IQCP ELIGIBILITY CROSSWALK TABLE

IQCP ELIGIBILITY CROSSWALK TABLE: The first column lists those CLIA regulations (general QC and specialty/subspecialty) that are eligible for IQCP based on federal requirements. The second column designates whether this CLIA requirement will be **IQCP eligible*** in New York State. In the third column, the title of the relevant NYS standard is provided.

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	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--	**N/A**	
(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 Sustaining Standard of Practice 1 (QC Design S1): Design of Individualized Quality Control Plan**
(d)(3) At least once each day patient specimens are assayed or examined perform the following for--	**YES**	**Quality Control Sustaining Standard of Practice 1 (QC Design S1): Design of Individualized Quality Control Plan**

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(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; (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.		**Parasitology Sustaining Standard of Practice 3 (PS3): Antigen Detection Assay Controls (for single use devices only)** **Virology Sustaining Standard of Practice 13 (VR S13): Positive Live Virus Culture Controls** **Forensic Toxicology Sustaining Standard of Practice 12 (FT S12): Single-Use Device Quality Control**

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(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** (NYS standard equivalent to the CLIA regulation)	**Process QC Sustaining Standard of Practice 5 (Process QC S5): 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** (NYS standard equivalent to the CLIA regulation)	**Process QC Sustaining Standard of Practice 4 (Process QC S4): Electrophoresis**
(e) For reagent, media, and supply checks, the laboratory must do the following:	**N/A**	

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(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 graded reactivity, if applicable.	**NO** (NYS standard equivalent to the CLIA regulation)	**Reagents Sustaining Standard of Practice 3 (REAG S3): Verification of Reagents and Media** **Bacteriology Standard of Practice 7 (BT S7): Antibiotic QC for Disk Diffusion Methods**
(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.	**NO** (NYS standard equivalent to the CLIA regulation)	**Reagents Sustaining Standard of Practice 3 (REAG S3): Verification of Reagents and Media** **Bacteriology Standard of Practice 1 (BT S1): Reagent QC**
(e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.	**NO** (NYS standard equivalent to the CLIA regulation)	**Reagents Sustaining Standard of Practice 3 (REAG S3): Verification of Reagents and Medi**

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(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 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.	**YES, for commercial media (except for sterility)** **NO, for in-house media** (NYS standard equivalent to the CLIA regulation)	**Reagents Sustaining Standard of Practice 3 (REAG S3): Verification of Reagents and Media** **Microbiology Sustaining Standard of Practice 2 (MB S2): Commercial Medium** **Microbiology Sustaining Standard of Practice 3 (MB S3): Media Prepared In-House** **Bacteriology Standard of Practice 6 (BT S6): Media QC for Disk Diffusion Methods**
Sec. 493.1261 Standard: Bacteriology.		

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(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\TM\. (a)(2) Each week of use for Gram stains.	**NO** (NYS standard equivalent to the CLIA regulation)	**Bacteriology Standard of Practice 1: Reagent QC**
(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.	**NO** (NYS standard equivalent to the CLIA regulation)	**Reagents Sustaining Standard of Practice 3 (REAG S3): Verification of Reagents and Media** **Bacteriology Standard of Practice 1: Reagent QC**

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(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** (NYS standard equivalent to the CLIA regulation)	**Reagents Sustaining Standard of Practice 3 (REAG S3): Verification of Reagents and Media** **Bacteriology Standard of Practice 6: Media QC for Disk Diffusion Method** **Bacteriology Standard of Practice 7: Antibiotic QC for Disk Diffusion Methods** **Bacteriology Standard of Practice 10: Reagent QC for MIC Methods**
(b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.	**YES**	**Bacteriology Standard of Practice 9: Disk Diffusion QC Frequency, Assessment and Recording (subpart a)** **Bacteriology Standard of Practice 11: MIC Quality Control Frequency, Assessment and Recording**

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results.	**NO** (NYS standard equivalent to the CLIA regulation)	**Bacteriology Standard of Practice 9: Disk Diffusion QC Frequency, Assessment and Recording (subpart b)** **Bacteriology Standard of Practice 11: MIC Quality Control Frequency, Assessment and Recording**
Sec. 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.	**NO** (NYS standard equivalent to the CLIA regulation)	**Mycobacteriology Sustaining Standard of Practice 5 (TB S5): Staining Quality Control**

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(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** (NYS standard equivalent to the CLIA regulation)	**Mycobacteriology Sustaining Standard of Practice 19: Verification of Reagents for Susceptibility Testing**
Sec. 493.1263 Standard: Mycology.		

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(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** (NYS standard equivalent to the CLIA regulation)	**Mycology Sustaining Standard of Practice 9 (MY S9): Quality Control of Probes and Stains**
(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).	**NO** (NYS standard equivalent to the CLIA regulation)	**Mycology Sustaining Standard of Practice 10 (MY S10): Antifungal Susceptibility Testing Quality Control**
(b)(1) The laboratory must establish limits for acceptable control results.	**NO** (NYS standard equivalent to the CLIA regulation)	**Mycology Sustaining Standard of Practice 10 (MY S10): Antifungal Susceptibility Testing Quality Control**
(b)(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.	**YES**	**Quality Control Sustaining Standard of Practice 1 (QC Design S1): Design of Individualized Quality Control Plan**

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(b)(3) The results for the control organism(s) must be within established limits before reporting patient results.	**NO** (NYS standard equivalent to the CLIA regulation)	**Mycology Sustaining Standard of Practice 10 (MY S10): Antifungal Susceptibility Testing Quality Control**
Sec. 493.1264 Standard: Parasitology.		
(a) The laboratory must have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens.	**NO** (NYS standard equivalent to the CLIA regulation)	**Parasitology Sustaining Standard of Practice 7 (PS7): Reference Material**
(b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.	**NO** (NYS standard equivalent to the CLIA regulation)	**Parasitology Sustaining Standard of Practice 4 (PS4): Ocular Micrometer Calibration** **Parasitology Sustaining Standard of Practice 5 (PS5): Ova and Extracellular Parasite Measurement**

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(c) Each month of use, the laboratory must check permanent stains using a fecal sample control material that will demonstrate staining characteristics.	**NO** (NYS standard equivalent to the CLIA regulation)	**Parasitology Sustaining Standard of Practice 2 (PS2): Quality Controls for Staining**
Sec. 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** (NYS standard equivalent to the CLIA regulation)	**Virology Sustaining Standard of Practice 12 (VR S12): Negative Cell Culture Controls** **Virology Sustaining Standard of Practice 15 (VR S15): RBC Controls for Hemadsorption (HAd) Assays** **Virology Sustaining Standard of Practice 16 (VR S16): Confirmation and Identification of Cultured Viruses**
Sec. 493.1267 Standard: Routine chemistry.		
For blood gas analyses, the laboratory must perform the following:	**N/A**	

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(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.	**YES**	**Quality Control Sustaining Standard of Practice 1 (QC Design S1): Design of Individualized Quality Control Plan** (Blood pH and Gases Standard 1 (BP S1) will be deleted effective December 31, 2015)
(c) Test one sample of control material each time specimens are tested unless automated instrumentation internally verifies calibration at least every 30 minutes.	**YES**	**Quality Control Sustaining Standard of Practice 1 (QC Design S1): Design of Individualized Quality Control Plan** (Blood pH and Gases Standard 1 (BP S1) will be deleted effective December 31, 2015)
Sec. 493.1269 Standard: Hematology.		
(a) For manual cell counts performed using a hemocytometer--	**N/A**	
(a)(1) One control material must be tested each 8 hours of operation; and	**NO** (NYS standard equivalent to the CLIA regulation)	**Hematology Standard 2 (HM S2)**

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(a)(2) Patient specimens and control materials must be tested in duplicate.	**NO** (NYS standard equivalent to the CLIA regulation)	**Hematology Standard 3 (HM S3)**
(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 4 (HM S4)**
(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**	**Quality Control Sustaining Standard of Practice 1 (QC Design S1): Design of Individualized Quality Control Plan**
§493.1278 Standard: Histocompatibility.		

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(b) HLA typing. The laboratory must do the following:	**N/A**	
(b)(6) Check each HLA typing by testing, at a minimum the following:	**N/A**	
(b)(6)(i) A positive control material.	**NO** (NYS standard equivalent to the CLIA regulation)	**Histocompatibility Standard 7 (HC S7)** **Histocompatibility Standard 19 (HC S19)**
(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.	**NO** (NYS standard equivalent to the CLIA regulation)	**Histocompatibility Standard 7 (HC S7)** **Histocompatibility Standard 18 (HC S18)**

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(b)(6)(iii) Positive control materials for specific cell types when applicable (that is, T cells, B cells, and monocytes).	**YES**	**Quality Control Sustaining Standard of Practice 1 (QC Design S1): Design of Individualized Quality Control Plan**
(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 system to ensure acceptable performance.	**YES**	**Quality Control Sustaining Standard of Practice 1 (QC Design S1): Design of 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.	**YES**	**Quality Control Sustaining Standard of Practice 1 (QC Design S1): Design of Individualized Quality Control Plan**

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

CLIA REGULATION Eligible for IQCP	IQCP Eligible in New York?	Relevant NYS Standard(s)
(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.	**YES**	**Quality Control Sustaining Standard of Practice 1 (QC Design S1): Design of Individualized Quality Control Plan**

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

Other NYS Standards that are equivalent to, or more stringent than, CLIA regulations:

- Andrology Standard 1 (AN S1)
- Andrology Standard 2 (AN S2)
- Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 14 (CILF S14): Normal Control Requirements
- Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 19 (CILF S19): Function Quality Control- Normal Specimen
- Cellular Immunology - Leukocyte Function Sustaining Standard of Practice 20 (CILF S20): Function Quality Control- Negative, Positive, and Multi-level Controls
- Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 11 (CINM S11): Control Requirements
- Cellular Immunology – Non-Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 35 (CINM S36): Leukocyte Adhesion Deficiency (unstimulated expression) – Positive Staining Control
- Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 9 (CIML S9): Normal Control Requirements
- Cellular Immunology – Malignant Leukocyte Immunophenotyping Sustaining Standard of Practice 13 (CIML S13): Specimen Quality Assurance
- Genetic Testing Standard 10 (GT S10)
- Hematology Standard 2 (HM S2)
- Hematology Standard 4 (HM S4)
- Hematology Standard 5 (HM S5)
- Histocompatibility Standard 7 (HC S7)
- Histocompatibility Standard 8 (HC S8)
- Histocompatibility Standard 9 (HC S9)
- Histocompatibility Standard 19 (HC S19)
- Microbiology Sustaining Standard of Practice 3
- (MB S3): Media Prepared In-House
- Microbiology Nucleic Acid Amplification Assay Sustaining Standard of Practice 5 (MNA S5): Quality Control Samples for Laboratory Developed and Modified FDA-approved MNAAs
- Microbiology Nucleic Acid Amplification Assay Sustaining Standard of Practice 6 (MNA S6): Quality Control Samples for Sequencing Assays
- Virology Sustaining Standard of Practice 6 (VR S6): Cell Culture Medium Quality Control
- Virology Sustaining Standard of Practice 18 (VRS18): Viral Neutralization and Hemagglutination-Inhibition (HI) Assay Controls

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.

IQCP ELIGIBILITY CROSSWALK TABLE

- Paternity/Identity Standard 28 (PIT S28)
- Trace Elements Sustaining Standard of Practice 6 (TE S6): Quality Control
- Blood Lead Sustaining Standard of Practice 5 (BL S5): Quality Control
- Forensic Toxicology Sustaining Standard of Practice 11 (FT S11): Initial Test Quality Control
- Forensic Toxicology Sustaining Standard of Practice 23 (FT S23): Confirmation Method Quality Control
- Forensic Toxicology Sustaining Standard of Practice 27 (FT S27): Urine SVT Calibration and QC Requirements
- Engraftment Monitoring Standard 1 (EM S1)

* **IQCP Eligible** means that IQCP allows the lab to implement a Quality Control Plan (QCP) containing something other than what is required by the specified regulation as long as the IQCP provides equivalent quality testing.