Clinical Laboratory Evaluation Program

NYS Department of Health

Email: CLEPCQ@health.ny.gov

Web: www.wadsworth.org/regulatory/clep/certificate-requirements

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Application to Amend Technical Director Certificate of Qualification

To qualify for a Technical Director Certificate of Qualification (TDCQ), you must meet the requirements in Subpart 58-6 of Title 10 of the New York State (NYS) Codes, Rules, and Regulations (10 NYCRR). You can find these regulations online at www.wadsworth.org/regulatory/clep/laws.

Please submit this application along with:

- A current curriculum vitae (CV).
- A non-refundable $150.00 application fee. Make checks or money orders payable to the New York State Department of Health.
- Additional pages as needed to complete Sections 1 through 3.

1. Personal Information:

CQ Code

Name: Last	First	Middle/Initial

Social Security Number (SSN) or Individual Taxpayer Identification Number (ITIN)	Other Name(s) Used/Known By

Home Address: Street	City	State	ZIP Code

Phone Number: Home/Mobile (with Area Code)	Work (with Area Code)

Email Address: Home	Work

2. Category(ies): Select each category you are applying for, either to add a new category or to amend the limitation on an existing one. In addition to the qualifying board or experience noted below, all applicants must document recent training/ experience that occurred within the last 10 years for each selected category.

- **"Experience"** is defined as two (2) postdoctoral years.
- Complete and attach the questionnaire available at www.wadsworth.org/regulatory/clep/certificate-requirements to document your recent experience in categories marked with an asterisk (*).
- Attach a third-party letter, following the "Instructions to Letter Writer" on page 4, to document your recent experience in categories *without* an asterisk.

Add	Amend	Category	**Requirements** (including experience occurring within the last 10 years):	
			Physician, License/Registration, and:	**Earned Doctoral Degree and:**
		Andrology *	ABPath(CP); AOBPath(LM) + 6 months, or Experience	ABB(ALD); ABB(BCLD) + 6 months; ABB(HCLD) + andrology exam or 6 months; ABCC(CC) + 1 year; NRCC(CC) + 1 year; or Experience
		Bacteriology *	ABPath(CP), AOBPath(LM), ABPath(MMB), or Experience	ABMM; ABB(PHLD); ABB(BCLD); or ABB(HCLD) + Microbiology/Public Health Microbiology/Molecular Diagnostics exam; ASCP(DMLI); or Experience
		Mycobacteriology *		
		Mycology *		
		Parasitology *		
		Virology *		
		Blood Banking Collection –		
		Comprehensive *	Experience with 1 year for allogeneic transfusion	
		Limited *	ABPath (BB/TM), ABPath(CP), AOBPath(LM), ABIM(Hem), or AOBIM(Hem)	
		Blood Lead	ABCC(CC), ABCC(TC), or Experience	
		Blood pH and Gases	ABPath(CP), AOBPath(LM), ABCC(CC), or Experience	ABCC(CC) or Experience
		Clinical Chemistry		
		Endocrinology		
		Fetal Defect Markers *		
		Cellular Immunology – Leukocyte Function * Malignant Leukocyte Immunophenotyping * Non-Malignant Leukocyte Immunophenotyping *	ABMLI; ASCP(DMLI); ABB(BCLD) + 1 year or Diagnostic Immunology and Hematology exam + 6 months flow; ABB(HCLD) + 1 year flow or Hematology exam + 6 months flow; ABCC(CC) + 1 year flow; or Experience	
		Clinical Toxicology	ABPath(CP); AOBPath(LM); ABCC(TC); ABCC(CC) + 6 months confirmatory testing; or Experience	ABCC(TC); ABCC(CC) + 6 months confirmatory testing; or Experience
		Cytogenetics	4 years with 2 years in clinical cytogenetics	
		Cytopathology	ABPath(AP) or AOBPath(AP)	
		Diagnostic Immunology *	ABPath(CP), AOBPath(LM), ABPath(MMB), ABCC(CC), ABMLI, ABMM, ASCP(DMLI), or Experience	ABCC(CC), ABMLI, ABMM, ASCP(DMLI), or Experience
		Forensic Identity	Experience	
		Parentage/Identity Testing		
		Forensic Toxicology	ABFT or Experience	
		Genetic Testing	ABCC(MD); AMBGG(CBG); ABMGG(LGG); or Experience	
		Hematology *	ABPath(CP); AOBPath(LM); ABIM(Hem) + 1 year; AOBIM(Hem) + 1 year; or Experience	Experience
		Histocompatibility	4 years; or Experience + 2 years immunology	
		Histopathology –		
		General (includes Dermato- and Oral Pathology)	ABPath(AP) or AOBPath(AP)	
		Dermatopathology	ABPath(AP), ABPath(DP), AOBPath(AP), AOBPath(DP), ABD, or ABD(DP)	
		Oral Pathology	ABPath(AP), AOBPath(AP), or dentist with ABOMP	
		Immunohematology	ABPath(CP), ABPath(BB/TM), AOBPath(LM), or Experience	Experience
		Oncology – Molecular and Cellular Tumor Markers	ABPath(AP) + ABPath(MGP); ABPath(CP) + ABPath(MGP); ABCC(MD); ABMGG(LGG); or Experience	ABCC(MD); ABMGG(LGG); or Experience
		Therapeutic Substance Monitoring/Quantitative Toxicology	ABPath(CP), AOBPath(LM), ABCC(CC), ABCC(TC), or Experience	ABCC(CC), ABCC(TC), or Experience
		Trace Elements	Experience with analytical atomic spectrometry	
		Transfusion Services *	ABPath(BB/TM); ABPath(CP) + 6 months; ABIM(Hem) + 6 months; AOBIM(Hem) + 6 months; or Experience	
		Transplant Monitoring	ABCC(MD) or Experience	

3. Certification:

A. **Administrative Violations:** I have had charges for administrative violations of local, state, or federal laws, rules, or regulations (including but not limited to the Public Health Law or related statutes concerning provision of or reimbursement for health care services) sustained against me, or such charges are currently pending.

☐ **Yes** ☐ **No**

If yes, attach a separate page with details.

B. **Criminal Convictions:** I have been convicted of any crime, including, but not limited to offenses 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 such charges are currently pending.

☐ **Yes** ☐ **No**

If yes, attach a separate page with details.

C. **Professional License/Certification Actions:** I have had a professional license or certification related to the practice of medicine, pathology, or laboratory science revoked, suspended, limited, or denied.

☐ **Yes** ☐ **No**

If yes, attach a separate page with details.

Applicant's Certification: By signing this application, I certify that all information provided to the Department of Health is true and correct. I understand that my Certificate of Qualification may be denied, revoked, suspended, limited, or annulled if any information is misrepresented. I also understand that additional penalties may apply for misrepresentation, concealment, or failure to disclose facts related to my eligibility for a Certificate of Qualification, including criminal convictions related to billing for laboratory services, or omission or misrepresentation on professional license, permit, or registration applications related to the operation of a clinical laboratory, or the concealment of ownership or controlling interest in a clinical laboratory.

I agree to cooperate with any investigation conducted by the Department of Health to verify the information provided in this application or related to this application or any complaint filed with the Department. I agree to provide any requested additional information promptly.

I agree to immediately report any changes to the information in this application to the Clinical Laboratory Evaluation Program at clepcq@health.ny.gov, including changes to my physical or email address.

Signature	**Date** (Month, Day, Year)

All signatures must be original. An electronic, stamped, or typed signature is not acceptable.

Submit this application, your current CV, and all supporting documents. Include the non-refundable $150.00 application fee (check or money order payable to the **New York State Department of Health**).

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

Instructions to Letter Writer

A third-party letter documenting training/experience is required for:

Applicant's Name

Who can write the letter: Usually, the applicant's primary supervisor (e.g., the laboratory director) should write it. If they're proven unable to attest, the Department may consider a letter from an administrator or another third party the applicant reported to. If the applicant is the director and has no other supervisor, the owner of the laboratory can write it. For corporate owners, this could be an officer or a member of the governing body. **The applicant's self-attestation is not acceptable.**

- Dates must include the month and year. The day may be included if appropriate.

A. Letter writer:

- **a.** Name
- **b.** Title in relation to the applicant
- **c.** Explain how your relationship allows you to attest to the applicant's training/experience

B. Laboratory where the applicant acquired training/experience:

- **a.** Name
- **b.** PFI (for NYS-permitted laboratories), if any, and CLIA number for *each* laboratory
- **c.** Address: Street, City, State, and ZIP Code
- **d.** Type: Examples include health department, hospital, independent, medical research, and university.

C. Detailed List of Performed/Supervised/Directed Tests: Provide a comprehensive list of the tests, analyses, and procedures the applicant personally performed, supervised, or directed. Include the following information for each.

- **a. Test Analyte/Procedure:** This refers to the specific substance being measured or process being performed. Examples include antibodies, drugs, gases, genes, hormones, markers, microbes, Mohs surgeries, vitamins, Whole Exome Sequencing (WES), and Whole Genome Sequencing (WGS).
- **b. Specify whether each is an FDA-approved assay or a laboratory-developed test (LDT).** See www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.
- **c. Manufacturer/Equipment:** This is the company that produced the test equipment or reagent, along with the specific instrument, kit, model, or platform used.
- **d. Method:** This describes the scientific technique or technology used. Examples include ELISA, FISH, flow cytometry, Gram stain, LC-MS/MS, multiplex PCR, and NGS.
- **e. Specimen Source:** This is the origin of the biological sample. Examples include B cells, blood, cerebrospinal fluid (CSF), buccal swab, FFPE tumor tissue, nail scraping, and vaginal swab.
- **f. Dates:** Include the month and year for the start and end of the applicant's experience. This may include the specific day if it's relevant.
- **g. Volume:** This is the number of tests, analyses, or procedures the applicant personally performed, supervised, or directed between the specified start and end dates. Round to the nearest approximation if precise figures are unavailable.

D. Describe the applicant's responsibilities in directing/supervising high complexity testing, as defined in paragraph **58-6.5(a)** of 10NYCRR, and the dates they performed these duties. (You can determine the complexity of FDA-approved tests by searching the FDA CLIA Test Complexity Database.)

Quick Guide to Applying

You can find additional instructions at www.wadsworth.org/regulatory/clep/certificate-requirements.

Note: You must be a *licensed* physician or dentist, or hold a doctoral degree in biological, chemical, clinical laboratory, or medical laboratory science or medical technology to qualify for a Technical Director CQ.

1. **Fill out Section 1**.
2. **Select each category you are applying for in Section 2** on page 2. You must document recent practical laboratory training or experience within the last ten (10) years for each selected category.
3. **Complete, sign, and date Section 3** on page 3.
4. Include a **non-refundable** $150.00 application fee (check or money order payable to the **NYS Department of Health**).
5. **Attach your current CV**, including publications (required for all applications).
6. **Attach a copy of your board certificate** for each qualifying board in paragraph 58-6.4(e) of 10 NYCRR. For certificates without an expiration date, proof of current certification must be submitted with every application.
7. **Attach copy of your current physician or dentist licenses and registrations** if applicable.
8. **For Recent Training (within 10 years):** Attach your residency and fellowship rotation schedules and certificates of completion if your training was in preparation for examination by a board listed in paragraph 58-6.4(e) of 10 NYCRR and completed within the last 10 years. Your schedules must include the dates and subspecialty of each rotation, including elective and research rotations. Dates must include the month and year and may include the day if relevant.
9. **For Recent Experience (within 10 years):** A third-party letter is required if you did not complete a residency or fellowship for board exam preparation or your entire training was more than 10 years ago. This letter must follow the "Instructions to Letter Writer" on page 4.
10. **For Categories with Asterisks:** Attach a complete questionnaire for every selected category with an asterisk in Section 2. Questionnaires are available at www.wadsworth.org/regulatory/clep/certificate-requirements.
11. **For Categories without Asterisks:** Attach a third-party letter for every selected category without an asterisk in Section 2 or complete and attach a general questionnaire. The letter must follow “Instructions to Letter Writer" on page 4.