

Clinical Laboratory Evaluation Program

NYS Department of Health

Email: CLEPCQ@health.ny.gov

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

Office Use Only	
Received:	
Cash Line:	
CQ Code:	

Application for Certificate of Qualification Technical Director

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 5.

1. Personal Information:

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	
Previous NYS CQ: If you have previously applied for or held a NYS CQ, please provide your CQ Code.			

2. Education and Training:

- **List all graduate and professional schools** you attended in chronological order, even if you did not graduate.
- **List any training** completed to prepare for examination by a board in paragraph 58-6.4(e) of 10 NYCRR.
- **For residencies and fellowships completed in the last 10 years, attach:**
 - Rotation schedules showing the dates and subspecialty of each rotation (including elective and research rotations).
 - Certificates of completion.

Institution Name	Campus Location		Program/ Specialty	Attended (Month, Year)		Degree Earned
	City	State		Start	End	

3. Board Certification: Only boards listed in paragraph 58-6.4(e) of 10 NYCRR are accepted.

- **List** your qualifying board certifications.
- **Attach** a copy of your current certificates.
- **Provide primary source verification** of current validity if your certificate does not display an expiration date.

Board	Date Certified (Month, Day, Year)

4. Licensure: List your current physician or dentist licenses and registrations in the United States (US) or the country where you intend to act as a technical director. Provide a copy of each.

State/Country	License Number	Date Issued (Month, Day, Year)	Expiration Date (Month, Day, Year)

5. Employment: Please provide your employment history for the last 10 years.

- Include the **PFI (for NYS-permitted labs, if applicable)** and **CLIA number** for *each* laboratory.
- Explain any **significant employment gaps** on an attached sheet.
- Attach your **current CV**, including publications.
 - Note: To determine the complexity of FDA-approved tests, search the *FDA CLIA Test Complexity Database*.

Laboratory Name			NYS PFI	CLIA Number	Name of Laboratory Director/ Applicant's Supervisor
Laboratory Address				Laboratory Type	
Street	City	State	Zip Code	(See page six 6)	
Applicant Title			Employment Dates (Month, Year)		
			Start	End	
Did the applicant direct/supervise high complexity testing at this facility? (Yes or No)			Dates the applicant directed/supervised high complexity testing at this facility (Month, Year)		
			Start	End	
Applicant's Duties/Responsibilities:					

6. Category(ies): Select each category you are applying for. All applicants must document recent training/experience within the last 10 years for each selected category.

- **"Experience"** is defined as 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 6, to document your recent experience in categories *without* an asterisk or complete and attach a general questionnaire.

Select	Category	Requirements	
		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
	Blood Banking Collection- Comprehensive *	Experience with 1 year for allogeneic transfusion	
	Blood Banking- 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
	Cellular Immunology- Leukocyte Function *	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	
	Cellular Immunology- 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	
	Cellular Immunology- 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 Chemistry	ABPath(CP), AOBPath(LM), ABCC(CC), or Experience	ABCC(CC) 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
	Endocrinology	ABPath(CP), AOBPath(LM), ABCC(CC), or Experience	ABCC(CC) or Experience
	Fetal Defect Markers *	ABPath(CP), AOBPath(LM), ABCC(CC), or Experience	ABCC(CC) or Experience
	Forensic Identity	Experience	
	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- Dermatopathology	ABPath(AP), ABPath(DP), AOBPath(AP), AOBPath(DP), ABD, or ABD(DP)	
	Histopathology- General- (Includes Dermal and Oral Pathology)	ABPath(AP) or AOBPath(AP)	
	Histopathology- Oral Pathology	ABPath(AP), AOBPath(AP), or dentist with ABOMP	
	Immunohematology	ABPath(CP), ABPath(BB/TM), AOBPath(LM), or Experience	Experience
	Mycobacteriology *	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
	Mycology *	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
	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
	Parasitology *	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
	Parentage/Identity Testing	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	
	Virology *	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

7. 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:

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

B. Laboratory where the applicant acquired training/experience:

- Name
- PFI (for NYS-permitted laboratories), if any, and CLIA number for *each* laboratory
- Address: Street, City, State, and ZIP Code
- 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.

- 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).
- 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.
- Manufacturer/Equipment:** This is the company that produced the test equipment or reagent, along with the specific instrument, kit, model, or platform used.
- Method:** This describes the scientific technique or technology used. Examples include ELISA, FISH, flow cytometry, Gram stain, LC-MS/MS, multiplex PCR, and NGS.
- 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.
- 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.
- 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 Sections 1 through 6.** Attach additional pages as needed.
2. **Select each category you are applying for in Section 6** on page 4. You must document recent practical laboratory training/experience within the last 10 years for each selected category.
3. **Complete, sign, and date Section 7** on page 5.
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 listed in **Section 3**. 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 Earned Doctoral Degree Holders (US):** Attach official transcripts for your doctoral degree earned in the US. Transcripts must show at least 16 semester hours of doctoral-level coursework or an approved thesis/research project in biological, chemical, clinical laboratory, medical laboratory science, or medical technology from an accredited US institution.
9. **For Earned Doctoral Degree Holders (Outside US):** Attach an equivalence evaluation of your doctoral degree from a current member of the National Association of Credential Evaluation Services (NACES) or the Association of International Credential Evaluators, Inc. (AICE). Use institutional code 000270 to share the report with the Wadsworth Center on EvalDirect.
10. **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.
11. **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 6.
12. **For Categories with Asterisks:** Attach a complete questionnaire for every selected category with an asterisk in Section 6. Questionnaires are available at www.wadsworth.org/regulatory/clep/certificate-requirements.
13. **For Categories without Asterisks:** Attach a third-party letter for every selected category without an asterisk in Section 6 or complete and attach a general questionnaire. The letter must follow "Instructions to Letter Writer" on page 6.

List of Abbreviations Used for Certifying Boards

Abbreviation	Board
ABB(BCLD)	American Board of Bioanalysis: Bioanalyst Clinical Laboratory Director
ABB(HCLD)	American Board of Bioanalysis: High Complexity Laboratory Director
ABB(PHLD)	American Board of Bioanalysis: Public Health Laboratory Director
ABB(ALD)	American Board of Bioanalysis: Andrology Laboratory Director
ABCC(CC)	American Board of Clinical Chemistry: Clinical Chemistry
ABCC(TC)	American Board of Clinical Chemistry: Toxicological Chemistry
ABCC(MD)	American Board of Clinical Chemistry: Molecular Diagnostics
ABD	American Board of Dermatology: Dermatology
ABD(DP)	American Board of Dermatology: Dermatopathology
ABFT	American Board of Forensic Toxicology
ABIM(Hem)	American Board of Internal Medicine in Hematology
ABOMP	American Board of Oral and Maxillofacial Pathology
ABMGG(CBG)	American Board of Medical Genetics and Genomics: Clinical Biochemical Genetics
ABMGG(LGG)	American Board of Medical Genetics and Genomics: Laboratory Genetics and Genomics
ABMLI	American Board of Medical Laboratory Immunology
ABMM	American Board of Medical Microbiology
ABPath(AP)	American Board of Pathology: Anatomic Pathology
ABPath(BB/TM)	American Board of Pathology: Blood Banking and Transfusion Medicine
ABPath(CP)	American Board of Pathology: Clinical Pathology
ABPath(DP)	American Board of Pathology: Dermatopathology
ABPath(MGP)	American Board of Pathology: Molecular Genetic Pathology
ABPath(MMB)	American Board of Pathology: Medical Microbiology
AOBIM(Hem)	American Osteopathic Board of Internal Medicine in Hematology
AOBPath(AP)	American Osteopathic Board of Pathology: Anatomic Pathology
AOBPath(LM)	American Osteopathic Board of Pathology: Clinical Pathology/Laboratory Medicine or Laboratory Medicine
AOBPath(DP)	American Osteopathic Board of Pathology: Dermatopathology
ASCP(DMLI)	American Society for Clinical Pathology Board of Certification; Diplomate in Medical Laboratory Immunology
NRCC(CC)	National Registry of Certified Chemists: Clinical
NRCC(TC)	National Registry of Certified Chemists: Toxicological