New York State Clinical Laboratory Standards of Practice
Control Requirements and IQCP Eligibility

The first column lists those CLIA regulations that are eligible for an Individualized Quality Control Plan (IQCP). The second column designates whether the CLIA requirement is IQCP eligible* for laboratories holding a NYS Clinical Laboratory Permit. In the third column, the title of the relevant NYS standard is provided.

Pathology categories are not eligible for IQCP.

CLIA Regulation Eligible for IQCP	IQCP Eligible for New York State	Relevant NYS Standard(s)
§493.1256 Standard: Control procedures.		
(d) Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at §§493.1261 through 493.1278.	N/A	
(d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section.	Yes	Quality Control Standard of Practice 1 (QC S1): Minimum Quality Control Requirements Quality Control Standard of Practice 2 (QC S2): Individualized Quality Control Risk Assessment Quality Control Standard of Practice 3

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(d)(3) At least once each day patient specimens are assayed or examined perform the following for— (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; (d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively;		(QC S3): Design of an Individualized Quality Control Plan Quality Control Standard of Practice 4 (QC S4): Quality Assessment Plan for Individualized Quality Control Plan Andrology Standard of Practice 1 (AN S1): Counts, Motility and Concentration Andrology Standard of Practice 3 (AN S3): Quality Control Requirements Cytogenetics Standard of Practice 11 (CG S11): Fluorescence in situ Hybridization (FISH) Acceptability Forensic Toxicology Standard of Practice 11 (FT S11): Single-Use Device Quality Control Microbiology Nucleic Acid Amplification Assay Standard of Practice 1 (MNA S1): Quality Control Samples for Laboratory Developed Tests Microbiology Nucleic Acid

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(d)(3)(iv) Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; and (d)(3)(v) Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition.		Amplification Assay Standard of Practice 2 (MNA S2): Quality Control Samples for Sequencing Assays
	No	Blood Lead Standard of Practice 5 (BL S5): Quality Control Cellular Immunology Categories (none are eligible for IQCP) Forensic Identity Standard of Practice 18 (FI S18): PCR Inhibition Detection Forensic Toxicology Standard of Practice 10 (FT S10): Quality Control of Initial Tests Trace Elements Standard of Practice 6 (TE S6): Quality Control

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(d)(4) For thin layer chromatography— (d)(4)(i) Spot each plate or card, as applicable, with a calibrator containing all known substances or drug groups, as appropriate, which are identified by thin layer chromatography and reported by the laboratory; and (d)(4)(ii) Include at least one control material on each plate or card, as applicable, which must be processed through each step of patient testing, including extraction processes.	No	Quality Control Standard of Practice 12 (QC S12): Thin Layer Chromatography
(d)(5) For each electrophoretic procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured.	No	Quality Control Standard of Practice 11 (QC S11): Electrophoresis
(e) For reagent, media, and supply checks, the laboratory must do the following:	N/A	
(e)(1) Check each batch (prepared in- house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as	Yes	Microbiology Standard of Practice 4 (MB S4): Microbial Growth Medium
	No	Reagents and Media Standard of Practice 2 (RGM S2): Verification of Reagents and Media – Control Procedures Virology Standard of Practice 5 (VR S5):

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graded reactivity, if applicable.		Cell Culture Medium Quality Control Forensic Identity Standard of Practice 17 (FI S17): Limited Sample Reagent Testing
(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.	No	Reagents and Media Standard of Practice 2 (RGM S2): Verification of Reagents and Media – Control Procedures
(e)(4) Before, or concurrent with the initial use— (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a	Yes	Bacteriology Standard of Practice 11 (BT S11): Minimum Inhibitory Concentration Quality Control Frequency, Assessment and Recording Microbiology Standard of Practice 4 (MB S4): Microbial Growth Medium

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biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.	No	Bacteriology Standard of Practice 10 (BT S10): Reagent Quality Control for Minimum Inhibitory Concentration Methods

Bacteriology		
CLIA Regulation Eligible for IQCP	**IQCP Eligible for New York State**	**Relevant NYS Standard(s)**
§493.1261 Standard: Bacteriology.		
(a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(1) Each day of use for beta-lactamase methods other than Cefinase™. (a)(2) Each week of use for Gram stains. (a)(3) When each batch (prepared in-house), lot number (commercially prepared), and shipment of antisera is prepared or opened, and once every 6 months thereafter.	Yes	Bacteriology Standard of Practice 1 (BT S1): Reagent Quality Control

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(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms.	No	Bacteriology Standard of Practice 6 (BT S6): Media Quality Control for Disk Diffusion Methods Bacteriology Standard of Practice 7 (BT S7): Antibiotic Quality Control for Disk Diffusion Methods
(b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results.	Yes	Bacteriology Standard of Practice 9 (BT S9): Disk Diffusion Quality Control Frequency, Assessment and Recording

Mycobacteriology		
CLIA Regulation Eligible for IQCP	**IQCP Eligible for New York State**	**Relevant NYS Standard(s)**
§493.1262 Standard: Mycobacteriology.		
(a) Each day of use, the laboratory must check all reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction.	Yes	Mycobacteriology Standard of Practice 3 (TB S3): Staining Quality Control

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(b) For antimycobacterial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using an appropriate control organism(s). (b)(1) The laboratory must establish limits for acceptable control results. (b)(2) Each week tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(3) The results for the control organism(s) must be within established limits before reporting patient results.	No	Mycobacteriology Standard of Practice 17 (TB S17): Verification of Reagents for Culture-Based Susceptibility Testing

Mycology		
CLIA Regulation Eligible for IQCP	**IQCP Eligible for New York State**	**Relevant NYS Standard(s)**
§493.1263 Standard: Mycology.		
(a) The laboratory must check each batch (prepared in-house), lot number (commercially prepared), and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism(s).	No	Mycology Standard of Practice 7 (MY S7): Quality Control of Stains

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(b) For antifungal susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antifungal agent(s) before, or concurrent with, initial use, using an appropriate control organism(s). (b)(1) The laboratory must establish limits for acceptable control results. (b)(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(3) The results for the control organism(s) must be within established limits before reporting patient results.	No	Mycology Standard of Practice 8 (MY S8): Antifungal Susceptibility Testing Quality Control

Parasitology		
CLIA Regulation Eligible for IQCP	**IQCP Eligible for New York State**	**Relevant NYS Standard(s)**
§493.1264 Standard: Parasitology.		
(c) Each month of use, the laboratory must check permanent stains using a fecal sample control material that will demonstrate staining characteristics.	Yes	Parasitology Standard of Practice 2 (PS S2): Quality Controls for Staining

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Virology		
CLIA Regulation Eligible for IQCP	**IQCP Eligible for New York State**	**Relevant NYS Standard(s)**
§493.1265 Standard: Virology.		
(a) When using cell culture to isolate or identify viruses, the laboratory must simultaneously incubate a cell substrate control or uninoculated cells as a negative control material.	No	Virology Standard of Practice 8 (VR S8): Negative Cell Culture Controls

Routine Chemistry		
CLIA Regulation Eligible for IQCP	**IQCP Eligible for New York State**	**Relevant NYS Standard(s)**
§493.1267 Standard: Routine chemistry.		
(b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (c) Test one sample of control material each time specimens are tested unless automated instrumentation internally verifies calibration at least every 30 minutes.	Yes	Blood pH and Gases Standard of Practice 1 (BP S1): Quality Control Requirements

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Hematology		
CLIA Regulation Eligible for IQCP	**IQCP Eligible for New York State**	**Relevant NYS Standard(s)**
§493.1269 Standard: Hematology.		
(a) For manual cell counts performed using a hemocytometer— (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate.	Yes	Hematology Standard of Practice 1 (HM S1): Quality Control Requirements
(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed.	Yes	Hematology Standard of Practice 2 (HM S2): Automated Coagulation Quality Control
(c) For manual coagulation tests— (c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and (c)(2) Patient specimens and control materials must be tested in duplicate.	Yes	Hematology Standard of Practice 3 (HM S3): Manual Coagulation Quality Control

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Histocompatibility		
CLIA Regulation Eligible for IQCP	**IQCP Eligible for New York State**	**Relevant NYS Standard(s)**
§493.1278 Standard: Histocompatibility.		
(b) HLA typing. The laboratory must do the following: (b)(6) Check each HLA typing by testing, at a minimum the following: (b)(6)(i) A positive control material. (b)(6)(ii) A negative control material in which, if applicable to the technique performed, cell viability at the end of incubation is sufficient to permit accurate interpretation of results. In assays in which cell viability is not required, the negative control result must be sufficiently different from the positive control result to permit accurate interpretation of results. (b)(6)(iii) Positive control materials for specific cell types when applicable (that is, T cells, B cells, and monocytes).	No	Histocompatibility Standard of Practice 2 (HC S2): Human Leukocyte Antigen Typing
(c) Disease-associated studies. The laboratory must check each typing for disease-associated HLA antigens using control materials to monitor the test components and each phase of the test	Yes	Quality Control Standard of Practice 1 (QC S1): Minimum Quality Control Requirements Quality Control Standard of Practice 2 (QC S2): Individualized Quality Control

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system to ensure acceptable performance.		Risk Assessment Quality Control Standard of Practice 3 (QC S3): Design of an Individualized Quality Control Plan Quality Control Standard of Practice 4 (QC S4): Quality Assessment Plan for Individualized Quality Control Plan
(d) Antibody Screening. The laboratory must do the following: (d)(6) Check each antibody screening by testing, at a minimum the following: (d)(6)(i) A positive control material containing antibodies of the appropriate isotype for the assay. (d)(6)(ii) A negative control material.	No	Histocompatibility Standard of Practice 3 (HC S3): Human Leukocyte Antigen Antibody Screening
(e) Crossmatching. The laboratory must do the following: (e)(3) Check each crossmatch and compatibility test for HLA Class II antigenic differences using control materials to monitor the test components and each phase of the test system to ensure acceptable performance.	No	Histocompatibility Standard of Practice 5 (HC S5): Crossmatching

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