but should not exceed 0.5 EU/mL.
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 8 CILF S8): Serum Component of Media If human serum is used for the functional assay, AB serum shall be used.	Red cells and red cell membranes are common contaminants of extracted cellular material. Use of other blood type plasma could cause agglutination, if mismatched.

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Standard	Guidance
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 9 (CILF S9): Reagent Verification Lot-to-lot evaluation of all reagents shall use a normal control specimen to ensure reagents give results within laboratory-derived reference range values.	Lot-to-lot checks, which include all steps of specimen processing, may be used for twice a year accuracy checks of the assay if there is no external proficiency testing program available. These checks may also be used as a competency assessment of staff.
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 10 (CILF S10): Biological Safety Cabinet Requirement The laboratory shall use aseptic techniques during all steps of cell culture set-up and manipulation using a biological safety cabinet (BSC).	The use of a biological safety cabinet is imperative to reduce environmental contamination and to reduce risk of exposure to any potential pathogen. Refer to General Systems Safety Standards for operational requirements of a BSC.
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 11 (CILF S11): Daily Calibration of the Flow Cytometer When a functional assay uses flow cytometric analysis, the following checks shall be performed and documented on each day of use, after maintenance procedures, and after the resolution of any instrumentation failures: a) calibration with stable beads labeled with fluorochromes; b) compensation for spectral overlap for each fluorescent dye that is used for testing; c) determination of adequate fluorescent resolution so that there is a measurable difference between the autofluorescence/non-specific peak and a dimly positive fluorescent peak for each fluorescent parameter used for testing; and, d) standardization to ensure that performance is consistent from day to day.	The manufacturer's recommended procedures should be followed. b) Electronic compensation can be first adjusted with individually fluorescent-labeled beads. Fine tune adjustments should be completed using cells stained with mutually exclusive antibodies brightly labeled with fluorescent dyes. c) Each laboratory should establish acceptable separation between fluorescent peaks of different intensities. Monitoring of acceptable differences between beads with different fluorochrome intensities ensures that the laser and photomultiplier tubes (PMT's) are functioning in a consistent manner. d) The instrument is monitored using a stable fluorescent bead by either using a fixed voltage and measuring the variability of fluorescent peak channel or adjusting voltages to place the fluorescent bead signal at the same peak channel and recording the voltage variability.

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Standard	Guidance
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 12 (CILF S12): Flow Cytometer Linearity When a functional assay includes quantitative measurement of a biomarker, which is dependent on Mean Fluorescence Intensity (MFI), the instrument shall be assessed for linearity on a monthly basis. The assessment of flow cytometers for linearity shall include: a) linearity at the settings used for clinical measurement using multi-level fluorescent beads; b) fluorescence sensitivity and resolution at settings used for clinical measurement; and, c) evaluation of any photomultiplier tube (PMT) changes.	For accurate quantification of any marker by flow cytometry, it is necessary to ensure fluorescence linearity for all fluorochromes routinely used by the laboratory. a) Correlation coefficient analysis of the Mean Fluorescence Intensity (MFI) versus fluorescent molecules per bead should be equal to or greater than 0.98 (1.0 is the ideal). b) Monitoring assesses the photomultiplier tube (PMT's) range of measurement related to the marker intensity (antigen density on or in the cell) and the ability to resolve populations of different intensities. c) Monitoring provides PMT performance history and large shifts or fluctuations indicate that maintenance may be required.

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Standard	Guidance
Cellular Immunology – Leukocyte Function Sustaining Standard of Practice 13 (CILF S13): Reference Range Requirements The laboratory shall have laboratory-derived reference ranges for each leukocyte function assay; which are: a) divided into pediatric, adult, and geriatric ranges and determined using specimens that are within the range of patient ages of the specimens routinely tested by the laboratory; b) determined using a minimum of 25 known healthy donors for each reference range group (pediatric, adult and geriatric); i. donor demographic records shall include age and sex; ii. these ranges shall be compared to published ranges to verify expected performance c) revised with each assay modification; and d) included on the patient report along with the implementation date of the current reference range.	The Cellular Immunology Submission Guidelines for Assay Approval (http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval/submission-checklists) provides guidance for specimen number and requirements. Assay modification and validation requires submission and approval by the Department of Health. b) If normal subjects within the pediatric or geriatric population group are not available for reference range development, peer-reviewed published ranges from prominent, acknowledged sources will be accepted when the testing methodologies are similar. Reference ranges should include race whenever possible. d) All reporting requirements (including normal values) noted in Section 58-1.11 of 10 NYCRR are applicable. The source of the ranges must be documented in the SOP and cited on reports.

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Standard	Guidance
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 14 (CILF S14): Normal Control Requirements A freshly prepared whole blood specimen, or a fraction thereof (e.g., peripheral blood mononuclear cells (PBMC) for function), from a healthy donor shall be included as a normal control: a) on each assay plate or analytical run for all Leukocyte Functional assays; b) set up to include stimulated and unstimulated conditions for each analytical run; c) collected in the same anticoagulant as the patient specimen or the anticoagulant used must have been shown to be functionally equivalent during the assay validation; and d) be stored under conditions as similar as possible to those of the test specimens.	c) Validation studies for each anticoagulant must be submitted to the department for NYS approval as required by Validation Sustaining Standard of Practice 5 (Validation S5): Performance Specifications.
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 15 (CILF S15): Specimen Replicates for Functional Analysis Well or testing replicates should have a coefficient of variation not greater than 20 percent. Greater differences require investigation for procedural errors prior to reporting. a) Functional assays shall be minimally analyzed in duplicate for each condition for each specimen. b) Proliferation and cytolytic assays set up in tissue culture plates shall be analyzed in triplicate for each condition for each specimen.	b) Specimens with abnormally low cell counts may be set up in duplicate for each condition for each specimen. b) Two wells of three may be averaged to report a response, if one of the three wells causes the replicate CVs to be greater than 20 percent. The remaining two wells must be not greater than 20 percent to be reportable.
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 16 (CILF 16): Stimulant Concentrations For functional assays, a minimum of two concentrations of stimulant determined to be in the optimal range during validation shall be used per specimen for each analytical run.	Specimens with abnormally low cell counts may be set up with one concentration of stimulant per specimen for each analytical run that was determined to be the optimal during validation.

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Standard	Guidance
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 17 (CILF S17): Function Assessment Each patient specimen shall be set up for each analytical run to include stimulated and unstimulated conditions.	The optimal storage condition and life span of functional stimulants should be determined during the validation studies. Cells being assessed for functional activity should be characterized and reported whenever possible.
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 18 (CILF S18): Evaluation during Functional Peak For *in vitro* functional assays, the laboratory shall examine and test each functional activity during the validated peak activity interval.	
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 19 (CILF S19): Function Quality Control- Normal Specimen Quality control for functional assays shall include: a) evaluation of the stimulated and unstimulated values of the normal control blood analyzed with the patient's specimen(s) for each analytical run. These values shall be determined, documented, and compared to the laboratory-derived reference ranges for each assay analyzed. b) Out of range results for the normal control shall require investigation for procedural error(s) during the assay run and be documented as a non-conformance. c) All patient results within the assay run shall be withheld until technical errors have been ruled out.	b) Requirements for the investigations of non-conformances are described in **Process Review Sustaining Standard of Practice 4** and **Control of Non-Conformities Sustaining Standard of Practice 1**.

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Standard	Guidance
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 20 (CILF S20): Function Quality Control- Negative, Positive, and Multi-level Controls Negative and positive controls for each functional assay shall be used, whenever available, for each analytic run or plate. Controls demonstrating multiple levels of function shall also be used, when available that demonstrate stability of the functional level over time, for each analytic run or plate. The limit of acceptable day-to-day variance observed with the control cells shall be defined in the procedure manual. If a control demonstrates inappropriate function activity, the analytical run shall be withheld until technical errors have been ruled out.	When available, controls demonstrating multiple levels of function, that demonstrate stability of the functional level over time, are recommended to be used for each analytic run or plate.
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 21 (CILF S21): Background Activity Assessments Media, diluent, or carrier solutions cultured with each specimen without the assay stimulant shall: a) be tested during each analytical run; b) demonstrate the lack of function activity; and, c) when functional activity is noted for the unstimulated condition, the analytical run shall be withheld until technical errors have been ruled out.	
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 22 (CILF S22): Verification of Target Cell Labeling Cellular labeling shall exhibit a low spontaneous release of label without effector interactions. Label maintenance shall be monitored and documented for each analytical run.	Assays using target labeling include Cytolytic and Phagocytosis.

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Standard	Guidance
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 23 (CILF S23): Effector to Target Cellular Ratios Assays using effector to target cell interactions shall be set-up minimally using three cellular ratios between effectors and targets determined to be in the optimal range for the functional activity for each analytical run.	Assays using effector to target ratios include Alloantigen, Cytolytic, and Phagocytosis. Less than three effector to target cell interactions may be used, if appropriately validated and approved by NYS.
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 24 (CILF S24): Result Review Results for each test and information used to generate those results shall be reviewed by an individual holding a Certificate of Qualification (CQ) in Cellular Immunology - Leukocyte Function. When a CQ holder is not available: a) a person qualified as a Cellular Immunology- trained supervisor may review and report results during a temporary absence of the CQ holder; b) the review must be in accordance to a protocol approved by the CQ holder prior to his/her absence; c) supervisor-reviewed results shall be reviewed by the CQ holder upon his or her return in a timely manner, not to exceed the length of the absence and this review must be documented.	Information used to generate results may include, but is not limited to, raw data, worksheets, instrument readings, and personal observations. Temporary absence, as defined in Subpart 58-1 of 10NYCRR, is less than 21 days in duration and includes the inability to access and review the stated above information.

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Standard	Guidance
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 25 (CILF S25): Proliferation Reporting For proliferation assays, results shall be reported as responsive or non-responsive.	For mitogen induced proliferation, the normal response to mitogen is expected to induce a positive stimulation response. For negative response-type antigen-induced proliferation assays, the normal response is the absence of proliferation due to lack of previous exposure. A responsive result is delineated by a proliferative response higher than the established response of unexposed normal donors and/or the stimulation index (response to antigen divided by background response) is not within one or two standard deviations of the mean value for the healthy unexposed control population. For positive response-type antigen-induced proliferation assays, the challenge with an antigen is expected to normally induce a positive stimulation response due to a previous exposure. Attempts should be made to know the vaccine history of the patient so that accurate interpretations can be made. For alloantigen-stimulated proliferation assays (one-way mixed lymphocyte compatibility), the challenge assesses the patient's ability to distinguish self from non-self and is expected to normally induce a positive stimulation response. Testing in this category does not include assays used for tissue typing compatibility.
Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 26 (CILF S26): Reporting Flow Cytometric Results for Functional Analysis Laboratories using flow cytometric analysis of function shall report: a) the characterized population analyzed; and, changes in biomarker expression due to stimulation including percentage and the quantitative change in mean fluorescence intensity (MFI).	

Cellular Immunology

Standard	Guidance
Non-Malignant Immunophenotyping	
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 1 (CINM S1): Client Instructions for Specimen Collection and Transport The laboratory shall provide specimen collection and transport instructions to clients indicating: a) the anticoagulant(s) that must be used for each assay offered; b) the maximum allowable transport time so that the laboratory can test within the required assay time frames; c) the requirement for specimen collection date and time needs to be documented; d) blood samples, for other than CD34 Stem Cell analysis, must be handled and transported in a manner to assist in the maintenance of the specimen between 18 - 25 degrees Celsius. Samples for CD34 Stem Cell analysis must be handled and transported in a manner to assist in the maintenance of the specimen between 2 – 8 degrees Celsius; e) blood specimens that do not meet collection and transport criteria will be rejected; and f) any other information considered significant for specimen analysis.	b) Assay time frames are the interval from the time of collection to the time of processing, when the specimen is stained, lysed, and fixed. If the specimen is not fixed during the staining process, then the specimen age end point would be time of data acquisition on the flow cytometer e) Blood specimens that do not meet collection and transport criteria for blood cannot be tested and reported with a disclaimer. These specimens are not irreplaceable. If other specimen types are to be tested, refer to the Client Instructions Standard in the Cellular Immunology- Malignant Leukocyte Immunophenotyping standards. f) For example, transfusion history is needed for glycosylphosphatidylinosistol (GPI)-anchored proteins for paroxysmal nocturnal hemoglobinuria (PNH*)* analysis.

Cellular Immunology

Standard	Guidance
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 2 (CINM S2): Specimen Age for Whole Blood For non-malignant leukocyte immunophenotyping in whole blood, laboratories must: a) process specimens within the manufacturer's recommendations for maximum specimen age; b) when there are no manufacturer's age requirements or unless other time frames are noted in this document, process specimens from the time of collection within: i. 30 hours if using EDTA anticoagulant; ii. 48 hours if using ACD or heparin anticoagulant; or iii. establish the maximum acceptable age of the specimen by internal validation.	The age of the specimen is calculated from the time the specimen is collected to the time the sample is fixed during the staining process, or a non-fixed sample has undergone data acquisition on the flow cytometer. b) Validation studies must be submitted to NYS as required by the Validation Standards in Part 1 – General Systems. For additional information, see the Test Approval webpage for Cellular Immunology (http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval). b) Viability analysis (CI-NML.S3) will be required if testing beyond the stated timeframes in i) and ii).
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 3 (CINM S3): Specimen Viability Any specimen tested beyond 30 hours, if using EDTA anticoagulant, and 48 hours, if using ACD or heparin anticoagulant, requires viability analysis. a) Specimens that are less than 50 percent viability must be rejected and a replacement specimen shall be requested; b) Specimens that have less than 80 percent viability may be tested and reported. Results shall be accompanied by a statement indicating that the results are based on a sample that was partially compromised due to the presence of greater than 20 percent non-viable leukocytes.	If the blood specimen is collected into a tube containing a preservative (e.g., Streck Cyto-Chex BCT), viability is not required.

Cellular Immunology

Standard	Guidance
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 4 (CINM S4): Antibody Lot Assessments For laboratory developed assays the laboratory must adjust the expected mean fluorescent intensity (MFI) values with each new lot of immunophenotyping antibody reagent for each population analyzed when the MFI changes by more than 15 percent.	Saturation should be determined by titering the antibody to obtain the best signal-to noise-ratio (S/N) for cellular analysis. When MFI differences are greater than 15 percent, the antibody reagent should be re-titered to check signal to noise (S/N) and investigate if the change is related to the lot's fluorochrome to protein (F/P) ratio.
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 5 (CINM S5): Antibody Fluorochrome Stability Instructions for the protection of staining reagents from light shall be written in the SOP and include room lighting conditions during the staining process and storage of the stained tube until data acquisition on the flow cytometer. When reagents with different stabilities are combined, the shortest stability length shall be used for the combined reagents. The stability length of each reagent shall be: a) the manufacturer's recommendation under the prescribed room lighting condition; or, b) determined by validation studies if not defined by manufacturer or when light conditions do not conform to manufacturer's recommendations. i. The validation shall determine the maximum incubation or storage length under specific lighting conditions. The maximum allowable difference of the gated population of interest from time zero is a change of plus or minus three percent and a change in the mean fluorescent intensity (MFI) value of 15% or less using specimens from both normal and abnormal individuals.	Some tandem fluorochrome conjugates have short stability periods (e.g., six hours). The stability length is measured from aliquoting the reagent into the staining tube to data acquisition on the flow cytometer. Fluorochromes are sensitive to photobleaching (room lighting conditions) and/or undergo emission spectra changes by prolong exposure to paraformaldehyde (formaldehyde).

Cellular Immunology

Standard	Guidance
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 6 (CINM S6): Daily Calibration of the Flow Cytometer On each day of use, after maintenance procedures, and after the resolution of any instrumentation failures, the following checks shall be performed on the flow cytometer and documented: a) calibration with stable beads labeled with fluorochromes; b) compensation for color spectral overlap for each fluorescent dye that is used for testing; c) determination of adequate fluorescent resolution so that there is a measurable difference between the autofluorescence/non-specific peak and a dimly positive fluorescent peak for each fluorescent parameter used for testing; and, d) standardization to ensure that performance is consistent from day to day.	b) Electronic compensation can be first adjusted with individually fluorescent-labeled beads. Fine tune adjustments should be completed using cells stained with mutually exclusive antibodies brightly labeled with fluorescent dyes. c) Each laboratory should establish acceptable separation between fluorescent peaks of different intensities. Monitoring of acceptable differences between beads with different fluorochrome intensities ensures that the laser and photomultiplier tubes (PMT's) are functioning in a consistent manner. d) The instrument is monitored using a stable fluorescent bead by either using a fixed voltage and measuring the variability of fluorescent peak channel or adjusting voltages to place the fluorescent bead signal at the same peak channel and recording the voltage variability.

Cellular Immunology

Standard	Guidance
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 7 (CINM S7): Flow Cytometer Linearity Flow cytometers shall be assessed for linearity on a monthly basis and documented. The assessment of flow cytometers for linearity shall include: a) linearity at the settings used for clinical measurement using multi-level fluorescent beads. Correlation coefficient analysis of the Mean Fluorescent Intensity (MFI) versus fluorescent molecules per bead must be equal to or greater than 0.98 (1.0 is the ideal); b) Fluorochrome sensitivity and resolution at settings used for clinical measurement; and c) evaluation of any photomultiplier tube (PMT) changes.	All markers used in the analysis must be FDA cleared or approved to be exempt from monthly linearity checks**.** For accurate quantification of any marker by flow cytometry, it is necessary to ensure fluorescence linearity for all fluorochromes routinely used by the laboratory. b) Monitoring assesses the photomultiplier tube's (PMT's) range of measurement related to the marker intensity (antigen density on or in the cell) and the ability to resolve populations of different intensities. c) Monitoring provides photomultiplier tube (PMT) performance history and large shifts or fluctuations indicate that maintenance may be required.
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 8 (CINM S8): Single Platform Volume Delivery Accuracy When using single-platform methods that are dependent on accurate volume delivery, the laboratory shall verify the accuracy of the volume delivery by automated or manual volume delivery apparatus used for the blood specimen and/or bead delivery, monthly using a gravimetric method, control beads, or another appropriate procedure.	If volume inconsistencies are noted or a manual pipette has been dropped, the volume dispensing apparatus must be checked immediately before resuming patient testing, as required in the Facility Design and Resource Management (FDRM) standards.

Cellular Immunology

Standard	Guidance
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 9 (CINM S9): Single Platform Requirements When the laboratory uses single-platform methods that use fluorescent bead counts, a) the manual shall indicate the use of a lyse/no wash procedure; and, b) bead event collection shall be 1000 or greater per sample tube.	
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 10 (CINM S10): Normal Reference Range Requirements Except for stem cell analysis, the laboratory shall verify or establish reference ranges for each leukocyte immunophenotyping marker. The laboratory shall have laboratory-derived reference ranges for each assay; a) which are:divided into pediatric, adult, and geriatric ranges and determined using specimens that are within the range of patient ages of the specimens routinely tested by the laboratory; b) determined using a minimum of 25 known healthy donors for each reference range group (pediatric, adult and geriatric) i. donor demographic records shall include age and sex; ii. these ranges shall be compared to published ranges to verify expected performance c) revised with each assay modification; and, d) included on the patient report along with the implementation date of the current reference range.	The Cellular Immunology Submission Guidelines for Assay Approval (http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval/submission-checklists) provides guidance for specimen number and requirements. Assay modification and validation requires submission and approval by the Department of Health. a) There are FDA cleared or approved test systems that require the development of reference ranges by the laboratory. b) If normal subjects within the pediatric or geriatric population group are not available for reference range development, peer-reviewed published ranges from prominent, acknowledged sources will be accepted when the testing methodologies are similar or equivalent. Reference ranges should include race whenever possible. When published references for a specific analyte do not describe the requirement to define separate age populations, a single reference group is acceptable. d) All reporting requirements (including normal values) noted in Section 58-1.11 of 10 NYCRR are applicable. The source of the ranges must be documented in the SOP and cited on reports.

Cellular Immunology

Standard	Guidance
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 11 (CINM S11): Control Requirements For each non-malignant leukocyte immunophenotyping marker being assayed, control(s) must be used on each day of testing using: a) two levels of whole blood equivalent commercial controls when available that fall within two different areas of the reportable range; b) one commercial and a freshly prepared whole blood specimen from a healthy donor, when the commercial control levels are not significantly differently; or c) a freshly prepared whole blood specimen from a healthy donor when commercial controls are not available. i. When a fresh whole blood control is used, it must be collected in the same anticoagulant as the patient specimen, or the anticoagulant used must have been validated to produce equivalent immunophenotypic results.	Equivalent commercial control should have same matrices as the expected patient specimen to allow the complete testing process to be quality controlled. The only allowed addition is preservative. The laboratory must verify the manufacturer's ranges for each lot of the commercial controls as required in the Examination Procedure (EP) standards. If sample preparation problems occur, additional control specimens should be used for trouble-shooting purposes. The whole blood normal control for each assay shall be stored under conditions as similar as possible to those of the test specimens.

Cellular Immunology

Standard	Guidance
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 12 (CINM S12): Positive-Negative Bio-marker Determination For laboratory developed assays, the laboratory shall: a) use negative staining cells within the same gated population, when using SS/CD45 gating, to determine the demarcation between positive and negative regions for isotype-matched antibodies; or, b) use isotype control antibodies for setting analysis cursors that distinguish negative from positive staining cells when using Forward Scatter/ Side Scatter gating techniques and/or analyzing cellular antigens of dim fluorescent intensity. These immunophenotyping negative controls (isotype controls) shall be isotype matched antibody at similar concentrations and fluorochrome to protein (F/P) ratios as the test antibody.	a) Biomarkers within the patient's testing panel that have concise negative and positive staining patterns may be used to define negative staining in other panel tubes that may contain more diffuse staining when analyzing within the same gated population with antibodies that are isotype-matched. The isotype control is the negative control to detect non-specific antibody binding.
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 13 (CINM S13): Listmode Data Storage The information pertaining to all leukocyte populations (no restrictive population gate) shall be stored using list-mode format for a minimum of two months	Histograms must be saved for two years as required in Subpart 58-1 of 10 NYCRR and Part 1 - General Systems Standards of the New York State Clinical Laboratory Standards of Practice.

Cellular Immunology

Standard	Guidance
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 14 (CINM S4): Result Review Results for each test and information used to generate those results shall be reviewed by an individual holding a certificate of qualification (CQ) in Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping prior to reporting. When a CQ holder is not available: a) a person qualified as a Cellular Immunology- trained supervisor may review and report results during a temporary absence of the CQ holder; b) the review must be in accordance to a protocol approved by the CQ holder prior to his/her absence; and c) supervisor reviewed results shall be reviewed by the CQ holder upon his or her return in a timely manner, not to exceed the length of the absence, and this review must be documented.	Information used to generate results may include, but is not limited to, raw data, worksheets, instrument readings, and personal observations. Minimally, the flow cytometric print-outs should be reviewed for accuracy in population gating and marker analysis. Temporary absence, as defined in Subpart 58-1 of 10NYCRR, is less than 21 days in duration and includes the inability to access and review the stated above information.
Lymphocyte Enumeration (including T-Lymphoid Analysis)	*All the general standards for Non-Malignant Leukocyte Immunophenotyping must also be followed.*
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 15 (CINM S15): Lymphocyte enumeration- Lymphocyte Event Collection At least 2,500 lymphocytes shall be collected per sample tube for quantification. When the required number of lymphocytes cannot be collected, the number shall be stated on the patient report with a disclaimer that the optimal collection of events is 2,500 lymphocytes.	In severe late stage AIDS or immunosuppressed patients, cell counts may be very low; under these conditions, collection of less than 2,500 lymphocytes is acceptable.

Cellular Immunology

Standard	Guidance
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 16 (CINM S16): Lymphocyte enumeration- Multi-color CD Subset Definitions	**STANDARD DELETED effective June 1, 2017**
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 17 (CINM S17): Lymphocyte enumeration- Quality Control using CD3 Tube Replicate The CD3 replicate shall be monitored when the analysis panel contains more than one stained tube. a) The CD3 percentage values shall not exceed a difference of 3 between the highest and lowest CD3 value within the patient's stained panel tubes; and b) The CD3 absolute values shall not differ by greater than 10 percent among the CD3 absolute values within the patient's stained panel tubes.	The use of different fluorochromes or different monoclonal antibodies for CD3 could affect this determination. When CD3 values do not replicate, the laboratory should document that the specimen was repeated and/or restained. b) Specimens with abnormally low CD3 cell counts may require a greater allowable difference between replicate tubes within the patient's stained panel, but should not exceed 20 percent.
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 18 (CINM S18): Lymphocyte enumeration- Quality Control using Lymphosum Determination When a lab analyzes T, B and NK cells, the lymphosum must be within 90 -105 percent.	Lymphosum refers to the sum of all subsets of lymphocytes ($CD3^+$ plus $CD19^+$ plus $CD3^-/CD56^+$ and/or $CD16^+$ cells). The laboratory should troubleshoot for technical difficulties when the lymphosum is out of optimal range.

Cellular Immunology	
Standard	**Guidance**
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 19 (CINM S19): Lymphocyte enumeration- Quality Control using T-Sum Determination The T-sum shall be monitored as follows: a) for three color analysis : The sum of $CD3^+CD4^+$ and $CD3^+CD8^+$ must be within 10 percent of the total CD3 mean. b) for four or more color analysis: The summation of the single positive T cells ($CD3^+CD4^+CD8^-$ and $CD3^+CD4^-CD8^+$ cells), the double positive T cells ($CD3^+CD4^+CD8^+$) and the double negative T cells ($CD3^+CD4^-CD8^-$) shall not exceed a difference of 3 of the total CD3 percentage mean.	If a greater difference is found, the laboratory should repeat the analysis, including restaining, to confirm that no preparation problems occurred. a) Three color analysis: A greater variance is acceptable in patients with an increased population of $CD4^-CD8^-CD3^+$ cells (e.g., delta/gamma T cells). b) As required in these standards (Cellular Immunology Non-Malignant Leukocyte Immunophenotyping Standard 16), i. T cell subsets need to be assessed for single-positive, double-positive, and double-negative expression of CD4 and CD8 subsets of CD3 lymphocytes. ii. Double positive (DP) $CD4^+CD8^+$ T lymphocytes should not be included in the single positive T cell populations and will affect the T-sum determination if this DP T cell subset has not been resolved.
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 20 (CINM S20):Lymphocyte Enumeration- Reporting Requirements Unless the single platform instrumentation only provides absolute numbers, percentages and absolute numbers of lymphocyte subsets shall be reported.	
CD34 Stem Cell Enumeration	*All the general standards for Non-Malignant Leukocyte Immunophenotyping must also be followed.*

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Standard	Guidance
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 21 (CINM S21): CD34 Stem Cell Enumeration- Specimen Age For CD34 stem cell enumeration, laboratories shall process specimens within the following age limits: a) the manufacturer's recommendations for maximum specimen age cut-offs for the specimen type and the assay testing system used; or b) for laboratory developed assays, specimens must be tested within 24 hr using timeframes validated by the laboratory and approved by NYS that demonstrates results at time zero (within zero to four hours of collection) and at the maximum time do not exceed a difference of 3 percent.	The age of a specimen is the interval from the time of collection to data acquisition. Data acquisition is the process of acquiring event information, including light scatter and fluorescent parameters, from the stained specimen tube on the flow cytometer. The specimen needs to be handled and transported in a manner that maintains an optimal viable condition and expedites testing.

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Standard	Guidance
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 22 (CINM S22): CD34 Stem Cell Enumeration- Apheresis Specimen Requirements On apheresis specimens, the laboratory shall quantify the number of cells prior to staining. If a dilution is necessary to be within the test system's target cell range: a) the dilution buffer shall contain a support protein to reduce or eliminate the "vanishing bead" phenomena, when using single platform methodologies; and, b) the dilution factor shall be documented and used for cell count calculations.	
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 23 (CINM S23): CD34 Stem Cell Enumeration- Specimen Staining/Processing Reagent Requirements For CD34 stem cell enumeration, the laboratory shall: a) use CD34 antibody reagent that: i. bind CD34 class II or class III epitopes; ii. be conjugated with a bright fluorochrome (eg., PE); and iii. not include the use of FITC conjugated antibodies to CD34 class II; b) use CD45 antibody reagent that detects all isoforms and glycoforms; and c) use ammonium chloride lyse reagent without fixative in a lyse/no wash manner.	

Cellular Immunology	
Standard	**Guidance**
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 24 (CINM S24): CD34 Stem Cell Enumeration- Viable Cell Assessment CD34 stem cell enumeration shall include the simultaneous determination of viable cells.	
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 25 (CINM S25): CD34 Stem Cell Enumeration- Analysis Requirements When performing CD34 stem cell analysis, the laboratory shall: a) collect at least 100 stem cell events per sample for quantification; and b) collect at least 1,000 bead events, if single platform methodologies are used.	Collection of 75,000 leukocyte events is strongly recommended. Sequential Boolean gating strategy is strongly recommended with a threshold/discriminator to remove non-leukocytes events (debris) in the plot determining the leukocyte gate. The gating strategy should exclude dead cells, platelet aggregates, myeloid/monocytic cells from the final determination while identifying stem cells based on bright $CD34^{+}$, dim to intermediate CD45 staining, and low side scatter (granularity).
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 26 (CINM S26):CD34 Stem Cell Enumeration- Control Requirements For the enumeration of CD34 stem cells, a low and high level control shall be assessed on each day of testing.	
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 27 (CINM S27):CD34 Stem Cell Enumeration- reporting requirements Viable CD34 stem cells shall be quantified and reported as absolute number of viable cells per microliter.	
Analysis of GPI anchored proteins for PNH diagnosis	*All the general standards for Non-Malignant Leukocyte Immunophenotyping must also be followed.*

Cellular Immunology	
Standard	**Guidance**
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 28 (CINM S28): Analysis of GPI-anchored proteins for PNH diagnosis – Specimen Stability Specimens for glycosylphosphatidylinositol (GPI) anchorage of Paroxysmal Nocturnal Hemoglobinuria (PNH) immunophenotyping shall: a) be processed within 48 hours of collection, when fixatives are used during the staining process; or b) undergo data acquisition on the flow cytometer within 48 hours of collection, when fixatives are not used in the staining process.	
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 29 (CINM S29): Analysis of GPI-anchored proteins for PNH diagnosis - Analysis Requirements A normal blood shall be stained and analyzed concurrently with patient specimen to define normal expression in the analysis of GPI anchored antigens	Both specimens (normal and patient) should be collected within four hours of each other since antigens are naturally shed post-collection. The degree of antigen expression determines the severity of the disease. Variable composite phenotype expressions may be present for each cell lineage within an abnormal specimen. Use of antibody and/or non-antibody controls is also recommended to define non-specific binding as the specimen ages post collection.
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 30 (CINM S30): Analysis of GPI anchored proteins for PNH Diagnosis - Positive Staining Control Analysis for Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis shall include a marker for a transmembrane antigen in each staining tube to provide a positive staining antibody control. Staining quality (percentage and mean fluorescent intensity) shall be documented.	Use of a lineage marker for this purpose can also provide assistance for population identification and gating (eg., for WBC's- CD45, CD15, and/or CD64; for RBC's- anti-glycophorin A or CD235a).

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Standard	Guidance
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 31 (CINM S31): Analysis of GPI anchored proteins for PNH Diagnosis - Requirements for Routine Analysis Routine analysis for GPI-anchorage (PNH) shall be used for the detection of specimens containing 1% or greater events of the anchorage deficiency within a gated population. For routine GPI anchored antigen (PNH) analysis, a minimum of 5,000 events shall be collected for each population analyzed.	A low differential for the monocyte population may permit fewer events to be collected for this population. Two parameter density plots of both GPI markers should be used to determine the double negative events to define complete deficiency (Type III) and partial deficiency (Type II) to be defined by the events of intermediate brightness for both markers.
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 32 (CINM S32): Analysis of GPI anchored proteins for PNH Diagnosis - Requirements for High Sensitivity Analysis High sensitivity analysis for GPI-anchorage (PNH) shall be used for the detection of specimens containing less than 1 to 0.01 percent of events demonstrating anchorage deficiency within a gated population. High sensitivity analysis for GPI-anchorage (PNH) immunophenotyping shall: a) collect a minimum of 250,000 events for each population analyzed; b) use two parameter density plots of both GPI markers to determine the double negative events to define complete deficiency (Type III) and partial deficiency (Type II) to be defined by the events of intermediate brightness for both markers.	A low differential for the monocyte population may permit fewer events to be collected for this population. High sensitivity analysis for GPI-anchorage (PNH) should be analyzed with a minimum of two lineage transmembrane biomarkers with light scatter parameters to accurately define each leukocyte population analyzed using a sequential Boolean strategy; Precautions should be taken to reduce cell carryover between analyzed marker tubes during rare event analysis.

Cellular Immunology	
Standard	**Guidance**
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 33 (CINM S33): Analysis of GPI anchored proteins for PNH Diagnosis - Review Criteria and Reporting The laboratory shall review the patient's history of any recent blood transfusions when assessing GPI anchored antigens. If laboratory cannot obtain transfusion history, a disclaimer must be on the report. The total PNH content per cell population shall be reported while acknowledging complete (type III) and partial (type II) deficiency components. Disease confirmation shall require an expression deficiency of at least two different GPI biomarkers including monoclonal antibodies and/or FLAER directed against two different GPI-anchored antigens assessed on a minimum of two different cell lineages (*e.g.*, RBC and neutrophils).	Transfused donor cells will dilute the patient's blood phenotype composition. FLAER is a fluorescently labeled inactive variant of the protein aerolysin that selectively binds GPI anchors on leukocytes. FLAER must be analyzed with an additional GPI biomarker per leukocyte lineage.
Leukocyte Adhesion Deficiency (unstimulated)	*All the general standards for Non-Malignant Leukocyte Immunophenotyping must also be followed. Laboratories that assess the stimulate upregulation using cell culture methods fall under the category of Cellular Immunology – Leukocyte Function.*
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 34 (CINM S34): Leukocyte Adhesion Deficiency (unstimulated expression) – Event Collection A minimum of 5,000 events shall be collected per population analyzed.	

Cellular Immunology	
Standard	**Guidance**
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 35 (CINM S36): Leukocyte Adhesion Deficiency (unstimulated expression) – Positive Staining Control Analysis for Leukocyte Adhesion Deficiency (LAD) shall include CD45, or a lineage-specific CD marker, in each staining tube to provide a positive staining antibody control. Staining quality (percentage and mean fluorescence intensity) shall be documented.	These markers should be used for leukocyte population identification for gating. Analysis for LAD Type 1 should include markers for the leukocyte β2 integrins (staining panels of CD18 with CD11a and CD11b. Analysis for LAD Type 2 should include the CD15s marker.
Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 36 (CINM S36): Leukocyte Adhesion Deficiency (unstimulated expression)- Report Requirements The patient report shall include leukocyte population identification with the biomarker expressions including percentage and the quality of expression or Mean Fluorescence Intensity (MFI).	

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Standard	Guidance
Malignant Leukocyte Immunophenotyping	
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 1 (CIML S1): Client Instructions for Specimen Collection and Transport The laboratory shall provide specimen collection and transport instructions to clients indicating: a) the anticoagulant(s), saline, or medium that must be used for each type of specimen to be collected; b) the requirement for specimen collection date and time must be documented with each specimen; c) if testing will occur in less than eight hours, specimens must be handled and transported in a manner to assist in the maintenance of the specimens between 18 and 25 degrees Celsius prior to testing. If testing is expected to occur in greater than eight hours, specimens must be handled and transported with cold packs to maintain specimens between 2 and 8 degrees Celsius prior to testing; d) the maximum time between collection and receipt so that the laboratory can test within required assay time frames; and, e) any other information considered significant for specimen analysis.	d) Assay time frames are the interval from the time of collection to the time of processing, when the specimen is stained, lysed, and fixed. If the specimen is not fixed during the staining process, then the specimen age end point would be time of data acquisition on the flow cytometer

Cellular Immunology

Standard	Guidance
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 2 (CIML S2): Specimen Age and Integrity Leukemia/lymphoma specimens: a) shall be tested within 48 hours of collection unless the specimen is deemed irreplaceable and specimen re-collection would be harmful to the patient; and b) shall be visually inspected for evidence of deterioration or unacceptable conditions upon receipt. Specimens, which are fixed, frozen, warmer than 37 degree Celsius or, in the case of peripheral blood or bone marrow, clotted or hemolyzed, shall be rejected.	Leukemia/Lymphoma specimens should be handled and transported in a manner that maintains optimal condition and expedites testing. Some specimen types and/or malignancies are more fragile and should be tested earlier.
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 3 (CIML S3): Specimen Viability Leukemia/lymphoma specimens shall be assessed for viability during specimen processing, prior to staining and fixation, on a non-fixed aliquot of the specimen's single cell suspension. a) Blood specimens greater than eight hours post collection shall be assessed for viability. Blood specimens that are less than 50 percent viability must be rejected and a replacement specimen shall be requested; b) When specimens have less than 80 percent viability, the report must note that the results are based on a sample that was partially compromised due to the presence of greater than 20% non-viable leukocytes; c) Specimens having less than 50 percent viability shall be reported only when it is an irreplaceable sample and an abnormal population is definitively determined by the combination of the flow cytometry results with other clinical and technical features of the case.	In some cases (e.g., CSF), an extremely low cell count may not allow viability to be analyzed. For such cases, the report must note that a viability assessment could not be determined due to the very low cell count. c) Examples of irreplaceable specimens are thymus, lymph node, spleen, and bone marrow.

Cellular Immunology	
Standard	**Guidance**
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 4 (CIML S4: Leukocyte Count Adjustment Prior to staining, the laboratory shall adjust the white blood cell concentration to optimize cell-to-reagent ratio and instrument acquisition event rate. The initial leukocyte concentration, the dilution calculations, and final leukocyte concentration for the specimen shall be documented.	
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 5 (CIML S5): Antibody Lot Assessments For each new lot of immunophenotyping antibody reagent, the laboratory must adjust the expected mean fluorescent intensity (MFI) values for each population analyzed when the MFI changes by more than 20 percent.	Lot checks should be conducted using a normal control blood to make the additional comparison against the laboratory's determination of expected normal expression levels. Saturation should be determined by titering the antibody to obtain the best signal-to noise (S/N) ratio for cellular analysis. When MFI differences are over 20 percent, the antibody reagent should be re-titered to check S/N and investigated if the change is related to the lot's fluorochrome to protein (F/P) ratio.

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Standard	Guidance
Cellular Immunology –Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 6 (CIML S6): Antibody Fluorochrome Stability Instructions for the protection of staining reagents from light shall be written in the SOP and include room lighting conditions during the staining process and storage of the stained tube until data acquisition on the flow cytometer. When reagents with different stabilities are combined, the shortest stability length shall be used for the combined reagent. The stability length of each reagent shall be: a) the manufacturer's recommendations under the prescribed room lighting condition; or b) determined by validation studies if not defined by manufacturer or when light conditions do not conform to manufacturer's recommendations. i. The validation shall determine the maximum incubation or storage length under specific lighting conditions. The maximum allowable difference from time zero, within the gated population, is a percent change of plus or minus three and a change in the mean fluorescent intensity (MFI) value of 20% or less using specimens from both normal and abnormal individuals.	Some tandem fluorochrome conjugates have short stability periods (e.g. six hours). The stability length is measured from aliquoting the reagent into the staining tube to data acquisition on the flow cytometer. Fluorochromes are sensitive to photobleaching (room lighting conditions) and/or undergo emission spectra changes by prolong exposure to paraformaldehyde (formaldehyde).

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Standard	Guidance
Cellular Immunology –Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 7 (CIML S7): Daily Calibration of the Flow Cytometer On each day of use, after maintenance procedures, and after the resolution of any instrumentation failures, the following checks shall be performed on the flow cytometer and documented: a) calibration with stable beads labeled with fluorochromes; b) compensation for color spectral overlap for each fluorescent dye that is used for testing; c) determination of adequate fluorescent resolution so that there is a measurable difference between the autofluorescent/non-specific peak and a dimly positive fluorescent peak for each fluorescent parameter used for testing; and d) standardization to ensure that performance is consistent from day to day.	The manufacturer's recommended procedures should be followed. b) Electronic compensation can be first adjusted with individually fluorescent-labeled beads. Fine tune adjustments should be completed using cells stained with mutually exclusive antibodies brightly labeled with fluorescent dyes. c) Each laboratory should establish acceptable separation between fluorescent peaks of different intensities. Monitoring of acceptable differences between beads with different fluorochrome intensities ensures that the laser and photomultiplier tubes (PMT's) are functioning in a consistent manner. d) The instrument is monitored using a stable fluorescent bead by either using a fixed voltage and measuring the variability of fluorescent peak channel or adjusting voltages to place the fluorescent bead signal at the same peak channel and recording the voltage variability.
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 8 (CIML S8): Flow Cytometer Linearity On a monthly basis, laboratories performing malignant leukocyte immunophenotyping shall assess and document their flow cytometer(s) for fluorescence linearity. The assessment of flow cytometers for linearity shall include: a) linearity at the settings used for clinical measurement using multi-level fluorescent beads. Correlation coefficient analysis of the Mean Fluorescent Intensity (MFI) versus fluorescent molecules per bead must be equal to or greater than 0.98 (1.0 is the ideal); b) fluorescence sensitivity and resolution at settings used for clinical measurement; and c) evaluation of any photomultiplier tubes (PMT) changes.	The intensity of cellular antigens (markers) can assist in assessing the characteristics of the aberrant population(s). For accurate quantification of any marker by flow cytometry, it is necessary to ensure fluorescence linearity for all fluorochromes routinely used by the laboratory. b) Monitoring assesses the PMT's range of measurement related to the marker intensity (antigen density on or in the cell) and the ability to resolve populations of different intensities. c) Monitoring provides photomultiplier tubes (PMT) performance history and large shifts or fluctuations indicate that maintenance may be required.

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Standard	Guidance
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 9 (CIML S9): Normal Control Requirements A freshly prepared whole blood specimen from a healthy donor shall be tested as a normal control at least monthly for malignant leukocyte immunophenotyping and results shall be documented. The normal control shall be used to evaluate: a) normal staining expression (percentage and intensity) of the biomarkers on all leukocyte populations; and b) appropriate flow cytometer(s) settings (PMT voltages, color compensation, etc) to achieve optimal resolution of leukocyte subpopulations and biomarker fluorescent quality and resolution.	Cell lines should also be used for the assessment of antibody reagents that are not positive on normal leukocyte populations. The whole blood normal control for each assay should be collected and stored under conditions as similar as possible to the whole blood test specimen. The normal control specimen should be used for the lot check process prior to finishing the current reagent lot to evaluate for lot differences in the laboratory derived normal expression definitions.
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 10 (CIML S10): Positive-Negative Bio-marker Determination To assess biomarker expression demarcation as positive or negative: a) negative staining cells within the same gated population shall be used if the antibodies are isotype-matched; b) when analyzing cellular antigens of dim fluorescent intensity, isotype control antibodies shall be used to assist the setting of cursors that distinguish negative from positive staining cells. These negative controls must be isotype-matched at similar concentrations and fluorochrome to protein (F/P) ratios as the test antibody.	a) Biomarkers within the patient's testing panel that have concise negative and positive staining patterns may be used to define negative staining in other panel tubes that may contain more diffuse staining when analyzing within the same gated population with antibodies that are isotype-matched unless the antibody of interest is polyclonal. The isotype control antibodies are the negative control to detect non-specific antibody binding.

Cellular Immunology	
Standard	**Guidance**
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 11 (CIML S11): Data Acquisition- Event Collection Data acquisition shall minimally include the collection of 10,000 leukocyte events, or 5,000 if the specimen presents as a single population, excluding cellular debris and dead cells. When the required number of leukocyte events cannot be collected, the patient report shall include a disclaimer that the optimal event collection was unattainable due to low cellular content of the specimen.	A specimen with low cellular content may require the collection of fewer events (e.g., cerebral spinal fluid and fine needle aspiration).
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 12 (CIML S12): Data Acquisition- Population Resolution and Gating When performing malignant leukocyte immunophenotyping, the laboratory shall: a) optimize for the best population separation to allow gates or regions to be cleanly drawn on specific leukocyte populations while reducing debris and non-leukocyte contamination; and b) complete data analysis using multiple gated regions set on the apparent populations, including normal leukocyte populations, with minimal contamination from other cell populations.	a) The operator should strive to fully use the plot area while reducing or eliminating any population overlap. Inclusion of cellular debris and dead cell events should be reduced by use of threshold/discriminator settings.

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Standard	Guidance
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 13 (CIML S13): Specimen Quality Assurance To ensure testing accuracy prior to reporting, the laboratory must document that: a) replicate antibody use on the aberrant population(s) within the patient's specimen testing panel is consistent (percentage and intensity) when using the same clone, fluorochrome, and manufacturer (conjugation process), and b) a normal leukocyte population within the specimen is analyzed concurrently to ensure normal staining activities, unless the specimen doesn't contain any normal population(s).	a) If results demonstrate inconsistencies with regard to the antigenic profile of the aberrant cell, the laboratory should review the analysis for procedural error and re-stain if necessary. b) The selected normal leukocyte population within the patient sample should be compared to the laboratory-derived normal expression determinations for the population analyzed. If differences are noted, the analysis should be reviewed for technical difficulties.
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 14 (CIML S14): Result Review Results for each test and information used to generate those results shall be reviewed by an individual holding a certificate of qualification (CQ) in Cellular Immunology – Malignant Leukocyte Immunophenotyping prior to release of test results. When a CQ holder is not available: a) a person qualified as a Cellular Immunology- trained supervisor or hematopathologist may review and document results during a temporary absence of the CQ holder; b) this process shall be in accordance with a protocol approved by the CQ holder prior to his/her absence; c) supervisor- or hematopathologist- reviewed results shall be reviewed by the CQ holder upon his or her return in a timely manner, not to exceed the length of the absence, and this review shall be documented.	Information used to generate results may include, but is not limited to, raw data, worksheets, instrument readings, and personal observations. Minimally, the flow cytometric print-outs should be reviewed for accuracy in population gating and biomarker analysis. Temporary absence, as defined in Subpart 58-1 of 10NYCRR, is less than 21 days in duration and includes the inability to access and review the stated above information. A qualified hematopathologist is licensed physician who is board certified for this subspecialty by the American Board of Pathology.

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Standard	Guidance
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 15 (CIML S15): Listmode Data Storage The information pertaining to all viable leukocyte populations (no restrictive population gate) shall be stored using list-mode format for a minimum of three months.	
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 16 (CIML S16): Report Requirements In addition to the report content requirements detailed in the General Systems Standard, the leukemia/lymphoma report shall include: a) specimen viability; b) descriptions of the light scatter characteristics of each identified aberrant population; c) the percentage of each identified aberrant population within the patient specimen; d) biomarker expression levels that are abnormal (higher or lower) for those observed on normal cells of similar hematopoietic lineage. The patient report shall include a description of the quality of staining (e.g., dim or low intensity, bright or high intensity); e) description of lineage and stage for each identified aberrant population; and f) declaration of any specimen condition that was less than optimal.	The flow cytometric results should be correlated with pathology results, when available, and whenever appropriate, should indicate the monoclonality and/or biphenotypic characteristics.

Cellular Immunology

Standard	Guidance
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 17 (CIML S17): Minimal Residual Disease Analysis - Client Instructions In addition to the requirements described in CI-ML.S1, the client instructions for Minimal Residual Disease (MRD) analysis shall also require: a) the submission of the patient's medical history; b) acknowledgement of collection timing during the treatment regimens related to the type of specimen submitted; c) defined amount of specimen (volume or cell number) needed to report test results for rare event analysis; and d) expedited transport to allow specimen age of less than 30 hours.	The standards for routine malignant immunophenotyping also need to be followed, but the more stringent requirement applies. a) The patient's medical history is critical for the testing laboratory to determine effective antibody selections and gating strategy to enrich the collection of rare event aberrant cells. b) The laboratory must capture the rare aberrant event while discriminating from normal mature cells and normal regenerating progenitor cells. Knowledge of the collection timing will assist the testing laboratory to discriminate between normal circulating cells and the minimal residual disease. c) Client instructions should convey assay requirements for specimen volume or cell number required to perform testing. Adequate numbers and viability of the cell type needed for the assay should be known prior to making the requested analysis. d) A fresher specimen will provide the least amount of dead cells comprising the analysis.
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 18 (CIML S18): Minimal Residual Disease Analysis- Event Collection for Rare Event Analysis Event collection for Minimal Residual Disease Analysis shall require: a) the collection of 500,000 leukocyte events per tube. When the required number of leukocyte events cannot be collected, the patient report shall include a disclaimer that the optimal event collection was unattainable; and b) reduction of cell carryover between analysis tubes.	The standards for routine malignant immunophenotyping also need to be followed, but the more stringent requirement applies. a) Client instructions should convey individual assay requirements for specimen volume or cell number required to perform testing. b) Sampling a water tube between the sample tubes can reduce carryover.

Cellular Immunology

Standard	Guidance
Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 19 (CIML S19): Minimal Residual Disease Analysis- Antibody Panel Design and Analysis Requirements	
Requirements for Antibody Panel Design and Analysis for Minimal Residual Disease Analysis shall include: a) the investigation of the patient's medical history to provide assistance in antibody selection and gating strategy to enrich the collection of the patient's rare event aberrant cells. Records of the patient's previous immunophenotypic analysis shall be maintained by the testing laboratory; b) design of sufficient antibody panels to enable the detection of new phenotypic profiles caused by immunophenotypic shifts. Tube antibody panels shall be comprised of a minimum of four colors with the use of replicate fluorescent antibodies between the stained tubes within the patient's testing panel; c) use of sequential gating to enable the detection of the rare event aberrant cell and discrimination from normal mature cells and normal regenerating progenitor cells. Knowledge of specimen collection timing within the patient's treatment regimen shall provide supportive assistance in this determination and shall be documented by the testing laboratory.	The standards for routine malignant immunophenotyping also need to be followed, but the more stringent requirement applies. b) Six or more colors per tube is recommended as more colors per tube will provide increased sensitivity and accuracy. It is also recommended to use of FITC and PE for the most critical aberrancy biomarkers with PE being used for the low expression biomarkers.

Cytogenetics

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Revised effective August 5, 2016.	
Cytogenetics Sustaining Standard of Practice 1 (CG S1): Informed Consent Materials The laboratory shall notify practitioners wishing to order a cytogenetic test that informed consent is required and shall make available to the practitioner test-specific information for patient use in decision-making and the informed consent process. These materials shall include: a) general description and statement of purpose for the test; b) indication that the individual may wish to obtain professional genetic counseling prior to giving consent; c) a statement that a positive result is an indication that the individual may be predisposed to or have the specific disease or condition tested for and may want to consider further independent testing, consult their physician or pursue genetic counseling; d) a general description of the disease or condition related to the test; e) the level of certainty that a positive test result serves as a predictor of the disease; f) the persons or organizations to whom the test result may be disclosed; g) a statement that no tests other than those authorized shall be performed on the biological sample and that the sample shall be destroyed at the end of the testing process or not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized in the consent; and, h) provision for the signature of the individual subject of the test or if the individual lacks the capacity to consent, the signature of the person authorized to consent for the individual.	Informed consent is not required for cancer cytogenetic testing. Laboratories should be aware that cytogenetic testing is also covered by Section 79-l of the Civil Rights Law. Reasonable effort should be made to obtain patient consent and document the process. While patient consent forms are recommended to be on file in the laboratory; the referring physician may sign the test requisition or other form indicating that she or he conveyed the required information to the patient and obtained consent. g) Research testing may be performed on residual specimen pursuant to a research protocol approved by an institutional review board provided that: i. the subject, or the subject's authorized representative, has provided written informed consent for the specific research; ii. the sample has been permanently stripped of identifying information; and iii. the research participant has consented to the de-identification.

Cytogenetics Sustaining Standard of Practice 2 (CG S2): Clinical Information The laboratory shall request clinical information necessary for proper initiation of test procedures and interpretation of test results, including, for prenatal analysis, the gestational dating.	This may be accomplished by including an appropriate section on the test requisition. If the clinical information is not included with the specimen, the laboratory should request this information. If the clinical information is not received, the laboratory record should be so noted and the report should state that the clinical information was not provided and should include any limitations of the result due to this omission.
Cytogenetics Sustaining Standard of Practice 3 (CG S3): Specimen Type The laboratory shall have a system to distinguish specimen types to assure proper processing, handling and analysis, to facilitate quality assurance review, and to segregate data for reporting.	The identification system should be part of the accession system in order to identify the specimen type.
Cytogenetics Sustaining Standard of Practice 4 (CG S4): Turn Around Times The laboratory shall establish critical limits for turn-around-times for all clinical tests, including standard methods, fluorescent in-situ hybridization (FISH), and chromosomal microarray analysis (CMA).	TAT targets should be based on criteria that include specimen type and indication/reason for referral. The laboratory should have a policy to ensure that later gestational age specimens are given priority so that results are released prior to the 25th week of gestation in order to allow patient decisions regarding pregnancy termination. Chromosomal microarray analysis (CMA) as used in these standards is intended to include array-based tests for copy number and/or heterozygosity/homozygosity including but not limited to array comparative genomic hybridization (aCGH).
Cytogenetics Sustaining Standard of Practice 5 (CG S5): Specimen Tracking The laboratory shall have the capability to track a specimen from accession number to microscope slide, karyotypes, FISH images, and CMA results, when applicable, and to report and conversely.	
Cytogenetics Sustaining Standard of Practice 6 (CG S6): Replicate Cultures	

The laboratory shall prepare replicate independently established cultures: a) for prenatal specimens, a minimum of three cultures shall be set up for each specimen; b) for other tissue or fibroblast cultures, a minimum of three cultures shall be set up for each specimen; and, c) for all other specimens, duplicate cultures shall be set up.	Analyzed cells should be selected from at least two independently established cultures, except for routine blood cultures when the laboratory has pre-determined that adequate numbers and quality of cells with consistent results are obtained from a single culture.
Cytogenetics Sustaining Standard of Practice 7 (CG S7): Media Quality Assurance The laboratory shall establish and implement a procedure for: a) contamination control in media; b) monitoring bacterial, viral, fungal and mycoplasma contamination; and, c) in-house growth support testing of tissue culture media.	a) Laboratories that choose not to routinely use antibiotics in cultures should document that individual cultures are routinely checked for signs of contamination. b) Laboratories that use commercially prepared media should retain the manufacturer's documentation that each shipment or lot of media has been subjected to appropriate quality control procedures. The user should visually examine each shipment for contamination, appearance, or evidence of exposure to extremes of temperature, and notify the media manufacturer of problems related to the quality of the media, including failure to support growth or provide expected colony size, or evidence of contamination. c) In-house growth support tests may include parallel testing of the mitotic index or cell doubling time of cultures and criteria for acceptance for growth support should be established. This may include growth support studies performed by the manufacturer if available.
Cytogenetics Sustaining Standard of Practice 8 (CG S8): Culture Quality Assurance The laboratory shall monitor and document the nature and rate of cultures that fail to yield metaphases, and take remedial action in all cases.	This should be an ongoing quality assurance monitor.
Cytogenetics Sustaining Standard of Practice 9 (CG S9): Vernier Readings Procedure The laboratory shall establish and implement a protocol for checking	

microscope stage vernier readings, and making corrections as necessary.	
Cytogenetics Sustaining Standard of Practice 10 (CG S10): Redundant Incubation Prenatal cultures shall be split between two incubators used exclusively for prenatal cultures with independent electrical circuits and emergency alarms.	If such arrangements are not feasible, the laboratory should establish a written protocol for prompt handling of prenatal cultures in the event of an equipment failure that might adversely affect viability and test outcome.
Cytogenetics Sustaining Standard of Practice 11 (CG S11): Replicate Processing Independently established prenatal cultures shall be processed so as to maintain individual culture integrity.	Processing includes setting up, feeding, and harvesting cultures, and labeling slides.
Cytogenetics Sustaining Standard of Practice 12 (CG S12): Culture Intervals The laboratory shall establish and implement procedures to ensure utilization of accepted intervals of culture to optimize cell division.	Approximate processing times vary for each diagnostic area, but generally should fall within the following time frames: Blood: 48-72 hours; 96 hours for special methods Amnio: 6-14 days Tissue: 1-6 weeks Bone Marrow - Direct: 72 hours Others: As established by the laboratory.
Cytogenetics Sustaining Standard of Practice 13 (CG S13): Karyotyping The laboratory shall prepare a minimum of two karyotypes per specimen: a) if more than one cell line is detected, a minimum of one karyotype per cell line; b) using photographic or other image reproduction techniques; c) using banded cells which meet the laboratory's pre-established criteria for banding quality and resolution; and, d) identified with the metaphase source and specimen identifiers.	c) The laboratory shall identify individual chromosomes by banding methods, including G, Q or R or other methods that allow identification of all homologs. The laboratory shall document policy and review procedures to ensure that the intended chromosome band resolution, or other appropriate measure for non-banded preparations, is attained and is appropriate to the specimen and clinical information provided in order to rule out the cytogenetic abnormality(ies) reasonably expected based on the clinical information provided.

	The average band resolution attained should be included in the result report (Cytogenetics Standard 21c). If the band resolution attained is not optimal for the clinical indications for testing, appropriate comments and recommendations should be included in the result report (Cytogenetics Standard 21d, e, f). d) The metaphase may be identified by vernier location, and/or film and frame number of photograph.
Cytogenetics Sustaining Standard of Practice 14 (CG S14): Spontaneous Breakage Studies For laboratories conducting spontaneous breakage studies a normal (negative control) shall be included with each culture event.	
Cytogenetics Sustaining Standard of Practice 15 (CG S15): Presumed Positive Breakage Studies For laboratories conducting breakage studies on presumed positive specimens, a normal (negative control) and if possible an abnormal control for the condition in question shall be included with each culture event.	
Cytogenetics Sustaining Standard of Practice 16 (CG S16): Metaphase Analysis The laboratory shall analyze a minimum number of metaphases as indicated below: a) a minimum of 20 metaphases, except for prenatal, in situ, which requires 15 metaphases; and, b) count cells from at least two cultures for all specimens except peripheral blood for constitutional chromosome abnormality analysis.	Analyzed means to establish the number of centric chromosomes in a metaphase AND evaluate individual chromosomes in their entirety, i.e., each metaphase is critically analyzed, including chromosome count, sex chromosome complement, cytogenetic aberrations and vernier location. The minimum count will often be exceeded when multiple cell lines are observed. Based on a laboratory's pre-established criteria, cells from replicate cultures may be analyzed. When mosaicism is suspected on the basis of a phenotype that does not fit with the karyotype or when sex chromosome abnormalities are suspected an analysis of at least 50 cells is

	recommended. When one cell with a sex chromosome aberration is identified by routine analysis, it is recommended that a minimum of 10 additional metaphase cells be analyzed.
Cytogenetics Sustaining Standard of Practice 17 (CG S17): Laboratory Developed FISH Analysis For laboratory-developed FISH tests, the laboratory shall analyze a number of cells appropriate to the specimen type, reason for referral, and aberrations expected. At a minimum, the laboratory must analyze: 1) for metaphase FISH a) to detect nonmosaic microdeletion – 10 cells b) to characterize abnormal chromosome – 5 cells c) for mosaic aberrations or samples expected to be mosaic based on indications – 20 cells 2) interphase FISH a) constitutional studies - 50 nuclei b) acquired studies i) suspension culture – 100 cells ii) tissue section – 50 tumor cells.	Unexpected results may require analysis of more cells. FDA-approved/cleared tests should be analyzed as described in the package insert or its equivalent. FISH for microduplications should include analysis of interphase nuclei. Lab should have policies for “borderline” results near cutoff values A pathologist must guide identification of tumor cells in tissue sections
Cytogenetics Sustaining Standard of Practice 18 (CG S18): Metaphase Preparation Acceptability Laboratories must establish criteria to determine the acceptability of standard metaphase chromosome preparations and document acceptability of each preparation prior to reporting.	Criteria may describe circumstances (for example, irreplaceable sample) under which a preparation not meeting acceptability criteria might be reported.
Cytogenetics Sustaining Standard of Practice 19 (CG S19): FISH Hybridization Acceptability Laboratories must establish criteria to determine the acceptability of each FISH hybridization and document the acceptability of each hybridization prior to reporting. Such criteria must include: a) signal intensity b) background/noise	

c) appropriate internal (normal homolog and/or control probe) and/or external controls	
Cytogenetics Sustaining Standard of Practice 20 (CG S20): FISH Analysis Accuracy With respect to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy, the laboratory minimally must confirm accuracy of FISH testing based on procedure, test design (fusion, breakapart, enumeration, etc) and specimen type (suspension, smear/touch, fixed tissue section, etc)	
Cytogenetics Sustaining Standard of Practice 21 (CG S21): Reporting In addition to the requirements of Part 58, the final report shall include: a) use of the current International System for Human Cytogenetic Nomenclature (ISCN); b) the number of cells analyzed and, when applicable, the number from which karyotypes were prepared; c) band resolution attained; d) in cases of culture failure or where a definitive diagnosis is not possible, suggestions for additional testing; e) an interpretation of findings; f) a statement on limitations of the test, including possible inaccuracies; g) suggestions as to whom the physician and/or patient may consult for discussion of prognosis implications of abnormal results (e.g., genetic counseling); h) Reports that include FISH results must include: 1) number of cells analyzed	A summary and interpretation of the results are recommended. a) Results may be reported in other formats in addition to ISCN

2) probe target and vendor 3) cutoff values for interphase FISH, and i) Reports that include CMA must include: 1) platform description, including number and distribution of probes 2) genome build used for analysis and interpretation.	
Cytogenetics Sustaining Standard of Practice 22 (CG S22): Report Signatory Reports shall contain the signature of the qualified person who reviewed, approved and/or diagnosed the case. Use of an electronic signature must be limited to the qualified person to ensure secure authorization and documentation for each occurrence.	For purposes of this standard, a qualified person is a director or assistant director who holds a valid New York State Certificate of Qualification in Cytogenetics.
Cytogenetics Sustaining Standard of Practice 23 (CG S23): Consent to Release Laboratories must obtain the subject's written consent, or if the individual lacks the capacity to consent, the signature of the person authorized to consent for the individual, before records, findings or results may be re-disclosed to any individual or organization other than those authorized on the test requisition to receive the result.	
Cytogenetics Sustaining Standard of Practice 24 (CG S24): Prenatal Diagnosis Confirmation The laboratory shall establish and implement procedures to obtain follow-up information for confirmation of all prenatal diagnosis.	The responsibility of obtaining this information cannot be delegated. Discrepancies of phenotypic sex and abnormal outcome should be fully evaluated. This is the only means a laboratory has to obtain the predictive value of the analysis.
Cytogenetics Sustaining Standard of Practice 25 (CG S25): Required Records Records for each case shall include: media used, reactions observed, culture conditions including incubation times, adverse observations, subculturing information (if any), number of cells analyzed and	

additional cells counted, type of banding utilized, the number of cells from which karyotypes were prepared and karyotypes prepared.	
Cytogenetics Sustaining Standard of Practice 26 (CG S26): Records Retention The laboratory shall have a system for maintaining and retrieving, for the required 25 years, the entire case record, including, when applicable, the original: a) metaphase and interphase images and karyotypes b) metaphase and interphase FISH images representative of results c) CMA analysis file(s) that include relative copy number and genotype, as applicable, and data quality metrics values.	This applies to image analysis software as well.

Cytokines

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. (CK S1 revised and effective July 14, 2014)	It is recommended that World Health Organization (WHO) international cytokine standards be evaluated as additional inter-assay control when available. Since these assays are not cleared or approved by the FDA, the laboratory must submit copies of package inserts and patient reports before initiating testing as described in the Submission Guidelines. These Guidelines can be found at www.wadsworth.org/clep.
Cytokine Standard 1 (CK S1) Laboratories shall establish or verify the reference interval for each cytokine for each matrix tested.	Normal range of values should be established for each matrix (e.g., serum, plasma, or CSF). The effect of diurnal variation on cytokine levels should be taken into consideration and should be included in collection instructions.
Cytokine Standard 2 (CK S2) All results that fall above the reference interval (highest point on the linear portion of standard curve) shall be diluted and retested.	False positive results may be obtained when the specimen is run neat due to matrix interference.
Cytokine Standard 3 (CK S3) All specimens shall be run in duplicate with non-automated methods unless validation studies indicate acceptable precision.	Laboratories should establish an acceptable range of variation for duplicate values (e.g., less than 20 percent coefficient of variation).

Diagnostic Immunology

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Laboratories performing donor testing must comply with Subpart 58-2. DI S1 through DI S3 effective May 11, 2012; DI S4 effective September 27, 2012; DI S5 through DI S7 effective July 25, 2012.	
Diagnostic Immunology Sustaining Standard of Practice 1 (DI S1): Syphilis Screening Algorithm Using Nontreponemal Tests All initial reactive nontreponemal tests shall be confirmed using a standard treponemal test unless the patient has had a known documented prior syphilis infection or the report contains a statement that the test has not been confirmed.	An initial test refers to the first or only test in the laboratory's protocol for syphilis testing. This is the standard CDC recommended protocol where screening for syphilis is performed with a non-treponemal test such as RPR, followed by a treponemal test if the non-treponemal test is reactive. Laboratories may use prior information to verify that confirmatory testing has been performed.
Diagnostic Immunology Sustaining Standard of Practice 2 (DI S2): Syphilis Screening Algorithm Using Treponemal Tests Syphilis screening algorithms using a treponemal enzyme or chemiluminescense immunoassay (EIA/CIA) initial test shall have an RPR performed on all reactive sera. If the results are discordant, the laboratory must either perform a treponemal assay other than EIA/CIA or indicate on the report that a confirmatory treponemal test is recommended.	This is called the Reverse Sequence Syphilis Screening protocol and is the alternative to the standard CDC protocol defined in Diagnostic Immunology Sustaining Standard of Practice 1. Laboratories may follow the standard protocol or the Reverse Sequence Syphilis Screening protocol. If results are discordant in the Reverse protocol, CDC recommends that an alternate treponemal test be performed using a methodology different from the initial treponemal test, such as *Treponema pallidum* particle agglutination (TP-PA). Reference: MMWR 2011 Vol. 60, No. 5.

Diagnostic Immunology

Standard	Guidance
Diagnostic Immunology Sustaining Standard of Practice 3 (DI S3): Non-Treponemal End Point Titration Diagnostic specimens found reactive for syphilis-reagin antibody shall be titrated to the end point onsite	Arbitrary limits to titrating patient specimens (e.g. greater than 512) are not acceptable. For specimens obtained from residents outside of New York City, results of titers greater than or equal to 16 must be telephoned immediately to the State Health Department. The requirement for on-site quantitation is considered to be met if: a) the facility has an indication to initiate on-site treatment; b) the same sample is forwarded for quantitation and confirmation to an approved laboratory; c) the laboratory documents ongoing comparison of the on-site RPR test result for each patient with the result obtained by the referral laboratory; and, d) as part of its quality assurance program, the laboratory investigates discordant results and initiates timely and appropriate corrective action, if necessary. The data should be retained and be available for Department review. Non-diagnostic specimens, such as insurance or donor testing where the results are not reported to the health care provider, do not need to be titrated.
Diagnostic Immunology Sustaining Standard of Practice 4 (DI S4): Food Allergy Testing The laboratory shall use IgE based assays for food allergy testing unless written approval to use other immunologic tests have been received from the Department.	Validation studies for other immunologic tests must be submitted for review and must be approved prior to offering testing. Please refer to the CLEP Submission Guidelines and the Guidelines for the Diagnosis and Management of Food Allergy in the United States when submitting a validation package. Validation Guidelines are posted on the CLEP website at http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.

Diagnostic Immunology

Standard	Guidance
Diagnostic Immunology Sustaining Standard of Practice Standard 5 (DI S5): Reporting Preliminary Positive HIV Test Results In accordance with NYSDOH regulations (Section 58-8.4) laboratories may report preliminary positive HIV test results, provided that: a) the laboratory has written policies and procedures for provision of preliminary positive HIV test results; b) a physician or other person legally authorized to request an HIV test has provided a written request to receive a preliminary positive test result; and c) the report prominently and clearly states that the finding is preliminary, that results of confirmatory testing will follow, and that such confirmatory results must be considered in making a diagnosis related to HIV infection.	A preliminary positive HIV result is one that has not been substantiated with HIV supplemental test(s). b) A written request in the form of a standing order for release of preliminary positive HIV test results is acceptable. In settings where multiple physicians are providing care, such as clinics and departments within a hospital, the standing order request may be made by the Department Director and be written to include all physicians providing care within that department.

Diagnostic Immunology

Standard	Guidance
Diagnostic Immunology Sustaining Standard of Practice Standard 6 (DI S6): Timeliness of Reporting Results for Expedited Maternal/Newborn HIV Testing Laboratories conducting expedited maternal/newborn HIV testing as mandated by Section 69-1.3 shall: a) establish and implement procedures to ensure identification of such specimens; b) report initial HIV test results (negative or preliminary positive) within 12 hours of obtaining consent for maternal testing or within 12 hours of birth when expedited newborn testing is performed in lieu of maternal testing; and c) either perform supplemental testing intended to confirm a preliminary positive test result and report results within 4 days of obtaining the preliminary positive result or refer a specimen for such testing within 24 hours of obtaining the preliminary positive result.	a) This standard is intended to facilitate the birthing facility's compliance with the regulatory requirements for obtaining HIV results of expedited maternal/newborn HIV testing. The laboratory's SOPM should describe procedures and protocols specific to specimen handling, including the need for the birthing facility to record either the time of the mother providing consent for testing or the time of the infant's birth; the specimen collection time; reporting of preliminary results; and where necessary, arrangements for prompt referral for screen and/or supplemental testing. Refer to Specimen Processing Sustaining Standard of Practice 5 (Processing S5): Urgent Test Request. b) Up to 12 hours is the allowable timeframe for reporting initial test results. However, results from the initial test should be transmitted as soon as possible, preferably within 1 hour of specimen collection. This is intended to facilitate the initiation of antiretroviral prophylaxis to reduce the risk of perinatal transmission. d) Up to 4 days is the allowable timeframe for reporting results of supplemental testing performed to confirm a preliminary positive result; however, supplemental test results should be transmitted as soon as possible.

Diagnostic Immunology

Standard	Guidance
Diagnostic Immunology Sustaining Standard of Practice Standard 7 (DI S7): Reporting Results From Anonymous HIV Testing on Specimens From Occupational Exposure Source Patients In accordance with Part 63 of the NYCRR Title 10, laboratories that perform HIV testing on specimens from occupational exposure source patients from whom consent for HIV testing can not be obtained shall: a) have a policy and/or procedure in place to allow for anonymous testing in such circumstances; and b)report the results of HIV tests only to the authorized submitter using only the specimen code and no patient-identifying information.	Part 63 of Title 10 of the NYCRR indicates that informed consent for HIV testing is not required for anonymous testing of a person who is the source of an occupational exposure, who is deceased, comatose, or otherwise unable to provide consent, and for whom no person authorized to consent on behalf of the source patient is immediately available. a) Submitters should be instructed to use a unique code that will identify the specimen but maintain the anonymity of the source patient involved in an occupational exposure when consent for HIV testing could not be obtained from the source patient. b) Only the attending health care professional (submitter) of the *exposed* person is authorized to submit specimens and receive results for anonymous HIV testing of an occupational exposure source patient from whom consent could not be obtained.

Fetal Defect Markers

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Effective July 14, 2014	
Fetal Defect Markers Sustaining Standard of Practice 1 (FEDM S1) The laboratory shall establish weekly gestational age dependent reference intervals for each marker tested based on in-house generated data which: a) include weekly gestational analyte marker concentration versus gestational age correlations each first and/or second trimester week for which the laboratory reports risk assessments; b) include a minimum of 100 samples for each marker per gestational weeks 11,12,13 for first trimester screening, and 15,16,17,18 for second trimester screening; 75 samples for week 19; and 50 samples for the border weeks 10.6 and 13.9 for the first trimester, and 14.0, 20, and 20.9 for the second trimester; c) addresses marker values for all specimen matrices accepted by the laboratory; d) includes the number of "normal" specimens employed for each weekly gestational age interval to determine cutoff percentile values or multiples of the median (MOM); e) is periodically updated by inclusion of each new determination performed in the laboratory; f) indicates the date of last recalculation; and g) is verified through follow-up of results by monitoring pregnancy outcomes, results of medical procedures (e.g., sonography) performed subsequent to testing, or epidemiological monitoring by comparison of in-house statistics with global databases.	Reference intervals may not be obtained or derived from manufacturer's inserts or published values from other laboratories. a) Weekly analyte concentrations for first trimester border weeks 10.6 and 13.9 and second trimester weeks 14.0 and 20.9 may be extrapolated from log linear plots of median vs. gestational age until sufficient data are accumulated. b) Samples should be representative of the routine regional patient population tested by the laboratory. c) There should be separate curves for serum and amniotic fluid. d) There should be separate values for each individual analyte marker.

Fetal Defect Markers Sustaining Standard of Practice 2 (FEDM S2) Laboratories performing supplemental testing for abnormal alpha-fetoprotein (AFP) results from amniotic fluid shall confirm by inhibition all AChE diagnostic bands detected in gels run on amniotic fluid prior to reporting of the AFP test results.	Laboratories may choose to refer supplemental testing of amniotic fluid to another New York State permitted laboratory.
Fetal Defect Markers Sustaining Standard of Practice 3 (FEDM S3) Reports shall contain the signature of the qualified person who reviewed, approved, and interpreted the test results. A qualified person is an individual who holds a valid New York State certificate of qualification in Fetal Defect Markers.	Laboratories using electronic signatures should have a procedure in place that ensures and documents the qualified person's authorization for each signature occurrence (such as access limited by password).

Forensic Identity

Standard	Guidance
All laboratories shall comply with the applicable requirements contained in the NYS DOH General Systems standards. Laboratories performing DNA analyses in forensic paternity cases shall also comply with applicable requirements in the NYS DOH Paternity/Identity Standards. All permitted laboratories performing forensic DNA testing shall also be in compliance with the most recent version of the Federal Bureau of Investigation Quality Assurance Standards for Forensic DNA Testing Laboratories and, as applicable, DNA Databasing Laboratories. In addition, the forensic identity laboratory shall meet the applicable Forensic Identity NYS standards outlined below. Revised and effective September 13, 2018	
QUALITY ASSURANCE PROGRAM	
Forensic Identity Standard 1 (FOID S1) The laboratory shall maintain a current, comprehensive quality system and corresponding quality manual which, at a minimum, address all the FBI standards and all relevant NYS General and Forensic Identity Standards.	
ORGANIZATION AND MANAGEMENT	
Forensic Identity Standard 2 (FOID S2) The organizational structure of the laboratory shall be defined and the interrelationship of all individuals indicated on a current organization chart. The following individuals shall be identified on this chart: the laboratory director, the assistant director, all other individuals with a current NYS Certificate of Qualification in Forensic Identity, the technical leader, the QA manager, the health and safety manager, all analysts, all technicians and all laboratory support personnel.	While the organization may choose to use other job titles, cross-reference to FBI-defined titles shall be made on this chart.

Forensic Identity

Standard	Guidance
PERSONNEL	
Forensic Identity Standard 3 (FOID S3) In addition to the requirements set forth in General Systems Human Resources Sustaining Standards, the laboratory must maintain records of the following for each employee: • documentation of review of current literature; • documentation of court testimony (or lack thereof) in any given calendar year.	Human resources information may be maintained in different on-site locations provided that a master list is developed which indicates the locations of all the information and all the information is readily available to auditors.
Forensic Identity Standard 4 (FOID S4) The laboratory shall have a documented training program for qualifying all technical and support staff participating in processing of evidentiary materials, sample analysis, technical or administrative review and/or reporting of results. Documentation of training shall be maintained. Successful completion of a competency exam shall mark the end of a training module and shall be formally recognized in writing by the laboratory director or an individual authorized by the laboratory director. All individuals, regardless of previous training and experience, shall successfully complete a qualifying test for the specific DNA technology to be used at the current laboratory prior to assuming casework responsibilities.	
Forensic Identity Standard 5 (FOID S5) Continuing education of the laboratory director and/or the technical leader shall include one national DNA forensics meeting at least every four years.	Please note; continuing education of staff is addressed in proposed Human Resources Sustaining Standard of Practice 10: Continuing Education.

Forensic Identity	
Standard	**Guidance**
Forensic Identity Standard 6 (FOID S6) The technical leader shall be readily available to fulfill all the duties of a technical leader and shall have the authority to halt testing if quality is compromised. If the technical leader is on-site less than 50% of the laboratory work week, on average, the laboratory shall have documented policies and procedures indicating how the technical leader fulfills his/her duties while off-site.	
Forensic Identity Standard 7 (FOID S7) Laboratories offering databasing services shall have a staff member designated as the individual responsible for interacting with the client CODIS manager. This individual shall maintain familiarity with CODIS requirements and procedures. This individual shall have a working knowledge of computers, computer networks including network security, and computer database management, with an understanding of DNA profile interpretation. If this individual is responsible for actual data interpretation, he/she shall be qualified as an analyst and shall participate in proficiency testing.	
FACILITIES AND SECURITY	
Forensic Identity Standard 8 (FOID S8) The laboratory shall have available a current floor plan of the laboratory with major equipment and pre-amplification and post-amplification areas indicated and with any relevant controlled flow of traffic. Areas maintained at different levels of security shall be indicated.	

Forensic Identity

Standard	Guidance
EVIDENCE OR SAMPLE CONTROL	
Forensic Identity Standard 9 (FOID S9) Specimens expected to yield low-copy number DNA shall be processed at separate times and/or in separate places in the laboratory than specimens expected to yield abundant DNA. Reference samples shall be processed at separate times and/or in separate places in the laboratory relative to evidence samples.	
Forensic Identity Standard 10 (FOID S10) The laboratory shall comply with Section 79-l of the NYS Civil Rights Law.	
Forensic Identity Standard 11 (FOID S11) The client instruction manual shall include a requirement that only properly sealed packages will be accepted for analysis (packages sealed in a tamper-evident manner, with the identification of the individual packaging the specimens indicated). Improperly sealed packages shall be returned to the submitting agency.	
Forensic Identity Standard 12 (FOID S12) Internal chain of custody procedures shall document that evidence is secured. All transfers of evidence shall be documented. The use, storage and disposition of derivative evidence shall be discernable from maintained case notes.	

Forensic Identity	
Standard	**Guidance**
Forensic Identity Standard 13 (FOID S13) The integrity of the original specimen shall be maintained by storage in a secured space with access limited to authorized staff. Evidence shall not be consumed in testing without prior written authorization by the submitting agency or authorized person. E-mail authorization is allowed. A printed copy of the e-mail communication should be included in the case file. A reasonable attempt shall be made to protect evidence from fire or water damage.	
Forensic Identity Standard 14 (FOID S14) The laboratory shall have a policy on disposition of samples. However, in no case shall the laboratory destroy unconsumed forensic casework evidence, personal effects items or the associated DNA extracts without the prior written authorization of the submitting agency. An exception will be made for liquid blood provided as a reference sample as long as dried blood samples are preserved.	
VALIDATION	
Forensic Identity Standard 15 (FOID S15) Non-DNA-based methods (e.g. serological methods) which are used to evaluate biological specimens for their suitability for DNA analysis shall also be validated and a summary of each validation study shall be made available. Validation of these methods shall be approved by the NYS DOH *prior* to their use in NYS casework.	

Forensic Identity	
Standard	**Guidance**
Forensic Identity Standard 16 (FOID S16) Software customized for the laboratory and software developed by the laboratory or modified in-house shall be validated prior to use for casework or databasing.	
ANALYTICAL PROCEDURES	
Forensic Identity Standard 17 (FOID S17) The laboratory shall have a documented policy addressing the process for deviating from established and approved standard operating procedures or policies.	
Forensic Identity Standard 18 (FOID S18) Analysis of the FBI-designated core CODIS STR loci shall be performed using a National DNA Index System (NDIS)-approved PCR kit.	
Forensic Identity Standard 19 (FOID S19) Laboratories performing mitochondrial DNA sequence analyses shall comply with the current Guidelines for Mitochondrial DNA (mtDNA) Nucleotide Sequence Interpretation as provided by the Scientific Working Group on DNA Analysis Methods (SWGDAM) and the data acceptance criteria as provided by the contracting laboratory or laboratory taking ownership of the profile(s).	

Forensic Identity

Standard	Guidance
Forensic Identity Standard 20 (FOID S20) If automation is used, the laboratory shall demonstrate that it can maintain the same high standards for and control over sample processing as with individual casework samples.	
Forensic Identity Standard 21 (FOID S21) In addition to routine quality control (QC) of critical reagents to ensure their proper functioning, QC testing shall be performed on *all* reagents prior to their use on a limited sample. (See FOID S16 discussion)	
Forensic Identity Standard 22 (FOID S22) The laboratory shall have available a method to detect inhibition of PCR amplification and shall include a control for PCR inhibition when the state of the evidentiary material suggests inhibitors of the polymerase chain reaction might be present.	
EQUIPMENT CALIBRATION AND MAINTENANCE	
Forensic Identity Standard 23 (FOID S23) Systems shall be in place to prevent critical analytical equipment (both hardware and software) from being modified in any way that would invalidate test results.	
REPORTS	

Forensic Identity	
Standard	**Guidance**
Forensic Identity Standard 24 (FOID S24) The laboratory shall have a system for maintaining and retrieving each case file, including case notes not contained in the final case report. Such files shall be adequately protected against modification or destruction either by using duplicated photographic or electronic medium with storage at a second secure site, by storage in secure fireproof file cabinets or by other suitable means providing equivalent protection. Case files shall be maintained for a minimum of 15 years.	
Forensic Identity Standard 25 (FOID S25) The contents of a case file shall be defined. The signature of the analyst responsible for data interpretation shall be included in the report and the analyst shall indicate his/her review of each page of the case report and file. The case record shall indicate the identities of the technical and administrative reviewers. The case identifier shall be indicated on all pages of the case file. The final case file shall indicate each page number and the total number of pages contained within the file.	A printed footer with the required information is acceptable if the cover page indicates that the analyst has reviewed and approved the entire file. At a minimum, the case file shall contain: the request for analysis, accessioning information, chain of custody documentation, all relevant analyses and worksheets, results, interpretation, reports rendered and documentation of the disposition of evidence and derivative samples. All items contained within the case file (e.g. photographs) shall be marked with the case identifier and secured to prevent their loss. Mistakes in case notations shall not be obliterated but shall be crossed out and the correct information entered alongside with the date and the initials of the person making the correction. Original electronic data shall be maintained as long as the case file and shall be protected from loss or modification.
Forensic Identity Standard 26 (FOID S26) When utilizing high throughput systems, the laboratory shall maintain the ability to access and document the specific results of an individual DNA analysis and all associated controls and processing information.	

Forensic Identity

Standard	Guidance
REVIEW	
Forensic Identity Standard 27 (FOID S27) A technical and administrative review of each case analysis, by a qualified individual(s) distinct from the primary analyst, shall be conducted prior to the release of the results of the case to the submitting agency. The laboratory shall define the qualifications and training required to act as a technical or administrative reviewer. The elements of administrative and technical reviews shall be defined in a review checklist.	
Forensic Identity Standard 28 (FOID S28) For databasing only, an expert system, approved by NDIS, can be used to replace the initial manual review of high quality data by an analyst. A second technical review is still required. Two independent NDIS-approved expert systems may be used for review of high quality data for databasing where NYSDOH approved validation studies have demonstrated that such expert systems, used jointly, work as reliably as manual reviews by qualified analysts.	

Forensic Identity

Standard	Guidance
PROFICIENCY TESTING	
Forensic Identity Standard 29 (FOID S29) All staff involved with processing of samples from New York shall participate in an ANAB-approved proficiency testing (PT) program. Each of these staff members participating in activities including screening, extraction, quantitation, amplification, analysis, interpretation and review, shall successfully participate in two proficiency tests per year. At least once a year, each staff member shall be tested for each New York State Forensic Identity Section-approved analytical method he/she is qualified to perform. Testing must be performed to the fullest extent that each staff member participates in casework/databasing. When no relevant ANAB-approved proficiency test is available, the lab shall participate in a proficiency testing program as available or internally develop an appropriate proficiency test using material for which the result is known (e.g. for presumptive or confirmatory testing). Every six months, each Forensic Identity-permitted laboratory must submit a brief summary of PT activities to the Forensic Identity Section. The following information should be reported for each staff member participating in external or internal proficiency testing in the previous six months: • name; • PT provider; • role of the PT participant, i.e., technical, technical review, administrative review; • analytes tested by this staff member; and • Laboratory Director or responsible Assistant Director signature verifying that the PT performance was completed satisfactorily. Any unsatisfactory PT performance must be reported to the Forensic Identity Section within two weeks of learning of the PT result.	Any lapse in proficiency testing due to temporary absence from laboratory activities such as for medical leave or military service shall be documented.

Forensic Identity	
Standard	**Guidance**
Forensic Identity Standard 30 (FOID S30) The process for implementing the laboratory's proficiency testing program shall be documented.	This shall include information on who administers the program, how and where the testing documentation is maintained, how results are communicated to laboratory members, and the process for taking corrective action when appropriate.
Forensic Identity Standard 31 (FOID S31) The staff member directing proficiency testing shall be readily able to produce the following information pertaining to NYS DOH proficiency testing: a list of all technical personnel and all individuals involved in technical and/or administrative review of case results. For each staff member, there shall be a listing of what tests/activities the individual is qualified to perform and the associated dates of qualification. The annual PT plan for each individual shall be detailed (what tests will be performed on each PT). Dates of distribution and submission of proficiency test results, what activities were tested and test results for each tested staff member shall be documented.	
CORRECTIVE ACTION	
Forensic Identity Standard 32 (FOID S32) The laboratory shall have a process for the isolation and recall of nonconforming materials, and for identification of affected tests.	

Forensic Identity

Standard	Guidance
Forensic Identity Standard 33 (FOID S33) Any incident that has the potential to affect interpretation of the case results (e.g. phenotype reported, statistical interpretation, conclusions drawn) or any incident involving staff misconduct affecting testing processes shall be reported to the NYS DOH Forensic Identity section within two weeks of the discovery of the nonconformance. (For non-NYS cases involved, the report can be made without reference to the specific case.)	
Forensic Identity Standard 34 (FOID S34) The laboratory shall retain records on corrective action for a minimum of 3 years. In situations where the investigation of the nonconformance and the corrective action taken led to an amended case(s) report, documentation shall be retained for as long as the case documentation. While the corrective action documentation may be kept in separate logs, a central listing of all incidents requiring corrective action shall be available to auditors upon request.	
AUDITS	
Forensic Identity Standard 35 (FOID S35) A list of all external and internal audits performed within the past 3 years, who conducted the audit, and the dates of the audit shall be available. The corresponding audit reports, the laboratory's response to any findings and any follow up documentation shall be available, on-site, for review.	
SAFETY	

Forensic Identity

Standard	Guidance
Forensic Identity Standard 36 (FOID S36) The laboratory shall have a designated health and safety manager and shall regularly monitor and annually review its health and safety program. At a minimum, this safety program shall address exposure to blood borne pathogens, chemical hygiene and emergency response plans in the event of staff injury or fire.	
SUBCONTRACTORS	
Forensic Identity Standard 37 (FOID S37) No laboratory shall subcontract any portion of the testing of evidence or reference material associated with a case to a different laboratory or to another part of its own laboratory located at a different location, unless that laboratory has a New York State Forensic Identity permit authorizing the test in question and this is agreed to in writing, in advance, by the submitting agency.	

Genetic Testing

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	Laboratories must submit full validation packages for all tests using molecular techniques except for assays labeled by the FDA as "For *in vitro* diagnostic testing." Copies of the Submission Guidelines can be downloaded from http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval/submission-checklists or call 518-485-5378.
Genetic Testing Standard 1 (GT S1) Identification of the patient shall be maintained through all phases of specimen processing and analysis.	It should be possible to go readily from accession number to patient files and report and conversely.
Genetic Testing Standard 2 (GT S2) For linkage analysis-based tests, each family studied shall be assigned a unique code to monitor relatedness between core families.	There should be a system in place to link family identifiers with individual patient identifiers.
Genetic Testing Standard 4 (GT S4) The SOPM shall include up-to-date references which document: a) linkage relationships for each disorder offered by indirect linkage methods, which minimally address: i) proximal or distal to disease gene; and, ii) recombination fractions and/or zero values at 95% confidence intervals; and, b) loci, probes, and/or primers and conditions of their use. c) clinical validity and utility if applicable and detection of variants in disease populations.	These may be literature references or, for in-house generated probes, the reference may be the laboratory's validation studies. Refer to Operating Procedures and Compliance Standards for additional SOPM requirements.

Genetic Testing

Standard	Guidance
Genetic Testing Standard 5 (GT S5) The laboratory shall notify practitioners wishing to order a genetic test that informed consent is required and shall make available to the practitioner test-specific information for patient use in decision-making and the informed consent process. These materials shall include: a) general description and statement of purpose for the test; b) indication that the individual may wish to obtain professional genetic counseling prior to giving consent; c) a statement that a positive result is an indication that the individual may be predisposed to or have the specific disease or condition tested for and may want to consider further independent testing, consult their physician or pursue genetic counseling; d) a general description of the disease or condition related to the test; e) the level of certainty that a positive test result serves as a predictor of the disease; f) the persons or organizations to whom the test result may be disclosed; g) a statement that no tests other than those authorized shall be performed on the biological sample and that the sample shall be destroyed at the end of the testing process or not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized in the consent; and, h) provision for the signature of the individual subject of the test or if the individual lacks the capacity to consent, the signature of the person authorized to consent for the individual.	Laboratories should be aware that genetic testing is also covered by Section 79-l of the Civil Rights Law. Reasonable effort should be made to obtain patient consent and document the process. While patient consent forms are recommended to be on file in the laboratory; the referring physician may sign the test requisition or other form indicating that she or he conveyed the required information to the patient and obtained consent. g) Research testing may be performed on residual specimen pursuant to a research protocol approved by an institutional review board provided that: i. the subject or the subject's authorized representative, has provided written informed consent for the specific research; ii. the sample has been permanently stripped of identifying information; and iii. the subject has consented to the de-identification.

Genetic Testing

Standard	Guidance
Genetic Testing Standard 6 (GT S6) Reports shall include: a) a statement of and an interpretation of findings; b) a statement on technical limitations of the test, including possible inaccuracies; c) suggestions for additional or alternative testing, if applicable; d) recommendations for referral to a genetic provider when appropriate; e) methodology used for the test; and, f) a list of all of the variants examined in the assay if applicable.	a) A summary and interpretation of the results directly applicable to the patient are recommended. The laboratory should also provide a voice or FAX number of a person qualified to assist practitioners with the interpretation of the results. b) Technical limitations should include the possibility of laboratory error. Literature references applicable to the analysis should be included.
Genetic Testing Standard 7 (GT S7) Reports shall contain the signature of the qualified person who reviewed, approved, and interpreted the test results, unless the test is defined as a screening test.	For purposes of this standard, a qualified person is a director or assistant director who holds a valid New York State certificate of qualification in the appropriate Genetic Testing subcategory. Laboratories using electronic signatures should have a procedure in place that ensures and documents the qualified person's authorization for each signature occurrence (such as access limited by password). A screening test is characterized by one or both of the following: a) The package insert indicates that the assay is for screening purposes only; and/or b) There is no pre-existing indication that the individual is at high risk for a genetic disease prior to testing, for example, newborn screening tests.
Genetic Testing Standard 8 (GT S8) The laboratory shall establish critical limits for turn-around-times of certain tests important for prompt patient management decisions.	The laboratory should have a policy to ensure that later gestational age specimens are given priority so that results are released prior to the 25th week of gestation in order to allow patient decisions regarding pregnancy termination.

Genetic Testing

Standard	Guidance
Genetic Testing Standard 9 (GT S9) The laboratory shall establish and implement procedures to obtain follow-up information for prenatal diagnosis confirmation.	Discrepancies should be fully evaluated.
Genetic Testing Standard 10 (GT S10) The laboratory shall run appropriate controls with each run of patient specimens.	Controls should be selected based on the patient population and should be as comprehensive as possible based on the rarity of the disease. For example, a heterozygous sample or a normal and a homozygous mutant sample is sufficient for single mutation assays. Cases of rare variants should be verified, e.g. bi-directional sequence or repeat of the sample.
Genetic Testing Standard 11 (GT S11) The laboratory shall keep up-to-date records of DNA probe documentation that minimally includes chromosome/band, and restriction enzyme(s) needed to visualize the RFLP.	
Genetic Testing Standard 12 (GT S12) For each applicable analysis, the laboratory reports shall contain: a) name of the test DNA locus as defined by the International Human Gene Mapping Workshop; b) name of the probe; c) name of the restriction endonuclease; and, d) size or alphanumeric description of all detected alleles.	b) This is relevant when performing Southern blot techniques. c) This is relevant when performing PCR/RFLP and Southern blot techniques. d) Any variant detected must be reported regardless of clinical implication. Alternatively, it must be clearly noted that the information can be made available to the physician.

Genetic Testing

Standard	Guidance
Genetic Testing Standard 13 (GT S13) Conditions of time, temperature and concentration which achieve desired amplification results shall be empirically determined, periodically verified and documented for each set of primers using known controls.	There should be equal amplification of normal and mutant alleles**.** Proper reaction conditions should be documented on worksheets.
Genetic Testing Standard 14 (GT S14) Laboratories must obtain the subject's written consent, or if the individual lacks the capacity to consent, the signature of the person authorized to consent for the individual, before records, findings, or results may be re-disclosed to any individual or organization other than those authorized on the test requisition to receive the result.	

Hematology

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. (HM S2 revised and effective July 14, 2014)	
CELLULAR HEMATOLOGY	
Hematology Standard 1 (HM S1)	Standard has been deleted. Number reserved for future use.
Hematology Standard 2 (HM S2) For manual cellular hematology procedures, one level of quality control material shall be run during each eight hours of operation. If a laboratory's primary cellular hematology procedures are manual methods, a minimum of two levels of quality control material are required during each eight hours of operation.	For manual white, red (including reticulocytes) and platelet cell counts, one level of assayed material, or one procedural control, during each eight hours of operation is required. Procedural control is defined as duplicate dilutions of either an assayed control or previously assayed patient specimen. These may be assayed by the same individual or by different people and the results compared to previously defined acceptable limits for differences between duplicates. White blood cell and platelet counts may be compared with a value estimated from a blood smear.
Hematology Standard 3 (HM S3) When cell counts are performed manually using a hemocytometer: a) testing shall be performed in duplicate (e.g., counting two hemocytometer chambers from one dilution); and, b) acceptable precision limits for duplicate specimens shall be defined.	

Hematology	
Standard	**Guidance**
COAGULATION	
Hematology Standard 4 (HM S4) For automated coagulation procedures, a minimum of two levels of quality control material shall be run: a) each eight hours of operation unless a quality control protocol has been validated as required in Quality Control Sustaining Standard of Practice 2 (QC Design S2) or Quality Control Sustaining Standard of Practice 1 (QC Design S1). b) each time a change in reagent occurs.	The quality control material should include a normal and at least one abnormal level in the expected range of patient samples.
Hematology Standard 5 (HM S5) For manual coagulation tests: a) each individual performing tests must test a minimum of two levels of quality control material: i. prior to testing patient results; ii. each time a change in reagents occurs; and, b) patient and control specimens shall be tested in duplicate.	

Histocompatibility

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Revised and effective July 14, 2014	
Histocompatibility Standard 1 (HC S1) Reports shall use terminology for HLA antigens which conforms to the latest report of the HLA Nomenclature Committee (WHO).	The World Health Organization Regional Office for the Americas/Pan Health Organization 525 23rd Street, N. W. Washington, D.C. 20037 Telephone: (202) 974-3000 Fax: (202) 974-3663 E mail: postmaster@paho.org Website: http://new.paho.org/usa
Histocompatibility Standard 2 (HC S2)	Standard has been deleted. Number reserved for future use.
Histocompatibility Standard 3 (HC S3)	Standard has been deleted. Number reserved for future use.
Histocompatibility Standard 4 (HC S4) If ABO and Rh typing is performed on site and reported, the laboratory shall have a New York State permit in Immunohematology.	
Histocompatibility Standard 5 (HC S5)	Standard has been deleted. Number reserved for future use.

Histocompatibility

Standard	Guidance
Histocompatibility Standard 6 (HC S6) If a laboratory provides histocompatibility testing for a transplant center, the laboratory shall: a) establish and document the HLA Class I and II specificities that should be identified for each type of transplant ; b) HLA type cells from organ donors referred to the laboratory; and c) use HLA antigen terminology that conforms to the latest report of the World Health Organization (WHO) Committee on Nomenclature. Potential new antigens not yet approved by this committee must have a designation that cannot be confused with WHO terminology.	HLA Class I specificities include HLA-A, HLA-B and Cw. HLA Class II specificities include HLA-DR, DQ and DP antigens. For some transplant protocols, identification of only Class I specificities may be sufficient. Other protocols may require identification of both Class I and Class II specificities. This standard now recognizes that laboratories may be using serological or DNA or a combination of methods to perform HLA typing. The laboratory must decide in conjunction with the transplant program(s) that they support, what level of antigen definition is required for the type of transplant being performed. In some cases, low resolution typing using serological methods may be adequate while in other cases, such as bone marrow transplant, high resolution typing by DNA analysis may be required. The laboratory should document discussions with transplant programs. a) The laboratory should be an active participant in the transplant center's clinical program when establishing the specificities needed. b) Laboratories should retype organ donors referred to the lab even if testing was previously done in another histocompatibility testing lab.

Histocompatibility

Standard	Guidance
SEROLOGICAL HLA TYPING	
Histocompatibility Standard 7 (HC S7) If a complement dependent lymphocytotoxic method is used for cell typing, it shall incorporate controls and; a) each typing tray shall minimally include one complement-dependent positive serum control known to react with all cells and one negative serum (or serum pool) control known to lack HLA antibody; and b) cell viability in the negative control at the end of incubation shall be that value established by the laboratory to be sufficient to permit accurate interpretation of results.	

Histocompatibility

Standard	Guidance
Histocompatibility Standard 8 (HC S8) The laboratory shall validate the specificity of antisera using cells of known type; and, a) specificity of sera obtained locally shall be validated using a cell panel from a minimum of 40 subjects from various ethnic groups, which includes cells with antigens and common splits to which HLA antibodies are directed, cells possessing only one defined antigen at a locus, and additional cells as needed to identify an antibody with certainty. b) specificity of individual sera obtained from commercial or other laboratory sources shall be verified using a method which includes a positive and negative control for each serum tested with each cell panel; c) reactivity of each lot of commercial typing trays shall be validated by pre-test against at least five different cells representing major specificities or by testing in parallel with previously validated trays; and, d) typing sera reactions shall be recorded, reviewed by a supervisor, and shall be used to modify locally prepared typing trays and applied to all tray interpretations.	
Histocompatibility Standard 9 (HC S9) Each lot of complement shall be tested to verify that it induces cytotoxicity in the presence of specific antibody but is not cytotoxic in the absence of specific antibody.	

Histocompatibility

Standard	Guidance
Histocompatibility Standard 10 (HC S10) When typing trays are locally prepared, the laboratory shall maintain sera inventory records which document the source, bleeding date, identification number, specificity and volume remaining for each serum lot.	
Histocompatibility Standard 11 (HC S11) In addition to applicable requirements in the Operating Procedures and Compliance Standards, the SOPM shall contain: a) the protocols for preparation and/or selection of typing reagents, whether locally or commercially prepared, and verification of reactivity; b) if the laboratory uses locally prepared cell panels, a list of individuals for fresh panel bleeding; c) the protocol for the preparation of lymphocytes; d) the scoring system protocol used for antigen assignment, including, where applicable, literature references and/or instrument calibration documentation; e) the policy for antigen redefinition and retyping, including, where applicable, the updating of results and issuance of amended reports; f) the policy for remediation for those individuals not meeting the laboratory's established level of performance for reproducibility of test results; g) a protocol for ensuring that reagents used for typing are adequate to define all HLA-A, B and DR specificities that are officially recognized by the most recent W.H.O. Committee on Nomenclature and for which reagents are readily available; and, h) have available and follow written criteria for the assignment of HLA antigens.	

Histocompatibility	
Standard	**Guidance**
Histocompatibility Standard 12 (HC S12) An established scoring system shall be used for the assignment of HLA antigens.	
Histocompatibility Standard 13 (HC S13) The laboratory shall use a sufficient number of antisera or monoclonal antibodies to clearly define all antigens which the laboratory types serologically.	
Histocompatibility Standard 14 (HC S14)	Standard has been deleted. Number reserved for future use.
Histocompatibility Standard 15 (HC S15) If the laboratory uses B lymphocyte-enriched preparation for class II typing, the proportion of B lymphocytes shall be that which has been determined by the laboratory to clearly define class II alleles.	
Histocompatibility Standard 16 (HC S16) Refrigerators and freezers must be monitored to ensure maintenance of optimal temperatures for storage of each type of specimen or reagent. The laboratory's storage of both critical reagents and relevant specimens must use an audible alarm system or centrally monitored temperature alarm system. a) The laboratory must have an emergency plan for alternative storage. b) For samples that may be required for future testing, the laboratory must have a system to retrieve specimens for further testing in a timely manner.	

Histocompatibility	
Standard	**Guidance**
MIXED LYMPHOCYTE CULTURE (MLC) TESTS	
Histocompatibility Standard 17 (HC S17) The laboratory shall have a protocol to establish a minimum acceptable level of cell viability.	
Histocompatibility Standard 18 (HC S18) The laboratory shall establish acceptable limits for background counts using an appropriate autologous cell control in each MLC test run.	
Histocompatibility Standard 19 (HC S19) For each MLC test run, unrelated stimulator cell controls for each responder cell shall be included.	
Histocompatibility Standard 20 (HC S20) The laboratory shall use a properly functioning biological safety cabinet (BSC) or other appropriately aseptic work area.	Refer to Safety Sustaining Standard of Practice 6 (SAF S6) for operational guidelines.

Histocompatibility

Standard	Guidance
ANTIBODY SCREEN AND CROSSMATCH	
Histocompatibility Standard 21 (HC S21) The laboratory shall use a technique that detects HLA-specific antibody with a specificity alternate or superior to that of the basic complement-dependent microlymphocytotoxicity assay.	These techniques are developed primarily for kidney transplants. The technique used in the laboratory is developed with the initial validation studies. These studies should use the complement-dependent microlymphocytotoxicity assay as the basis for deciding the conditions necessary to detect HLA antibodies at the specificity required. Initial validation studies should establish the concentration of the patient sera to be used by testing anti-sera of known concentration and the appropriate incubation times.
Histocompatibility Standard 22 (HC S22) The laboratory shall use well characterized panels of both T and B lymphocytes to identify antibodies to differentiate Class II antibodies from Class I.	All cells have Class I antigens. B-lymphocytes have also express Class II antigens and are used to distinguish antibodies to HLA Class II antigens from antibodies to Class I antigens.
Histocompatibility Standard 23 (HC S23) The laboratory shall use crossmatching techniques that are documented to have increased sensitivity in comparison with the basic microlymphocytotoxicity test.	The technique used in the laboratory is developed with the initial validation studies. Laboratories may use increased incubation times or the addition of antiglobulin to increase sensitivity.

Histocompatibility

Standard	Guidance
Histocompatibility Standard 24 (HC S24) For testing performed for the purpose of transplantation, the laboratory shall have available and follow written policies and protocols specifying the histocompatibility testing (HLA typing, antibody screening, compatibility testing and crossmatching) to be performed for each type of cell, tissue or organs to be transfused or transplanted. The policies must include, as applicable: a) timing of collection of specimens for final crossmatch done prior to transplantation; b) timing and acceptable reactivity of specimens for crossmatch post transfusion or following a sensitizing event; c) testing protocols for cadaver donor, living, living-related and combined organ and tissue transplants d) testing protocols for patients at high risk for allograft rejection; e) the circumstances under which MLC's will be performed; and, f) the sensitivity and specificity of the test system required to support clinical transplant protocols (for example, antigen or allele-level typing).	d) High risk patients are those that have had previous transplants, infections, transfusions, etc. These patients may need more frequent testing.
Histocompatibility Standard 25 (HC S25) The laboratory shall maintain serum specimens and related records for potential transplant recipients for the purpose of: a) initial typing; b) periodic screening; c) pretransplantation crossmatch; and, d) screening following a sensitizing event.	This standard assumes there is collaboration between the laboratory and transplant facility.

Histocompatibility	
Standard	**Guidance**
Histocompatibility Standard 26 (HC S26) For renal transplants or for combined organ transplant in which one of the organs is a kidney, the laboratory shall have available results of the final crossmatches before the transplant. For nonrenal transplantation, if HLA testing and final crossmatching were not performed prospectively because of an emergency situation, records must reflect any information concerning the transplant provided to the laboratory by the transplant candidate's physician.	Crossmatch results for non-renal transplants may be reviewed retrospectively.
DNA-BASED TESTING	
Histocompatibility Standard 27 (HC S27)	Standard has been deleted. Number reserved for future use.
Histocompatibility Standard 28 (HC S28)	Standard has been deleted. Number reserved for future use.
Histocompatibility Standard 29 (HC S29)	Standard has been deleted. Number reserved for future use.
DNA-BASED TESTING USING RESTRICTION ENZYMES	
Histocompatibility Standard 30 (HC S30)	Standard has been deleted. Number reserved for future use.

Histocompatibility	
Standard	**Guidance**
DNA-BASED TESTING USING PROBES	
Histocompatibility Standard 31 (HC S31) For in-house developed assays, pre-hybridization, hybridization and autoradiography shall be carried out under empirically determined, periodically verified and documented conditions of concentration and temperature determined by the nature of the probe as determined during initial validation process. Hybridization conditions shall minimize the possibility of cross-hybridization and maximize the specificity of binding between probe and test DNA; and,	
Histocompatibility Standard 32 (HC S32)	Standard has been deleted. Number reserved for future use.
DNA-BASED TESTING USING AMPLIFICATION	
Histocompatibility Standard 33 (HC S33) For in-house developed methods, primers shall be of known specificity and sequence. Conditions of time, temperature and concentration which optimize amplification product specificity or quantity shall be empirically determined and documented for each set of primers during the initial validation. The conditions shall be periodically verified.	
Histocompatibility Standard 34 (HC S34)	Standard has been deleted. Number reserved for future use.
Histocompatibility Standard 35 (HC S35)	Standard has been deleted. Number reserved for future use.

Histocompatibility	
Standard	**Guidance**
Histocompatibility Standard 36 (HC S36)	Standard has been deleted. Number reserved for future use.

Immunohematology

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. (IH S8 revised and effective July 14, 2014)	
Immunohematology Standard 1 (IH S1) All tests including but not limited to ABO and Rh_o(D) grouping, antibody detection and identification shall employ methods, techniques, or procedures which have been approved or recommended for the particular reagent in use by the FDA or the American Association of Blood Banks, and which are of demonstrated effectiveness in a manner acceptable to the Department.	
Immunohematology Standard 2 (IH S2) All blood grouping sera, reagents, devices, methods, and procedures shall conform to the recommended minimal requirements of the FDA.	Testing should be performed following the manufacturer's package insert.
Immunohematology Standard 3 (IH S3) ABO grouping tests shall include both forward grouping and reverse grouping, except in the case of hospital transfusion services verifying a blood group determination performed elsewhere, in which case forward grouping alone may be performed.	Forward grouping shall include the use of anti-A and anti-B. Anti-A,B is optional. Reverse grouping shall consist of A cells and B cells. Use of A_2 cells is optional. For infants under four months of age, only forward grouping is required.

Immunohematology

Standard	Guidance
Immunohematology Standard 4 (IH S4) For anti-human globulin and antibody screening cell testing, if a negative reaction is not seen on a given run, an investigation shall be performed, and controls shall be run.	The routine use of negative controls on each day of use are not required for anti-human globulin and antibody screening cells, provided manufacturer's instructions are followed.
Immunohematology Standard 5 (IH S5) The reactivity and specificity of each reagent shall be determined whenever a new lot is used.	Exception to standard: New York State does not require that each shipment of antibody identification cell panels be tested with a known antibody.
Immunohematology Standard 6 (IH S6) Quality control records shall be retained for five years.	
Immunohematology Standard 7 (IH S7) To detect the presence of unexpected antibodies, blood samples shall be tested using at least a two cell antibody screen designed for this purpose, tested individually, except that pooled screening cells may be used for testing blood donor specimens.	The use of pooled screening cells is not permitted for recipients.
Immunohematology Standard 8 (IH S8) Centrifuges used for testing of red blood cell agglutination: a) shall undergo RPM and timer checks quarterly; and, b) shall undergo a functional calibration to determine optimal centrifugation conditions prior to testing, after any repairs to the centrifuge, and on an annual basis. Documentation of such checks and functional calibrations, which include records of actual results, shall be maintained.	Repairs that require a functional calibration prior to resumption of use include those that may affect the speed or timer function of the centrifuge.

Immunohematology

Standard	Guidance
Immunohematology Standard 9 (IH S9) A microscope shall be available in all immunohematology laboratories if use of a microscope is specified by the facility's SOPM or by a test kit manufacturer's package insert.	
Immunohematology Standard 10 (IH S10) Microscopic examination shall be performed in red blood cell agglutination tests whenever indicated by the procedure in use.	

Microbiology

Standard	Guidance
The following Microbiology standards are applicable to the subspecialty testing categories as follows: Bacteriology (MB S1-S11); Mycobacteriology (MB S1-S9); Mycology (MB S1-S11); Parasitology (MB S6, MB S8-S9); Virology (MB S1, MB S6, MB S8-S11).	
The following specialty sustaining standards of practice and applicable general system standards shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Effective May 1, 2011.	
Microbiology Sustaining Standard of Practice 1 (MB S1): Quality Control Stock Cultures The laboratory shall maintain stock cultures for all quality control procedures.	Maintenance of stock cultures should be standardized in a manner that minimizes the opportunity for contamination or alteration of relevant characteristics. Stock cultures should consist of low-passage material rather than laboratory-adapted high passage material. Validated patient isolates, proficiency testing specimens, or commercially prepared controls may be used unless otherwise required by manufacturer. American Type Culture Collection (ATCC) controls are not required, except for use in susceptibility testing.

Microbiology

Standard	Guidance
Microbiology Sustaining Standard of Practice 2 (MB S2): Commercial Medium Each lot or shipment of commercially prepared media shall be tested: a) on-site for growth, selectivity, and/or inhibition and biochemical responses; or, b) by the manufacturer in accordance with established criteria. Quality control checks for sterility, growth, selectivity and/or inhibition and biochemical responses need not be retested by the user provided that: i. for each shipment or lot of media, the laboratory has documentation on the media label, package insert, technical manual, or other document, that the manufacturer's quality control practices conform to specifications; and, ii. the laboratory documents receipt and condition of each shipment or lot of media, and notifies the media manufacturer of: - cracked Petri dishes; - unequal filling of plates; - cracked media in plates; - hemolysis; - freezing; - excessive number of bubbles; or - contamination.	Media may be tested concurrent with initial use provided QC results are reviewed prior to release of patient results.
Microbiology Sustaining Standard of Practice 3 (MB S3): Media Prepared In-House A sample of each batch of microbiological media prepared in-house shall be tested, prior to or concurrent with initial use, for sterility, ability to support growth, selectivity and/or inhibition, and biochemical responses.	Media may be tested concurrent with initial use provided results are reviewed prior to release of patient results.

Microbiology

Standard	Guidance
Microbiology Sustaining Standard of Practice 4 (MB S4): Expiration Date Prepared In-House The expiration date for each batch of in-house prepared microbiological media shall not exceed 8 weeks from the preparation date for plated and non-screw cap tubed media and six months from the preparation date for screw cap tubed media provided the laboratory: a) has taken into account the inclusion of labile components such as antibiotics; b) stores the media under required conditions (e.g. temperature, shielded from light, proper humidity); and, c) has previously tested at least one batch of each medium type and shown it to perform as expected at the end of the designated shelf life.	c) This testing should be repeated when changing vendors.
Microbiology Sustaining Standard of Practice 5 (MB S5): Media for Satellite Locations Laboratories that supply media to satellite locations are responsible for either sending or maintaining quality control documentation and for notification of each satellite location of a recall.	In compliance with Reagents Sustaining Standard 4 (REAG S4), satellite laboratories are responsible for maintaining inventory control documentation which includes the name of the central laboratory provider.
Microbiology Sustaining Standard of Practice 6 (MB S6): Specimen Criteria The SOPM shall define specimen types acceptable for each assay and shall include collection, storage and transport criteria, and rejection criteria.	

Microbiology

Standard	Guidance
Microbiology Sustaining Standard of Practice 7 (MB S7): Automated Identification Systems The laboratory shall check each new lot number or shipment received of reagents with positive and negative reactivity quality control organisms for automated identification systems (QC). A streamlined quality control may be instituted when using microbial automated identification systems (MIS) provided that they follow a written protocol that ensures that they: a) performed a verification study; b) maintain documentation that the manufacturer has performed adequate QC to ensure that the system performs appropriately; c) maintain documentation that states that the distributor has followed all the manufacturer's requirements for shipping and storage; d) store and maintain the system according to the manufacturer's requirements; e) perform streamlined QC as directed by the manufacturer that integrates the manufacturer's risk mitigation information ; f) maintain records of all QC performed; g) remediate all QC failures and repeat QC in triplicate before resuming patient testing; and h) notify the manufacturer and distributor of the unresolved QC failure.	The streamlined quality control protocol is subject to the requirements of Quality Control Sustaining Standard of Practice (QC Design S1): Design of Individualized Quality Control Plan. Automated systems used exclusively to screen for bacterial contamination of blood components must also follow this standard. Non-automated screening tests for bacterial contamination of blood components, such as pH or glucose, are covered under the permit category of Blood Services – Transfusion or Blood Services – Collection. Identification of the organism requires a Bacteriology –Comprehensive permit. a) A review of historical data may be used for the verification study. Refer to Reagents Sustaining Standard of Practice 2 (REAG S2): Verification- General Requirement and Reagents Sustaining Standard of Practice 3 (REAG S3): Verification of Reagents and Media for quality control requirements for all other reagents.

Microbiology

Standard	Guidance
Microbiology Sustaining Standard of Practice 8 (MB S8): Laboratory Worksheets Laboratory records shall include worksheets and/or electronic records that include all tests and test results that led to the identification of microorganisms.	Worksheets and/or electronic records should include identification of the media or host systems used and the corresponding observations for each medium as well as biochemical test reactions where appropriate.
Microbiology Sustaining Standard of Practice 9 (MB S9): Reports Reports shall include: a) the test methodology; b) an interpretation, when necessary, to explain the significance of the test result; c) a qualifier identifying an assay limitation, if appropriate; and, d) a recommendation for follow-up testing, if appropriate.	These requirements are in addition to those required by Reporting Sustaining Standard 1 (Reporting S1). a) Examples of assay methodology include culture, EIA, PCR, etc. Specific test systems are not required to be listed on a test report. b) Report qualifiers are used to convey information that would affect the significance and/or clinical interpretation of the test result. c,d) Rapid antigen tests for influenza virus are particularly vulnerable to assay sensitivity issues because of antigenic variations among circulating influenza sub-types/strains and/or the emergence of novel sub-types/strains. The laboratory should be alert to these performance issues and include qualifiers and recommendations for follow-up testing as appropriate.

Microbiology

Standard	Guidance
Microbiology Sustaining Standard of Practice 10 (MB S10): Laboratory Response Network (LRN) The laboratory shall have a section in the SOPM describing policies and practices related to their activities as a Laboratory Response Network (LRN) sentinel (formerly level A) laboratory, if applicable, including: a) maintaining updated LRN guidelines and protocols related to the testing, identification and reporting of select and emergent agents including information regarding special handling and safety practices to be employed; b) providing staff with information regarding the biosafety level(s) (BSL) recommended for the microbiological testing being performed and identifying the highest BSL available for each category of microbiological testing; c) identifying the LRN reference laboratory for their facility and contact information for individual(s) to be contacted if a select agent is suspected; and, d) distribution of information to health care providers regarding specimen collection and submission instructions that should be followed when infection with a select agent or other infectious agent requiring special handling is suspected.	Laboratories holding a clinical laboratory permit in either Bacteriology – Comprehensive or Virology are currently considered LRN sentinel (formerly Level A) laboratories, unless designated as a LRN reference laboratory. Information regarding laboratory testing for critical and emergent agents is available to all laboratories on the CDC website. LRN sentinel laboratories holding NYS clinical laboratory permits are advised to regularly access the NYSDOH Health Commerce System (HCS) for updated information related to testing, identification and reporting of these agents. Information regarding NYS HCS accounts can be obtained at 1-(866) 529-1890, option 1. Laboratories serving NYC should also access the NYC Department of Health and Mental Hygiene's Health Alert Network (HAN); for information, contact 1-888-NYCMED-9 or nycmed@health.nyc.gov. The Wadsworth Center may define the levels of testing (e.g. rule out only) and identification (e.g. presumptive only) and the reporting pathway for a particular agent. The Wadsworth Center's LRN distributes this information as needed to sentinel laboratories by fax and/or electronic copy to the laboratory director and posts these announcements on the HCS. NYS and NYC LRN reference laboratory contacts and other LRN information is available on the NYSDOH LRN website which is accessed through the HCS. The Wadsworth Center LRN program staff can be contacted at LRNexec@health.state.ny.us. Biosafety levels and associated recommendations and practices are described in the CDC publication "*Biosafety in Microbiological and Biomedical Laboratories*" (BMBL) and on the CDC website at www.cdc.gov. Laboratories must comply with infectious disease reporting requirements as outlined in the Public Health Sustaining Standard of Practice 1 (Public Health S1): Reporting. Laboratories must comply with pertinent items of USA Patriot Act and the Select Agent Rule (e.g. disposal/transfer of select rule—see Microbiology Sustaining Standard 11 (MB S11)).

Microbiology

Standard	Guidance
Microbiology Sustaining Standard of Practice 11 (MB S11): Inventory and Track of Select Agents The laboratory shall establish and implement an inventory and tracking system that ensures that all samples and their derivatives suspected or confirmed to contain select agents are accounted for until laboratory findings establish the absence of a select agent. If a select agent is confirmed then documentation of its transfer including record of appropriate packing and shipping or destruction within seven days must be completed.	A list of select agents (Biological Diseases/Agents List) can be found at the federal Centers for Disease Control and Prevention website at http://www.selectagents.gov. Inventory and tracking documentation shall include the identity of all individuals accessing such materials, as well as completion of APHIS/CDC forms 3 (Report of Theft, Loss or Release of Select Agents or Toxins) and 4 (Report of Identification of a Select Agent or Toxin) for organisms and toxins isolated from clinical specimens. This tracking system includes select agents used as control material and for those specimens that are suspected to be positive for a select agent. Tracking will begin at the time it is suspected that a specimen contains a select agent.

Microbiology

Nucleic Acid Amplification (MNAA) Assay

Standard	Guidance
Unless otherwise stated these standards apply to FDA-approved assays, modified FDA-approved assays and laboratory-developed nucleic acid amplification assays and sequencing assays used for the detection/identification/characterization of infectious agents. Laboratories may not report results obtained using laboratory-developed assays or modified FDA-approved assays without prior approval of the assay protocol by the Clinical Laboratory Evaluation Program as per Validation Sustaining Standard of Practice 5 (Validation S5). Application and submission guidelines are available at http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval. These standards apply to all microbial agents including HIV and supplement the general systems standards that pertain to molecular test methods.	
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Effective May 1, 2011.	
Microbiology Nucleic Acid Amplification Assays Sustaining Standard of Practice 1 (MNA S1): Employee Training and Competency The laboratory's training and competency program shall: a) include practices and procedures that must be implemented in order to reduce the likelihood of cross contamination and other technical errors; b) include direct observation adequate to confirm technical competence in all aspects of each molecular technique; c) require successful testing of a blinded assessment panel that includes samples representative of those expected in the laboratory; d) include documentation that items b and c have been satisfied prior to approving an individual to perform independent testing; and e) include documentation of annual competency assessments for each individual performing molecular assays.	This standard includes requirements in addition to those stated in Human Resources Sustaining Standard 6 (HR S6) and Human Resources Sustaining Standard 8 (HR S8). b,e) A single representative assay may be used to assess competency when using the same methodology, including specimen preparation/extraction, for more than one agent. d,e) Documentation of training should include a direct observation of operator adherence to molecular workflow. Assessment panels may include proficiency test samples or other characterized materials. Sample ranges should be representative of the entire assay range where appropriate however it certain instances it is impractical to obtain high concentrations. A panel should include representative samples with at least one sample at or near the limit of detection. See also Proficiency Test Sustaining Standards and Quality Assessment Sustaining Standard 3 (QA S3).

Microbiology

Nucleic Acid Amplification (MNAA) Assay

Standard	Guidance
Microbiology Nucleic Acid Amplification Assays Sustaining Standard of Practice 2 (MNA S2): Prevention and Remediation of Nucleic Acid Contamination The SOPM shall include a description of practices and procedures intended to prevent nucleic acid contamination including: a) a workflow pattern that utilizes separate areas and moves unidirectionally from pre- to post-amplification processes; b) dedicated pre-amplification equipment, reagents, supplies, and PPE that have been neither stored nor used in post-amplification areas or other areas that may result in exposure to amplicon, plasmids, and culture-amplified materials; c) the handling, processing and storing of clinical specimens and pre-amplification reagents and supplies (e.g. extraction reagents, mastermix, probes) in a manner that prevents exposure to amplicon; d) a decontamination and remediation plan to be implemented in the event that amplicon contamination is identified.	**Item a of this standard does not apply to FDA approved Closed System Amplification Tests (CSATs).** Pre-amplification activities include the storage, processing and extraction of clinical specimens and preparation of assay reagents. Post-amplification activities include those processes that occur after molecular amplification has been performed and result in an exponential increase in the amount of nucleic acid product (amplicon). a) The unidirectional workflow pattern is intended to ensure that pre-amplification procedures are performed in a work area that excludes amplification products (amplicon). The high level of concern is based on the significant risk of generating false-positive test results due to amplicon contamination of patient specimens and/or pre-amplification supplies and reagents. Failure to adhere to the established unidirectional workflow pattern requires implementation and documentation of additional measures for monitoring and preventing amplicon contamination. These measures may include the use of UNG in PCR assays, use of amplicon contamination monitoring programs such as swipe testing of molecular areas, and the use of decontamination products designed to eliminate nucleic acid contaminants. a) The practices and space designation policies should be tailored to the laboratory's test menu and design. Ideally, a laboratory should have 3 separate rooms for performing nucleic acid amplification assays: a pre-amplification reagent preparation room; a room used for specimen preparation/nucleic acid extraction and for template addition; and, a room dedicated to post-amplification processes. An alternative arrangement may be developed within a room where reagent preparation (e.g. mastermix set-up and template addition) are performed in distinct areas provided that **strictly dedicated and delineated areas, PCR workstations, supplies, reagents, etc.** are utilized for separating the two pre-amplification phases of work. However, it remains a high priority that post-amplification procedures be performed in a separate room. a) It is suggested that negative controls in addition to those required when performing FDA approved assays be included when "open

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Nucleic Acid Amplification (MNAA) Assay

Standard	Guidance
	amplicon" systems are utilized in a laboratory that does not have at least two separate rooms for pre- and post-amplification activities. a) Individuals performing CSATs may return to pre-amplification areas since the closed systems do not release amplicon into the environment provided that assay and discard procedures are followed. b) This refers to all equipment, furniture, instruments, supplies, reagents and PPE, including, but not limited to, pipets, pipettors, bulbs, tips, pens, discard containers, and clerical and cleaning supplies. PPE includes all laboratory coats/smocks, booties, hair bonnets, gloves, safety glasses and other individually-worn barriers. Worksheets and manuals that have been in post-amplification areas must not be brought into pre-amplification areas. b) Plugged (aerosol barrier) tips or positive displacement pipets are recommended for pre-amplification procedures. c) Ideally, a room under positive pressure relative to the post-amplification room should be used for preparation of mastermix and other "clean" reagents. d) The remediation plan should: define the decontamination procedure(s) to be employed; include root cause investigation, corrective action, competency assessment with retraining if necessary, and evidence supporting the adequacy of the remediation/decontamination procedures (e.g. environmental monitoring, increasing the number of negative controls per run).

Microbiology

Nucleic Acid Amplification (MNAA) Assay

Standard	Guidance
Microbiology Nucleic Acid Amplification Assays Sustaining Standard of Practice 3 (MNA S3): Instrumentation The laboratory shall: **a)** operate instruments and run internal performance checks according to the manufacturer's instructions and/or the laboratory's validated procedures; and, **b)** verify the uniformity of temperature across all sample chambers at inception, annually, and after servicing.	a) Instruments include all instruments used for nucleic acid testing such as thermal cyclers, real time PCR instruments, optical instruments, heat blocks, automated extraction systems, and sequencing instrumentation. b) Documentation of manufacturer verification is acceptable. Verification should include monitoring of temperature ramping rates where applicable. This may be met by using a verified low positive control in every well or an electronic check for temperature homogeneity. b) Cross platform verification can be performed by monitoring positive controls utilized in each instrument run.
Microbiology Nucleic Acid Amplification Sustaining Standard of Practice 4 (MNA S4): Reagent Storage Probes, primers and other labile reagents used in nucleic acid amplification assays shall be stored and maintained in accordance with manufacturer's instructions. In the absence of these, the laboratory's own validation data shall be used to establish acceptable storage and maintenance parameters.	Probes, primers and mastermix should be stored in small aliquots to minimize the number of freeze-thaw cycles. An acceptable number of freeze-thaw cycles may be stated by the manufacturer or established by monitoring control results that are appropriate (e.g. low level analyte) for identifying reagent deterioration. Bulk mastermix storage and preparation criteria should be validated by the laboratory to ensure the integrity of the reagent over the designated shelf life interval. Expiration dates for these reagents shall be based on laboratory validation studies where appropriate.

Microbiology Nucleic Acid Amplification Assay Sustaining Standard of Practice 5 (MNA S5): Quality Control Samples for Laboratory Developed and Modified FDA-approved MNAAs Each assay protocol for all laboratory developed MNAA assays and modified FDA approved assays shall define the acceptable detection range for all controls and each run shall include at least: a) one control capable of detecting amplification inhibition by patient specimens unless the CLRS-approved application/method exempts the requirement; b) for qualitative assays, a negative control and a low range positive control that assess the entire assay, including specimen preparation/extraction (except for sequence based assays); c) for quantitative assays, a negative control and at least 2 positive controls that assess a reasonable portion of the linear range of the assay including specimen preparation/extraction; and, d) additional negative controls in laboratories that manipulate amplicon but do not use separate rooms for pre- and post-amplification processes.	This standard applies to controls to be used with laboratory developed assays and FDA-approved assays that have been modified by the laboratory. Controls for unmodified FDA-approved assays should minimally include those recommended by the manufacturer and those that meet the requirements of other applicable standards. 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. a) 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. a) Inhibition controls are not required if the run includes isolates only and not patient specimens. b,c) A low-range positive is defined as having a value of not more than 10-fold above the assay detection limit. b,c) 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. d) Processes that involve manipulation of amplicon include conventional PCR and nucleic acid sequencing. d) It is recommended that the number of negative controls equal at least 2% of the patient specimen test number and that these are interspersed randomly throughout patient specimens (e.g. 2 per 96-well plate). Note: Refer to the Application for Approval of Infectious Agent Nucleic Acid Amplification Tests (http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval/submission-checklists) for additional guidance related to assay control ranges or exemptions from use of inhibition controls.
Microbiology Nucleic Acid Amplification Assay Sustaining Standard of Practice 6 (MNA S6): Quality Control Samples for Sequencing Assays	Laboratories using a core facility do not need to provide negative and positive sequencing amplification controls if the assay performed by the core facility includes negative and positive sequencing controls.

Microbiology

Nucleic Acid Amplification (MNAA) Assay

Standard	Guidance
Each sequencing assay shall include a a) negative amplification control; b) negative sequencing control; c) positive sequencing control; and d) positive amplification and inhibition controls when testing primary specimens using laboratory developed assays or modified FDA approved assays.	a,b) The negative amplification control may also be used as the negative sequencing control. a) Purified plasmid that is supplied with a commercially available kit may be used as a positive sequencing control. Previously tested and well characterized PCR product of the target from clinical samples can also be used as sequencing controls. d) Positive amplification controls and inhibition controls are not necessary when performing sequencing on clinical isolates. d) Positive amplification and inhibition controls may be omitted when testing primary specimens for genotyping assays for prognostic purposes. If there is no amplification product or genotype resulting from a primary specimen, the report must document that the result may be due to the following: virus was below the limit of detection in the sample, mutations were present in the virus genome, or inhibitors were present in the sample that prevented amplification. Note: Refer to the Application for Approval of Infectious Agent Nucleic Acid Amplification Tests (http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval/submission-checklists) for further information.

Microbiology

Nucleic Acid Amplification (MNAA) Assay

Standard	Guidance
Microbiology Nucleic Acid Amplification Assay Sustaining Standard of Practice 7 (MNA S7): Reports for Laboratory Developed and Modified FDA Approved Sequence-based Assays Reports shall describe the relationship between the observed result and the predicted phenotype.	This standard does not apply to sequence-based assays for identification. For unmodified FDA -approved assays reporting should be consistent with the manufacturer's instructions. Reports containing test results generated using sequencing, probe-based, and other genotype assays should include information stating the relationship between the observed result(s) and the related characteristic such as prediction of drug resistance or virulence. Mutations should not be reported as indicative of drug resistance or virulence unless there is well-supported documentation in peer-reviewed literature. Refer to the Application for Approval of Infectious Agent Nucleic Acid Amplification Tests (http://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval/submission-checklists) for additional requirements.

Microbiology

Nucleic Acid Amplification (MNAA) Assay

Standard	Guidance
Microbiology Nucleic Acid Amplification Assay Sustaining Standard of Practice 8 (MNA S8): Task Separation for FDA-Approved Closed System Amplification Test (CSATS) The laboratory shall: a) Handle, process, and store clinical specimens, reagents and supplies in a manner that prevents exposure to amplicon, plasmids, and culture-amplified materials; and b) Locate the instrument in an area free of open amplicon systems.	A CSAT refers to an assay in which all steps, including post-amplification steps, are performed and contained within a closed system. A closed system is defined as an instrument in which the patient specimen is directly added to the test unit, device, or cartridge, sealed, and then the testing process is initiated with no additional external manipulation or addition of reagents (either manually or robotically). CSAT instrumentation should be segregated from areas in which specimens are routinely processed in order to avoid cross-contamination. An individual performing CSAT may return to pre-amplification areas since the closed systems do not release amplicon into the environment provided that assay and discard procedures are followed.
Microbiology Nucleic Acid Amplification Assay Sustaining Standard of Practice 9 (MNA S9): Controls for FDA-Approved Closed System Amplification Tests (CSATs) Positive target controls and negative controls that assess the entire assay shall be run on each new lot number or shipment prior to reporting patient results and on each day of use for FDA-Cleared Closed System Amplification tests (CSATs) unless the laboratory has validated a reduced quality control schedule that minimally includes a: a) positive target control run at least monthly; b) negative control run at least weekly.	The validation studies should demonstrate acceptable quality control results at the interval corresponding to the laboratory's quality control schedule. The laboratory is not required to run quality control every day in the time period to verify reagent stability.

Microbiology

Bacteriology

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. The laboratory must also follow the Microbiology and Molecular Microbiology Standards. Effective May 1, 2011; BT S9 and BT S11 revised and effective July 1, 2014.	
Bacteriology Standard of Practice 1 (BT S1): Reagent QC The laboratory shall check positive and negative reactivity with control organisms as follows: a) each day of use for beta-lactamase and all stains other than Gram stain; b) each week of use for Gram stain; c) every 6 months for antisera.	c) Polyvalent antisera should be tested with at least one organism from each polyvalent group.
Bacteriology Standard of Practice 2 (BT S2): Urine Loops Non-disposable urine loops shall be calibrated monthly.	Calibration may be performed using a blue-dye methodology or by using a calibrated drill bit.
Bacteriology Standard of Practice 3 (BT S3): Anaerobic Containers The environmental conditions of anaerobic bags, jars, and glove boxes shall be monitored and documented each day of use.	An oxygen sensitive indicator such as methylene blue, resazurine, or a control culture of *Clostridium novyi B* should be placed in anaerobic jars or chambers to ensure anaerobic conditions are met.

Microbiology

Bacteriology

Standard	Guidance
Bacteriology Standard of Practice 4 (BT S4): Aerobic Blood Cultures Macroscopically negative aerobic blood cultures shall be subcultured at some point before discarding.	Subcultures need not be done on blood cultures performed by radiometric methods or automated non-radiometric methods if the bottles are monitored for five days.
ANTIMICROBIAL SUSCEPTIBILITY TESTING: DISK DIFFUSION AND MINIMAL INHIBITORY CONCENTRATION	
Bacteriology Standard 5 (BT S5): Defining Antibiotic Panels Antibiotic panels appropriate to the specimen source and organism isolated shall be defined.	Guidelines should be established for the number and type of antibiotics tested and/or reported for organisms isolated from different sources. It is recommended that, in a hospital setting, the laboratory periodically reviews the most current formulary established by the pharmacy and/or the Infection Control Committee.
Disk diffusion methods (Standards 6-9)	
Bacteriology Standard of Practice 6 (BT S6): Media QC for Disk Diffusion Methods Each batch of media used for antimicrobial susceptibility testing shall be checked with the appropriate control strains before, or concurrent with, initial use utilizing approved reference organisms.	If performed concurrently with patient testing, QC results should be reviewed prior to release of patient results.
Bacteriology Standard of Practice 7 (BT S7): Antibiotic QC for Disk Diffusion Methods Using known reference organisms, the laboratory shall check each new lot of antimicrobial disks before, or concurrent with, initial use.	If performed concurrently with patient testing, QC results should be reviewed prior to release of patient results.

Microbiology

Bacteriology

Standard	Guidance
Bacteriology Standard of Practice 8 (BT S8): Antibiotic Disk Distribution Antibiotic disks shall be evenly distributed over the culture plate not less than 15 mm from the outer edge of the plate and no closer than 24 mm from center to center except when specifically directed otherwise by the manufacturer's directions or generally accepted standards of practice.	Generally, no more than 12 disks should be distributed on a 150 mm petri plate and no more than 5 disks on a 100 mm plate. For *Haemophilus* species, *Neisseria gonorrhoeae*, and *Streptococcus* species (including *Streptococcus pneumoniae*), no more than 9 disks per 150 mm plate and no more than 4 disks per 100 mm plate should be used.
Bacteriology Standard of Practice 9 (BT S9): Disk Diffusion QC Frequency, Assessment and Recording For antimicrobial susceptibility disk diffusion testing, the laboratory shall: a) use the appropriate control organism(s) to check the procedure each day of testing; or b) test each appropriate control strain a minimum of once each week during which patients are tested, provided the laboratory has demonstrated satisfactory performance of quality control testing by testing control strains each day of use for at least 20 days; c) record zone sizes for each antimicrobial quality control test; and d) verify quality control results are within established zone diameter ranges.	b) This alternative quality control practice is subject to the requirements of Quality Control Sustaining Standard of Practice (QC Design S1): Design of Individualized Quality Control Plan. c) Zone sizes may be measured using a ruler, sliding calipers, templates, or other appropriate measurement devices prepared for this purpose. d) The laboratory may establish zone diameter ranges using relevant references.

Microbiology

Bacteriology

Standard	Guidance
Minimal inhibitory concentration methods (MIC) (standards 10-11)	
Bacteriology Standard of Practice 10 (BT S10): Reagent QC for MIC methods Each batch of macrodilution tubes, microdilution plates, concentration strips, and agar dilution plates used for MIC antimicrobial susceptibility testing shall be checked with the appropriate control strains before, or concurrent with, initial use using approved reference organisms.	If performed concurrently with patient testing, QC results should be reviewed prior to release of patient results.
Bacteriology Standard of Practice 11 (BT S11): MIC Quality Control Frequency, Assessment and Recording For MIC antimicrobial susceptibility testing, the laboratory shall: a) use the appropriate control organism(s) to check the procedure each day of testing; or b) test each appropriate control strain a minimum of once each week during which patients are tested, provided the laboratory has demonstrated satisfactory performance of quality control testing or by satisfactory testing of control strains each day of use for at least 20 days; c) record the actual MIC obtained during quality control testing; and d) verify quality control results are within established acceptable ranges.	b) This alternative quality control practice is subject to the requirements of Quality Control Sustaining Standard of Practice (QC Design S1): Design of Individualized Quality Control Plan. d) The established MIC range is the acceptable interpretive criteria for that drug-microorganism combination used for QC. The laboratory may establish MIC ranges using relevant references.

Microbiology

Mycobacteriology

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. The laboratory must also follow the designated Microbiology Standards. Effective July 15, 2018.	
Mycobacteriology Sustaining Standard of Practice 1 (TB S1): Biological Safety Cabinet (BSC) A class II or higher biological safety cabinet (BSC) shall be used when: a) processing specimens submitted for mycobacteriological testing, including slide preparation; b) handling or processing unsealed mycobacteriology cultures; c) performing any other procedures that have the potential to create aerosols.	Operational guidelines for biological safety cabinets can be found in the Safety Standards of the General Systems Standards Part 1.
Mycobacteriology Sustaining Standard of Practice 2 (TB S2): Centrifugation Safety For all mycobacteriology procedures that use centrifuges: a) aerosol-free centrifuge cups shall be used; b) centrifuge cups shall be opened in a class II or higher BSC.	

Microbiology

Mycobacteriology

Standard	Guidance
Mycobacteriology Sustaining Standard of Practice 3 (TB S3): Specimen Centrifugation Specimens shall be centrifuged for a minimum of 15 minutes at greater than or equal to 3,000 x g.	
Mycobacteriology Sustaining Standard of Practice 4 (TB S4): Cross-Contamination The laboratory shall design procedures that minimize the possibility of cross-contamination including but not limited to: a) only one patient specimen shall be opened and manipulated at a time in a BSC; b) positive control organisms shall not be present in the BSC when patient specimens are being processed.	Batch staining with jars or dishes is not good laboratory practice. This does not apply to automated staining systems. b) False positive results have been reported due to contamination with a control that contained a high concentration of organisms i.e. TB or NTM culture.
Mycobacteriology Sustaining Standard of Practice 5 (TB S5): Staining Quality Control For mycobacteriological staining, a positive and negative control shall be run with each new shipment or lot of stain and each time of use.	

Microbiology

Mycobacteriology

Standard	Guidance
Mycobacteriology Sustaining Standard of Practice 6 (TB S6): Fluorochrome Stains The laboratory shall have documentation that positive fluorochrome stains in newly diagnosed patients are: a) confirmed by carbol fuchsin stain; or, b) independently evaluated by a second person.	Carbol fuchsin stain is the preferred method for confirmation in newly diagnosed patients.
Mycobacteriology Sustaining Standard of Practice 7 (TB S7): Reporting Smear Results Reports of all positive and negative smear stain results shall: a) be communicated to the ordering physician or other authorized person within 30 hours of the receipt of the specimen; and b) indicate that culture is being performed.	a) Reporting time should be periodically monitored to ensure compliance. b) Culture is necessary due to the limited sensitivity of microscopy.
Mycobacteriology Sustaining Standard of Practice 8 (TB S8): Laboratories testing only Smears- Specimen Submission and Result Notification Laboratories testing only smears shall: a) submit specimens for culture to a laboratory holding a New York State clinical laboratory permit in Mycobacteriology; and b) notify the reference laboratory if the specimen being sent is the first smear positive specimen from the patient.	Part (a) of the standard is to be followed regardless of the smear result. b) This notification is essential so that the reference laboratory can comply with Mycobacteriology Sustaining Standard of Practice 15 (TB S15). b) The patient smear history can be reviewed in the LIMS system of the referring laboratory.

Microbiology

Mycobacteriology

Standard	Guidance
Mycobacteriology Sustaining Standard of Practice 9 (TB S9): Retention of Stained Slides Stained slides of direct smears from primary specimens shall be retained until the final culture report has been issued.	Fluorochrome slides will fade with time, so they should be retained in the dark. The slides may be restained with a carbol fuchsin method if necessary.
Mycobacteriology Sustaining Standard of Practice 10 (TB S10): Nucleic Acid Amplification Nucleic acid amplification for *M. tuberculosis* complex shall be performed on all primary respiratory specimens that test smear positive and are from patients who have not been previously diagnosed with tuberculosis.	If the laboratory does not have the capability to perform nucleic acid amplification testing, an additional respiratory specimen shall be immediately requested and sent to a New York State permitted laboratory that performs nucleic acid amplification. Non-amplified nucleic acid assays do not satisfy this standard. Specimens from patients with a known history of non-tuberculous Mycobacteria (NTM) infection and without clinical suspicion of tuberculosis (e.g., cystic fibrosis patients) do not need nucleic acid amplification testing performed.
Mycobacteriology Sustaining Standard of Practice 11 (TB S11): Media For all specimens other than blood, at least one solid and one liquid medium shall be inoculated for culturing acid fast bacilli (AFB).	

Microbiology

Mycobacteriology

Standard	Guidance
Mycobacteriology Sustaining Standard of Practice 12 (TBS 12): Culture Purity The purity of a positive liquid culture shall be verified by: a) acid fast staining microscopy; and b) plating on enriched, non-selective culture media (eg. Chocolate agar) to ensure that cultures are not contaminated with non-acid fast bacilli.	
Mycobacteriology Sustaining Standard of Practice 13 (TBS 13): Retention of Isolates Laboratories shall save the original and subsequent *M. tuberculosis* complex isolates from all patients for 12 months.	Multiple isolates may be requested from the same patient for public health investigation. Isolates may be retained on appropriate media and stored at 4-8 degrees C or may be frozen at -70 degrees C to -80 degrees C.
Mycobacteriology Sustaining Standard of Practice 14 (TB S14): Identifying *M. avium* complex and *M. gordonae* Laboratories shall use only AFB morphology and NYS or FDA approved methods to identify *M. avium* complex and *M. gordonae*.	Identification of *M. avium* complex or *M. gordonae* by biochemical methods is not satisfactory. However, new technologies may be acceptable as long as they are appropriately validated and approved by NYS Clinical Laboratory Reference System or cleared by the FDA.

Microbiology

Mycobacteriology

Standard	Guidance
Mycobacteriology Sustaining Standard of Practice 15 (TB S15): Submission of Isolates to a Public Health Laboratory Laboratories shall submit to either the Wadsworth Center or the NYC Public Health Laboratories: a) all initial isolates of *Mycobacterium tuberculosis* complex from newly diagnosed patients within the next business day of a positive identification of *M. tuberculosis* complex; b) all *M. tuberculosis* complex isolates presenting a change in susceptibility pattern. The initial isolate and the subsequent isolate demonstrating an altered susceptibility pattern shall both be submitted.	Isolates recovered from patients residing in New York City should be submitted to the NYC Public Health Laboratories; isolates from patients residing outside of NYC (upstate and out-of-state) should be submitted to the Wadsworth Center in Albany, NY. If a TB culture positive report has been received from either public health laboratory, isolates do not need to be submitted. Refer to the latest version of the Laboratory Reporting and Specimen Submission Requirements for Communicable Diseases available at: http://www.wadsworth.org/regulatory/clep/laws. a) To expedite genotype testing, an aliquot of at least 1 ml of the primary broth medium should be sent rather than waiting for a mature subculture on a slant. b) A change in drug susceptibility may be identified by the health care provider or through the patient's history.
Mycobacteriology Sustaining Standard of Practice 16 (TB S16): Referral of Positive Isolates for Susceptibility Testing If susceptibility is not performed in-house, the initial positive culture on a newly diagnosed patient shall be submitted to a New York State permitted laboratory by the next business day of identification as *Mycobacterium tuberculosis* complex.	Whenever possible, the initial positive culture (i.e., equal to or greater than 1 ml broth aliquot or slant) should be submitted and a subculture should be retained in the originating laboratory The submitting laboratory should provide the date of identification to the reference laboratory. For laboratories not performing susceptibility testing in-house, the submitting laboratory should periodically monitor whether the interval between the initial identification and the receipt of culture by the reference laboratory is acceptable.

Microbiology

Mycobacteriology

Standard	Guidance
Mycobacteriology Sustaining Standard of Practice 17 (TB S17): Susceptibility Testing Susceptibility testing shall be performed using the indirect testing method.	Indirect susceptibility testing utilizes a pure culture as inoculum. Using a specimen as inoculum (direct susceptibility method) is not acceptable.
Mycobacteriology Sustaining Standard of Practice 18 (TB S18): First-Line Tuberculosis Drugs All initial isolates of *M. tuberculosis* complex shall, at a minimum, be tested for susceptibility to the following first-line tuberculosis drugs: Rifampin, Isoniazid, Pyrazinamide, Ethambutol using culture or nucleic acid based methods. All isolates predicted to be resistant by nucleic acid based methods shall be confirmed by culture-based susceptibility testing. Isolates predicted to be susceptible by nucleic acid methods other than whole genome sequencing shall be confirmed by culture-based susceptibility testing.	For all isolates identified as *M. tuberculosis* complex: If the laboratory does not perform pyrazinamide susceptibility testing, the isolate should be submitted within 24 hours to a New York State permitted laboratory for pyrazinamide testing.

Microbiology

Mycobacteriology

Standard	Guidance
Mycobacteriology Sustaining Standard of Practice 19 (TB S19): Verification of Reagents for Culture-Based Susceptibility Testing For anti-mycobacterial culture-based susceptibility tests, the laboratory shall check each batch of media and each lot number and shipment of anti-mycobacterial agent(s) before or concurrent with initial use, using an appropriate control organism(s) and a) establish limits for acceptable control results; b) use the appropriate control organism(s) to check the procedure each week tests are performed; c) use a control strain of *M. tuberculosis* that is fully susceptible to first line drugs for susceptibility tests performed on *M. tuberculosis* complex isolates; d) verify that the results for the control organism(s) are within established limits before reporting patient results; and e) document the results of all control procedures performed.	
Mycobacteriology Sustaining Standard of Practice 20 (TB S20) **STANDARD DELETED**	

Microbiology

Mycobacteriology

Standard	Guidance
Mycobacteriology Sustaining Standard of Practice 21 (TB S21): Second-Line Drugs Additional culture or nucleic acid based susceptibility testing shall be performed for second-line drugs for all initial positive cultures of *M. tuberculosis* complex from newly diagnosed patients if culture-based resistance is detected for one or more first-line drugs, with the exception of mono-resistance to pyrazinamide. If second-line drug susceptibility cannot be performed in-house, the isolate shall be referred within 24 hours to a New York State permitted laboratory for testing. All isolates predicted to be resistant by nucleic acid based methods shall be confirmed by culture-based susceptibility testing. Isolates predicted to be susceptible by nucleic acid based methods other than whole genome sequencing shall be confirmed by culture based susceptibility testing.	Whenever possible, the initial positive culture (i.e., 3 ml broth aliquot or slant) should be immediately referred and a subculture should be retained in the originating laboratory.
Mycobacteriology Sustaining Standard of Practice 22 (TB S22): Reporting First-Line Drugs Susceptibility test results for first-line drugs shall be reported within 24 hours of findings. If applicable, the report shall specify that second line drug susceptibility testing is being performed.	Test results for susceptibility to first line drugs should not be held pending the results of the additional testing.

Microbiology

Mycobacteriology

Standard	Guidance
Mycobacteriology Sustaining Standard of Practice 23 (TB S23): Turn Around Time for Susceptibility Testing For initial diagnostic specimens, the average time from identification of *M. tuberculosis* complex from culture to reporting of susceptibility results for first line drugs shall not exceed 17 days for 70% of such specimens.	The laboratory receiving the primary specimen is responsible for ensuring that the turn-around-time requirement is met. This standard applies to laboratories performing smears only and laboratories performing susceptibility testing.

Microbiology

Mycology

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Effective July 14, 2014	
Mycology Sustaining Standard of Practice 1 (MY S1): Biological Safety Cabinet (BSC) A class II or higher biological safety cabinet (BSC) shall be used whenever: a) processing patient specimens submitted for isolation of pathogenic fungi; b) handling or processing cultures of pathogenic fungi.	Additional required use of the BSC should be established by the laboratory director based on an infectious agent risk assessment (refer to Safety Standards).
Mycology Sustaining Standard of Practice 2 (MY S2): Centrifugation For all mycology procedures that use centrifuges: a) aerosol-free centrifuge cups shall be used; b) centrifuge cups shall be opened in a class II or higher BSC.	

Microbiology

Mycology

Standard	Guidance
Mycology Sustaining Standard of Practice 3 (MY S3): Microscopy Identification of molds and yeast shall include direct microscopic examination of the clinical specimen or the isolate using an appropriate mounting medium or stain unless a New York State- or FDA-approved nucleic acid or mass spectroscopic identification method is used.	Based upon clinical history and nature of the clinical specimen, a direct examination may be performed with one of the following reagents or stains: potassium hydroxide; India ink; Cellufluor; Gram stain; Giemsa stain, ethenamine silver stain, or other appropriate method(s). (Note: The listed examples are not all-inclusive). Mold and yeast isolates may be examined with Cellufluor, India ink, Giemsa stain, Gram stain, or other appropriate method(s). (Note: The listed examples are not all-inclusive).
Mycology Sustaining Standard of Practice 4 (MYS4): Culture Incubation The mycology laboratory shall: a) incubate cultures at 30 ± 2° C; and b) provide sufficient humidity to prevent drying of inoculated plates	b) Insufficient humidity is evident when agar is cracked before the end of the incubation period.

Microbiology

Mycology

Standard	Guidance
Mycology Sustaining Standard of Practice 5 (MYS5): Culture Media for Isolation of Molds and Yeasts Laboratories shall utilize a combination of culture media for isolation of molds and yeasts as appropriate for clinical specimens being tested.	Examples of suitable media are as follows (Note: The listed examples are not all-inclusive): a) general purpose media such as: Sabouraud dextrose agar--no antibacterial or antifungal agents,; b) general purpose media with cycloheximide such as: Sabouraud dextrose agar - with antibacterial agents and cycloheximide,; c) enriched media such as: BHI agar, SABHI agar d) specialized media such as: chromogenic agars and formulations that might aid in isolation and presumptive identification of fastidious and dimorphic pathogenic fungi and *Malassezia* species.

Microbiology

Mycology

Standard	Guidance
Mycology Sustaining Standard of Practice 6 (MY S6): Identification of Pathogenic Molds Methods for identification of pathogenic molds shall include: a) a medium to stimulate production of characteristic spores and biochemical tests to differentiate fungi; or b) an FDA-approved or NYS-approved diagnostic system(s).	
Mycology Sustaining Standard of Practice 7 (MY S7): Identification of Pathogenic Yeasts Methods for identification of pathogenic yeasts shall include: a) media for phenotypic tests; or b) FDA-approved or NYS-approved diagnostic systems.	a) Examples of appropriate media for the identification of yeast include Cornmeal or cream of rice medium with Tween 80, rapid assimilation of trehalose (RAT), and urease.
Mycology Sustaining Standard of Practice 8 (MY S8): Reference Material A reference collection of photographs or reference materials to identify microscopic fungal elements shall be readily available in the laboratory for comparison with diagnostic specimens	

Microbiology

Mycology

Standard	Guidance
Mycology Sustaining Standard of Practice 9 (MY S9): Quality Control of Probes and Stains The laboratory shall minimally check the reactivity of each batch (prepared in-house), lot number (commercially prepared), and shipment when prepared or opened as follows: a) a positive control as required by CLIA for lactophenol cotton blue; b) positive and negative control organisms for all stains and probes.	The laboratory should establish frequency of QC checks based upon published guidelines from consensus organizations.
Mycology Sustaining Standard of Practice 10 (MY S10): Antifungal Susceptibility Testing Quality Control For antifungal susceptibility tests, the laboratory shall : a) verify manufacturer's limits or establish limits for acceptable control results; b) check each batch of media and each lot number and shipment of antifungal agent(s) using appropriate control organism(s) before or concurrent with initial use; and c) verify that the results for the control organism(s) are within established limits before reporting patient results.	Clinical and Laboratory Standards Institute (CLSI) or European Committee on Antimicrobial Susceptibility Testing (EUCAST) approved methods include guidelines for appropriate quality control strains.
Mycology Sustaining Standard of Practice 11 (MY S11): Susceptibility Testing Reports Susceptibility testing reports shall include: a) an interpretation, to explain the significance of the test result; and/or b) a qualifier identifying an assay limitation, if appropriate.	a) Interpretative guidelines based upon the CLSI or EUCAST documents or FDA approved commercial products may be used.

Microbiology

Parasitology

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Effective July 25, 2012	
Parasitology Sustaining Standard of Practice 1 (PS1): Stool Specimen Preservation for Morphological Examination Stool specimens to be used for parasitological identification based on morphology shall be a) examined immediately; b) preserved immediately upon collection using the fixative appropriate for the test being ordered; or c) refrigerated for no more than three hours from time of collection to either examination or preservation.	The laboratory should choose the fixative that is most appropriate for its testing purposes, eg. PVA for Trichrome, 10% formalin or SAF for acid-fast stain, ethanol for DNA extraction. When it is anticipated that the time of collection will not be recorded or transport time will be prolonged, laboratories are encouraged to provide stool transport kits with preservatives to clients. Specimens must be refrigerated and preserved with 3-hours of collection when not examined immediately. Specimens to be used for antigen testing or DNA extraction may be stored in ethanol, potassium dichromate, frozen, refrigerated or in Cary-Blair transport medium depending on the assay utilized. Consult the package insert or CLRS-approved laboratory-developed method for instructions. It is recommended that ova and parasite examinations include a concentration step whenever compatible with subsequent testing, as the concentration step is designed to facilitate recovery of parasites.

Microbiology

Parasitology

Standard	Guidance
Parasitology Sustaining Standard of Practice 2 (PS2): Quality Controls for Staining Permanent stains shall be checked using a positive and negative control, at a minimum, with each new shipment or lot, and once per month of use.	Controls may be obtained commercially, previously tested patients or proficiency-testing samples.
Parasitology Sustaining Standard of Practice 3 (PS3): Antigen Detection Assay Controls Excluding single use devices, each antigen detection assay shall be verified for performance with at least one positive control and one negative control each time the test is performed.	Positive and negative controls supplied with commercially available tests are acceptable. Quality control plans for single use devices must follow either Quality Control Sustaining Standard or Practice 1 (QC Design S1): Design of Individualized Quality Control Plan or Quality Design Sustaining Standard of Practice 2a (QC Design S2a): Minimum Requirements.
Parasitology Sustaining Standard of Practice 4 (PS4): Ocular Micrometer Calibration Laboratories shall calibrate ocular micrometers: a) annually for each objective; and b) with any change in objective or eyepiece.	Calibration figures or conversion factors for determining size using each objective should be readily available at the microscope. a) The SOP should contain instructions for calibration and examples to show how each objective is calibrated.

Microbiology

Parasitology

Standard	Guidance
Parasitology Sustaining Standard of Practice 5 (PS5): Ova and Extracellular Parasite Measurement Using a calibrated ocular micrometer, laboratories shall a) measure and document the size of all ova and extracellular protists; b) demonstrate annually that each analyst can accurately measure organisms or objects.	Size is an important criterion for clinical parasitology and may be a critical factor to distinguish morphologically similar organisms (e.g. eggs of *Paragonimus westermani* vs. *Fasciola*). a) Documentation may be on worksheets or electronic records. b) Proficiency may be established by calibration of the ocular micrometer for each analyst or measurement of an organism or object as part of annual competency assessment.
Parasitology Sustaining Standard of Practice 6 (PS6): Examination of Blood Smears The SOP for identification of blood borne parasites should include: a) a description of the number of fields that need to be examined for both positive and negative results; and b) examination at 10X for the detection of filarids, if such testing is indicated.	Giemsa stain is recommended; however, Wright's stain or a Wright-Giemsa combination stain may also be used. a) an adequate number of fields [e.g., 300 oil immersion fields (10x100)] should be examined under oil immersion before calling a specimen negative.
Parasitology Sustaining Standard of Practice 7 (PS7): Reference Material A reference collection of slides, photographs, or gross specimens of identified parasites shall be readily available in the laboratory for comparison with diagnostic specimens.	Textbooks with photographs, bench aids, tables including drawings and sizes, previously stained slide preparations, preserved specimens, or slides from proficiency testing programs are examples of acceptable reference material.

Microbiology

Parasitology

Standard	Guidance
Parasitology Sustaining Standard of Practice 8 (PS8): Report Content Reports for ova and parasite examination shall indicate if the examination did not include tests to detect *Cryptosporidium spp., Giardia intestinalis* or *Entamoeba histolytica/dispar*.	The tests included in an ova and parasite exam may vary considerably. This standard is intended to inform clinicians if any of the three most common parasites in New York State are not tested for when an Ova and Parasite test is performed. If a test for a specific organism is ordered, (e.g. Giardia antigen detection) this standard does not apply.
Parasitology Sustaining Standard of Practice 9 (PS9): Single-Use Antigen Assays Reports based solely on an immunochromatographic card test (lateral flow, rapid tests) shall include statements recommending that results from these tests be confirmed by another method.	It is recommended that all specimens be confirmed by another method.
Parasitology Sustaining Standard of Practice 10 (PS10): Reporting Negative Results If a single specimen is submitted for testing and the results are negative, reports shall indicate that one negative specimen does not rule out the possibility of a parasitic infection.	Many parasites can be easily missed if a single blood or stool specimen is tested. To improve detection it is recommended that three specimens be collected on separate days over a period of not more than seven days.
Parasitology Sustaining Standard of Practice 11 (PS11) Specimen Retention For positive stool or blood specimens, the laboratory shall retain, for a minimum of one year: a) permanently stained slides; or, b) a portion of the specimen, properly preserved and stored.	a) The staining method used is the choice of the laboratory, but the stain should be appropriate for the organism. Common permanent stains include modified acid-fast, trichrome, and Giemsa.

Microbiology

Virology

Standard	Guidance
These standards apply to **conventional tube culture** and to **centrifugation-enhanced rapid** methods unless otherwise specified. All laboratories performing viral culture using conventional tube cultures and/or rapid culture modifications (e.g. shell vials), shall additionally comply with the applicable requirements contained in the General Systems Standards and with designated Microbiology Standards.	
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
Virology Sustaining Standard of Practice 1 (VR S1): Cell Culture Systems The laboratory shall utilize cell cultures and methods appropriate for the isolation and/or detection of the viral agents specified in its test menu.	

Microbiology

Virology

Standard	Guidance
Virology Sustaining Standard of Practice 2 (VR S2): Cell Culture Records The laboratory shall maintain records for each commercial cell culture lot received including: cell culture type and vendor; lot number; passage level (if appropriate); date of receipt; condition at the time of receipt including the percentage of monolayer confluence; and any corrective action taken for cell culture lots that are of questionable or unsatisfactory condition at the time of receipt. Similar records shall be maintained for cell cultures prepared in house.	The SOPM should include the criteria for assessing the quality of cell cultures at receipt (e.g. degree of monolayer confluence, adverse conditions such as cell rounding, detached monolayers, pH extremes or microbial contamination). Date of seeding rather than date of receipt should be recorded for cell cultures prepared in-house.
Virology Sustaining Standard of Practice 3 (VR S3): Cell Culture Shelf Life and Condition Cell cultures used for testing patient specimens shall be examined microscopically and confirmed for acceptability as defined in the SOPM on the day of inoculation and used within: a) the expiration date, if provided by the vendor or b) 10 days after the monolayers become 100% confluent or c) 10 days of receipt, if monolayers were 100% confluent when received.	Slightly sub-confluent monolayers are optimal for viral culture. Crowded, overgrown, or aged cultures may result in decreased virus susceptibility.
Virology Sustaining Standard of Practice 4 (VR S4): Mycoplasma Screening of Cell Cultures Diploid and continuous cell lines shall be tested at least every 6 months for *Mycoplasma* contamination while the cell lines are in use.	Documentation by the vendor that the cells are free of mycoplasma contamination is acceptable for commercially supplied cell lines.

Microbiology

Virology

Standard	Guidance
Virology Sustaining Standard of Practice 5 (VR S5): Cell Culture Medium The laboratory shall maintain records for each lot of cell culture maintenance and growth medium including the type, vendor, lot number and the receipt and expiration dates. Similar records shall be maintained for culture media prepared in-house and for medium components added by the laboratory.	The type of medium refers to its formulation, e.g. Eagle's MEM with 2% FBS.
Virology Sustaining Standard of Practice 6 (VR S6): Cell Culture Medium Quality Control Quality control of cell culture medium shall be documented and minimally ensure that cell culture media have been tested for sterility and toxicity prior to use and have an acceptable pH at the time of use.	Documentation by the vendor that appropriate sterility, toxicity and other quality control testing has been performed on commercially supplied medium is acceptable. However, appropriate in-house testing must be performed if components are added by the laboratory. Sterility testing, if necessary, should be performed using bacterial culture techniques. Visual inspection to confirm an acceptable pH range for medium containing a colorimetric pH indicator is acceptable. The possibility of viral inhibition by a medium component (e.g. serum) should be considered and investigated if there is evidence to suggest a decrease in viral culture sensitivity.
Virology Sustaining Standard of Practice 7 (VR S7): Biological Safety Cabinet (BSC) Use A class II or higher BSC shall be used for inoculating cell cultures with clinical specimens and for all procedures involving the maintenance and processing of inoculated cell cultures and culture-amplified materials.	Refer to Safety Sustaining Standard of Practice 6 (Safety S6) for operational guidelines.

Microbiology

Virology

Standard	Guidance
Virology Sustaining Standard of Practice 8 (VR S8): Specimen Processing Procedures The SOPM shall include specimen processing and inoculation procedures for each type (e.g. swab, tissue, blood) of specimen.	Processing procedures include dilution, fractionation, centrifugation, decontamination, homogenization or other treatments utilized for rendering specimens suitable for cell culture inoculation. Inoculation procedures primarily refer to inoculum volume and adsorption steps (if performed).
Virology Sustaining Standard of Practice 9 (VR S9): Cell Culture and Culture Medium Lot Numbers Dates of culture manipulations and microscopic observations shall be recorded on each specimen worksheet.	Culture manipulations include all processing steps such as inoculation, medium changes, subpassage and harvesting. This standard is consistent with the requirement for recreating the test process as stated in standards Quality Management System Sustaining Standard 1 (QMS S1)(t) and Reagents Sustaining Standard 4 (Reagent S4).

Microbiology

Virology

Standard	Guidance
Virology Sustaining Standard of Practice 10 (VR S10): Specimen Criteria The SOPM shall define the remedial action that may be employed for specimens that exhibit contamination or toxicity.	Remedial action for specimens causing adverse culture events (e.g. contamination, toxicity) may include reinoculation, sub-passage, filtration, recollection).
Virology Sustaining Standard of Practice 11 (VR S11): Viral Culture Criteria and Timepoints The SOPM shall define culture criteria including: a) inoculation and incubation conditions (e.g. temperature); b) minimal culture duration; c) minimally acceptable culture observation and documentation schedules; d) maintenance/processing schedules (e.g. media changes, hemadsorption [HAd], staining); e) conditions that render a culture unacceptable or uninterpretable, including an unacceptable monolayer condition at completion (see Virology Sustaining Standard 21 (VR S21)).	a) Inoculation includes specimen adsorption conditions, if applicable. c) Observation includes the microscopic examination of monolayers for evidence of cytopathic effect (CPE), toxicity and contamination. c) The minimal frequency for microscopically observing cultures and recording results is every other day during the first week of incubation and then every 2 to 3 days thereafter. c) Optimally, cultures should be observed on the first day after specimen inoculation in order to initiate timely remediation of adverse events (e.g. toxicity, contamination) and to detect rapidly growing agents. The SOPM should define exceptions and describe remedial action for handling of potentially compromised cultures.

Microbiology

Virology

Standard	Guidance
Virology Sustaining Standard of Practice 12 (VR S12): Negative Cell Culture Controls Uninoculated (negative) lot-matched cell culture controls shall be processed, incubated, maintained and observations recorded in parallel with patient specimens for the entire duration that each lot is in use.	Uninoculated (negative) controls are observed for evidence of unacceptable occurrences such as monolayer deterioration, CPE, HAd and other conditions that should not occur in uninoculated cell cultures. Troubleshooting and corrective action are based on adverse findings as described in the SOPM. Maintenance of controls in parallel with patient specimens requires that the same lot of cell culture medium being used for medium changes on patient specimens is used for the controls. When using centrifugation-enhanced rapid methods, processing includes the centrifugation step. The possibility that a defective lot of culture medium may be the source of deterioration or contamination in uninoculated (negative) controls should be considered. The need to repeat medium quality control testing should be determined (see Virology Sustaining Standard 6 (VR S6): Cell Culture Medium Quality Control).

Microbiology

Virology

Standard	Guidance
Virology Sustaining Standard of Practice 13 (VR S13): Positive Live Virus Culture Controls Live virus-inoculated (positive) culture controls shall be employed as deemed necessary with the exception of genetically engineered cell lines where they shall be included for every run.	With the exception of genetically engineered cell lines, virus-inoculated (positive) culture controls need be employed only as necessary (e.g. suspected performance problems; assessing a new cell culture type or source; training and remediation activities). In lieu of the routine use of positive live virus controls, the laboratory should identify appropriate indicators that would be useful in identifying cell culture sensitivity problems (see Virology Sustaining Standard 20 (VR S20): Viral Culture Performance Monitoring). Virus-inoculated positive controls are included in every run when using genetically engineered cell lines to confirm the stability and activity of the transfected plasmid as well as the reactivity of the enzyme and substrate. Virus preparations used for inoculating positive controls should optimally consist of low-passage material derived from clinical isolates rather than laboratory-adapted strains and should be inoculated at a low multiplicity of infection (m.o.i).
Virology Sustaining Standard of Practice 14 (VR S14): RBC Suspensions The laboratory shall maintain records for each lot of red blood cells (RBC) used for viral detection/identification procedures and shall include the RBC type, vendor, lot number and date of expiration.	

Microbiology

Virology

Standard	Guidance
Virology Sustaining Standard of Practice 15 (VR S15): RBC Controls for Hemadsorption (HAd) Assays RBC Controls in each HAd run shall include: a) a negative control that is an uninoculated cell culture monolayer that is lot-matched to that used for patient specimens; and, b) at least one positive control per lot number of RBCs.	Negative RBC controls are intended to determine whether the RBCs react with uninoculated cell culture monolayers. Virology S12 requires that negative HAd controls be performed in parallel with HAd assays performed on patient inoculated cell cultures. Positive RBC controls should confirm that the RBCs react in the expected manner with virus-inoculated monolayers.

Microbiology

Virology

Standard	Guidance
Virology Sustaining Standard of Practice 16 (VR S16): Confirmation and Identification of Cultured Viruses Each run shall include a: a) positive control; b) lot-matched negative (uninoculated) cell culture control.	a) The positive control is intended to confirm detection system reactivity. This standard does not require the positive control to be lot-matched to patient specimens and allows the use of appropriate commercial controls. The optional use of lot-matched virus-inoculated positive controls would serve to monitor cell culture sensitivity. If live virus preparations are used for inoculating positive controls, they should optimally consist of low-passage material derived from clinical isolates rather than laboratory-adapted material and should be inoculated at a low m.o.i. b) The negative cell culture control reveals background or non-specific reactivity of the detection system and serves to assist with reading. Using lot-matched uninoculated cells (see Virology Sustaining Standard 12 (VR S12): Negative Cell Culture Controls) also serves to identify problems that may be associated with the specific lot of cell cultures used for specimen inoculation. When using an indirect antibody staining format, additional controls may be incorporated to rule out reactivity of the conjugate (labeled secondary antibody) with the cell substrate. Alternatively, these may be utilized as needed for troubleshooting purposes if, for example, the negative control (b) yields positive or unacceptable results. In this case, diluent or an irrelevant antibody would be substituted for the primary unlabeled antibody.

Microbiology

Virology

Standard	Guidance
Virology Sustaining Standard of Practice 17 (VR S17): Viral Neutralization and Hemagglutination-Inhibition (HI) Assays For neutralization and HI assays, the laboratory shall: a) use an established optimal concentration of antibodies or antisera; and, b) use the proper concentration (e.g. TC_{ID50} or hemagglutinating units) of test and control viruses.	Optimal concentrations of control virus material and antibody preparations may need to be re-established or confirmed with prolonged storage. Repeated freeze-thaw cycles should be avoided.
Virology Sustaining Standard of Practice 18 (VRS18): Viral Neutralization and Hemagglutination-Inhibition (HI) Assay Controls For neutralization and HI assays, the laboratory shall include appropriate controls in each run (e.g. matched virus-antibody control; virus-diluent control; unmatched virus-antibody control; RBC controls; viral dose control).	
Virology Sustaining Standard of Practice 19 (VR S19): Rapid Centrifugation-enhanced Virus Culture Methods The laboratory shall: a) perform centrifugation using closed or sealed buckets or rotor; b) include in the SOPM the speed required to achieve the appropriate g-force for each type of rotor in use and record the centrifuge speed setting at the beginning of each run; c) include in the SOPM the acceptable temperature range for the centrifugation step.	c) Temperature-controlled centrifuges are preferred for these procedures. Laboratories not using a temperature-controlled centrifuge should be aware of the potential for detrimental effects on culture monolayers and culture sensitivity resulting from over-heating of the centrifuge chamber. Laboratories using temperature-controlled centrifuges should not begin culture centrifugation until an appropriate temperature has been reached.

Microbiology

Virology

Standard	Guidance
Virology Sustaining Standard of Practice 20 (VR S20): Viral Culture Performance Monitoring The laboratory shall monitor key indicators of viral culture performance as defined in the QA Program and shall review these monthly and implement timely troubleshooting and remediation activities as necessary.	Appropriate key indicators of viral culture performance should be selected based on the scope of testing and the methods performed by the laboratory. Examples include: unacceptable observations/results with negative and positive controls; unanticipated variations in isolation rates; discrepancies between different methods; discrepancies with results obtained by other laboratories; shift or staff-related performance variations; rate of unsatisfactory or incomplete specimens; and, rate of contaminated specimens.
Virology Sustaining Standard of Practice 21 (VR S21): Reporting Criteria Reports shall include qualifiers for cultures: a) that are incomplete or uninterpretable; b) which the isolate identification is considered presumptive, i.e. an isolate is not confirmed by a specific viral identification system.	a) A viral culture result cannot be interpreted as negative unless at least 50% of the expected area of monolayer coverage is still present (on the side of the tube, surface of the coverslip, or bottom of the well) and is of normal morphology at the end of the minimal incubation period (See VR S11). Negative culture results should include a qualifier in cases where optimal specimen transport time/conditions have not been met. b) Specific viral identification systems include immunologic or nucleic acid detection assays as well as genetically engineered cell line systems designed for the detection of viral agents.

Oncology

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Revised and effective October 1, 2017.	

Soluble Tumor Markers

Oncology Standard 1 (OC S1) Reports shall include: a) the name of the manufacturer and the testing methodology used; b) a statement indicating that values obtained with different assay methods or kits cannot be used interchangeably; c) a statement indicating that results cannot be interpreted as absolute evidence of the presence or absence of malignant disease; and, d) if AFP or hCG is the analyte, a statement indicating that the test is not interpretable in pregnant females.	c) The laboratory should refer to the manufacturer's instructions for the limitations of the test.

Oncology

Standard	Guidance
Oncology – Molecular and Cellular Tumor Markers	
Oncology Standard 2 (OC S2) Reports shall: a) indicate the testing methodology used; b) indicate the limits of sensitivity (both analytic and diagnostic) of the method used; c) include an interpretation of findings; and d) contain the signature of the qualified person who reviewed, approved, and interpreted the test results. A qualified person is an individual holding a valid New York State certificate of qualification in the Oncology – Cellular Tumor Markers subcategory. e) if the report contains results from **FISH** testing, it shall include: i) use of the current International System for Human Cytogenetic Nomenclature (ISCN); i) number of cells analyzed i) probe target and vendor i) cutoff values for interphase FISH	b) i) Analytical sensitivity: generally the number of tumor cells or alleles in a background of normal cells that need to be present to obtain a positive signal; e.g., five tumor cells in 100 normal cells; or 5% minor allele frequency; or similar. ii) Diagnostic sensitivity: given the analytical sensitivity, what is the diagnostic sensitivity; e.g., the assay is able to detect a variant in 95% of patients with variants in this region of the genome. d) Laboratories using electronic signatures should have a procedure in place that ensures and documents the qualified person's authorization for each signature occurrence (such as access limited by password). e,i) Results may be reported in other formats **in addition** to ISCN
Oncology Standard 3 (OC S3): FISH testing For **FISH** testing, method validation, result reporting, patient testing and any other procedure or operation must comply with all applicable cytogenetics requirements.	

Oncology

Standard	Guidance
Oncology Standard 4 (OC S4): FISH Hybridization Acceptability Laboratories must establish criteria to determine the acceptability of each FISH hybridization and document the acceptability of each hybridization prior to reporting. Such criteria must include: d) signal intensity e) background/noise f) appropriate internal (normal homolog and/or control probe) and/or external controls	
Oncology Standard 5 (OC S5): Laboratory Developed FISH Analysis The laboratory shall analyze a number of cells appropriate to the specimen type, reason for referral, and aberrations expected. At a minimum, the laboratory must analyze for interphase FISH: i) suspension culture – 100 cells ii) tissue section – 50 tumor cells.	Unexpected results may require analysis of more cells. FDA-approved/cleared tests should be analyzed as described in the package insert or its equivalent.
Oncology Standard 6 (OC S6): Ongoing Verification of Examination Accuracy for FISH testing A representative sample of all probes used in your laboratory must be regularly verified on a rotating schedule through e.g. proficiency testing or similar mechanisms.	The representative sample must minimally contain examples for each procedure, test design (fusion, breakapart, enumeration, etc) and specimen type (suspension, smear/touch, fixed tissue section, etc) used in the laboratory.

Parentage/Identity Testing

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	During the on-site visit, a litigation package for a randomly selected patient sample shall be prepared and submitted for Departmental review.
GENERAL REQUIREMENTS	
Paternity/Identity Standard 1 (PIT S1)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 2 (PIT S2) Analysis of all test subject specimens in a paternity/ identity case shall be performed in the same laboratory using the same methods and techniques.	Samples from mother, child(ren), and alleged father(s) should all be analyzed in the same laboratory and for DNA procedures, in the same test run.
INDIVIDUAL IDENTIFICATION	
Paternity/Identity Standard 3 (PIT S3) The laboratory shall establish procedures to ensure the verification of the identity of all individuals who present themselves for testing; and such verification shall: a) include photographs, fingerprints or similar evidence of identity; and, b) be documented and retained as part of the record.	
Paternity/Identity Standard 4 (PIT S4) The date of birth of the child shall be recorded.	

Parentage/Identity Testing	
Standard	**Guidance**
Paternity/Identity Standard 5 (PIT S5) A transfusion history for the preceding three months shall be recorded for each individual.	
Paternity/Identity Standard 6 (PIT S6) A history of a bone marrow transplant shall be recorded for each individual.	
Paternity/Identity Standard 7 (PIT S7) The laboratory shall keep a record of all identifying information including, but not limited to: name, relationship, race, and place and date of the collection of the specimen.	
Paternity/Identity Standard 8 (PIT S8) Identifying information regarding each individual to be tested shall be affirmed by the signature of that person or the guardian.	

Parentage/Identity Testing

Standard	Guidance
SPECIMEN COLLECTION, HANDLING, AND IDENTIFICATION	
Paternity/Identity Standard 9 (PIT S9) A paternity/identity standard operating procedure manual shall be developed, adopted, and maintained as part of the laboratory's SOPM and shall minimally include, in addition to applicable SOPM requirements stated in the Operating Procedures and Compliance Standards, the following: a) algorithms used for the calculation and computation of the paternity index, the probability of paternity and the determination of exclusion, including documentation of software program logic; b) frequency tables for each marker and method, including the source of the frequency data; c) protocols for the maintenance of chain-of-custody; d) policies for resolution of discrepancy between duplicate test runs and/or interpretations; e) the methods used for determining the racial background of test subjects and for assigning race for purposes of calculation; and, f) literature references used to document loci, probes, and/or primers and conditions of their use.	
Paternity/Identity Standard 10 (PIT S10) Specimens shall be collected, received, handled, sampled and stored so as to preserve their identity, integrity, and security.	
Paternity/Identity Standard 11 (PIT S11) The name of the phlebotomist or specimen collector shall be documented in the record.	

Parentage/Identity Testing

Standard	Guidance
Paternity/Identity Standard 12 (PIT S12) The laboratory shall develop and implement chain-of-custody procedures.	
Paternity/Identity Standard 13 (PIT S13) The chain-of-custody for each specimen shall be maintained and documented in the record.	
Paternity/Identity Standard 14 (PIT S14) Each specimen shall be identified with a firmly attached label bearing the subject's full name, the date of specimen collection, and initials of the person who collected the specimen, as well as any other information required for unique identification of each specimen.	
Paternity/Identity Standard 15 (PIT S15) The accuracy of the labeling process and the information on the labels shall be verified by the test subject or guardian before the specimens are removed from his or her presence.	In situations where the subject or guardian is incapable of verifying the labeling, a responsible witness may do so.

Parentage/Identity Testing

Standard	Guidance
Paternity/Identity Standard 16 (PIT S16) Any laboratory accepting specimens collected outside its premises or those of its patient service center shall develop and implement a system which: a) establishes the positive identification of all individuals to be tested and includes with the specimen evidence of such identification; b) establishes and maintains a chain of custody in accordance with pre-established protocols for chain of custody which meet or exceed criteria recognized by the NYS Family Court System; c) rejects the specimen(s) if the external chain of custody does not meet the laboratory's pre-established acceptance criteria; and d) includes a written agreement with the collector when the specimen collector is other than a *bone fide* employee of the paternity testing laboratory, which may be another laboratory under permit, that defines the testing laboratory's procedures and requirements for chain of custody, and the testing laboratory shall verify and monitor the collector's compliance with such requirements.	It is the responsibility of the laboratory to maintain chain of custody, and such responsibility may not be relegated. The director must be able to certify that the test result was prepared in a manner intended to insure acceptance into evidence in a court. Therefore, all paternity testing performed under NYS permit shall meet the standards for court admissibility, regardless of whether the test order source is the court, with or without under a Child Protective Services contract; a physician in private practice; or any other individual or entity authorized by law. Third-party cases (i.e., "brokers") may, in the eyes of the court, be uncertifiable because the laboratory can not reasonably be expected to maintain complete control of chain of custody when using brokers as independent agents.
Paternity/Identity Standard 17 (PIT S17) Results shall be read and interpreted independently by at least two individuals prior to reporting.	Observations and interpretations from both individuals should be documented as independent events.
DNA-BASED PATERNITY/IDENTITY TESTING	
Paternity/Identity Standard 19 (PIT S19)	Standard has been deleted. Number reserved for future use
Paternity/Identity Standard 20 (PIT S20)	Standard has been deleted. Number reserved for future use

Parentage/Identity Testing

Standard	Guidance
Paternity/Identity Standard 21 (PIT S21) All polymorphic loci shall: a) be validated by family studies demonstrating Mendelian inheritance and a frequency of mutation and/or recombination of 0.5 percent or less; b) have a chromosomal location recorded by the International Human Gene Mapping Workshop; and, c) be documented in the literature, including identification of the restriction endonucleases and probes used to detect the polymorphism.	
Paternity/Identity Standard 22 (PIT S22)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 23 (PIT S23) All records demonstrating polymorphisms including autoradiographs, computer-generated images and recordings shall be retained as part of the record.	The laboratory should have a system for maintaining and retrieving original image. This also applies to image analysis software.
Paternity/Identity Standard 24 (PIT S24) In addition to the requirements of Part 58, the report shall contain: a) name of the test DNA locus as defined by the International Human Gene Mapping Workshop; b) name of the probe, where applicable; c) name of the restriction endonuclease, where applicable; and, d) size or alphanumeric description of reported alleles.	

Parentage/Identity Testing	
Standard	**Guidance**
Paternity/Identity Standard 25 (PIT S25) The SOPM shall contain the criteria employed for determining that two bands represent the same allele, including the protocols used to determine acceptable inter- and intra-gel variations in band size and mobility.	See Operating Procedures and Compliance Standards for additional SOPM requirements.
DNA-BASED TESTING USING RESTRICTION ENZYMES	
Paternity/Identity Standard 26 (PIT S26)	Standard has been deleted. Number reserved for future use
Paternity/Identity Standard 27 (PIT S27)	Standard has been deleted. Number reserved for future use
Paternity/Identity Standard 28 (PIT S28) The laboratory shall use a known human DNA control and, where appropriate, test gels in every run to monitor restriction enzyme activity, fragment production and electrophoretic separation.	The cell line K562 is commonly used as the human DNA control.
DNA-BASED TESTING USING PROBES	
Paternity/Identity Standard 29 (PIT S29) Probes that are developed in-house shall be validated by family studies demonstrating Mendelian inheritance of the detected polymorphism and by extensive population studies.	

Parentage/Identity Testing	
Standard	**Guidance**
Paternity/Identity Standard 30 (PIT S30) For in-house developed methods, pre-hybridization, hybridization and autoradiography shall be carried out under empirically determined, and documented conditions of concentration and temperature determined by the nature of the probe as determined during the initial validation studies; Hybridization conditions shall minimize the possibility of cross-hybridization and maximize the specificity of binding between probe and test DNA; and, These studies shall be periodically verified	
Paternity/Identity Standard 31 (PITS 31)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 32 (PIT S32)	Standard has been deleted. Number reserved for future use.
DNA-BASED TESTING USING AMPLIFICATION	
Paternity/Identity Standard 33 (PIT S33)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 34 (PIT S34)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 35 (PIT S35) Primers shall be of known specificity and sequence. Conditions of time, temperature and concentration which optimize amplification product specificity or quantity shall be empirically determined, periodically verified and documented for each set of primers.	

Parentage/Identity Testing	
Standard	**Guidance**
Paternity/Identity Standard 36 (PIT S36)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 37 (PIT S37)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 38 (PIT S38)	Standard has been deleted. Number reserved for future use.
Paternity/Identity Standard 39 (PIT S39) For in-house developed methods, the number of amplification cycles determined during the initial validation studies shall be set at a level that minimizes the synthesis of extraneous DNA, but is sufficient to synthesize detectable levels of test DNA.	
Paternity/Identity Standard 40 (PIT S40)	Standard has been deleted. Number reserved for future use.
Human Leukocyte Antigen (HLA) Paternity/Identity (Standard 41-51)	Laboratories using HLA-typing for parentage testing must comply with Histocompatibility standards.
Blood Genetic Marker Paternity/Identity Testing (Standards 52-59)	Testing no longer being performed by laboratories and category deleted.
PROBABILITY, CALCULATIONS AND REPORTS	

Parentage/Identity Testing

Standard	Guidance
Paternity/Identity Standard 60 (PIT S60) Each laboratory shall establish an advisory committee on population statistics and calculation of probability of paternity, composed of persons with training and experience in statistics, population genetics, immunology and genetics.	
Paternity/Identity Standard 61 (PIT S61) The committee shall establish the procedures for computation of probability. Such procedures shall be reviewed at least annually.	
Paternity/Identity Standard 62 (PIT S62) The committee shall establish procedures to assure that gene and haplotype frequencies are obtained from examination of population of adequate size.	
Paternity/Identity Standard 63 (PIT S63) Computer assisted analyses shall be reviewed, verified and signed by a supervisor and/or laboratory director before issuance.	
Paternity/Identity Standard 64 (PIT S64) The method of calculation shall be validated.	
Paternity/Identity Standard 65 (PIT S65) If only manual calculations are performed, they shall be performed in duplicate.	

Parentage/Identity Testing

Standard	Guidance
Paternity/Identity Standard 66 (PIT S66) The report shall minimally contain the following information: a) the date(s) the samples were collected; b) the name of each individual tested and the relationship to the child; c) the racial origin(s) assigned by the laboratory to the mother and alleged father for the purpose of calculation; d) the phenotypes established for each individual in each genetic marker system examined; e) a statement as to whether or not the alleged father can be excluded; f) if an opinion of nonpaternity is rendered, the basis for the opinion shall be provided; g) if there is a failure to exclude, the report shall include: i. the paternity index for each genetic marker system reported; ii. the combined paternity index; and, iii. the probability of paternity, including the prior probability used to calculate the probability of paternity; h) an explanation of the nature of the problem, if the results are inconclusive; and i) the signature of the qualified person who reviewed, approved, and interpreted the test results.	g) iii) Most laboratories use a prior probability of 0.5. i) A qualified person is an individual holding a valid New York State certificate of qualification in the Parentage / Identity Testing category. Laboratories using electronic signatures should have a procedure in place that ensures and documents the qualified person's authorization for each signature occurrence (such as access limited by password).

Pathology

Standard	Guidance
All laboratories shall comply with applicable requirements of 10NYCRR Subparts 58-1.12 and 58-1.13. Additionally, the following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
Pathology Standard 1 (PA S1) Reports shall: a) include the signature of the pathologist who examined, reviewed and/or diagnosed the case; and b) indicate limitations of the result due to the laboratory not being provided with requested clinical information.	a) Laboratories using electronic signatures should have a procedure in place that ensures and documents pathologist authorization for each signature occurrence (such as access limited by password).
Pathology Standard 2 (PA S2) SOPM entries for specimen processing procedures shall include complete and distinct instructions for all phases of the process, including fixing, embedding, cutting, staining and cover-slipping.	Instructions for the preparation and use of solutions (including stains) should indicate direction of workflow, using, for example, flow charts or consecutive numbering of steps. Laboratories using instrumented slide preparatory methods (e.g., ThinPrep, SurePath) meet this standard by including in their SOPM the device's operating and maintenance protocols as approved by the FDA and issued by the device manufacturer.

Pathology

Standard	Guidance
Pathology Standard 3 (PA S3) To ensure proper specimen identification, the laboratory shall: a) not report on any slide or specimen unless it is identified by a unique patient identifier and anatomic site from which it was obtained; b) label all slides and specimens received with patient name or other unique identifier; and, c) have a procedure for follow-up when the clinical information on the requisition is inconsistent with the findings.	a) This requires the laboratory to be able to identify the source of material submitted for examination; it does not require the anatomic site to be on the slide or container at the time of acceptance. In addition to the information required by 10NYCRR Paragraph 58-1.12 (e) (5), gynecologic cytology requisition forms should solicit information on duration of current pregnancy, menopausal status and whether the patient is at risk for developing cervical cancer or its precursors.

Pathology

Cytopathology

Adopted Standard	Adopted Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
Cytopathology Sustaining Standard of Practice 1 (CY S1): Department Approval Laboratories that examine specimens submitted for cytologic evaluation must hold a valid permit in the category of Cytopathology.	
Cytopathology Sustaining Standard of Practice 2 (CY S2): Staining of Gynecologic Slides The laboratory shall use a Papanicolaou or modified Papanicolaou staining method for gynecologic cytology slides.	While the actual staining technique may vary depending on the type of stain used and the modification of the method, any modification must include the four main steps of the standard Papanicolaou method: fixation, nuclear staining, cytoplasmic staining, and clearing.
Cytopathology Sustaining Standard of Practice 3 (CY S3): Prevention of Cross Contamination Between Specimens During the Staining Process The laboratory shall ensure that: a) gynecologic and non-gynecologic cytology slides are stained separately; and b) non-gynecologic cytology slides that have high potential for cross-contamination are stained separately from other non-gynecologic slides, and the stains and solutions are filtered or changed following staining.	10 NYCRR Subparagraph 58-1.13(b)(3)(iii) requires separate staining of gynecologic and non-gynecologic slides. In general, all stains and solutions should be filtered or changed at intervals appropriate to the laboratory's workload to ensure staining quality meets the laboratory's pre-established criteria. b) A toluidine blue stain may be used to determine the cellularity of non-gynecologic specimens.

Cytopathology Sustaining Standard of Practice 4 (CY S4): Targeted Re-examination The laboratory must establish a system for targeted re-examination of at least 10 percent of gynecologic slides interpreted as negative for each cytotechnologist. Documentation of re-examination must be available in the laboratory for inspection by the Department. Cases must be randomly selected from the total caseload including patients who are at increased risk of developing cervical carcinoma, as determined based on clinical information and results of previous studies, if performed.	Slides reviewed as part of 10 percent re-examination must be included in the workload limit of the cytology supervisor or the cytotechnologist performing the re-examination.
Cytopathology Sustaining Standard of Practice 5 (CY S5): Reporting Results for Re-examined Slides For gynecologic cytology, the laboratory shall not release reports of results for slides selected for re-examination until the re-examination is completed and any discrepancies between initial examination and re-examination are resolved.	For this standard, re-examination includes the targeted re-examination required in Cytopathology Sustaining Standard of Practice 4.
Cytopathology Sustaining Standard of Practice 6 (CY S6): Comparison of Results The laboratory must compare: a) clinical information with cytology final reports, if available; and b) all gynecologic cytology reports with a diagnosis of high grade squamous intraepithelial lesion (HSIL), adenocarcinoma or other malignant neoplasms with the histopathology report, if available to the laboratory (either on site or in storage).	Cytology-histology correlation studies should be completed in a timely manner. In general, if cytology and biopsy specimens are obtained concurrently, both reports, as well as correlation studies, should be completed within one week. For workload calculations, retrospective cytology-histology correlation studies are for quality assurance purposes and are considered a non-screening activity. Any discrepancies or inconsistent findings must be reconciled.

Cytopathology Sustaining Standard of Practice 7 (CY S7): Diagnosis of HSIL Retrospective Review of Previous Gynecologic Slides For each patient with a current high grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm: a) the laboratory shall review all gynecologic slides received within the previous five years, including those that were interpreted as unsatisfactory, negative, or within normal limits, if available to the laboratory (either on-site or in storage); b) if significant discrepancies are found that could affect current patient care, the laboratory shall notify the patient's medical practitioner and issue an amended report. The laboratory's written procedures for retrospective review shall include time frames for completion; and c) results of initial examinations and all re-examinations must be documented.	Retrospective reviews have the potential for an amended report and are considered a screening activity. b) If discrepancies are found that would <u>not</u> affect <u>current</u> patient care, the laboratory need not issue an amended report, but need only document that finding in its records. "Could affect current patient care" minimally includes situations where an archived slide indicates upon re-examination: 1. a more serious disease state than that reported following initial examination, and/or abnormal cells identified upon re-examination are of a cell type different from those present on a current slide; or 2. an absence of disease, and abnormal cells were reported following initial examination.

Cytopathology Sustaining Standard of Practice 8 (CY S8): Laboratory Statistical Evaluations The laboratory must conduct and document an annual evaluation to determine the number of: a) cytology cases examined; b) specimens processed sorted by specimen type; c) cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); d) gynecologic cases with a diagnosis of high grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm for which histology results are available for comparison; e) gynecologic cases where cytology and histology are discordant; and f) gynecologic cases where any re-examination of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm.	

Cytopathology Sustaining Standard of Practice 9 (CY S9): Establishing a Workload Limit The laboratory director shall establish a maximum slide examination workload limit for each individual who performs primary screening (i.e., screener) and shall ensure that the examination workload limit is: a) not greater than 80 gynecologic slides examined per 24 hour period, in no less than 8-hour workday, calculated using calculation guidance set forth in Cytopathology Sustaining Standard of Practice 10; or b) a combined total of 100 gynecologic and non-gynecologic slides examined per 24 hour period, in no less than 8-hour workday, provided that the number of gynecologic slides does not exceed 80; the slide calculation is done using calculation guidance set forth in Cytopathology Sustaining Standard of Practice 10; 1) the 100 slide limit represents an absolute maximum and shall not be exceeded; c) prorated based on the actual number of hours spent examining; d) inclusive of the examination of slides at all sites or laboratories where the screener is employed; 1) records of the total number of slides examined by each individual who performs primary screening and the number of hours spent examining slides in a 24 hour period must be maintained by the laboratory, irrespective of the site or laboratory where the examinations are performed; e) assessed at least every six months, except that screeners using a semi-automated gynecologic cytology screening device shall be assessed at least every three months for the first year they use the device; and f) adjusted as necessary, and reasons for any adjustment are	Input from an assistant director responsible for cytopathology, supervisors, and pathologists performing testing onsite at the laboratory should be considered in establishing a workload limit. This slide examination workload limit is applicable to cytotechnologists and pathologists who examine previously unevaluated cytology slides. A period of 8 hours is used to prorate the number of slides that may be examined. Only the actual number of hours spent examining slides (excluding the time spent on non-screening duties and breaks) is used for calculation. Formula #1: (Number of hours examining slides X 80) ÷ 8 Formula #2: (Number of hours examining slides X 100) ÷ 8 Example: An individual who performs primary screening and spends 4 hours examining slides may examine a maximum of: • 40 gynecologic slides or • a combined total of 50 gynecologic and non-gynecologic slides, provided that the number of gynecologic slides does not exceed 40

documented.	
Cytopathology Sustaining Standard of Practice 10 (CY S10): Workload Calculation For purposes of calculating slide examination workload: a) gynecologic cytology slides prepared using a liquid-based slide preparatory methods and examined using manual screening shall be counted as 1 slide; 1) This includes slides screened using FDA-approved semi-automated gynecologic cytology screening device's full manual review feature; b) gynecologic cytology slides screened using an FDA-approved semi-automated gynecologic cytology screening device with field of view only review may be counted as 0.5 slide; c) gynecologic slides that are screened using both field of view and subsequent full manual review on a semi-automated gynecologic cytology screening device shall be counted as 1.5 slides; d) non-gynecologic cytology slides prepared using a liquid-based slide preparatory method that result in cell dispersion over one-half or less of the total available slide may be counted as 0.5 slide; and e) gynecologic and non-gynecologic slides prepared by conventional smear techniques shall be counted as 1 slide.	Liquid-based slide preparatory techniques include cytocentrifugation, filtering, and monolayering techniques, but not liquid-based cover slips. Any instrument used to assist in the adherence of cells to the slide is covered by this standard. "Field of view" is an identified microscopic area, selected based on processed image data from an entire scanned slide, presented to a screener for review by the screening device software.

Cytopathology Sustaining Standard of Practice 11 (CY S11): Establishing a Workload Limit: Measures of Performance The slide examination workload limit shall be established based on the screener's performance using assessment of the following, with documentation of assessments being retained for two years: a) comparison of the screener's interpretation with a pathologist's confirmation of patient slides, including gynecologic slides interpreted to exhibit reactive changes, reparative changes or epithelial cell abnormality, and all non-gynecologic slides; b) evaluation of each screener's interpretations against the laboratory's overall statistical values. Discrepancies must be documented, including the reason for any deviation and corrective action taken; and c) verification of negative cases, to include; 1) for cytotechnologists, a 10 percent re-examination by a pathologist, cytology supervisor, or cytotechnologist with three years of experience, of gynecologic slides interpreted as negative by the cytotechnologist; 2) for pathologists who perform primary screening, a method for verifying negative cases initially screened by them, such as exchanging slides with another pathologist or sending slides out for secondary review.	The laboratory director may delegate responsibility for screeners' assessment to an Assistant Director responsible for cytopathology. Input from supervisors and pathologists performing testing onsite at the laboratory should be considered. Screeners should be given an opportunity to discuss discrepancies. a) Refer to Cytopathology Sustaining Standard of Practice 13 (CY S13): Pathologist Review of Gynecologic Slides. b) The laboratory director, or assistant director responsible for cytopathology, shall determine the definition of a discrepancy for the laboratory.

Cytopathology Sustaining Standard of Practice 12 (CY S12): Exceeding Gynecologic Slide Workload Limit No screener shall exceed the slide examination workload limit without express written approval of the laboratory director. The director may consider increasing the gynecologic slide examination workload limit, for a particular screener who performs only gynecologic slide examinations, based on the screener's experience, documented accuracy assessed according to Cytopathology Sustaining Standard of Practice 11, and performance on proficiency testing. The upper limit of such approval is 96 gynecologic slides examined per 24 hour period, in no less than 8-hour workday, calculated using Cytopathology Sustaining Standard of Practice 10. This must include work performed at other laboratories.	This standard applies to all slides examined manually and/or using a FDA-approved semi-automated gynecologic cytology screening device. The director must notify the Department by submitting a Documentation of Increased Workload Limit Form for each screener.
Cytopathology Sustaining Standard of Practice 13 (CY S13): Pathologist Review of Gynecologic Slides A pathologist shall confirm interpretation of each gynecologic slide that has been interpreted as: a) Reactive or reparative changes; b) Atypical or suspicious squamous or glandular cells; c) Squamous Intraepithelial Lesion, low or high grade; d) Dysplasia; e) Cervical Intraepithelial Neoplasia; or f) Squamous cell carcinoma, adenocarcinoma or other malignant neoplasm.	The laboratory must specify the descriptive nomenclature used for reporting patient results. The Bethesda System is an example of a recognized system of narrative descriptive nomenclature for gynecologic cytology.

Cytopathology Sustaining Standard of Practice 14 (CY S14): Pathologist Examination of Non-gynecologic Slides All non-gynecologic slide preparations shall be examined by a pathologist.	
Cytopathology Sustaining Standard of Practice 15 (CY S15): Resolution of Discordant Interpretations The laboratory shall establish a procedure to resolve discrepancies whenever a slide is interpreted by more than one cytotechnologist and the interpretations are discordant.	
Cytopathology Sustaining Standard of Practice 16 (CY S16): Reporting Laboratory reports shall: a) use narrative descriptive nomenclature for all results; and b) for gynecologic cytology, indicate the semi-automated gynecologic cytology screening device used for examination, if any, and the slide preparation method used for such a device; 1) Laboratories that perform only examinations using manual screening need not indicate the method on the report.	Descriptive nomenclature must be specified. When cytotechnologists' interpretations are recorded on worksheets in "code", the laboratory should have a mechanism to ensure that the correct nomenclature is used in reporting results. This standard applies to devices approved by the FDA for primary (initial) gynecologic cytology screening. Manual screening means evaluation of material on a slide, performed by a person using a microscope, in a manner that allows visualization and evaluation of the entire viewable area of a slide. Viewable area for conventional slide preparation (a smear prepared by hand) is the entire slide. Viewable area for slides prepared using liquid-based slide preparatory techniques (e.g., an instrument deposits a monolayer of washed and re-suspended cellular material) is the circular or other area pre-marked on the slide.

Cytopathology Sustaining Standard of Practice 17 (CY S17): Correlation of Results Cytologic diagnosis of gynecologic and non-gynecologic cases must be correlated with the results of ancillary studies, if any.	Ancillary studies may include immunohistochemistry, flow cytometry and molecular studies.
Cytopathology Sustaining Standard of Practice 18 (CY S18): Results Retrieval The laboratory shall establish and implement a system for timely retrieval of results and other information pertinent to the generation of results.	Information pertinent to the generation of results, which includes, but is not limited to, instrument printouts of quality control data and archived review reports, shall be retained by the laboratory as required in 10NYCRR Subpart 58-1. In accordance with Records Retention Sustaining Standard of Practice 2: Reports, requests for reports must be fulfilled within 24 hours. Records that duplicate information on reports should be searchable numerically (accession number) and/or alphabetically (patient name).
Cytopathology Sustaining Standard of Practice 19 (CY S19): Transfer of Slides Documentation of slides referred for consultation must be maintained. Documentation of slides lent to a proficiency testing program or other entity, including an acknowledgment of receipt by the other party, must be maintained. All slides must be retrievable upon request.	

Pathology

Histopathology

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
Histopathology Standard 1 (HT S1) Every tissue specimen submitted for analysis shall be examined and reported by a pathologist	
Histopathology Standard 2 (HT S2) The laboratory shall use accepted terminology of a recognized system of disease nomenclature in reporting results.	
Histopathology Standard 3 (HT S3) A laboratory that performs only the tissue-processing component of a histopathology examination must hold a permit in the category of histopathology.	Procedures to identify non-infectious antigens, e.g., immunohistochemical staining of tissue, may be performed under a histopathology permit.
Histopathology Standard 4 (HT S4) The laboratory shall monitor paraffin containers on automated processors and/or hot paraffin cabinets for conformance with the defined temperature range for the paraffin in use.	Tissue flotation baths do not require temperature monitoring.

Pathology

Histopathology

Standard	Guidance
Histopathology Standard 5 (HT S5) Immunohistochemical and gram stains shall be checked for positive and negative reactivity with each patient slide or group of slides.	

Trace Elements

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Effective July 14, 2014	
Trace Elements Sustaining Standard of Practice 1 (TE S1): Method Detection Limit Calculation Initial validation of each element for each matrix shall include calculation of the method detection limit (MDL), and shall be based on the average of results from ten separate runs of the matrix blank or base level.	Calculation of the method detection limit may be based on the IUPAC convention of three standard deviations. If a matrix blank is unavailable, such as for essential nutrient elements, an alternative approach can be used (e.g., use of a low-level QC, matrix-matched calibration standard, reagent blank, etc.).
Trace Element Sustaining Standard of Practice 2 (TE S2): Materials Contamination Control The laboratory shall implement procedures to ensure that materials distributed for specimen collection and processing are free from significant contamination for each element tested.	To ensure that containers are free from contamination for each element tested, specimen collection tubes should be lot-tested and certified as trace element-free, or manufacturer-certified for trace element use. The laboratory should inform clients of proper collection techniques, including the importance of using appropriate trace element supplies Where appropriate, glassware and plastic ware used during the analysis should be acid-washed (e.g., in 10% (by volume) nitric acid). Alternatively, disposable glassware and plastic ware should be verified as contamination-free by randomly checking materials by lot.

Trace Elements

Standard	Guidance
Trace Element Sustaining Standard of Practice 3 (TE S3): Processing Contamination Control To minimize contamination errors during specimen collection and testing: a) work shall be performed in a clean area; and, b) specimen aliquots shall be protected from dust contamination before and during analysis.	a) Clean area refers to space that is dedicated to testing for trace elements, and is regularly cleaned by wet wiping flat surfaces. b) If a Class 100 clean room is unavailable, specimen aliquots should be protected by use of dust protection devices (e.g., furnace AAS carousels containing unanalyzed samples should be protected with dust covers before and during analysis)
Trace Elements Sustaining Standard of Practice 4 (TE S4): Order of Testing If venous blood specimens are collected for multiple analyses including trace element testing, a volume sufficient for the initial trace element test and any repeat analysis should be transferred to a trace element-free tube under clean conditions before any other processing or testing of the specimen.	Implementing this protocol may minimize specimen contamination from other testing areas. As an alternative, the testing for trace elements may be completed prior to other testing.
Trace Elements Sustaining Standard of Practice 5 (TE S5): Calibration On each day of testing, the laboratory must run a calibration curve that: a) includes a blank and at least 3 calibration standards; b) is matrix matched to the specimens being tested, unless validation studies indicate the absence of matrix effects; and c) is run at least every eight hours of testing, unless longer instrument stability is validated.	b) Dilution of a sample prior to analysis may not eliminate matrix effect. Validation studies must be preformed to verify that there is no change in the slope of the calibration if aqueous standards are used c) Less stable methods may require more frequent calibration.

Trace Elements

Standard	Guidance
Trace Elements Sustaining Standard of Practice 6 (TE S6): Quality Control The laboratory shall: a) ensure that the two levels of quality control in each test run for all non-essential toxic elements, include a normal and abnormal-high concentration; b) use matrix matched material; c) run at least one level of quality control at the end of each batch of specimens; and d) adjust the frequency of calibration based on quality control results.	c) a batch is an auto sampler tray or carousel.
Trace Elements Sustaining Standard of Practice 7 (TE S7): Unacceptable Specimens Whole blood specimens with visible clots, or urine specimens with visible blood or fecal materials, shall be rejected as unsatisfactory for analysis.	

Trace Elements

Standard	Guidance
Trace Elements Sustaining Standard of Practice 8 (TE S8): Repeat Analysis All trace element results that are above or below the laboratory's defined action threshold must be verified by repeat analysis. The laboratory shall: a) define action thresholds for abnormal-high and, where necessary, abnormal-low trace element levels except for those elements reportable under 10NYCRR Parts 22.6 and 22.7; b) establish criteria for the maximum discrepancy allowable which is consistent with proficiency testing performance criteria; and c) perform a third analysis when the discrepancy between the first two results is greater than the maximum allowed in (b) above.	A new aliquot from the original specimen should be used when reanalysis is performed. The action threshold is defined as that level where clinical intervention would be expected. For many trace elements, where there is no consensus on the clinical threshold for concern, the laboratory must define one and should be based on toxicity, deficiency or both. Repeat analysis is not required for values that fall within the normal reference interval. For non-essential trace elements, only values that exceed the upper threshold need to be repeated, while for essential elements, values that are either above the upper threshold (abnormal-high) or below the lower threshold (abnormal-low), must be repeated. Note that a lower threshold (abnormal-low) is not required for "non-essential" trace elements.
Trace Elements Sustaining Standard of Practice 9 (TE S9): Reporting Potential Contamination When a specimen is received in a collection container that is not certified as trace element-free, the report shall indicate that a non-certified trace element-free specimen collection was used and might produce a falsely elevated result.	When a specimen is received in a collection tube that is either not provided by the testing laboratory or not certified as trace element-free, the trace element result can be reported without comment when the element has no lower action level and the result is below the high action level.

Toxicology

Blood Lead – Comprehensive Testing

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Effective August 5, 2016.	Refer to 10NYCRR Subpart 67-3 for additional blood lead reporting requirements. Contact information for reporting blood lead is also found in Public Health Reporting Sustaining Standard of Practice 1 (Public Health S1).
Blood Lead Sustaining Standard of Practice 1 (BL S1): Materials Contamination Control The laboratory shall implement procedures to ensure that materials used for blood lead collection and processing are free from significant lead contamination.	Significant lead contamination refers to an amount of lead that would change the blood lead level by more than 1 microgram/dL. Blood collection tubes should be lot-tested, certified as lead-free, or manufacturer-certified for trace element use to ensure that containers are free from lead contamination. Collection tubes are suitable for use when the mean lead concentration or difference in blood lead is less than or equal to 0.5 micrograms/dL. Collection materials such as alcohol swabs and blood containers should be lead-free. The laboratory should inform clients of proper collection techniques, including the importance of patient hand washing prior to collection of capillary specimens. Glassware and plastic ware used during the analysis should be acid-washed (e.g., in 10% (by volume) nitric acid). Alternatively, disposable glassware and plastic ware should be verified as contamination-free by randomly checking materials by lot.

Toxicology

Blood Lead – Comprehensive Testing

Standard	Guidance
Blood Lead Sustaining Standard of Practice 2 (BL S2): Processing Contamination Control To minimize lead contamination during specimen collection and testing: a) work shall be performed in a clean area; and, b) specimen aliquots shall be protected from dust contamination before and during analysis.	a) Clean area refers to space that is dedicated to testing for lead and/or other trace metals, and is regularly cleaned by wet wiping flat surfaces. b) If an ISO 5 (a.k.a, Class 100) clean room is unavailable, specimen aliquots should be protected by use of dust protection devices (e.g., furnace AAS carousels containing unanalyzed samples should be protected with dust covers before and during analysis).
Blood Lead Sustaining Standard of Practice 3 (BL S3): Order of Testing If blood specimens are collected for multiple analyses including lead testing, a volume sufficient for the initial lead test and any repeat testing should be transferred to a lead-free tube under clean conditions before any other processing or testing occurs to the specimen.	Specimen contamination from other testing areas may be minimized by implementing this protocol. As an alternative, the test for blood lead can be completed prior to other testing.
Blood Lead Sustaining Standard of Practice 4 (BL S4): Calibration The laboratory shall perform instrument calibration: a) with a minimum of three standards plus a blank, or in accordance with the manufacturer's requirements where they exist specifically for blood lead analysis; and b) at least every eight hours of testing, unless longer instrument stability is validated.	

Toxicology

Blood Lead – Comprehensive Testing

Standard	Guidance
Blood Lead Sustaining Standard of Practice 5 (BL S5): Quality Control Three levels of quality control shall be included with each test run.	The controls should include a low (approximately 5 micrograms/dL), an intermediate (10 - 30 micrograms/dL), and a high (greater than 30 micrograms/dL) level material. The Department anticipates that these suggested ranges will be modified as control materials from commercial vendors that are in compliance with CDC recommendations become available. Laboratories with methods having an upper calibration limit of 30 µg/dL would only need to run an elevated control when diluting elevated samples ≥30 µg/dL.
Blood Lead Sustaining Standard of Practice 6 (BL S6): Unacceptable Specimens Blood specimens with visible clots shall be rejected as unsatisfactory for analysis.	
Blood Lead Sustaining Standard of Practice 7 (BL S7) **STANDARD DELETED**	

Toxicology

Blood Lead – Comprehensive Testing

Standard	Guidance
Blood Lead Sustaining Standard of Practice 8 (BL S8): Repeat Analysis All specimens which initially result in blood lead levels greater than or equal to 5 micrograms/dL shall be reanalyzed a second time if the volume of the original specimen permits. Use the average of the two consecutive test results to determine whether the discrepancy is large enough (see guidance for definitions) to require a third analysis. A third analysis shall be performed when: a) large discrepancies are obtained between two consecutive results; or b) initial test results are greater than 40 micrograms/dL.	A new aliquot from the original specimen should be used for the reanalysis. Specimen volume for capillary samples may be insufficient for retesting purposes. Large differences between two consecutive tests are defined as differences exceeding 3 micrograms/dL for blood lead levels 5 to 20 micrograms/dL; 4 micrograms/dL for values 21 to 40 micrograms/dL; or 10% for values exceeding 40 micrograms/dL. In these cases, the specimen should be analyzed a third time, the outlier result should be discarded and either report the average or the first obtained of the remaining results.
Blood Lead Sustaining Standard of Practice 9 (BL S9): Reporting Potential Contamination If a specimen is received in a blood collection container that is not certified for blood lead testing, and the result is above the reference value (≥ 5µg/dL), the report shall indicate that the use of unverified containers might produce a falsely elevated result.	When a specimen is received in a blood collection tube that is either not provided by the testing laboratory or not certified as lead-free and the blood level is less than 5 micrograms/dL, the blood lead result can be reported without comment. Trace element “free” tubes or containers that have been lot-tested in-house are acceptable alternatives to manufacturer certified blood lead tubes, and need not be footnoted in the test report.

Toxicology

Blood Lead – Comprehensive Testing

Standard	Guidance
Blood Lead Sustaining Standard of Practice 10 (BL S10): Potential for Fingerstick Contamination Elevated capillary blood lead levels (greater than 5 micrograms/dL) shall be reported with a comment that capillary blood levels greater than 5 micrograms/dL may be due to contamination from lead found on the finger surface and require confirmation with venous blood.	
Blood Lead Sustaining Standard of Practice 11 (BL S11): Single Use Devices Laboratories using blood lead analyzers that are based on single-use, disposable sensors i.e., ASV screen-printed electrode technology must follow the Blood Lead Standards for ASV Screen-Printed Sensors.	
Blood Lead Sustaining Standard of Practice 12 (BL S12): Reporting In addition to the report requirements defined in Reporting Sustaining Standard of Practice 1 (Reporting S1): Report Content, the laboratory report must contain: a) the methodology used in analysis; and b) for test results on exposed adults, a reference interval of <5 ug/dL.	

Toxicology

Blood Lead – ASV Screen-Printed Sensors

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Effective August 5, 2016.	Refer to 10NYCRR Subpart 67-3, for additional blood lead reporting requirements. Contact information for reporting blood lead is also found in Public Health Reporting Sustaining Standard of Practice 1 (PH S1). Laboratories using lead analyzers that are based on single-use, disposable sensors, i.e., ASV screen-printed electrode technology, must follow these standards. **Reference**: Guidelines for Measuring Lead in Blood Using Point of Care Instruments, Advisory Committee on Childhood Lead Poisoning Prevention, October 24, 2013. http://www.cdc.gov/nceh/lead/ACCLPP/20131024_POCguidelines_final.pdf

Toxicology

Blood Lead – ASV Screen-Printed Sensors

Standard	Guidance
Blood Lead ASV Sensors Sustaining Standard of Practice 1 (BLS S1): Materials Contamination Control The laboratory shall implement procedures to ensure that materials used for blood lead collection and processing are free from significant lead contamination.	Significant lead contamination refers to an amount of lead that would change the blood lead level by more than 1 microgram/dL. Blood collection tubes should be lot-tested, certified as lead-free, or manufacturer-certified for trace element use to ensure that containers are free from lead contamination. Collection tubes are suitable for use when the mean lead concentration or difference in blood lead is less than or equal to 0.5 micrograms/dL. Collection materials such as alcohol swabs and blood containers should be lead-free. The laboratory should inform clients of proper collection techniques, including the importance of patient hand washing prior to collection of capillary specimens. Glassware and plastic ware used during the analysis should be acid-washed (e.g., in 10% (by volume) nitric acid). Alternatively, disposable glassware and plastic ware should be verified as contamination-free by randomly checking materials by lot. Should an unexpected number of elevated blood lead test results occur, contamination from materials and/or containers would merit an investigation. Work with clinical health care providers to ensure proper collection techniques, including the importance of preparing the skin collection site prior to collection of capillary specimens.

Toxicology

Blood Lead – ASV Screen-Printed Sensors

Standard	Guidance
Blood Lead ASV Sensors Sustaining Standard of Practice 2 (BLS S2): Processing Contamination Control To minimize lead contamination during specimen collection and testing: a) work shall be performed in a clean area; and, b) specimen aliquots shall be protected from dust contamination before and during analysis.	a) Clean area refers to space that is dedicated to testing for lead and is regularly cleaned by wet wiping flat surfaces.
Blood Lead ASV Sensors Sustaining Standard of Practice 3 (BLS S3): Order of Testing If blood specimens are collected for multiple analyses including lead testing, a volume sufficient for the initial lead test and any repeat testing should be transferred to a lead-free tube under clean conditions before any other processing or testing of the specimen.	Specimen contamination from other testing areas may be minimized by implementing this protocol. As an alternative, the test for blood lead can be completed prior to other testing.
Blood Lead ASV Sensors Sustaining Standard of Practice 4 (BLS S4): Calibration The laboratory shall perform instrument calibration in accordance with the manufacturer's requirements.	
Blood Lead ASV Sensors Sustaining Standard of Practice 5 (BLS S5): Use of Capillary Blood If a capillary tube is used to collect a blood specimen, the laboratory must implement procedures to ensure there are no air-gaps present in the capillary during collection. Capillary blood specimens with visible clots shall be rejected as unsatisfactory for analysis	This specimen is appropriate for screening purposes only and is typically used with a point-of-care (POC) device. Consult the manufacturer's packaging / package insert(s) for additional details including the mixing of blood with anticoagulant reagents.

Toxicology

Blood Lead – ASV Screen-Printed Sensors

Standard	Guidance
Blood Lead ASV Sensors Sustaining Standard of Practice 6 (BLS S6): Use of Venous Blood When using a venous blood specimen for the analysis, the laboratory shall: a) Use blood tubes containing either ethylenediaminetetraacetic acid (EDTA) or heparin as anticoagulants during blood collection; b) reject specimens for anodic stripping voltammetry (ASV) analysis that are in EDTA tubes and are less than half full; c) use tan topped tubes (certified lead free), royal blue topped tubes containing EDTA (certified for a limited number of trace elements including lead) or other tubes, containing an anti-coagulant, which have been tested and found to be suitable for blood lead measurements; d) reject blood specimens with visible clots.	Venous blood is the preferred specimen for blood lead testing purposes. Refer to manufacturer's insert for instructions on sample mixing. Make sure to thoroughly mix the blood before withdrawing an aliquot for processing.
Blood Lead ASV Sensors Sustaining Standard of Practice 7 (BLS S7): Repeat Analysis All specimens which initially result in blood lead levels greater than or equal to 5 micrograms/dL shall be reanalyzed a second time if the volume of the original specimen permits. Use the average of the two consecutive test results to determine whether the discrepancy is large enough (see guidance for definitions) to require a third analysis. When large discrepancies are obtained between two consecutive test results, the laboratory must either: a) perform a third analysis; or; b) report test results as inconclusive and add a comment that there was insufficient specimen to repeat the analysis.	A new aliquot from the original specimen should be used for the reanalysis. Specimen volume for capillary specimens may be insufficient for retesting purposes. In this case, report initial result and refer patient for confirmatory testing (See BLS S9). Large discrepancies between two consecutive tests are defined as differences exceeding 3 µg/dL for blood lead levels 5 to 20 µg/dL; 4 µg/dL for values 21 to 40; or 10% for values exceeding 40 µg/dL. In these cases, the specimen should be analyzed a third time, the outlier result should be discarded and either report the average or the first obtained of the remaining results. For any result exceeding 5 µg/dL, or if there is any uncertainty in the validity of the test, the patient should be referred for confirmatory testing (See BLS S10).

Toxicology

Blood Lead – ASV Screen-Printed Sensors

Standard	Guidance
Blood Lead ASV Sensors Sustaining Standard of Practice 8 (BLS S8): Reporting Potential Contamination If a specimen is received in a blood collection container that is not certified for blood lead testing, and the result is above the reference value (≥ 5µg/dL), the report shall indicate that the use of unverified containers might produce a falsely elevated result.	When a specimen is received in a blood collection tube that is either not provided by the testing laboratory or not certified as lead-free and the blood level is less than 5 micrograms/dL, the blood lead result can be reported without comment. Trace element "free" tubes or containers that have been lot-tested in-house are acceptable alternatives to manufacturer certified blood lead tubes, and need not be footnoted in the test report.
Blood Lead ASV Sensors Sustaining Standard of Practice 9 (BL S9): Potential for Fingerstick Contamination Elevated capillary blood lead levels (greater than 5 micrograms/dL) shall be reported with a comment that capillary blood levels greater than 5 micrograms/dL may be due to contamination from lead found on the finger surface and require confirmation with venous blood.	

Toxicology

Blood Lead – ASV Screen-Printed Sensors

Standard	Guidance
Blood Lead ASV Sensors Sustaining Standard of Practice 10 (BLS S10): Confirmatory Testing with LeadCare and/or LeadCare II When blood lead concentrations greater than or equal to 5 micrograms/dL are obtained from a venous sample the laboratory must either: a) if sufficient sample remains, refer the specimen to a NYS-permitted laboratory holding the permit category of Toxicology – Blood Lead - Comprehensive for confirmatory testing by a high complexity reference method (ICP-MS or GFAAS); or b) indicate on the report the method used and that the result needs to be confirmed by a high complexity reference method (ICP-MS or GFAAS).	a) An unopened venous specimen is preferable for confirmatory testing. When this is not possible or feasible (e.g. with young children), and the confirmed result is also elevated, the confirming laboratory can acknowledge the issue on the test report. Test result comment example: "The test specimen may have been compromised during previous testing. Result should be confirmed with another venous blood specimen." b) Preliminary results may be released with a comment that results of confirmatory testing by a high complexity reference method are pending. b) Examples of reference methods include high complexity tests such as inductively coupled mass spectrometry (ICP-MS) and graphite furnace atomic absorption spectrometry (GFAAS). b) The following comment can be used on laboratory test reports to clinical health care providers: "For children 5 years old and younger, blood lead levels ≥5 µg/dl indicate that they may have been exposed to lead at levels higher than most children. The blood lead level should be confirmed using a venous blood sample and a NYS-permitted high complexity analytic method according the recommendations of the CDC Advisory Committee on Childhood Lead Poisoning Prevention. Since no safe BLL in children has been identified, no detectable level should be considered 'normal'."

Toxicology

Blood Lead – ASV Screen-Printed Sensors

Standard	Guidance
Blood Lead ASV Sensors Sustaining Standard of Practice 11 (BLS S11): Confirmatory Testing with LeadCare Plus or LeadCare Ultra When blood lead concentrations greater than or equal to 40 micrograms/dL are obtained from a venous sample the laboratory must either: a) if sufficient venous blood remains, refer the specimen to a NYS-permitted laboratory holding the permit category of Toxicology – Blood Lead - Comprehensive for confirmatory testing by a high complexity reference method (ICP-MS or GFAAS); or b) indicate on the report the method used and that the result needs to be confirmed by a high complexity reference method (ICP-MS or GFAAS).	a) An unopened venous specimen is preferable for confirmatory testing. When this is not possible or feasible (e.g. with young children), and the confirmed result is also elevated, the confirming laboratory can acknowledge the issue on the test report. Test result comment example: “The test specimen may have been compromised during previous testing. Result should be confirmed with another venous blood specimen.” a) Preliminary results may be released with a comment that results of confirmatory testing are pending. b) Examples of reference methods include high complexity tests such as inductively coupled mass spectrometry (ICP-MS) and graphite furnace atomic absorption spectrometry (GFAAS). b) The following comment can be used on laboratory test reports to clinical health care providers: “For children 5 years old and younger, blood lead levels ≥5 µg/dl indicate that they may have been exposed to lead at levels higher than most children. The blood lead level should be confirmed using a venous blood sample and a NYS-permitted high complexity analytic method according the recommendations of the CDC Advisory Committee on Childhood Lead Poisoning Prevention. Since no safe BLL in children has been identified, no detectable level should be considered ‘normal’.”

Toxicology

Blood Lead – ASV Screen-Printed Sensors

Standard	Guidance
Blood Lead ASV Sensors Sustaining Standard of Practice 12 (BLS S12): Method Comparison When specimens have been referred for confirmatory testing, laboratories must compare and maintain a log of blood lead results obtained from their device(s) with results reported using the confirmatory reference method.	Differences in results greater than 3 µg/dL for blood lead levels 5 to 20 µg/dL; 4 µg/dL for values 21 to 40 µg/dL; or 10% for values exceeding 40 µg/dL require further investigation. A review of competency assessments of testing personnel as well as data from quality control and proficiency testing can provide insights on testing performance.
Blood Lead ASV Sensors Sustaining Standard of Practice 13 (BLS S13): Reporting In addition to the report requirements defined in Reporting Sustaining Standard of Practice 1 (Reporting S1): Report Content, the laboratory report must contain: a) the methodology used in analysis; and b) for test results on exposed adults, a reference interval of <5 ug/dL.	

Toxicology

Erythrocyte Protoporphyrin

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
Erythrocyte Protoporphyrin Standard 1 (EP S1) Blood specimens with visible clots shall be rejected as unsatisfactory for analysis.	
Erythrocyte Protoporphyrin Standard 2 (EP S2) Specimens shall be protected from exposure to light.	Venous specimen collection tubes should be wrapped in aluminum foil. For extraction methods, analysis should be performed under subdued light.
Erythrocyte Protoporphyrin Standard 3 (EP S3) If specimens are routinely analyzed for erythrocyte protoporphyrin as a single replicate only, all specimens which initially result in erythrocyte protoporphyrin levels greater than or equal to 35 µg/dL shall be repeated a second time, and in addition, a third analysis shall be performed when: a) large discrepancies are obtained between two consecutive results; or, b) initial test results are greater than 100 µg/dL.	If the difference in results between the first and second specimen exceeds 15% for values of 35 to 100 µg/dL, the specimen should be analyzed a third time. The outlier result should be discarded and the two remaining values averaged and reported.

Toxicology

Erythrocyte Protoporphyrin

Standard	Guidance
Erythrocyte Protoporphyrin Standard 4 (EP S4) If specimens are routinely analyzed for erythrocyte protoporphyrin in duplicate (or triplicate, etc.), e.g., with acid extraction methods, repeat testing shall be performed when a discrepancy exists between the replicate results.	Such a discrepancy is defined as: a) A difference greater than 6 µg/dL between two replicate values for erythrocyte protoporphyrin values greater than 40 µg/dL; or, b) A difference of 15% between two replicate values for erythrocyte protoporphyrin values of greater than or equal to 40 µg/dL.

Toxicology

Clinical Toxicology

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Effective August 5, 2016.	
Clinical Toxicology Standard 1 (CT S1) Laboratories holding a Toxicology - Clinical Toxicology - Comprehensive permit shall either: a) maintain the ability to confirm presumptive positive results on-site by a quantitative confirmatory method; or b) report the presumptive positive result as unconfirmed; or c) refer the specimen to another laboratory holding a New York State permit in Toxicology - Clinical Toxicology – Comprehensive for confirmation by a quantitative method.	
Clinical Toxicology Standard 2 (CT S2) Laboratories holding a Toxicology - Clinical Toxicology – Qualitative Testing Only permit shall either: a) clearly state on the report that all presumptive positive findings are unconfirmed; or b) refer the specimen to a laboratory holding a New York State permit in Toxicology - Clinical Toxicology – Comprehensive for confirmation by a quantitative confirmatory method.	
Clinical Toxicology Standard 3 (CT S3) Reports shall state the assay cutoff levels.	

Toxicology
Forensic Toxicology

The standards set forth below apply to the analysis of specimens collected from the human body for drugs and chemicals where the legal defensibility of laboratory services must be established and maintained. Relevant laboratory services include workplace drug testing programs and medico-legal investigations, including human performance testing and postmortem toxicology, where such medico-legal investigations are conducted by private sector laboratories. Public sector forensic toxicology laboratories must be approved under Executive Law, Article 49-B for services provided to the criminal justice system.

Laboratories engaged in the practice of forensic toxicology must be compliant with requirements under each of the following Fundamental Standards of Practice: Quality Management System; Human Resources; Facilities and Resource Management; Pre-Examination, Examination and Post-Examination Procedures; and Quality Assessment and Improvement. The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided. Effective March 2008, FT S12 revised and effective July 14, 2014; FT S19 and FT S23 revised and effective August 5, 2016; FT S27, FT S35, FT S38 and FT S37 revised and effective October 1, 2017.	During the on-site visit, the surveyor will request a copy of a litigation package for a randomly selected positive donor sample to be submitted for Departmental review.

Forensic Toxicology
Workplace Drug Testing

Standard	Guidance
Specimen Collection and Handling, Laboratory Security Standards FT S1 through FT S9 apply to laboratories holding either an Initial Testing or Comprehensive Permit	
Forensic Toxicology Sustaining Standard of Practice 1 (FT S1): Specimen Collection Facility All collection sites from which the laboratory accepts donor specimens shall have the following: a) a clean surface for handling the specimen and suitable for completing the required paperwork; b) a secure temporary storage capability to maintain a specimen, including sealing of the specimen, until it is tested or shipped to the laboratory; c) a space to provide donor privacy appropriate to the specimen being collected; d) a means of restricting access to authorized personnel during the collection; e) ability to restrict access to collection supplies; f) ability to store records securely; and g) a complete SOPM on the collection and handling of donor specimens.	The laboratory shall have a written agreement with the collector, which may be another laboratory under permit, that defines the testing laboratory's procedures and requirements for specimen collection and chain of custody. A structured training and certification program provided by the laboratory to the collection sites should be considered to enhance the integrity of the specimen collection process. Where the testing laboratory provides the facilities for the collection of donor specimens, the laboratory director or designee shall verify through on-site quality audits that the collection site is appropriately designed and managed for compliance with this standard. Where collection sites are not operated by the testing laboratory, quality-audits of specimen submissions should be conducted and findings used for intervention when collection problems are identified.

Forensic Toxicology
Workplace Drug Testing

Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 2 (FT S2): Specimen Collection Procedures The laboratory shall have an SOPM for specimen collection that minimally includes: a) a description of acceptable forms of verification of donor identity; b) The explanation and/or instructions to be given to the donor concerning the collection procedure; c) a description of the measures to be taken to remove opportunities for specimen adulteration or substitution; d) a clear statement that viewing of the specimen at all times by donor and collector prior to sealing the specimen container is required; e) a clear statement that use of tamper evident label/seal to secure the specimen, annotated by donor initials and date of collection by collector, is required; f) directions for completing the custody and control form (CCF) (test requisition); and g) directions for linkage of the specimen to the donor and the completed CCF.	Laboratories are encouraged to use the federal Department of Health and Human Services *Specimen Collection Handbook for Federal Workplace Drug Testing Programs* (available for download from the DHHS website, http://dwp.samhsa.gov) and the Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs as guides in establishing policies and procedures for specimen collection. f) The custody and control form (CCF), when used as a test requisition, must 10 NYCRR Section 58-1.7 requirements, except that cross-reference to a standing order or client roster that allows identification of tests ordered for each donor may be used instead of listing tests on the CCF form. g) The signed CCF and the specimen container may be linked by bar-code or other unique identifier, preferably through use of evidence tape with the same unique number as on the CCF and affixed to the CCF for use at time of specimen collection.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 3 (FT S3): Specimen Acceptance Criteria The testing laboratory shall: a) monitor the completeness and adequacy of collection documents submitted with donor specimens; b) ensure that specimens are submitted for analysis in a sealed container, the seal of which is to be broken by the laboratory; c) ensure that the condition of the specimen container seal is documented upon receipt in the laboratory; d) notify collectors when problems are identified and document remediation; and, e) provide collectors a copy of the SOPM for specimen collection and training materials.	Monitoring compliance could be a QA indicator. The testing laboratory should ensure, to the extent practicable, that collectors are adequately trained on the collection procedure for each type of specimen, including donor identification and instruction, specimen identification, chain-of-custody, and record keeping. The laboratory should offer additional training to address a documented pattern of non-compliance with laboratory collection policies.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 4 (FT S4): Specimen Acceptance Criteria The laboratory shall develop criteria for the acceptability of donor specimens that are consistent with federal Workplace Drug Testing Program criteria. Such criteria shall be documented and available at collection and testing sites, and shall: a) identify the attributes of an acceptable specimen, including the amount of specimen, identification, temperature (urine), seal(s) condition, collector's signature, and complete documentation of chain-of-custody; and b) identify fatal flaws as including, but not limited to i. mismatch between the specimen ID number on the container and the number on the CCF; ii. lack of a specimen ID number on the container and/or CCF; iii. missing collector signature and printed name; iv. missing or broken tamper-evident seal on the specimen container; and v. insufficient specimen to conduct the required analyses. c) identify collection errors that can be recoverable through affidavit from the collector. d) describe course of action taken whenever the criteria for acceptability are not met.	These policies and procedures must be documented as part of the SOPM. a) The required amount of specimen should be adequate for retesting should a retest be ordered. b) CCFs that lack collector signature and/or documentation that specimen temperature was acceptable may be recoverable.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 5 (FT S5): Specimen Collection Recoverable Errors Specimens that fail to meet one or more criteria for acceptability shall not be tested, except that the laboratory may test such a specimen if: a) the specimen is not able to be re-collected under circumstances that duplicate those under which the rejected specimen was collected, considering the purpose of the testing, and the test findings are expected to be analytically sound and legally defensible; b) for urine specimens, the CCF does not document that specimen temperature was acceptable, the laboratory has requested a memorandum for record (MFR) from the collector stating that specimen temperature was within the acceptable range; c) the collector's signature is absent, the laboratory has requested a MFR signed by the collector attesting to his or her collection of the specimen; and, d) the CCF does not contain the name of the ordering physician, the laboratory has requested a MFR from the collector with the name of the physician.	a) For example, specimens for random drug testing can be recollected, while specimens obtained at the scene of an accident cannot be recollected. Incident-related specimens typically cannot be duplicated by a collection later in time. Fatal flaw exemptions for specimen rejection may include limited specimen amounts and missing collector identifiers. The test report must include a statement that acknowledges the collection flaws. b,d) The MFR should be on record with the laboratory prior to reporting test findings, and should be retained attached to the CCF. Test findings may be reported with comment if the urine specimen temperature is not recovered by MFR.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 6 (FT S6): Internal Chain of Custody The laboratory shall use chain-of-custody procedures to document, minimally: a) the identification of all persons handling the specimen, aliquot or batch; b) the date of each receipt, handling and transfer and/or action upon the specimen, aliquot or batch; c) the purpose of the action/transaction, including accessioning, temporary storage, analysis, long-term storage, and disposal; and d) chain of custody documentation shall be completed at the time of each action.	Chain of custody documentation may be either hard copy or electronic. Whenever chain-of-custody procedures are applied to batches of specimens and aliquots, the form used to document chain-of-custody shall identify all specimens/aliquots included in the batch, either individually, or using a range of accession numbers.
Forensic Toxicology Sustaining Standard of Practice 7 (FT S7): Laboratory Security The laboratory shall implement security measures that preserve the integrity of specimens, aliquots and analytical records, including: a) a list of authorized personnel for each section of the laboratory where specimens, aliquots and records of analyses are received and stored, and analysis is performed; b) access for authorized personnel shall be limited according to such listing by the use of physical barriers and/or locks; c) authorized personnel shall sign in and out using log book or electronic record minimally each workday; d) sign-in, sign-out and continuous escort procedures for individuals with legitimate reasons for gaining access (e.g., telephone repair technicians); and e) a system to detect any security breach.	Laboratories that perform clinical and forensic testing in the same area may designate a time when the area used for analysis will be open only to authorized personnel and closed to general laboratory personnel. For example, security measures such as key codes and/or locks prevent a technician whose job duties are limited to screening from accessing other testing and/or storage areas. Authorized personnel are employees who have received training in forensic principles and practices as appropriate for assigned duties, and are duly authorized by the director. Access records for authorized personnel need not document each entrance and exit into testing space, such as lunch and other breaks. Security and access records may be maintained either as hardcopy or in an electronic format.

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Standard	**Guidance**
Forensic Toxicology Sustaining Standard of Practice 8 (FT S8): Specimen Storage The laboratory shall hold original specimens in a dedicated, secured space, under conditions necessary to ensure specimen integrity, until the specimens are discarded. Specimen chain-of-custody for stored specimens must be maintained, including annotations for specimen discard.	The secure space could be a locked room or a locked refrigerator. The laboratory director should minimize the number of personnel with authorized access to this area (e.g., for preparing aliquots for testing, or for other reasons explicitly approved by the laboratory director, such as retrieval for re-testing). Access and purpose must be documented.
Forensic Toxicology Sustaining Standard of Practice 9 (FT S9): Aliquot Discard Aliquots shall not be returned to the original container.	

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 10 (FT S10): Initial Test Validation Laboratory validation of an initial drug test, in addition to meeting the requirements of *Validation Sustaining Standard 5 (VAL S5): Performance Specifications*, shall be designed to verify manufacturer claims for performance around the cutoff, and shall, for assays that are not single-use devices, assess the laboratory's ability to detect and correct any carryover that might occur between aliquots. Validation shall minimally be as follows: a) The accuracy, precision and linearity shall be evaluated through *replicate* analyses of specimens prepared to contain target drug(s) and/or metabolite(s) at assay cutoff concentration and, minimally, at approximately 50%, 75%, 125% and 150% around the cutoff; except that: b) for assays where a qualitative endpoint result is obtained by visual inspection: i. the accuracy and the ability to differentiate positive and negative specimens shall be evaluated with drug-free specimens and with specimens prepared to contain target drug(s) and/or metabolite(s) at 50%, 75%, 125% and 150% of the cutoff concentration; and, ii. variability in the interpretation of the endpoint among analysts shall be assessed.	Documentation of method validation should clearly record the study design, analytical findings and conclusions. As used in this standard, "cutoff" is the analyte concentration used to set a threshold analytical response to distinguish negative from non-negative analytical responses.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 11 (FT S11): Initial Test Quality Control For initial test methods that require periodic calibration, each batch prepared for analysis shall contain, minimally, 10% calibrators and/or quality control samples as follows: a) at least one certified to contain no drug or metabolite; b) at least one with drug or metabolite at 25% above the cutoff concentration; c) at least one with drug or metabolite at 25% below the cutoff concentration; and d) blind samples so as to comprise at least one percent of the batch.	d) A blind sample is quality control material that is indistinguishable, by the analyst, from samples submitted for routine analysis

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 12 (FT S12): Single-Use Device Quality Control Quality control for initial test methods that employ single-use devices shall be conducted using at least one control certified to contain no drug or metabolite and at least one control with drug or metabolite at 25 percent above the cutoff concentration as follows: a) each day testing is performed; or, b) for devices with integrated function checks that are designed and verified to monitor device performance under relevant environmental conditions and variance in operator performance, the laboratory may develop an individualized quality control plan, however external quality control must be analyzed at a minimum frequency of 10 percent of each lot of devices, scheduled to effectively monitor device stability over the period that the lot remains in use; or c) for validity point-of-collection tests, each day testing is performed, at least one control that is normal for the specific validity test and one control that is abnormal must be tested. The results must be correct before donor specimens are tested.	b) The laboratory should refer to device stability studies as a guide in scheduling QC over the period that a lot remains in use.
Forensic Toxicology Sustaining Standard of Practice 13 (FT S13): Single-Use Device Quality Control, Referral of Negative Specimens Quality control for initial test methods that employ single-use devices shall include re-testing, by a laboratory holding a Forensic Toxicology - Comprehensive permit, of at least one of every 50 donor specimens (2%) that test negative, and discrepant results shall be investigated.	

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 14 (FT S14): Single-Use Device Quality Control, Operator Variance The laboratory shall ensure that each analyst that conducts testing using single-use devices participates in the quality control program, and such participation shall be documented.	For example, if there are five analysts, the analysis of the negative and positive control specimens should be cycled through each analyst.
Forensic Toxicology Sustaining Standard of Practice 15 (FT S15): Single-Use Device Workflow Whenever testing with single use devices is conducted contemporaneously with specimen collection, all pre-examination (donor preparation, specimen collection and accessioning), examination, and post-examination (certification and reporting of results) procedures shall be completed for this donor before the collector begins the subsequent donor encounter.	Such procedure shall be included in the laboratory's instructions to collectors for specimen collection and analysis.
Forensic Toxicology Sustaining Standard of Practice 16 (FT S16): Referral of Non-Negative Specimens Laboratories holding a permit in Forensic Toxicology - Initial Testing Only shall refer under chain of custody, for confirmation testing, to a laboratory that holds the Forensic Toxicology – Comprehensive permit: a) specimens that test non-negative for drug(s); and, b) if initial specimen validity testing is performed, specimens that meet the initial test criteria for adulteration or substitution.	Laboratories permitted for initial testing only may report a specimen as dilute if the specimen tested negative for drugs and the criteria for a dilute specimen are met. See Forensic Toxicology Sustaining Standard 33 (FT33).

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 17 (FT S17): Specimen Preparation for Referral Laboratories holding a permit in Forensic Toxicology - Initial Testing Only shall re-seal collection containers and initiate chain-of-custody documentation before sending such containers for confirmatory testing to a laboratory that holds the Forensic Toxicology – Comprehensive permit.	This standard applies to devices that require chain-of-custody seals to be broken for removal of an aliquot for testing. Re-capping alone is not re-sealing; re-sealing means applying a new evidence seal (e.g., evidence tape) that is initialed by the person preparing the container for transfer.

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Standard	Guidance
Confirmation Testing These standards apply to laboratories holding the Forensic Toxicology - Comprehensive Permit	
Forensic Toxicology Sustaining Standard of Practice 18 (FT S18): Confirmation Testing Method Principle Confirmation testing shall be performed using: a) a new aliquot of the specimen taken from the original container; and, b) b) a method that differs in physical and/or chemical principle from the initial (screening) test, and where possible a procedure that combines chromatographic separation and mass spectrometric identification, or other detection method acceptable to the department.	Confirmatory testing definitively identifies the presence of a specific drug and/or its metabolite(s) to refute or substantiate the finding of the initial test. a) The aliquot used for initial testing, substitution or adulteration testing is not acceptable for confirmatory testing, with the possible exception of specimens that cannot be re-collected, such as incident-related specimens, i.e., specimens obtained at the scene of an accident b) If there exists no generally accepted confirmatory assay that employs chromatography and mass spectrometry, department approval is required if the laboratory wishes to use an alternative method for confirmation**.** Laboratories should submit validation packages as described in the Submission Guidelines, copies of which may be downloaded from www.wadsworth.org/clep.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 19 (FT S19): Confirmation Method Periodic Re-Validation In addition to the initial validation of confirmatory test methods, the laboratory shall demonstrate, annually thereafter, the following performance characteristics: a) accuracy and precision at the cutoff concentration; b) accuracy and precision at 40 percent of the cutoff concentration; c) upper limit of linearity; d) limit of detection; e) limit of quantification; f) analytical specificity; and, g) carryover.	Documentation of method validation, as required by Validation Sustaining Standard 2 (VAL S2): Use of Validated Procedures, must clearly state the study design, the analytical findings, conclusions, and source of specimens and how they were characterized. Limit of quantification means the lowest concentration of analyte that can be identified (mass spectrometric criteria for identification are met) and measured within assay performance specifications for accuracy. Limit of detection means the lowest concentration of analyte that can be identified (mass spectrometric criteria for identification are met), but not quantified within performance specifications (typically, +/- 20%). Analytical specificity validation should entail the analysis of validation materials that contain the target drug at 40% cutoff and potentially interfering drugs at high concentrations consistent with overdose.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 20 (FT S20): Confirmation Method Calibration a) the laboratory shall maintain a record of the purity of all drug standard(s) for the period they are in use, and for two years thereafter. b) calibration and/or control materials prepared from standards must be validated for drug concentration before being placed into use. c) where calibration materials do not replicate the state of drug in the biological matrix being analyzed (e.g., calibrators for hair analysis), the laboratory must verify the accuracy of assay calibration through analysis of reference materials (e.g., NIST or PT survey-validated), or when such materials are not available, through comparative analyses with a method approved by the Department. d) Control materials must be prepared using a different source or lot of standard than used in the preparation of calibrator.	Calibrators and/or control materials prepared using the standards must be linked by lot number and dates of preparation.
Forensic Toxicology Sustaining Standard of Practice 21 (FT S21): Mass Spectrometer Function Checks Mass spectrometer(s) shall undergo function checks, including tuning, at a frequency recommended by the manufacturer or established by the laboratory where the laboratory determines that function checks need to be performed more frequently. The laboratory's review of data to determine compliance with established function check criteria shall be documented.	The SOPM should contain the criteria for acceptable function checks, which may be the manufacturer's criteria or more stringent criteria established by the laboratory.

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 22 (FT S22): MS Full Scan Identification Full scan identification of analytes, if used, shall be accomplished using a mass spectra reference library established by the laboratory using authentic standards on the instrument used for specimen analysis, or using a commercially available library that has been verified by the laboratory.	
Forensic Toxicology Sustaining Standard of Practice 23 (FT S23): Confirmation Method Quality Control Each batch of specimens for confirmatory testing shall contain, minimally, 10% calibrators and/or quality control samples as follows: a) at least one control certified to contain no drug or metabolite; b) at least one control with drug or metabolite concentration at 25 percent above the cutoff concentration; c) at least one control or calibration material with drug or metabolite concentration at or less than 40 percent of the cutoff concentration; and, d) a control to assess the efficiency of hydrolysis, where appropriate.	

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Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 24 (FT S24): Chromatographic Criteria and Analyte Identification The laboratory shall establish and document its criteria for: a) the quality of chromatography; b) the identification of the analyte and the determination of its concentration; and, c) the detection and correction of carryover.	a) Quality of chromatography includes peak symmetry and peak resolution. b) When performing selected ion monitoring after electron ionization, a minimum of three ions must be monitored for the target analyte and a minimum of two ions for the internal standard. Ion ratios of qualifier ions should be within 20% of the target ion ratio determined from the assay calibrator(s). Ion ratios for soft-ionization techniques (chemical ionization) should be within 25% of the appropriately established target ion ratio where the reproducibility of ion-relative abundances may be expected to be less than that for electron ionization. When monitoring one precursor to get one product ion in tandem mass spectrometry, the resolution of the first mass analyzer should be set to unity. If multiple ions are monitored, ion ratios should be within 25% of the appropriately established target ion ratio.
Forensic Toxicology Sustaining Standard of Practice 25 (FT S25): Retest Specimen Assay Requirements When analyzing retest specimens, the laboratory shall: a) use a method with a limit of detection that is no greater than 40% of the confirmation assay cutoff used in the original analysis; and, b) limit its analysis to the drug(s) that were detected in the original analysis and to specimen validity testing.	A retest specimen is one that has been reported as a confirmed positive and has been questioned by the donor or physician (MRO), and has been authorized for reanalysis by the physician (MRO). The laboratory that receives a request for a retest to be performed by another laboratory must ensure that the laboratory is approved, forward the specimen under chain-of-custody, and supply a copy of the original confirmatory report. Refer to Forensic Toxicology 23 (FT S23): Confirmation Method Quality Control for QC requirements.

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Standard	Guidance
Specimen Validity Testing Analytical protocols and interpretive criteria for specimen validity testing (SVT) must have rigor and defensibility equivalent to that of protocols for the forensic detection of abused substances. The National Laboratory Certification Program has conducted and/or reviewed extensive studies on the physiochemical characteristics of biological specimens and has established criteria for the interpretation of SVT test findings. Laboratories that perform SVT should adopt testing, quality control and reporting requirements as provided in the Mandatory Guidelines. The Guidelines were published on October 1, 2010, and are available at http://www.samhsa.gov/workplace/resources/drug-testing/archive-guidelines-forms. Please note that the test findings from specimen validity testing (creatinine and specific gravity) may not be reported for purposes of clinical diagnosis or management.	
Forensic Toxicology Sustaining Standard of Practice 26 (FT S26): SVT Validation Validation protocols for specimen validity testing shall include, as applicable: a) characterization of the analytical accuracy, precision and linearity around the cutoff concentration; b) establishment of the limit of quantitation (LOQ) for quantitative tests and/or the limit of detection (LOD) as appropriate for the test performed; c) investigation of the analytical specificity of tests for specific adulterants; and, d) establishment of procedures to control for possible carryover.	Specimen validity testing means procedures to detect adulteration, substitution and/or dilution. Biomarkers may also be used to establish the authenticity of the specimen such as immunoglobulins (IgG) in collected oral fluid specimens. Documentation of method validation should clearly record the study design, analytical findings and conclusions.

Forensic Toxicology Sustaining Standard of Practice 27 (FT S27): Urine SVT Calibration and QC Requirements	
For **urine specimen validity testing**, each batch of donor specimens must include the following calibrators and controls for tests performed by the laboratory as follows:	Laboratories that hold the Forensic Toxicology –Initial Testing Only permit may conduct tests for specimen validity; however, in accordance with Forensic Toxicology Sustaining Standard 16 (FT S16): Referral of Non-Negative Specimens, any specimen (including negatives) identified as adulterated, substituted or invalid must be forwarded to an approved laboratory for additional testing to confirm adulteration or substitution before any finding can be reported. Negative, dilute specimens need not be referred.
Creatinine a) creatinine initial test: i) a calibrator at 2 mg/dL; ii) a control in the range of 1.0 mg/dL to 1.5 mg/dL; iii) a control in the range 3 mg/dL to 20 mg/dL; and, iv) a control in the range 21 mg/dL to 25 mg/dL. b) creatinine confirmatory test: i) a calibrator at 2 mg/dL; ii) a control in the range of 1.0 mg/dL to 1.5 mg/dL; and iii) a control in the range 3 mg/dL to 4 mg/dL. c) the creatinine concentration must be measured to one decimal place on both the initial and confirmatory tests.	Laboratories that hold the Forensic Toxicology – Initial Testing Only permit and conduct validity point-of-collection tests, each day testing is performed, at least one control that is normal for the specific validity test and one control that is abnormal must be tested. The results must be correct before donor specimens are tested. See Forensic Toxicology Sustaining Standard 12 (FT S12): Single-Use Device Quality Control.
Specific Gravity d) specific gravity initial and confirmatory tests: i) a calibrator at 1.0000; ii) a control targeted at 1.0020; iii) one control in the range 1.0040 to 1.0180; iv) one control greater than or equal to 1.0200 but not greater than 1.0250.	a) Donor specimens determined by the initial test to have a creatinine concentration less than 2 mg/dL must be repoured for confirmatory testing.
e) the refractometer must display to a minimum four decimal places	e) Federal Mandatory Guidelines and the Department require the refractometer to display to four decimal places.
pH f) pH Screen: i) one control below the lower decision point in use, ii)one control in the pH range 4.5 to 9; and, iii)one control above the upper decision point in use.	f) pH Screening Assay: Colorimetric pH tests, dipsticks, and pH paper that have a narrow dynamic range and do not support the cutoffs for specimen adulteration (pH less than 3 or greater than or equal to 11) may be used only to determine if an initial pH validity test must be performed;
g) pH initial test (colorimetric): i) one calibrator at 4; ii) one calibrator at 11; iii) one control in the range of 3 to 3.8; iv) one control in the range 4.2 to 5; v) one control in the range of 5.0 to 9; vi) one control in the range of 10 to 10.8; vii) one control in the range of 11.2 to 12;	g) Colorimetric pH tests that have the dynamic range of 2 to 12 to support the 3 and 11 pH cutoffs must be capable of measuring pH to one decimal place.

h) pH initial test (pH meter): i) one calibrator at 3; ii) one calibrator at 7; iii) one calibrator at 10; iv) one control in the range of 3 to 3.8; v) one control in the range 4.2 to 5; vi) one control in the range of 10 to 10.8; vii) one control in the range of 11.2 to 12. i) pH initial or confirmatory test (pH meter test), when the screening result indicates that the pH is below the lower decision point in use: i) one calibrator at 4; ii) one calibrator at 7; iii) one control in the range of 3 to 3.8, iv) one control in the range 4.2 to 5. j) pH initial or confirmatory test (pH meter test), when the screening result indicates that the pH is above the upper decision point in use: i) one calibrator at 7; ii) one calibrator at 10; iii) one control in the range of 10 to 10.8; iv) one control in the range 11.2 to 12.	The pH meter may be used for the initial test, and where a pH screen was not performed to establish whether the specimen pH is high or low, the pH meter must be calibrated and quality control performed for the full range of pH.
Nitrite k) **i**nitial and confirmatory nitrite tests must have: i) a calibrator at the cutoff concentration, ii) a control without nitrite (i.e., certified negative urine), iii) one control in the range of 200 mcg/mL to 250 mcg/mL, and iv) one control in the range of 500 mcg/mL to 625 mcg/mL;	
Oxidizing adulterant tests (other than nitrite): l) initial tests must include: i) an appropriate calibrator at the cutoff used by the laboratory for the compound of interest, ii) a control without the compound of interest (i.e., a certified negative control), and iii) at least one control with one of the compounds of interest at a measurable concentration; and m) confirmatory tests must: i) use a different analytical method than that used for the initial test, ii) include an appropriate calibrator,	l) The laboratory should design calibration and quality control protocols to be consistent with those provided in the Mandatory Guidelines for Federal Workplace Drug Testing Programs when detecting the presence of general oxidants, chromium (VI), halogens, glutaraldehyde, pyridine (pyridinium chlorochromate) and surfactants.

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iii) include a control without the compound of interest (i.e., a certified negative control), and iv) include a control with the compound of interest at a measurable concentration.	

pH f) pH Screen: i) one control below the lower decision point in use, ii)one control in the pH range 4.5 to 9; and, iii)one control above the upper decision point in use. g)pH initial test (colorimetric): i) one calibrator at 3; ii) one calibrator at 11; iii) one control in the range of 2 to 2.8; iv) one control in the range 3.2 to 4; v) one control in the range of 4.5 to 9; vi) one control in the range of 10 to 10.8; vii) one control in the range of 11.2 to 12; h)pH initial test (pH meter): i) one calibrator at 4; ii) one calibrator at 7; iii) one calibrator at 10; iv) one control in the range of 2 to 2.8; v) one control in the range 3.2 to 4; vi) one control in the range of 10 to 10.8; vii) one control in the range of 11.2 to 12. i) pH initial or confirmatory test (pH meter test), when the screening result indicates that the pH is below the lower decision point in use: i) one calibrator at 4; ii) one calibrator at 7; iii) one control in the range of 2 to 2.8; iv) one control in the range 3.2 to 4. j) pH initial or confirmatory test (pH meter test), when the screening result indicates that the pH is above the upper decision point in use: i) one calibrator at 7; ii) one calibrator at 10; iii) one control in the range of 10 to 10.8; iv) one control in the range 11.2 to 12.	f) pH Screening Assay: Colorimetric pH tests, dipsticks, and pH paper that have a narrow dynamic range and do not support the cutoffs for specimen adulteration (pH less than 3 or greater than or equal to 11) may be used only to determine if an initial pH validity test must be performed; g) Colorimetric pH tests that have the dynamic range of 2 to 12 to support the 3 and 11 pH cutoffs must be capable of measuring pH to one decimal place. The pH meter may be used for the initial test, and where a pH screen was not performed to establish whether the specimen pH is high or low, the pH meter must be calibrated and quality control performed for the full range of pH.
Nitrite k) initial and confirmatory nitrite tests must have: i) a calibrator at the cutoff concentration,	

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ii) a control without nitrite (i.e., certified negative urine), iii) one control in the range of 200 mcg/mL to 400 mcg/mL, and iv) one control in the range of 500 mcg/mL to 625 mcg/mL. **Oxidizing adulterant tests** (other than nitrite): l) initial tests must include: i) an appropriate calibrator at the cutoff used by the laboratory for the compound of interest, ii) a control without the compound of interest (i.e., a certified negative control), and iii) at least one control with one of the compounds of interest at a measurable concentration; and m) confirmatory tests must: i) use a different analytical method than that used for the initial test, ii) include an appropriate calibrator, iii) include a control without the compound of interest (i.e., a certified negative control), and iv) include a control with the compound of interest at a measurable concentration.	l) The laboratory should design calibration and quality control protocols to be consistent with those provided in the Mandatory Guidelines for Federal Workplace Drug Testing Programs when detecting the presence of general oxidants, chromium (VI), halogens, glutaraldehyde, pyridine (pyridinium chlorochromate) and surfactants.

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Hair Specimens n) Where possible adulteration or substitution of the hair specimen exists, the laboratory should: i. determine the integrity of the head hair sample by performing a digestion test; ii. perform microscopic identification; iii. perform a dye test; iv. determine solubility of head hair in methanol; and, v. perform additional validity tests as appropriate for the observed indicators or characteristics. **Oral Fluid Specimens** o) Where possible adulteration or substitution of the oral fluid **specimen** exists, the laboratory should perform validity tests as appropriate for the observed indicators or characteristics. **Sweat Patch Specimens** p) Where possible adulteration or substitution of the sweat patch specimen exists, the laboratory should: i. determine the lactic acid concentration; and, ii. perform additional validity tests as appropriate for the observed indicators or characteristics.	Validity tests of hair, oral fluid and sweat patches should be performed when the following conditions are observed: b) Abnormal physical characteristics (e.g., split hair collections have different hair color, mixture of different types of head hair; unusual oral fluid color or texture, unusual odor, semi-solid characteristics; sweat patches collected from an individual have different color or unusual odor); or, e) Reactions or responses characteristic of an adulterant are obtained during initial or confirmatory drug tests (e.g., non-recovery of standards, unusual response). The determination the immunoglobulins (IgG) biomarker concentration should be considered in the assessment of potential substitution of oral fluid specimens.

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Standard	Guidance
Reporting and Specimen and Records Retention Requirements (Applicable to Initial and Comprehensive Testing Categories)	
Forensic Toxicology Sustaining Standard of Practice 28 (FT S28): Report to Authorized Test Orderer a) Laboratory reports shall be released only to the ordering physician / medical review officer (MRO) or other persons authorized by law to order laboratory services, who shall be named on the report. b) Unconfirmed non-negative results shall not be reported.	This standard precludes the release of reports to an institution, a human resources department of a firm, or a company official not qualified to authorize testing.
Forensic Toxicology Sustaining Standard of Practice 29 (FT S29): Report Certification a) A person qualified as a certifying scientist shall certify all reports before they are released. A test report is certified only if: b) documentation for external and internal chain of custody form is complete; c) quality control and assay performance requirements were satisfied; and, d) the analytical data support the test findings and interpretive criteria are applied appropriately.	Minimally, the certifying scientist must qualify as a technologist pursuant to 10 NYCRR Subpart 58-1 and must have: Documented training and experience in each analytical method and procedure used by the laboratory that is relevant to the reports of results that the individual certifies; and Documented training and experience in reviewing and reporting test results, maintenance of chain of custody, and remedial action.
Forensic Toxicology Sustaining Standard of Practice 30 (FT S30): Criteria for a Negative Test Result A specimen is reported negative when each initial drug test is negative or it is negative on a confirmatory drug test and each validity test result indicates that the specimen is a valid specimen.	

Forensic Toxicology
Workplace Drug Testing

Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 31 (FT S31): Authorized Reporting – Initial Testing Only Laboratories a) Laboratories holding a permit in Forensic Toxicology - Initial Testing Only shall report only specimens that are determined to be negative on initial drug testing. Reports must include: b) drug(s) and/or metabolite(s) tested for; c) initial test cut-off concentration for each drug and metabolite; d) a statement that the specimen was dilute if criteria for dilution are met; and, e) the name of the certifying scientist releasing the report.	Laboratories holding a permit in Forensic Toxicology - Initial Testing Only may issue a report that a specimen is dilute if the methods for creatinine and specific gravity are properly validated, analytical runs are designed to include requisite control materials, and the specimen validation test results meet criteria for a dilute specimen, as noted in standard Forensic Toxicology Sustaining Standard 34 (FT S34).
Forensic Toxicology Sustaining Standard of Practice 32 (FT S32): Criteria for a Positive Test Result A specimen is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive.	

Forensic Toxicology
Workplace Drug Testing

Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 33 (FT S33): Confirmation Testing Report Content Reports issued by laboratories holding a permit in Forensic Toxicology - Comprehensive shall identify: a) drug(s) and/or metabolite(s) tested for; b) initial and confirmation test cut-off concentrations for each drug and metabolite; c) the result of all drug test findings recorded as either positive or negative; d) the name of the certifying scientist releasing the report; e) the method used for confirmation testing, if the presence of a drug is detected; f) results of specimen validity testing if the specimen was determined to be dilute, adulterated, substituted or invalid; g) all non-negative test results; h) disclaimers as necessary to assist interpretation of test findings. i) the result of retesting as "Reconfirmed" or "Failed to Reconfirm", if the test ordered was a retest.	c) The laboratory may report the drug concentration for drug(s) reported as positive. f) The laboratory should report numerical values that support a specimen that is reported dilute, adulterated, or substituted. g) Confirmed positive drug test(s) are to be reported when the specimen is also determined to be adulterated, substituted or invalid. h) Examples of disclaimers include: acknowledgement when the integrity of specimens through validity testing has not been evaluated; and, acknowledgement when testing algorithms for hair do not assess environmental contamination.
Forensic Toxicology Sustaining Standard of Practice 34 (FT S34): Reporting Criteria – Dilute Urine Specimen A urine specimen is reported dilute when the creatinine concentration is greater than or equal to 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.	

Forensic Toxicology
Workplace Drug Testing

Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 35 (FT S35): Reporting Criteria – Substituted Urine Specimen A urine specimen is reported substituted when the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200 on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (i.e., a refractometer is used to test both aliquots) on two separate aliquots.	
Forensic Toxicology Sustaining Standard of Practice 36 (FT S36): Reporting Criteria – Adulterated Urine Specimen A urine specimen is reported adulterated when: a) the pH is less than 4 or equal to or greater than 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot; b) the nitrite concentration is greater than or equal to 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multiwavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot; or c) the presence of other adulterants is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.	

Forensic Toxicology Sustaining Standard of Practice 37 (FT S37): Reporting Criteria – Invalid Urine Specimen A urine specimen is reported invalid when: a) inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test; or the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is greater than or equal to 2 mg/dL on either or both the initial or confirmatory creatinine tests); b) the pH is greater than or equal to 4 and less than 4.5 or greater than or equal to 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots; c) the nitrite concentration is greater than or equal to 200 mcg/mL using a nitrite colorimetric test or greater than or equal to the equivalent of 200 mcg/ mL nitrite using a general oxidant colorimetric test for both the initial test and the confirmatory test or using either initial test and the nitrite concentration is greater than or equal to 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots; d) the possible presence of oxidants (Cr VI, pyridine, glutaraldehyde, halogens, surfactants) is detected by an initial test and a confirmatory test on a second aliquot, but the confirmatory test does not differ in analytic principle from the initial test; e) interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained); or, f) interference with the drug confirmatory assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance. g)	

Forensic Toxicology
Workplace Drug Testing

Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 38 (FT S38): Reporting Criteria – Oral Fluid SVT An oral fluid specimen is reported substituted when the laboratory performs validity tests as appropriate for the observed indicators and determines the specimen does not possess the characteristics of an authentic oral fluid specimen. An oral fluid specimen is reported adulterated when the concentration of the adulterant is above the concentration of the calibrator used to verify that the adulterant was present in the specimen. An oral fluid specimen is reported as an invalid result when: a) Interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained); b) Interference with the drug confirmatory assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance; or, c) The physical appearance of the specimen is such that testing the specimen may damage the laboratory's instruments.	Determination of IgG concentration as less than 0.10 mcg/mL may serve as a biomarker for substitution.

Forensic Toxicology
Workplace Drug Testing

Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 39 (FT S39): Reporting Criteria – Hair and Sweat Patch SVT A hair and sweat patch sample is reported adulterated when the concentration of the adulterant is above the concentration of the calibrator used to verify that the adulterant was present in the sample. A hair and sweat patch sample is reported as an invalid result when: a) interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained); b) interference with the drug confirmatory assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance; or, c) the physical appearance of the specimen is such that testing the system may damage the laboratory's instruments.	
Forensic Toxicology Sustaining Standard of Practice 40 (FT S40): Reporting Criteria – Split Specimen Appearance Where a split specimen is collected, if the physical appearances of the split specimen are clearly different and the primary specimen was screened negative for drugs, the specimen is reported as invalid.	

Forensic Toxicology
Workplace Drug Testing

Standard	Guidance
Forensic Toxicology Sustaining Standard of Practice 41 (FT S41): Specimen Retention Laboratories holding a permit in Forensic Toxicology - Comprehensive shall retain specimens that were reported positive, adulterated, substituted or invalid for a minimum of one year in secured storage under conditions appropriate for ensuring stability for valid retesting. Specimen retention must be extended on written request by the authorized person who ordered the test.	Laboratories holding a permit in Forensic Toxicology – Initial Testing Only may discard specimens that test negative after the report has been released.
Forensic Toxicology Sustaining Standard of Practice 42 (FT S42): Records Retention The laboratory shall retain for a minimum of two years, or, for analyses that are under legal challenge, for an indefinite period, all records that would be required for a valid re-creation and scientific review of the testing process.	This includes the following records: a. Standards, calibrators, controls and reagents associated with each analytical run, including the identification of the person who prepared each material, and/or the source and date of receipt; b. Instrument printouts, chromatograms and similar documentation of data or results generated during the analysis, such as worksheets; c. Cross-reference between chain-of-custody forms and the identity of the individual tested; d. Identity of analyst(s); and, e. Evidence of review and certification of the report by a person qualified as a certifying scientist.
Forensic Toxicology Sustaining Standard of Practice 43 (FT S43): Database Security Electronic databases of test results and reports stored in any media shall be secure from access by unauthorized individuals.	Unless the laboratory has a means of verifying the person receiving the results is authorized to receive the results, verbal reporting, including by telephone, is not permitted. Pursuant to 10NYCRR Subpart 58-1, all verbal reports shall be followed by a written report in a timely manner.

Forensic Toxicology
Medico-Legal Investigations – Postmortem – Human Performance Testing

Standard	Guidance
Laboratories engaged in the analysis and interpretation of drugs and chemicals in biological samples for legal purposes other than analyses performed in support of drug-free workplace drug testing programs must be compliant with requirements under each of the following Fundamental Standards of Practice: Quality Management System; Human Resources; Facilities and Resource Management; Pre-Examination, Examination and Post-Examination Procedures; and Quality Assessment and Improvement, with qualification as expressed in this section. These qualifications shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
Quality Management System Fundamental Standard of Practice (QMS F1)	The forensic toxicology laboratory must be in full compliance with the Quality Management System Fundamental Standard of Practice and its sustaining standards QMS S1 through S4.
Director Fundamental Standard of Practice 1 (DIR F1) : Director Oversight	The forensic toxicology laboratory must be in full compliance with the Director Fundamental Standard of Practice and the sustaining standards DIR S1 through 3, except that: DIR S3(k): Consultation is provided to clients authorized to order laboratory services in medico-legal investigation.
Human Resources Fundamental Standard of Practice 1 (HR F1): Staff Qualifications	The forensic toxicology laboratory must be in full compliance with the Human Resources Fundamental Standard and the sustaining standards HR S1 through 12, except that: a) HR F1: Supervisors and technical personnel must have training and experience in forensic science commensurate with responsibilities; b) HR S2: Technical personnel engaged solely in forensic testing do not require licensure through the State Education Department.

Forensic Toxicology
Medico-Legal Investigations – Postmortem – Human Performance Testing

Standard	Guidance
Facility Design and Resource Management Fundamental Standard of Practice 1 (FDRM F1)	The forensic toxicology laboratory must be in full compliance with the Facility Design and Resource Management Fundamental Standard and its sustaining standards under General Facilities, Laboratory Equipment, Reagents & Supplies, Laboratory Safety and Laboratory Information Systems, where applicable to medico-legal testing, except that: FDRM F1: Non-conformance does not present imminent jeopardy to the integrity of laboratory services, to employee safety, or to medico-legal investigations. In addition, the laboratory shall be in compliance with the following Forensic Toxicology standard(s): a) Forensic Toxicology Sustaining Standard 7 (FT S7): Laboratory Security, and b) Forensic Toxicology Sustaining Standard 21 (FT S21): Mass Spectrometer Function Checks
Operating Procedures and Compliance Fundamental Standard of Practice 1 (SOP F1)	The forensic toxicology laboratory must be in full compliance with the Operating Procedures and Compliance Fundamental Standard and its sustaining standards SOPM S1 through S7, except that: SOPM S2(d): requirements for study subject preparation rather than patient preparation; SOPM S2(g)(ix): reporting case results rather than patient results; and, SOPM S2(h): reportable range for the analytical method rather than for patient test results.

Forensic Toxicology
Medico-Legal Investigations – Postmortem – Human Performance Testing

Standard	Guidance
Pre-Examination Procedures Fundamental Standard of Practice 1 (PEP F1)	The forensic toxicology laboratory must be in full compliance with the Pre-Examination Fundamental Standard and its sustaining standards under Examination Requisition and Specimen Processing, except that: a) Requisition S1: No private-sector establishment other than a laboratory under NYS forensic toxicology permit shall accept specimens for the purpose of toxicological medico-legal investigation; and, b) Requisition S3, S4: References to patients and patient preparation are replaced with study subjects and study subject preparation. In addition, the laboratory shall be in compliance with the following Forensic Toxicology standard(s) to the extent practical and appropriate for the medico-legal investigation: a) Forensic Toxicology Sustaining Standard 2 (FT S2): Specimen Collection Procedures b) Forensic Toxicology Sustaining Standard 3 (FT S3): Specimen Acceptance Criteria c) Forensic Toxicology Sustaining Standard 4 (FT S4): Specimen Acceptance Criteria d) Forensic Toxicology Sustaining Standard 6 (FT S6): Internal Chain of Custody e) Forensic Toxicology Sustaining Standard 9 (FT S9): Aliquot Discard

Forensic Toxicology
Medico-Legal Investigations – Postmortem – Human Performance Testing

Standard	Guidance
Examination Procedures Fundamental Standard of Practice 1 (EP F1)	The forensic toxicology laboratory must be in full compliance with the Examination Procedures Fundamental Standard and its sustaining standards under Validation of Laboratory Procedures, Determination of Calibration and Calibration Verification Procedures, Establishment of Quality Control Procedures and Process Quality Control, except that: a) EP F1: Non-conformance shall not present imminent jeopardy to the integrity of laboratory services, to employee safety, or to medico-legal investigations. b) Validation S5(d): If the instrument will be hand-carried or otherwise transported to the site of the investigation, the laboratory shall document the portability of the system. c) QC Design S3 and QC Design S4: References to accepted medical and analytical requirements mean medico-legal and analytical requirements. In addition, the laboratory shall be in compliance with the following Forensic Toxicology standard(s) to the extent practical and appropriate for the medico-legal investigation: a) Forensic Toxicology Sustaining Standard 18 (FT S18): Confirmation Testing Method Principle b) Forensic Toxicology Sustaining Standard 20 (FT S20): Confirmation Method Calibration c) Forensic Toxicology Sustaining Standard 22 (FT S22): MS Full Scan Identification d) Forensic Toxicology Sustaining Standard 24 (FT S24): Chromatographic Criteria and Analyte Identification

Forensic Toxicology
Medico-Legal Investigations – Postmortem – Human Performance Testing

Standard	Guidance
Post- Examination (Process Review – Reporting – Records Retention Fundamental) Standard of Practice 1 (Process Review F1)	The forensic toxicology laboratory must be in full compliance with the Post-Examination Fundamental Standard and its sustaining standards under Process Review, Reporting, Records Retention, and Confidentiality, except that: a) Process Review F1: Non-conformance does not present imminent jeopardy to the integrity of laboratory services, to employee safety, or to medico-legal investigations. In addition, the laboratory shall be in compliance with the following Forensic Toxicology standard(s) to the extent practical and appropriate for the medico-legal investigation: a) Forensic Toxicology Sustaining Standard 28 (FT S28): Report to Authorized Test Orderer b) Forensic Toxicology Sustaining Standard 29 (FT S29): Report Certification c) Forensic Toxicology Sustaining Standard 32 (FT S32): Criteria for a Positive Test Result d) Forensic Toxicology Sustaining Standard 33 (FT S33): Confirmation Testing Report Content e) Forensic Toxicology Sustaining Standard 41 (FT S41): Specimen Retention f) Forensic Toxicology Sustaining Standard 42 (FT S42): Records Retention

Forensic Toxicology
Medico-Legal Investigations – Postmortem – Human Performance Testing

Standard	Guidance
Quality Assessment and Improvement Fundamental Standard of Practice (QA F1)	The forensic toxicology laboratory must be in full compliance with the Quality Assessment and Improvement Fundamental Standard and its sustaining standards under Proficiency Testing, Referral and Contract Laboratories, Resolution of Complaints and Identification and Control of Nonconformities, and Corrective Action.

Transplant Monitoring

Standard	Guidance
The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
Engraftment Monitoring Standard 1 (EM S1) The laboratory shall include a sensitivity control in each patient run.	For this control, it is suggested that a small amount of a positive sample be mixed with an excess of a negative sample, e.g., 1:20 for a 5% sensitivity.
Engraftment Monitoring Standard 2 (EM S2) The final report shall include, at minimum, a summary of the method that was used, the DNA loci tested, and the objective findings in a readily interpretable format.	