CLINICAL LABORATORY EVALUATION
PROGRAM BIGGS LAB – WADSWORTH CENTER
NYS DEPARTMENT OF HEALTH
EMPIRE STATE PLAZA
ALBANY, NEW YORK 12237

E-Mail: CLEPCQ@health.ny.gov
Web: www.wadsworth.org/regulatory/clep

APPLICATION TO AMEND CERTIFICATE OF QUALIFICATION

Please refer to Part 19 of 10NYCRR, available on our website (www.wadsworth.org/regulatory/clep/laws) for a description of Certificate of Qualification (CQ) requirements. Please read and follow the instructions carefully. Incomplete or incorrectly completed applications will delay processing.

1. PERSONAL INFORMATION: **CQ Code:** _____ **CQ Expiration Date:** _____

Last Name	First Name		MI
Home Address/Street	**City**	**State**	**ZIP**
Telephone Number(s) with Area Code			
(Home or Mobile)	**(Work)**		
Home Email Address	**Work Email Address**		

Please be reminded, if you are intending to request a directorship, or assistant directorship at a laboratory holding a NYS permit, please make the necessary additions using eCLEP at the Health Commerce System https://commerce.health.state.ny.us after your Certificate of Qualification is successfully amended.

SIGNATURE: _____ **DATE:** _____

NOTE: ALL SIGNATURES MUST BE ORIGINAL. TYPED, ELECTRONIC, OR STAMPED SIGNATURES WILL NOT BE ACCEPTED.

There is no fee to amend a CQ. Submit this form, **a current curriculum vitae,** and other supporting documentation to:

Postal Service

Clinical Laboratory Evaluation Program
Biggs Lab – Wadsworth Center
NYS Department of Health
Empire State Plaza
Albany, NY 12237

Express Service

Clinical Laboratory Evaluation Program
Biggs Lab – Wadsworth Center
NYS Department of Health
Dock J – P1, Empire State Plaza
Albany, NY 12237

Please remember to indicate the requested category(ies) on page 2 and submit any required Questionnaires to complete your amendment application.

2. CATEGORIES REQUESTED: Check each category you seek to add to your certificate.

All Applicants must demonstrate recent experience in addition to the Requirements listed below. Recent Experience means acceptable training or experience in a specific category of clinical laboratory testing within the six years prior to this application. Categories marked with an asterisk require a Questionnaire be completed and submitted along with the application. Questionnaires are available on our website at www.wadsworth.org/regulatory/clep/certificate-requirements.

CHECK BELOW:	CATEGORIES	REQUIREMENTS	
		MD/DO, License, Registration, and:	**Earned Doctoral Degree and:**
	Andrology *	ABP(CP) + 6 mos, AOBP(LM) + 6 mos, or Experience	ABB(HCLD) or Experience
	Bacteriology *	ABP(CP), AOBP(LM), ABMM, ABP(MMB), or Experience	ABB(HCLD), ABMM, or Experience
	Blood Banking Collection – Comprehensive *	Experience	
	Blood Banking Collection – Limited *	ABP(CP), AOBP(LM), or ABIM(Hem)	
	Blood Lead	ABP(CP), AOBP(LM), ABCC(TC), ABFT, or Experience	ABB(HCLD), ABCC(TC), ABFT, NRCC, or Experience
	Blood pH and Gases	ABP(CP), AOBP(LM), ABCC(CC), or Experience	ABB(HCLD), ABCC(CC), NRCC, or Experience
	Cellular Immunology – • Leukocyte Function • Malignant Leukocyte Immunophenotyping • Non-Malignant Leukocyte Immunophenotyping	Experience	Experience
	Clinical Chemistry	ABP(CP), AOBP(LM), ABCC(CC), or Experience	ABB(HCLD), ABCC(CC), NRCC, or Experience
	Clinical Toxicology	ABP(CP), AOBP(LM), ABCC(CC), ABCC(TC), or Experience	ABB(HLCD), ABCC(CC), ABCC(TC), NRCC, or Experience
	Cytogenetics	Experience	Experience
	Cytopathology	ABP(AP), or AOBP(AP)	
	Diagnostic Immunology *	ABP(CP), AOBP(LM), ABP(MMB), ABMLI, ABMM, or Experience	ABB(HCLD), ABMLI, ABMM, or Experience
	Endocrinology	ABP(CP), AOBP(LM), ABCC(CC), or Experience	ABB(HCLD), ABCC(CC), NRCC, or Experience
	Fetal Defect Markers *	Experience	Experience
	Forensic Identity	Experience	Experience
	Forensic Toxicology	ABCC(TC), ABFT, or Experience	ABCC(TC), ABFT, or Experience
	Genetic Testing	Experience	Experience
	Hematology *	ABP(CP), AOBP(LM), ABIM(Hem) + 6 mos, or Experience	Experience
	Histocompatibility	Experience	Experience
	Histopathology – General	ABP(AP) or AOBP(AP)	
	Histopathology – Dermatopathology	ABP(AP), ABP(DP), AOBP(AP), or AOBP(DP)	
	Histopathology – Dermatopathology Mohs testing only	ABD	
	Histopathology – Oral Pathology	ABP(AP) or AOBP(AP)	ABOMP (DDS Only)
	Immunohematology	ABP(CP), AOBP(LM), or Experience	Experience
	Mycobacteriology *	ABP(CP), AOBP(LM), ABMM, ABP(MMB), or Experience	ABB(HCLD), ABMM, or Experience
	Mycology *	ABP(CP), AOBP(LM), ABMM, ABP(MMB), or Experience	ABB(HCLD), ABMM, or Experience
	Oncology – Molecular and Cellular Tumor Markers	ABP(AP) + ABP(MGP), ABP(CP) + ABP(MGP), or Experience	Experience
	Parasitology *	ABP(CP), AOBP(LM), ABMM, ABP(MMB), or Experience	ABB(HCLD), ABMM, or Experience
	Parentage/Identity Testing	Experience	Experience
	Therapeutic Substance Monitoring/Quantitative Toxicology	ABP(CP), AOBP(LM), ABCC(CC), or Experience	ABB(HCLD), ABCC(CC), NRCC, or Experience
	Trace Elements	Experience	Experience
	Transfusion Services *	ABP(BB/TM), ABP(CP) + 6 mos, ABIM(Hem) + 6 mos, or Experience	
	Transplant Monitoring	Experience	Experience
	Virology *	ABMM, ABP(MMB), or Experience	ABB(HCLD), ABMM, or Experience
	Virology – limited to antigen detection and molecular methods *	ABP(CP) or AOBP(LM)	ABB(HCLD)

NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM
CERTIFICATE OF QUALIFICATION APPLICATION

Training and/or experience must be documented in the form of letters from, or Questionnaires signed by, laboratory directors or supervisors under whom the training and/or experience was acquired.

INSTRUCTIONS TO AUTHORS OF LETTERS DOCUMENTING EXPERIENCE:

A third-party letter documenting experience is required for _____

Include a description of your relationship to the applicant and how you can attest to the applicant's training and/or experience in the applied categories.

Include the name, PFI/CLIA number, address, and facility type (hospital, medical research, etc.) where the training and/or experience was gained.

Include the dates (month and year) of training and/or experience. Include the number of specific tests/analytes and procedures personally performed, supervised and/or directed by the applicant, along with the specimen source(s), methodology, and equipment for each, and whether each is an FDA- Approved assay or laboratory-developed test (LDT). Details of testing experience and volume(s) may be provided in table form. If documentation of laboratory management experience is required, please see part 19.3(c) of 10NYCRR below for laboratory director management experience criteria.

19.3(c) 10NYCRR: To qualify for, and maintain, a certificate of qualification, a laboratory director and any assistant director shall demonstrate that he or she possesses knowledge of basic clinical laboratory sciences and operations, and shall have the training and/or experience and physical capability to discharge the following responsibilities: (1) provide advice to referring health care providers regarding the significance of laboratory findings and ensure that reports of test results include pertinent information required for the interpretation of laboratory data; (2) maintain an effective working relationship with applicable accrediting and regulatory agencies, administrative officials, and the medical community, (3) define, implement and monitor standards of performance for the laboratory and for other ancillary laboratory testing programs in conformance with the department's clinical laboratory standards of practice; (4) monitor all work performed in the laboratory to ensure that medically reliable data are generated; (5) assure that the laboratory participates in monitoring and evaluating the quality and appropriateness of services rendered, within the context of a quality management system, regardless of where the testing is performed; (6) ensure that sufficient qualified personnel are employed with documented training and/or experience to supervise and perform the work of the laboratory; (7) ensure that policies and procedures are established for monitoring staff to assess competency and, whenever necessary, to provide remedial training to improve skills; (8) specify in writing the responsibilities and duties of all laboratory personnel; (9) provide continuing education to laboratory staff; (10) ensure that a current and complete procedure manual is available to all personnel; and (11) set goals, develop and allocate resources within the laboratory; (12) provide effective administrative direction of the laboratory, in conjunction with the individual(s) responsible for financial management of the laboratory, to ensure adequate resources are available to operate the laboratory in a manner consistent with all state and federal requirements; (13) select all reference laboratories for services not offered by the laboratory; (14) promote a safe laboratory environment for personnel and the public; and (15) ensure that the laboratory, when applicable, is enrolled in a proficiency testing program acceptable to the department for the testing performed and that the laboratory adheres to the proficiency testing program's administrative and technical requirements.