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

OFFICE USE ONLY
Rec'd._____
Fee No._____
Entered_____

APPLICATION FOR CERTIFICATE OF QUALIFICATION

Refer to the Instructions and 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.

Enclose a non-refundable $150.00 application fee payment by check or money order made payable to "New York State Department of Health" and a current curriculum vitae (CV) with this application.

1. PERSONAL INFORMATION:

Have you previously held a NYS CQ? ☐ **Yes** ☐ **No** **If yes, provide CQ Code:** _____

Last Name	First Name		MI
Social Security Number	**Any other name you are known by:**		
Home Address/Street	**City**	**State**	**ZIP**
Telephone Number(s) with Area Code			
(Home or Mobile)	**(Work)**		
Home Email Address	**Work Email Address**		

2. GRADUATE/PROFESSIONAL EDUCATION: List all medical schools, colleges and universities attended in chronological order whether or not a degree was received.

Name of Medical School, College or University	Location City/State	Major Subjects	Attended From (Mo/Yr)	Attended To (Mo/Yr)	Degree

3. BOARD CERTIFICATION: List your board (re)certifications below and provide a copy of your certificate(s).

Abbreviation of Board and Specialty (see list of abbreviations in instructions)	Date Certified	Date Recertified

4. QUALIFICATION FOR BOARD: Indicate the specific training and/or experience which qualified you to sit for board examination. For any residency and/or fellowship that occurred within the previous six years, provide a list of the dates and discipline of each rotation.

Institution	Title of Program	Discipline of Study	Dates of Study

5. PHYSICIAN AND DENTIST LICENSURE: Provide a copy of your current registration issued by New York State or your state of practice.

State	License Number	Year of Issuance	Expiration Date

6. EMPLOYMENT: All sites within the previous six years must be listed along with job title and the name of your director or supervisor. If applicable, indicate NYS permit PFI number or CLIA number of the laboratory. Add additional pages as necessary. Explain any significant gaps in your employment history on a separate sheet. Include a copy of your current curriculum vitae with a list of relevant publications.

PFI/CLIA#	Name of Institution		
Institution Address		**Institution Description**	
Name of Director or Supervisor	**Your Title**	**Start Date (Mo/Yr)**	**End Date (Mo/Yr)**
Describe laboratory duties / areas of responsibility:			

7. 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)

8. CERTIFICATION

a. Have you ever had charges of administrative violations of local, state, or federal laws, rules, and regulations, including, but not limited to, the Public Health Law or related statutes concerning the provision of health care services, or reimbursement for such services, sustained against you, or are such charges currently pending?

☐ **Yes** ☐ **No**

If yes, provide details on a separate sheet and attach to this form.

b. Have you ever been convicted of any crime, including, but not limited to, any offense related to the furnishing of or billing for clinical laboratory services and medical care, services, or supplies, which is considered an offense involving theft or fraud, or are such charges currently pending?

☐ **Yes** ☐ **No**

If yes, provide details on a separate sheet and attach to this form.

c. Have you ever had any professional license or certification related to the practice of medicine, pathology, or laboratory science revoked, suspended, limited, or denied?

☐ **Yes** ☐ **No**

If yes, provide details on a separate sheet and attach to this form.

d. In signing this application, I hereby certify that the information I have given the Department of Health as a basis for obtaining a Certificate of Qualification is true and correct. I understand that under Public Health Law my Certificate of Qualification may be denied, revoked, suspended, limited, or annulled if any fact is misrepresented in this application. I also understand that additional penalties may apply if I misrepresent, conceal, or fail to disclose facts or information regarding my initial or continuing eligibility for a Certificate of Qualification, including conviction of any crime related to billing for laboratory services, omission or misrepresentation of material facts in applying for professional license, permit or registration related to the operation of a clinical laboratory or the concealment of ownership or controlling interest in a clinical laboratory.

Changes in any of the information in this application must be reported to the Clinical Laboratory Evaluation Program immediately, to include changes in physical or email address.

I also agree to submit to any investigation made by the Department of Health to verify the information provided in this application, any other investigation in connection with this application, and/or any complaint filed with the Department. If additional information is requested, I agree that it will be provided in a timely manner.

_____ _____

Signature **Date**

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

Submit this application, a current curriculum vitae and required supporting documentation along with the non-refundable $150.00 application fee 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

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.

NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION
PROGRAM CERITIFICATE OF QUALIFICATION

APPLICATION CHECKLIST

All Applicants:

- ☐ **Provide a copy of your current curriculum vitae.**
- ☐ **Include a non-refundable $150.00 application fee, payable by check or money order to "New York State Department of Health".**
- ☐ **Sections 1-6. Complete sections and attach additional sheets as necessary.**
- ☐ **Section 7. Indicate the category(ies) you are requesting by marking the appropriate check box and circling either the appropriate board certification or "experience" for each category requested. For those categories marked with an asterisk, please also complete and submit the appropriate Questionnaire(s), available under Applications and Forms at www.wadsworth.org/regulatory/clep/certificate-requirements.**
  - **If you indicate that you are qualified by experience, include documentation of at least two (2) years of laboratory management experience and at least two (2) years of category-specific experience, as described in part 7 of the instructions. Please note only the previous six years is relevant to this application.**
- ☐ **Section 8. Complete, date and sign.**

For licensed physicians

- ☐ **Provide a copy of your physician license and registration.**

- **If you are board certified by an entity listed in the application instructions and completed your entire residency within the previous six years:**
  - ☐ **Provide a copy of the board certificate(s).**
  - ☐ **Provide a list of the dates and disciplines of each rotation during your residency.**

- **If you are board certified by an entity listed in the application instructions and all or a portion of your residency occurred more than six years ago:**
  - ☐ **Provide a copy of the board certificate(s).**
  - ☐ **For rotations during your residency that occurred within the previous six years, provide a list of the dates and disciplines.**
  - ☐ **For any categories for which your residency rotations occurred more than six years ago, provide documentation of experience gained within the previous six years, as described in part 7 of the instructions.**

For PhD and other earned doctorate applicants

- ☐ **Provide an original transcript of your doctoral studies.**
- ☐ **Provide a copy of any acceptable board certificate(s).**
- ☐ **Provide documentation of experience gained within the previous six years, as described in part 7 of the instructions.**